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European Radiation Dosimetry Group e. V.

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ISO/IEC 17025 Guidance for IMS: Suggestions on How to Interpret and Implement the Requirements Including Examples from Accredited Laboratories

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ISO/IEC 17025 Guidance for IMS: Suggestions on How to Interpret and Implement the Requirements Including Examples from Accredited Laboratories

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Content:

Abstract

Individual monitoring of external radiation is an activity usually regulated by national regulatory bodies in most countries. Regulations generally contain technical requirements to be met by the individual monitoring services (IMS), in order to ensure that the measurements are correct and therefore the dosimetry results are reliable. In some countries, the requirements include or even consist of the accreditation of the service according to the standard ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories". This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories [1]. It is a fact that accreditation is a growing trend among European IMS as a way to guarantee confidence in their technical competence. The acceptance of the dosimetry results between countries and their indentation in the respective National Dose Registries is facilitated if laboratories conform to the ISO/IEC 17025 standard.

In the framework of the activities of EURADOS (European Radiation Dosimetry Group) working group 2 "Harmonisation of Individual Monitoring in Europe" and attending to the concern of many European IMS in the process of accreditation, this guide has been prepared by a dedicated task group composed not only of experienced IMS staff, quality managers and accreditation auditors but also by IMS personnel involved in the course of accreditation. The purpose of this task group was to assist and encourage IMS to apply for accreditation and to share their own accreditation experience.

This document intends to be a practical reference for IMS on how to interpret and implement the ISO/IEC 17025 requirements for testing laboratories to the specific activity of a personal dosimetry service for external radiation, emphasising those aspects of special interest. As a new edition of the ISO/IEC 17025 standard was released in 2017 [1], this guide also identifies the major differences of ISO/IEC 17025:2017 in comparison to the 2005 version [2]. The objective is to provide accredited IMS with suggestions and examples on how to implement the novelties in their quality systems. It is also aimed to serve as a guide for accreditation auditors, who can find useful information and examples that could help them in decision making at audit. In the case of any doubt or discrepancy between what could be understood from the explanations of this publication and the text of the standard, the requirement of the standard should always prevail. At no time has it been the intention of the authors to exclude other multiple ways of fulfilling the requirements that only the auditor can judge.

The guide is structured following the ISO/IEC 17025:2017 contents and provides:

- Identification of changes or novelties regarding ISO/IEC 17025:2005.
- Suggestions on how to interpret the requirement applied to individual monitoring services.
- Suggestions on how to implement the requirement including practical recommendations.
- Examples of accredited dosimetry laboratories with different layouts.
- Assistance to prepare audits giving some examples of possible auditor's questions and how to show evidence of compliance.
- Cross references with other ISO/IEC 17025:2017 clauses to take into account in order to be consistent.

1. Introduction

1.1 Structure of tables

Even though it is a general thought that accreditation is a proof of uniformity between IMS, experience has demonstrated that conforming to ISO/IEC 17025 does not indicate all the IMS operate in the same way. Different requirements can be interpreted in several approaches and still conform to the requirements of the standard. This of course depends on the IMS setup and the auditor's custom-made assessment.

This report provides advice to already accredited IMS taking into account novelties from the 2017 edition, as well as to IMS that are about to apply for the accreditation process. The structure of the report is conceived in the table form (Table 1) providing clear overview of the specific interest to the user. Tables are complemented with a series of annexes making available examples from already accepted national accreditation bodies of the authors' respective countries. The purpose of the report was to "harmonise" the accreditation process and contribute to the uniformity among IMS.

Table 1

New in ISO/IEC 17025:2017?
Suggestions on how to interpret the requirement
Suggestions on how to implement the requirement
Examples from accredited laboratories
Audits • **Possible auditor's questions** • **Showing evidence of compliance**
Cross reference with other ISO/IEC 17025:2017 sub-clauses

2. Terms and definitions

As most of the terms related to quality and management systems are given in relevant ISO (e.g. ISO 9000:2015; ISO/IEC 17025:2005, JCGM 200:2012, etc.) and technical terms related to external dosimetry are given in international documents or standards (e.g. RP 160 and BSS), these general terms are not included in this section. The purpose of this glossary was to avoid confusion between similar terms used in the report.

Accreditation – third-party attestation related to a conformity assessment body conveying formal demonstration of its competence, consistent operation and impartiality to carry out specific conformity assessment tasks [3].

Competence – demonstrated ability to apply knowledge and skills.

Conformity assessment body in this document is the body competent to carry out conformity assessment tasks for the laboratory providing an external dosimetry service: Individual Monitoring Service (IMS) or Approved Dosimetry Service (ADS). According to RP 160, there is distinction between ADS and IMS. IMS can provide personal dosemeters to users without necessarily being approved [4]. In this document IMS, ADS and laboratory are synonyms with no distinctions, representing a body responsible for the calibration, reading or interpretation of individual monitoring devices.

Customer – organisation or person that received a product or service.

Decision rule – A rule that describes how measurement uncertainty is accounted for when stating conformity with specified requirement [1]. Decision rule can be applied at different sections, such as reporting limit, depending on the agreement with the client.

Dosemeter – (test or calibration item) radiation meter designed to measure the quantities absorbed dose or dose equivalent.

Dosimetry system – dosemeter, reader and all associated equipment and procedures used for assessing the indicated value.

Employees, personnel, staff – people who work for an IMS or ADS, who have enough qualifications and training to carry out the technical or management activities, which are their responsibility.

Exposed worker – a person either self-employed or working for an employer, who is subject to an exposure incurred at work and liable to result in doses exceeding one or other of the dose levels equal to the dose limits for members of the public [5].

Influencing parameters – parameters whose effect on the indicated value results in a change of response.

Method - measurement procedure, calibration process, calculations, evaluation of measurement uncertainty etc.

Pre-defined criteria – the interval, between upper and lower limits of sequence of values, within which the values are considered to be satisfactory.

Procedure – specified way to carry out an activity or a process [3].

Reference materials – A set of dosemeters irradiated in accredited laboratory with traceability to SI units.

Risk and opportunities assessment – process of identifying, evaluating and defining measures to control risks and enhance opportunities for the IMS to achieve its purpose and objectives.

3. Requirements from ISO/IEC 17025:2017

This chapter is structured according to the clauses and sub-clauses in ISO/IEC 17025:2017

3.1 Clause 4: General requirements

3.1.1 Sub-clause 4.1: Impartiality

New in ISO/IEC 17025:2017?

Partial (It expands the requirements of ISO/IEC 17025:2005 sub-clause 4.1 "Organisation").

Suggestions on how to interpret the requirement

IMS must demonstrate that their activities are carried out in an impartial and structured way, avoiding any commercial, financial or other pressure to compromise impartiality:

- IMS should identify and analyse the potential risk to impartiality related to technical and managerial activities. Internal and external threats, commercial or financial pressures should also be considered [1].
- If any risk to impartiality is identified, the IMS has to demonstrate how that risk is eliminated or minimised [1].

Suggestions on how to implement the requirement

- The IMS management shall be committed to impartiality [1]. An impartiality policy should be defined or a statement about impartiality should be included in the IMS quality policy if it has one.
- The risks to impartiality must be identified, taking into consideration: ownership, governance, structure of IMS (hierarchical dependence or relationship with other departments in the case of belonging to a higher organisation), regulatory bodies, management, staff, customers, providers, shared resources, finances, contracts, marketing, etc [1]. The IMS should analyse the potential risk to its impartiality [1]. Contract reviews, any changes in the IMS activities or results from internal audits or management reviews are useful tools for risk analysis.
- An action plan to design and implement actions to eliminate or minimise risks concerning impartiality must be established [6]. All of the activities performed must be documented.
- All of the aspects related to impartiality must be revised in the Management review [6].
- IMS in order to ensure that staff act impartially shall:
    - Avoid bias arising from conflicts of interest (financial or non-financial) [1],
    - Explore personal interests and factors that can affect staff's impartiality,
    - Identify the links between individuals/team and organisational performance (e.g. how does the team or individuals work? contribute to IMS goals and priorities?),

- Analyse relations between IMS' staff and customers/providers. (E.g. family or personal relationships between IMS' staff and exposed worker or financial relation with a staff member and a medical clinic). Also the possible relation between the IMS staff and the regulatory body can affect staff's impartiality. These relations could have a strongly positive impact and can be addressed as opportunities.

Examples from accredited laboratories

- Impartiality policy signed by IMS Manager.
- Including risk to impartiality in the risk management plan.
- Introducing practical actions to reduce or minimise risks. e.g.:
  - A signed document, updated on specific time intervals, for every person involved in IMS practices, where it is stated that the worker acts impartially.
  - Methods and procedures independent on personnel effect (more automated procedures).
  - Modification of measurement procedures so that the test person who performs the measurement ignores the identification of the customer.
  - Position rotation (if possible) of personnel who are involved in the measurement procedure.
  - Predefined time period for new personnel to adopt IMS ethics.
- Analysing the risks to impartiality and revise them at least once a year (e.g. in Management Review).

Audits

- **Possible auditor's questions**
  - Is the management committed to impartiality?
  - How does the IMS demonstrate that its Management is committed to impartiality?
  - Are the potential risks to impartiality identified?
  - How does the IMS identify the risks to its impartiality in an ongoing manner?
  - Has the IMS identified all possible risks to impartiality?
  - How does the IMS eliminate or minimise risks?
  - Have adequate measures been taken to avoid identified risks to impartiality?
  - Are the measures taken effective? Do the measures taken guarantee that risks have been eliminated or minimised?
  - Are the activities well documented?
- **Showing evidence of compliance**
  - Impartiality policy (or statement about impartiality) signed by the IMS manager.
  - Procedure or documents for risk identification and management (including risk to impartiality).
  - Reports for definition, monitoring and evaluation of effectiveness of measures taken to guarantee that risks have been eliminated or minimised.

○ Management review report (including impartiality items).
Cross reference with other ISO/IEC 17025:2017 sub-clauses • 4.2 Confidentiality • 5 Structural requirements • 6.2 Personnel • 6.6 Externally provided products and services • 7.1 Review of requests, tenders and contracts • 7.8 Reporting of results • 8.2 Management system documentation • 8.5 Actions to address risks and opportunities • 8.8 Internal audits • 8.9 Management reviews

3.1.2 Sub-clause 4.2: Confidentiality

New in ISO/IEC 17025:2017?

Partial (It expands the requirements of ISO/IEC 17025:2005 sub-clauses 4.1 "Organisation", 4.7 "Service to the Customer" and 5.4.7 "Control of data").

Suggestions on how to interpret the requirement

IMS shall commit itself to be legally responsible for keeping the data collected or produced during its activities for a customer confidential [1]. In addition:

- If confidential information is required to be released by law or by contractual arrangements, the IMS shall inform the customer in advance, unless the law prohibits it [1].
- The identity of a source providing data about a customer of the IMS shall not be shared with the customer without the source's agreement and all information obtained shall be kept confidential [1].
- All persons and bodies shall keep all information obtained or created when acting on the IMS' behalf confidential [1].

Suggestions on how to implement the requirement

It is preferable that the IMS regulates all issues concerning confidentiality in the contract with its customer. The contract can include:

- A statement that the IMS is legally responsible and committed to keeping all information obtained about the customer's information confidential.
- Which confidential information the IMS by contractual arrangements or laws may release or put in the public domain.
- A statement that no confidential information will be released without notification of the customer, unless the law prohibits this.
- A statement that the identity of a source providing data about the customer will be kept confidential.

It is preferable that the IMS personnel, management, providers and external personnel (auditors, regulators…) etc. sign a confidentiality declaration or this is included in their contract with the IMS [6]. For external parties, requirements for confidentiality should also apply to their possible suppliers.

NOTE! The European GDPR [7] puts further duties on IMS operating in the EU in relation to management and publishing of individual person's data and requires the IMS to have a separate data policy.

Examples from accredited laboratories

- Legally binding contract with the customers.
- Contracts containing confidentiality clause or separate confidentiality declarations accepted by employees, providers and external personnel.
- Data policy (EU GDPR [7]).

Audits

- **Possible auditor's questions**
  - How does the IMS fulfil the requirement to be legally responsible for the management of all information about its customer?
  - How does the IMS keep the information confidential?
  - How does the IMS inform the customer if confidential information is released?
  - How does the IMS keep confidential the identity of a source providing information about its customers?
  - How does the IMS fulfil its requirement to ensure that all employees of the IMS keep information about the customers confidential?
  - How does the IMS fulfil its requirement to ensure that suppliers and external parties keep information about the customer of the IMS confidential?
- **Showing evidence of compliance**
  - Procedure for handling of confidential information. Contract example.
  - Procedure for handling confidentiality of the employees. Confidentiality declaration signed.
  - Procedure for handling confidentiality of suppliers and external parties. Confidentiality declaration signed.
  - Internal audits and Management review report (including confidentiality matters).

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 5 Structural requirements
- 6.2 Personnel
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.8 Reporting of results
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.2 Clause 5: Structural requirements

3.2.1 Sub-clauses 5.1 to 5.7

New in ISO/IEC 17025:2017?

Partial (New section corresponding to the new structure of the standard. Sub-clause 5.2 is new in this document. The requirements of ISO/IEC 17025:2005 sub-clauses 4.1 "Organisation" and 4.2 "Management System" have been drafted differently).

Suggestions on how to interpret the requirement

This section defines a series of requirements for the IMS management.

- The structure and organisation of the IMS must be clearly defined: Legal identity, internal organisation and assignment of responsibilities of the personnel, both of the IMS management (or person who assumes overall responsibility for all IMS activities) and of the people who perform technical and management activities [1].
- In addition, the IMS must implement measures to ensure the maintenance of the management system against possible changes that may occur [1].

IMS activities which conform to ISO/IEC 17025:2017 shall be defined and documented. IMS procedures shall be documented to the extent necessary, in order to ensure consistency of activities and validity of results [1].

Deputies for key personnel are not necessarily required [6].

Suggestions on how to implement the requirement

- The IMS is requested to have documents showing its legal identity, whether it corresponds to a private or state company. These documents are part of the records to be maintained by the IMS.
    - Founding documents of the company, statutes or any other similar document.
- It is necessary to clearly identify the person who assumes the overall responsibility for the IMS. It does not refer to technical responsibility, but rather to the person in charge of management, with the capacity to assign the necessary funds to maintain the management system.
- The IMS must define the range of activities covered by the management system fulfilling ISO/IEC 17025:2017, indicating the locations where each of them is carried out. The range of activities need not include those activities that have been permanently subcontracted. The structure and organisation of the IMS should be documented, indicating how it is included in the upper organisation, as well as the responsibilities and relationships among the staff.
    - The IMS must have an updated organisation chart that shows the structure of the organisation and the levels of responsibility, lines of communication and dependencies of its staff (not only of the IMS but the upper organisation).
    - The IMS activities must be well documented to ensure the validity of the results.

- The IMS must have enough personnel to carry out its technical and quality activities, so as to ensure the effectiveness of the management system [1].
    - It is necessary to define the responsibilities associated with each job and the personnel with the necessary qualifications to carry out each of the activities.
    - Now, the terms "technical manager" and "quality manager" are not mentioned, even though the functions are still included in the standard. (5.2 and 5.6).
    - It is no longer necessary to have deputies for key positions. However, the IMS must analyse and evaluate the risk to its management system associated with this situation and take the actions considered as necessary (e.g. assignment of functions to another person or interruption of activities in the event of absence of the responsible person, etc.). Although the standard does not require it, it may be advisable to maintain the designation of substitutes for key personnel, or to establish in the system's documentation the way to act in case of their absence.
- IMS must ensure communication processes are in place to meet the client's requirements and others that ensure the effectiveness and maintenance of the management system against possible changes [1].
    - Management must ensure that staff is aware of the importance of their activities and the way they contribute to achieving the objectives of the management system. It is necessary to establish internal communication processes among all staff (e.g. assistance to Management Review, use of email, direct communications, attendance at meetings that deal with management system issues, etc.).
    - According to the next sub-clause 6.2.4, management must ensure that appropriate communication processes are established within the IMS considering the effectiveness of the management system. IMS management shall communicate to personnel their duties, responsibilities and authorities.
    - Regarding the communication requirements, it is suggested to communicate to the IMS manager the results of the Management Review addressing the effectiveness of the management system [6].
    - IMS must analyse the possible situations that threaten the integrity of the management system (e.g. in the Management Review or in the risk analysis.etc.).

Examples from accredited laboratories

- Founding documents of the company, statutes or any other similar document.
- Organisation chart describing structure and organisation (see Annex A)
- Documents including:
    - Identification of management that has overall responsibility.
    - Identification of technical and management activities covered by the management system and fulfilling ISO/IEC 17025:2017.

- Location (or location map) of the places where the technical activities are carried out.
- Description of jobs.
- Staff responsibilities.
- Personnel records.
- Communication processes.

- Risk analysis pertaining to the substitution of key personnel.
- Results of analysis the possible situation that threaten the management system.
- Attendance of all staff at Management Review meeting.
- For example, if the IMS is not providing neutron dosimetry and subcontracts the service permanently (ongoing basis), this activity cannot be included in the range of activities.

Audits

- **Possible auditor's questions**
  - Is the legal identity of the IMS established in the quality documents?
  - Are there documents that define the legal identity of the IMS? Is there an updated organisation chart of the IMS and of the upper organisation?
  - Does the organisation show clearly the relationships, responsibilities and dependencies (both in the IMS and in the rest of the organisation, if applicable)?
  - Is the management that has overall responsibility for the IMS identified?
  - Has the IMS defined the scope of the activities performed?
  - Are the activities externally supplied excluded?
  - Are the facilities where the activities are performed identified?
  - Does the IMS declare to comply with the ISO/IEC 17025:2017 standard?
  - Do the activities performed meet the established requirements (ISO/IEC 17025:2017, customers, regulatory authorities, etc.)?
  - Has the IMS defined its structure and organisation? (e.g. in an organisation chart)
  - Are the responsibilities, authorities and interrelationships of personnel affecting the results of IMS activities well defined?
  - Are the IMS activities well documented in order to ensure its consistent application and the validity of the results?
  - Does the IMS have qualified personnel assigned for:
  - Implementation, maintenance and improvement of the management system?
  - Identification of deviations from technical and managerial activities?
  - Initiation of actions to prevent or minimise such deviations?
  - Reporting to IMS management any question about the management system and its improvement?

- Ensuring the effectiveness of IMS activities?
- Has the IMS management made sure that staff is informed about the importance of complying with the requirements of the standard, the regulatory authorities, the customers and providers, etc.?
- Has the IMS management established measures to ensure that staff members are aware of their activities and how they contribute to the objectives of the management system?
- Does the IMS management establish effective communication procedures for the organisation to comply with the requirements of the standard, the regulatory authorities, the customers and providers, etc. considering the effectiveness of the management system?
- Has management established measures to ensure the maintenance of the management system against possible changes?
- If there have been changes in the IMS management system, has the management ensured the integrity of the system?

- **Showing evidence of compliance**
  - Founding documents of the company, statutes or any other similar document.
  - Documents describing:
  - Legal identity of the IMS.
  - Management that has overall responsibility for the IMS.
  - Responsibilities and dependences of personnel.
  - Description of jobs.
  - Activities performed and those covered by ISO/IEC 17025:2017.
  - Statement of compliance with ISO/IEC 17025:2017.
  - Personnel designed for activities in sub-clause 5.6.
  - Updated organisation chart.
  - Records from internal communication processes.
  - Report from Management Review.
  - Risk analysis (in the event of the absence of key personnel, in case of changes affecting management system, etc.) and actions to do.
  - Actions taken in case of changes or threaten the management system and evaluation of their effectiveness.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 4.2 Confidentiality
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts

- 8.2 Management system documentation
- 8.5 Actions to address risks and opportunities
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

3.3 Clause 6: Resource requirements

3.3.1 Sub-clause: 6.2 Personnel

New in ISO/IEC 17025:2017?

No (It replaces ISO/IEC 17025:2005 sub-clause 5.2 "Personnel").

Suggestions on how to interpret the requirement

The quality of a service is determined largely by the quality of its staff, and therefore close attention must be paid to staff recruitment, training and management (RP 160) [4].

Accurate laboratory test results depend on the staff being competent in performing the range of procedures that take place throughout the measurement process.

- The IMS personnel shall act impartially, according to the IMS management system and have all necessary qualifications, education and training in order to perform IMS activities. (6.2.1) and ensure the effectiveness of them (5.6) [1].
- The competence requirements for every task influencing the results shall be documented (Requirements for education, qualifications, training, technical knowledge, skills and experience) (6.2.2) [1].
- IMS laboratories should have competent staff that can perform all the tasks and responsibilities assigned to them. Also staff shall be able to evaluate deviations (6.2.3) [1]. (See Annex C)
- IMS should have clear, good and frequent communication with personnel for their duties, responsibilities and authorities (6.2.4) [1].
- IMS shall have procedures and keep relevant records in order to define staff adequacy requirements, selection, training, authorisation, supervision and monitoring competence of personnel. The competence of all staff must be documented (6.2.5) [1]. (See Annex E)
- IMS activities such as development of new methods or modification of existing ones, analysis, review, report of results, shall be done after authorisation (6.2.6) [1].

Suggestions on how to implement the requirement

Ensure impartiality

- Impartiality has high importance in the new ISO/IEC 17025:2017 standard, and is one of the factors that can act to increase the positive reputation of any scientific laboratory.
    - Impartiality entails one major element: honesty in operation and reporting results of the IMS.
    - See also section "4.1 Impartiality" for recommendations to ensure that staff act impartially.

Assess the needs for competence

- IMS have to assess personnel competence, taking into account methods and workload [1].
- This can include a required diploma, qualifications and training programmes required; access to knowledge databases and networks; and other matters (human behaviour, spoken languages…).

Ensure personnel qualifications meet IMS requirements

- The requirements for each staff position may vary depending on the size and complexity of methods of the IMS. E.g., in small laboratories with limited personnel, staff may have many responsibilities and perform many tasks, whereas in larger laboratories with more personnel, staff may be more specialised and perform a more limited number of tasks.

Ensure adequately qualified staff

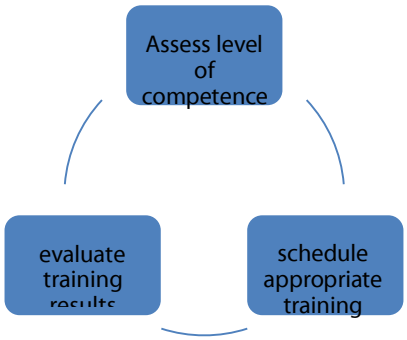
- Staff shall have adequate training and experience for the position to which they are assigned. If you detect that a staff member is performing tasks for which he/she is not appropriately trained, this staff member must undertake appropriate training. Identify appropriate courses for each staff member and provide funding to finance these. The training program has to include evaluation of the new competence and the evaluation has to be documented.
- Supervise (before authorisation) and monitor (after authorisation) [1].

Examples of supervision/monitoring methods [6]

- Direct observation
- measuring samples known dose
- blind samples
- inter/intra laboratory comparisons
- reanalysis of results
- exams/tests

IMS should keep records of staff's supervision/monitoring.

The assessment and the competence of staff have to be continuously improved in following scheme:



Examples from accredited laboratories

- Organisational Chart
  - OC is helpful in order to have a clear overview of the position of the IMS in the organisation (if IMS is part of a bigger organisation) and the organisational structure within the IMS itself. It also helps staff understand the relation between management, technical operations, and administrative personnel (See Annex A).

- Job descriptions
    - In ISO/IEC 17025:2017 job descriptions are not a requirement but it helps see the tasks and responsibilities of each position in one overview. (See Annex B)
- Copies from relevant certificates for every staff member.
- Induction training for every new staff member. Induction training including the following areas:
    - IMS management system
    - Dosimetry methods
    - Safety/security
    - Equipment
    - Software
    - Specific job tasks
- Training certificates and the evidence of any following evaluation in personnel folders.
- [6.2.5. e] Good practice: Make an Annex D.

In an Annex D the authorisations and responsibilities are defined for each activity in the IMS. Definitions for each activity performed in IMS which position is authorised to perform the activity, which position is responsible for the correct performance of the activity (See Annex D).

Audits

- **Possible auditor's questions**
    - Does the IMS have a documented system for personnel management?
    - Does the qualification of personnel meet with job requirements?
    - Do new personnel have enough training?
    - The authorisation process for new hiring personnel?
    - Have you assessed the training needs for the present year?
- **Showing evidence of compliance**
    - Updated training plan
    - Check actions performed and evaluation of results and effectiveness
    - Authorised and complete personnel records:
    - Documentation of personnel qualifications and training
    - Training certificates
    - Curricula vitae
    - Commitment to confidentiality and impartiality

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 4.2 Confidentiality
- 5 Structural requirements

- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.2 Selection, verification and validation of methods
- 7.4 Handling of test or calibration items
- 7.5 Technical records
- 7.8 Reporting of results
- 7.11 Control of data and information management
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.6 Improvement
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

3.3.2 Sub-clause 6.3: Facilities and environmental conditions

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clauses 5.3 "Accommodation and environmental conditions" and ISO/IEC 17025:2017 and 6.3 "Facilities and Environmental Conditions" have different structure, but the logic of the requirement has not changed).

Suggestions on how to interpret the requirement

- The objective of this requirement is for the IMS to demonstrate that it has adequate facilities for the proper execution of activities. The standard sets requirements to those environmental conditions which can have an effect on the results of IMS activities.
- Measures to control facilities may include access to and use of areas affecting IMS activities, prevention of contamination and effective area separation, including sites or facilities outside of IMS permanent control [1].
- It is expected for the requirements of facilities and environmental conditions to be documented [1].

Suggestions on how to implement the requirement

- IMS shall establish suitable facility and environmental conditions in such a way that they cannot influence adversely any quantity measured (6.3.1) [1].
- IMS shall identify influencing parameters and define environmental operating conditions and the range of accepted variations. Influences that can adversely affect the quality of measurements in an IMS could include (but are not limited to) temperature, light, radiation, humidity, electrical supply and electromagnetic disturbances. International standards, manufacturer's type test results, manufacturer's user manuals, IMS tests or other relevant valid knowledge could be used in order to identify influencing parameters and the range of accepted variations in operating conditions.
    - IMS shall act, taking appropriate measures, in order to minimise the possible adverse effect of parameters and document them. Possible deviations from the documented conditions shall be included in a risk assessment (6.3.2) [1].
    - Furthermore, IMS shall establish a method of monitoring influencing parameters and evaluation of possible variations out of predefined ranges. The methods may vary depending on the significance of the influencing parameter. IMS could select a method of continuously recording any influencing parameters values or a notification method when the parameter's values are out of the range of accepted variations. When documented criteria are not met, measures should be implemented (6.3.3) [1].
    - IMS shall identify significant parameters (if there are any) to control the facilities such as control of access, prevention of contamination, etc. (6.3.4) [1].

- IMS shall provide advice, in written form, to all stakeholders in the process from the moment dosimeters are sent from the facility until they are returned to the facility for measurement on proper use of the dosimeter.

Examples from accredited laboratories

Establish acceptance criteria for environmental conditions.

Dosemeters should be kept in reproducible conditions of temperature, humidity, light exposure and low background radiation recommended by relevant literature. Several standards are giving recommendations for environmental conditions for photon dosemeters (See Annex F).

IMS shall monitor, control as planned by procedure and record influencing conditions (See Annex G). If you state particular temperature, humidity and light exposure conditions, then the IMS has to be equipped with adequate calibrated equipment to measure these conditions. In the case that the influence of environmental conditions is too low (documented) or the deviation that could lead to a significant effect on quantity measured is extremely rare, IMS could use a "notification" method in order to avoid keeping unnecessary records. Overall, the frequency of monitoring should be proportionate to the risk recognised by the laboratory's risk assessment and based on quality control and type tests results. It is important to periodically validate results with the calibrated equipment. For more details, see 6.4. Equipment.

In the case of acceptance criteria not being met, depending on the influencing parameter, measures defined in a risk assessment shall be implemented. Large deviations:

- in temperature and humidity are resolved by installing air-condition in the laboratory where dosimeters and reader are stored;
- of light exposure can be controlled with covers designed to cover the reader and dark drawers for storage of dosemeters; window covers to prevent additional light reaching the facility. Maintenance of the light exposure can also be controlled with special light bulbs;
- in natural background radiation should be investigated. If the natural background radiation remains stable, there is no need for continuous monitoring (IMS has to have documented evidence). Monitoring is needed in case there are radiation sources inside or near the laboratory.

Access to the laboratory should be restricted and clearly marked with signs such as

- "*No Entrance. Staff Only*" or
- special pass cards.

During the dosimetry process, dosemeters are usually sent to the customer and received back by the IMS after a designated monitoring period via postal mail. During this cycle, the IMS cannot have control of the facility and environmental conditions. For this purpose, the IMS shall:

- provide instructions for the proper handling, transport and use of the dosemeter;
- use stickers "*do not x ray*", "*photo material*", "*thermo sensitive*" etc. on sending envelopes to prevent possible negative influences.

Good practice:

- Follow IEC 62387:2020 (Environmental performance requirements and tests) [8].
- It is preferable to reduce the variations of environmental conditions rather than keeping records of performance. This allows your IMS to avoid the use of extra equipment such as thermometers, survey meters... (as they all need to have valid calibration certificates).

Audits

- **Possible auditor's questions**
  - How did the IMS set up criteria for environmental conditions? How does the IMS control and monitor established criteria?
  - How does the IMS control environmental conditions when dosemeters are sent to the customers? Did the IMS include possible deviations in the risk assessment?
  - How does the IMS prevent possible exposure of the dosemeters in an IMS facility?
  - Does the IMS have a procedure in case environmental conditions are out of pre-defined operating conditions?
  - Is there any incompatible activity carried out in the laboratory? If yes, is there an effective separation which avoids cross contamination?
  - Are there access controls to the laboratory's areas which may influence the quality of the test?
- **Showing evidence of compliance**
  - Type testing provided by the manufacturer according to IEC 62387:2020 [8]
  - Documented type test performed by IMS (according to 62387:2020 is suggested)
  - Instruction on proper use, care and handling of the dosemeters for the customers
  - Risk matrix including possible deviations that could arise from environmental conditions during the cycle: sent dosemeter – received dosimeter – measured dosemeter
  - Procedures on handling the equipment
  - Plan for monitoring of the environmental conditions
  - Forms for monitoring of the environmental conditions. Certificates of calibrations for equipment used to measure environmental conditions
  - Records of the environmental conditions monitoring

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 5 Structural requirements
- 6.4 Equipment
- 6.6 Externally provided products and services
- 7.2 Selection, verification and validation of methods
- 7.4 Handling of test or calibration items

- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 7.10 Nonconforming work
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.3.3 Sub-clause 6.4: Equipment

New in ISO/IEC 17025:2017?

No (It replaces ISO/IEC 17025:2005 sub-clause 5.5 "Equipment").

Suggestions on how to interpret the requirement

- IMS shall have access to equipment that can have an influence on the results. Equipment includes: instruments, standards, software, reference materials, consumables and auxiliary apparatus [1].
- If any equipment is outside the permanent control of the IMS, it shall meet all requirements of the standard [1].
- IMS shall have written instructions for handling, use and maintenance of equipment in order to assure proper performance and prevent contamination.
- IMS shall establish a calibration programme for each equipment whose:
  - measurement uncertainty affects the results [1]
  - metrological traceability is required [1].
- All equipment shall be:
  - Uniquely identified and labelled indicating status of calibration or period of validity [1]
  - Periodically calibrated, verified and maintained [1].
- IMS shall keep records for equipment including:
  - Name and version, if applicable [1]
  - Manufacturer and model or type [1]
  - Unique identification as serial number, for instance [1]
  - Location [1]
  - Calibration dates and validity date [1]
  - Record of maintenance, malfunction and reparations [1].

Suggestions on how to implement the requirement

- Procedures to describe dealing with equipment shall be written. Forms or record templates are necessary as well.
- Calibration periods for required equipment shall be established by the IMS. It can be based either on national legislation or international recommendations. For instance, the European Commission, in the document RP-160, *Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation* [4], recommends the reader reference calibration to be performed every one or two years. For reusable dosemeters the individual normalisation/calibration factors should be checked periodically and adjusted if necessary.
- The IMS shall establish a calibration, verification and maintenance plan for relevant equipment and keep records of these activities [1].
- Every item of equipment which can influence the results shall be clearly labelled indicating status of calibration or period of validity [1].

- It's important to remember that software is considered as equipment [1]. The version shall be identified and changes shall be authorised, documented and validated before implementation (in case the software is developed in-house). Validation of commercial software is not required but all changes shall be documented on an equipment card.
- Most of the requirements of this sub-clause can be met with good quality procedures. Every IMS shall establish them according to their own needs.

Examples from accredited laboratories

- Equipment cards including relevant information of the equipment (ID code, trademark, model and version, provider, serial number, location) and record of calibrations, verifications and maintenance.
- Equipment labels indicating the state of use of the equipment, mainly readers, densitometers, ovens, irradiators, ... The use of a colour coding system can be useful: green (ready to use), orange (with restrictions of use) and red (out of use).
- Every dosemeter should have a traceable individual normalisation/calibration factor to normalise the response of all the dosemeters to a reference value. The IMS shall maintain records of the calculation procedure, results and acceptance.
- If the dosemeters are reusable, the IMS must periodically check the individual normalisation/calibration factor of the dosemeters and keep a record of the calculation procedure, results and acceptance. For passive solid state dosemeters, a suggested frequency is every 10 uses or every 2 years, whichever occurs first.
- Having an acceptance procedure of equipment prior to first use and back into service after any alteration, as repairs or long periods unused, is good practice.

Audits

- **Possible auditor's questions:**
  - How do you prevent the use of equipment which is not calibrated?
  - Could you please show us what actions you did to improve the accuracy of your system?
  - How do you avoid unforeseen adjustments to the equipment that could invalidate the results?
  - Could you show evidence of the calculation and check of the individual normalisation/calibration factor of the dosemeters? Are there any established criteria to replace a reusable dosemeter?
  - Could you show us a calibration report after a service of the TLD reader?
- **Showing evidence of compliance:**
  - Procedures or documents (technical manuals, for instance) for dealing with readers, dosemeters, ovens and irradiators including calibration, verification and maintenance periodicity, acceptance criteria and actions to be taken in the case that the they are not met.
  - Equipment cards for all relevant instruments and software including basic information, and calibration, verification and maintenance dates and acceptance records.

○ Labels on equipment indicating unique identification or code, state of use and calibration dates or validity period.
Cross reference with other ISO/IEC 17025:2017 sub-clauses • 6.3 Facilities and environmental conditions • 6.5 Metrological traceability • 6.6 Externally provided products and services • 7.2 Selection, verification and validation of methods • 7.4 Handling of test or calibration items • 7.7 Ensuring the validity of results • 7.8 Reporting of results • 8.8 Internal audits • 8.9 Management reviews

3.3.4 Sub-clause 6.5: Metrological traceability

New in ISO/IEC 17025:2017?

No (It replaces ISO/IEC 17025:2005 sub-clause 5.6 "Measurement traceability").

Suggestions on how to interpret the requirement

- The IMS shall establish and maintain metrological traceability of its measurement results [1].
- Measurement results shall be traceable to SI units through either:
  - calibration by a competent laboratory [1] (i.e. The National Metrology Institute or an accredited calibration laboratory);
  - the use of certified reference materials from a competent producer with traceability to SI units [1];

Note that metrological traceability pertains to reference quantity values of measurement standards and results, not the organisation providing the results.

Suggestions on how to implement the requirement

- Metrological Traceability is a property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations each contributing to the measurement uncertainty [1], [9].
- It is essential that the calibration of dosimeters is traceable to the corresponding primary standard. This requirement can be met by calibration of the dosimeters in the Secondary Standard Dosimetry Laboratory or by a different calibration method traceable to SI unit.
- All parts of the chain of calibrations shall be documented.
- Measurement uncertainty shall be estimated by a recognised method and shall be notified to the customer.
- Measurement methods and results shall be documented.
- All equipment that can influence results shall be calibrated and traceable to the corresponding primary standard.
- Re-calibrations shall be performed at predefined specific intervals.
- Equipment shall be labelled, coded or identified.

Examples from accredited laboratories

- Calibration periods have been established.
- System calibrations are performed on a yearly basis.
- Regular checks of equipment and calibration certificates are performed.
- Equipment is identified through labelling and coding (good practice not only for this sub-clause: a label on every item of equipment contains a unique id, the next re-calibration date and other useful information e.g. use restrictions).

Audits

- **Possible auditor's questions:**
  - How do you decide if the calibration laboratory is competent?

- How often do you check your calibration procedures?
- How often your equipment is calibrated? Why in these periods?
- How do you present traceability in your test reports?

- **Showing evidence of compliance:**
  - Proof of competence of calibration laboratory used.
  - Proof of traceability from test report.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.4 Equipment
- 6.6 Externally provided products and services
- 7.2 Selection, verification and validation of methods
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 8.8 Internal audits
- 8.9 Management reviews

3.3.5 Sub-clause 6.6: Externally provided products and services

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clauses 4.5 "Subcontracting of tests and calibrations" and 4.6 "Purchasing services and supplies" have been included in this section).

Suggestions on how to interpret the requirement

The main objective of this requirement is to ensure that all externally provided products (e.g. standards and measuring equipment, auxiliary equipment, consumables and reference materials) or services (e.g. calibration, sampling, testing, facility and equipment maintenance, proficiency testing, assessment and auditing) that affect the quality of the IMS activities are adequate.

The standard requires the IMS:

- To define requirements and implement control actions that ensure the suitability of the externally provided products or services [1].
- Ensure that the externally provided products and services meet the established requirements before being used or provided to the customer [1].
- Define criteria for the selection, evaluation and re-evaluation of external providers and establish actions derived from monitoring of performance and re-evaluations of external providers [1].

In relation to subcontracting, it has been considered there are possible difficulties in finding accredited subcontractors (depending on the field of activity). Now, use of an accredited subcontractor is not mandated, but the IMS must evaluate if the external provider (subcontractor) meets the requirements established by the IMS and also the relevant requirements of the reference standard when applicable. However, national accreditation entities may establish more restrictive criteria.

Suggestions on how to implement the requirement

- The IMS shall ensure the suitability of the externally provided products and services that affect IMS results [1].
- The IMS is requested to have documents (procedure or similar) showing the management of the externally provided products and services, describing:
    - Requirements for products or service to be acquired [1].
    - Acceptance criteria for the products or services externally provided [1].
    - Criteria for evaluation, selection, monitoring and re-evaluation of external providers [1].
    - A system to ensure the conformity of the externally provided products and services to the established requirements [1].
    - Actions resulting from evaluation, monitoring and re-evaluation of the external providers [1].
- The IMS must retain records of all externally provided products and services [1].
- External providers must be informed about products and services to be provided, acceptance criteria established by the laboratory, competence needed and activities that the laboratory intends to perform in the provider's facilities [1].

Examples from accredited laboratories

- Documents (procedure or similar) describing the management of externally provided products and services that affect the quality of the results.
- Designation of the person in charge of defining requirements of the services or products to be acquired externally.
- Purchase requests in which the requirements for products or services are established.
- Reception documents, delivery note, or similar.
- Review (quantitative and qualitative) of the externally provided products or services.
- Signed evidence of verification and approval of compliance with the pre-use requirements.
- Criteria for external provider selection. Examples:
    - Does the external provider have a certified or accredited management system?
    - Has the external provider been audited by the IMS?
    - Is the external provider considered adequate based on previous experiences?
    - Is the external provider unique? (There is no other provider for the product or service required).
- Periodic evaluation of external providers.
- Criteria for external provider evaluation, monitoring and re-evaluation. Examples:
    - Does the external provider meet the delivery terms?
    - Do the products or services externally provided meet the established requirements?
    - Are the products supplied in a good condition?
    - Is the post-sales service adequate?
    - Has the activity of the IMS been affected by any circumstance derived from externally provided products and services?
- Opening the non-conformity process if necessary in case of:
    - Incidents related to the externally provided products and services.
    - Negative evaluation of the external provider.
- Evaluation table based on the severity of non-compliance.
- Records of the corrective actions taken.
- Communication with the external providers to meet the requirements (established by the IMS and the standard).
- Analysis and evaluation of risks and opportunities associated with both the externally provided products and services and the performance of external providers.

Audits

- **Possible auditor's questions**
  - Are the products and services considered adequate?
  - Does the IMS have a document indicating the procedure for:
    - Defining, reviewing and approving the requirements for externally provided products and services?
    - Ensuring that the products and services meet the established requirements?
    - Defining the criteria for the selection, evaluation, performance monitoring and re-evaluation of external providers?
  - Are records of established requirements for externally supplied products and services maintained?
  - Do the purchase requests describe the services and products requested?
  - Is there evidence of technical review and approval of purchase request?
  - Is the adequacy of the externally provided products and services reviewed before use? Are records of inspections / verifications carried out on externally provided products and services maintained?
  - Are records of selection, evaluation, performance monitoring and re-evaluation of external providers maintained?
  - Does the IMS communicate to external providers its requirements to:
    - The products and services to be supplied?
    - The acceptance criteria?
    - The competence, including any required qualification of personnel?
    - The activities that the IMS, or its customers, intends to perform at the external provider facilities?
- **Showing evidence of compliance**
  - Document describing the management for externally provided products and services.
  - Lists of responsibilities (or similar) including the assigned person for defining, reviewing and approving the requirements for externally provided products and services.
  - Records of the activities carried out:
    - Initial evaluation, performance monitoring and re-evaluation of external providers.
    - Purchase requests.
    - Technical review and approval of purchase requests.
    - Reception documents.
    - Inspections / verifications carried out on externally provided products and services.
    - Acceptance (of meeting the established requirements) before use.

- Actions taken in case of incidents affecting the IMS activity.
- Records of communication with providers.
  - Information related to products and services, acceptance criteria, requested competences, etc.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 4.2 Confidentiality
- 5 Structural requirements
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 7.1 Review of requests, tenders and contracts
- 7.5 Technical records
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 7.10 Nonconforming work
- 7.11 Control of data and information management
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.4 Clause 7: Process requirements

3.4.1 Sub-clause 7.1: Review of requests, tenders and contracts

New in ISO/IEC 17025:2017?

No (It replaces the requirements of ISO/IEC 17025:2005 sub-clauses 4.4 "Review of requests, tenders and contracts" and 4.1 "Service to the customer").

Suggestions on how to interpret the requirement

- The IMS is required to have a procedure for reviewing requests, tenders and contracts that ensures:
  - Requirements are adequately defined [1].
  - The IMS can meet the customers' requirements for dose measurements [1].
  - The customer agrees to eventual use of external suppliers [1].
- The IMS will agree the procedure to be used with the customer and inform them when the customer's desired procedure is inappropriate. If the procedure differs from the tender the IMS must ensure the customer agrees and the integrity of any results are not compromised [1].
- The IMS is required to inform the customer of any deviations from the contract. If deviations occur after work has commenced a new contract review shall be carried out and communicated to the appropriate staff [1].
- The IMS shall cooperate with the customer to clarify requests and to monitor IMS performance [1].
- The IMS shall retain records of reviews and significant change, including any relevant discussions with customers relating to the contract [1].
- When the customer requests whether a dose value is below or above a certain tolerance, the decision rule used shall be agreed with the customer [1].

Suggestions on how to implement the requirement

- The IMS is usually requested by the customer to provide a definite amount of dosemeters, of different types.
- To match the standard, the list of dosemeters that are provided and the testing to be undertaken must be agreed very clearly between the IMS and the customer.
- A contract or agreement letter must be accepted when a new customer asks for any new work. All requirements must be documented.
- The contract must clearly specify the periodic issuing of dosemeters and how any change in periodicity is managed.
- Any changes to a contract must be recorded and agreed with the customer. Customers must also be informed of any deviations from the contract.
- The IMS and customer should agree metrics to monitor the performance of the IMS when agreeing the contract.

- The IMS should have a procedure to record and retain details of any communications with the customer. This can include, but is not limited to, contract discussions, customer complaints, progress discussions or results (record retention must adhere to GDPR guidelines [7]).
- The detection limit of the dosemeters for the measured dose quantities should be documented and communicated to the customer.

Examples from accredited laboratories

For the dose measurement in itself there is not always a specific request made to an IMS from a customer, but there are "requests" somewhat hidden, but still present.

Some examples:

- Customer must be provided with detailed instructions on how to wear dosimetry (chest side, over/under protective apron, not exposing to heat, avoiding contamination, using protective plastic bag, etc. etc.). These instructions act like a contract i.e. results from dosimetry measurements will only be valid if you follow the instructions provided.
- It must be clearly stated in which cases you are not able to read dosemeters. Trivial cases must be included: dosimeters issued by another service, broken dosemeters, dirty dosemeters, etc.
- Background subtraction. If you send transport or background dosemeters to the customer, to store them properly is a very important request. If you subtract background in a different way, or you don't subtract it at all, this must be clearly stated in advance, so that the customer may understand the meaning of the dose value.

In these cases, the request does not come from the customer, that is very often not aware of all these details, but to match the standard these requests must be clearly stated, documented and understood.

- If you provide any dose report, you must have an agreement with the customer about conditions of the service. Since most of the customers of IMS are routine customers, agreement does not necessarily need to be in the form of a contract. It can be simplified with accepting terms and conditions of IMS services.
- Attention must be payed to unusual customers, e.g. exposed workers in own department, small customers (only one dosemeter), long standing customers (maybe agreement never existed or was produced so long ago it is no longer retained), etc. If these situations are exceptions to the general contract it is not a problem, but it must be stated.

Audits

- **Possible auditor's questions**
  - How does the IMS ensure that the customer receives the appropriate information about the methods used for personal monitoring?
  - How does the IMS handle requests from a customer?
  - How has the IMS documented the decision rule used?

- **Showing evidence of compliance**
  - Records of reviews of contracts and changes to contracts
  - Records of communications between the IMS and customers, including customer complaints
  - Documentation of decision rule(s) and communication hereof.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 4.2 Confidentiality
- 5 Structural requirements
- 6.2 Personnel
- 6.6 Externally provided products and services
- 7.2 Selection, verification and validation of methods
- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 7.8 Reporting of results
- 7.10 Nonconforming work
- 8.4 Control of records
- 8.8 Internal audits
- 8.9 Management reviews

3.4.2 Sub-clause 7.2: Selection, verification and validation of methods

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clause 5.4.5 "Validation of methods" have been drafted differently with some editorial or minor changes).

Suggestions on how to interpret the requirement

Verification, according to ISO/IEC 17025:2017 is the provision of objective evidence that a given item fulfils specified requirements [1]. It is often an internal process.

One example of a verification report for an IMS is a manufacturer's type test report on conformance with IEC 62387:2020 [8]. This kind of verification report will conclude if the passive dosimetry system is in line with the requirements set by IEC 62387:2020 [8]. However, it will not conclude if these requirements are adequate for an intended use (fit for purpose). This implies that the verification report will not give information to the IMS on the customer specific requirements or their unique needs and requests if they exist (e.g. your client might have a specific requirement on energy range that differs from the one specified in the verification report).

When IMS verify if the performance characteristics are fit for purpose with their own personnel, equipment and specific environmental conditions (with legislation/customer specific needs and requests/standards, etc.), the IMS are validating the method.

Validation is:

- According to ISO/IEC 17025:2005 (cl. 5.4.5.1) validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled [2].
- According to ISO/IEC 17025:2017 (3.8 and 3.9) method validation is the provision of objective evidence that the method fulfils specified requirements, where the specified requirements are adequate for an intended use [1].

Requirement: Non-standard methods, laboratory-developed methods and standard methods used outside of their scope shall be validated (7.2.2.1) [1]. As IMS are using laboratory-developed methods, these methods will require validation.

The performance characteristics of validated methods must be consistent with specified requirements (7.2.2.3) [1].

Validation of methods has to be documented and approved [1].

Suggestions on how to implement the requirement

- Validation must be planned and acceptance criteria must be predefined. It can be achieved using the two following principles, often in combination:
    - The validity of the method can be described and demonstrated using scientific knowledge and acknowledged experience.
    - Intercomparisons, proficiency testing, or reference materials can be used in order to demonstrate the validity of the IMS method.
- The extent of validation should always be chosen with consideration of the intended use of the results.
- Costs, risks and technical possibilities should be taken into account during the validation of a method.

- A list of performance characteristics of method could include, but not limited to, the following:
    - Selectivity (is the most suitable?)
    - Linearity
    - Repeatability
    - Reproducibility
    - Detection limit
    - Robustness
    - Uncertainty of results

Examples from accredited laboratories

Techniques for the determination of a method performance:

- Applicable international standards for the definition of parameters to be evaluated in a method validation process and for the establishment of acceptance criteria (see Annex H).
- Comparison of method performance with other dosimetry methods.
- Calibration at Secondary Standards Dosimetry Laboratory.
- Regularly participation in intercomparison exercises organised by authorities or recognised organisations in field of radiation protection (IAEA, EURADOS…).
- Bilateral inter-laboratory tests.
- Systematic assessment of the factors influencing the dosimetry results.
- Effective Quality Control program.
- Assessment of uncertainty of results based on JCGM 100:2008 [10].
- Testing staff member competence to perform measurements based on the specific method.

Method performance demonstration (See Annex H):

- A report with results from validation studies and the comparison of information obtained by them with standards requirements.
- IMS performance in intercomparison or in inter-laboratory tests.
- Results from various performed tests (Type test, quality control tests…).
- Certificates of equipment (dosemeters, readers, materials, etc.) or/and manufacturer's equipment performance test.

IMS has to define actions to be taken when validation results are found to be outside of pre-defined acceptance criteria.

Audits

- **Possible auditor's questions**
    - Is your method based on specific standards (and which)?
    - Is your quality control program documented?
    - Which are the accepted limits in intercomparison or in inter-laboratory tests?

- Are there results outside the uncertainty range acceptable? Is that validated?
- Did you validate your software? (In the case that the used software or a part of them is developed by IMS).
- How did you perform the software validation?
- What kind of tests have you performed in order to check the validity of your results?
- Where is the selected validation method based?
- Which method has been used for uncertainty estimation?

- **Showing evidence of compliance**
  - Demonstration of method's validation documentation.
  - Demonstration of intercomparison data and results.
  - Demonstration of validation records.
  - Demonstration of method's uncertainty.
  - Certificates for equipment (dosemeters, readers, materials, etc.)

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 7.1 Review of requests, tenders and contracts
- 7.2 Selection, verification and validation of methods
- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 7.7 Ensuring the validity of results
- 8.8 Internal audits
- 8.9 Management reviews

3.4.3 Sub-clause 7.3: Sampling

Sampling, from a quality assurance perspective, can be interpreted as the selection of a subset (a statistical sample) of entities from within a population to estimate characteristics of the whole population. In individual dosimetry, this concept is not applicable. All dosemeters returned to IMS by a customer after the end of monitoring period are measured and reported.

3.4.4 Sub-clause 7.4: Handling of test or calibration items

New in ISO/IEC 17025:2017?

No (It replaces the requirements of ISO/IEC 17025:2005 sub-clause 5.8 "Handling of test and calibration items").

Suggestions on how to interpret the requirement

- The main purpose of this requirement is to ensure proper handling of the dosemeters during the cycle: storage - preparation – transportation – wearing – measuring – disposal.
- The sub-clause requires procedures to avoid any deterioration, contamination, loss or damage of the dosemeters [1].
- For the dosemeters received with the deviations from specified conditions, deviations have to be recorded and the report shall indicate a disclaimer for the results affected by the deviation, in the case the measurement has been performed [1].

Suggestions on how to implement the requirement

- The IMS needs to identify activities that are involved in the dosimetry process: sending, receiving, measuring and storing the dosemeters. These activities shall be defined in an IMS procedure(s) with an overview to the risk assessment. Some activities will need detailed explanations, some not.

Examples from accredited laboratories

- Read manufacturer's specifications for all the elements that compose a dosemeter (card, film, holder, bag, etc.).
- Add the IMS requirements to the manufacturer's requirements, including obvious ones (dosemeters must not be exposed to ionising radiation, films must not be exposed to light, dosemeter needs to be stored in appropriate environmental conditions, etc.).
- IMS need to make procedures for each step of the process when the dosemeter is under its responsibility: preparing, storage or reading, etc.
- If you have an identification for dosemeters (barcode or similar), to be compliant with sub-clause 7.4.2 [1] you must have a strong system (software), to show it is not possible to mix dosemeters, wearers and measurement results. Any deviations upon receiving the dosemeters under your IMS responsibility, such as damaged dosemeter, needs to be recorded.
- If dosemeters are not identified (like TLD sometimes are not) the IMS should adjust its procedure. In that case you must enforce quality control procedures to be sure identification is not lost or confused.
- If the IMS states limits for environmental conditions, then these must be traceable. E.g.: if you state a temperature between 15 and 30°C, you must have a calibrated instrument to monitor this condition and store it: you must demonstrate condition did not change even when the laboratory was unoccupied.

Note

See section "6.3 Facilities and environmental conditions" for recommendations to ensure your laboratory has set up the environmental conditions according the requirements [1].

See Annex I, EURADOS AM2018 experience sharing – Bad results as a consequence of improperly handled dosemeters.

Audits

- **Possible auditor's questions**
  - How can you be sure the reading of all dosemeters has been completed correctly and no data has been wrongly reported (e.g. TLD data has not been reversed)?
  - How can you be sure the link between a measurement result and the worker's name is not lost or confused?
  - Is the staff preparing dosemeters inside your laboratory competent to handle them?
  - Are you sure dosemeters coming from your customers are not contaminated and are not damaging the readings of many dosemeters in your lab?
  - How does the IMS verify the integrity of the items while they remain under its responsibility?
  - What measures have been taken to avoid deterioration, contamination, loss or damage of the items during the time they are under IMS responsibility?
  - How does the IMS maintain and record the conditions when the items need to be stored under specified environmental conditions?
  - Are records of receipt of the test or calibration items maintained? In case of deviations in the receipt conditions, are they documented?
  - When there is a doubt about the adequacy of an item, are there records of the consultation with the client about the process taken to rectify the situation?
  - If the client requires to test the item, admitting a deviation, does the report of results include the identification of the results that may be affected by the deviation during the receipt process?
- **Showing evidence of compliance**
  - Can you show us the procedures for transportation, receipt, handling, protection, storage and retention of dosemeters?
  - Can you show me the manufacturer's specifications for your dosemeters?
  - Records of communication with client.
  - Records of reception, transportation, handling, protection, storage, retention.
  - Records of environmental conditions, if needed.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 6.3 Facilities and environmental conditions

- 6.4 Equipment
- 7.2 Selection, verification and validation of methods
- 7.5 Technical records
- 7.7 Ensuring the validity of results
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.4.5 Sub-clause 7.5: Technical records

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clauses 4.13 "Control of records" and 4.13.2 "Technical records" have been drafted differently).

Suggestions on how to interpret the requirement

This section is complemented with requirements of ISO-17025:2017 sub-clauses 7.11 "Control of data and information management", 8.2 "Management system documentation" and 8.4 "Control of records" [1].

The main objective of this requirement is to ensure that the IMS maintains technical records for each IMS activity, containing information enough to enable the repetition or review of the activity.

Records are referred to raw data, measurement results and to all types of information that could affect results (date of activity, personnel name, reagents and materials, instruments, calibrations, environmental conditions, etc.).

Both manual and electronic records are affected by the requirements of this section.

Suggestions on how to implement the requirement

- The IMS shall establish a process for the identification, collection, access, filing, storage, maintenance and disposal of quality and technical records (manual and electronic) [1].
- The records for each test or calibration shall contain sufficient information to facilitate, if possible, the identification of factors affecting the result and uncertainty [1].
- Observations, data and calculations shall be recorded at the time they are made [1].
- Records shall include the identity of personnel responsible for performance of each test or calibration and for checking of results [1].
- In the case of using templates in electronic format for data collection, calculations or generation of results, they must be adequately protected against unauthorised changes.
- The IMS is required to implement measures in order to avoid loss of information. Protection measures and periodic backups are required to ensure the integrity of data.
- Retention times of records shall be established depending on national legislation, accreditation requirements, contractual agreements, etc. The IMS should decide the records storage time, in some cases from 3 to more than 30 years.
- Amendments to technical records must be traceable to the original version [1].
- Errors detected in manual records shall be crossed out (not erased) and then the correct value shall be written down. Date and the personnel responsible for the correction shall be identified. Both the original and amended data shall be kept.
- In the case of electronic records, equivalent measures to avoid loss or change of original data shall be taken.

Examples from accredited laboratories

- Processes for the identification, collection, storage, access, maintenance and destruction of technical records, affecting both manual and electronic records.
- Maintaining a set of records for all technical activities carried out (dosemeter reception and dispatch, quality control activities, irradiations, element correction factors, calibrations, oven treatments, reading of dosemeters, dose evaluation, etc.) including, at least, the following information: activity carried out, date, identification of equipment, environmental conditions, applied methods, observations and personnel responsible for carrying out the activity and reviewing the data and results.
- Adequate storage of technical records, ensuring confidentiality and conservation.
- In the case of amendments:
    - In manual records: crossing out the original text and writing the new text with identification of authorised personnel (signature) and date.
    - In electronic records: using the "Track changes" option of the text editors or saving new file, including corrections, identified differently from the original one.
- Control of access to the facilities where the technical records are stored.
- Use of remote servers for technical records storage (in electronic format).
- Periodic backups.
- Validation and protection measures against unauthorised or accidental changes when a template or spreadsheet is used for data generation or calculations.
- Use of passwords for accessing to servers, spreadsheet and templates.
- Period of storage of the technical records, considering the requirements affecting the IMS activity (current legislation, accreditation requirements, customer requirements, etc.). One example to be used could be IAEA GSR Part 3, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards" §3.104. recommends "Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure" [11].
- Considering the risks associated with maintenance, information retrieval (specific formats), access control, protection, confidentiality of technical records.

Audits

- **Possible auditor's questions**
    - Do the records for test include the following information, when it is relevant?
        - Activity description
        - Item identification
        - Date

- Personnel responsible for each activity
- Personnel responsible for checking the data and results
- Equipment identification
- Environmental conditions
- Applied methods
- Information about sampling and transport (in case of)
- Observations

- Does the IMS have all the technical records associated with the activity carried out?
- Does the information in technical records allow the identification of the factors affecting the result of the measurement and its associated measurement uncertainty?
- Does the information in technical records allow, if necessary, the repetition of test / calibration?
- Have adequate measures to prevent damage, deterioration and loss of information been taken?
- Are the technical records easily legible and recoverable?
- Are backup copies made periodically?
- Is the specific software (spreadsheet or electronic template) correctly validated?
- Have protection measures against improper software modifications been established?
- Is the integrity of information guaranteed?
- Is the process used to identify changes adequate? (signature and date)
- Are changes traceable to the original version?
- Is the following information available?
  - Original data and files
  - Correction date
  - Indication of the corrected items
  - Identification of personnel responsible for the corrections

- **Showing evidence of compliance**
  - Document describing the management of documentation including control of data and technical records.
  - Records of all technical activities carried out, including all the information required by the standard.
  - Records of the backups.
  - Records of validation and protection of specific software, spreadsheets or templates used for data recording, calculations and obtaining results.

- In the case of amendments: original and modified records with identification of the corrected items, date and the personnel responsible for the corrections.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.2 Selection, verification and validation of methods
- 7.4 Handling of test or calibration items
- 7.6 Evaluation of measurement uncertainty
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 7.9 Complaints
- 7.10 Nonconforming work
- 7.11 Control of data and information management
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.6 Improvement
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

3.4.6 Sub-clause 7.6: Evaluation of measurement uncertainty

New in ISO/IEC 17025:2017?

No (It replaces the requirements of ISO/IEC 17025:2005 sub-clause 5.4.6 "Estimation of uncertainty of measurement").

Suggestions on how to interpret the requirement

IMS shall evaluate measurement uncertainty. When reporting the result of a measurement, the uncertainty of the measurement should be estimated and reported [1].

Reasonable and appropriate measures to quantify and minimise uncertainties should be taken.

The amount of effort put into the estimation of uncertainty should be realistic in view of its purpose in the protection of exposed workers [4].

In particular radiation fields a normalisation factor should be required to be applied in order to minimise uncertainties in the measurement of $H_p(10)$ and in the estimation of effective dose [12].

The uncertainties in the measured values and the calculated values should be reported with measurement results. As an alternative, IMS should share information relating to the measurement procedure and its characteristics, including the uncertainties, on a report or with a different method. In any case customers shall be informed about the uncertainty of measurement.

Suggestions on how to implement the requirement

IMS must be able to demonstrate a certain coverage interval level (accuracy criteria) for a dose measurement by:

- identifying all contributions that are of significance to measurement uncertainty;
    - for most dosimetric systems the main contributions to uncertainty originate from the energy and angular dependence of response. However, any other contributions must be identified and quantified.
- performing appropriate tests or using results from available publications/manufacturer type tests;
- evaluating measurement uncertainty at the chosen confidence interval.
- ICRP 60 statement from paragraph 271 conveys that for the doses of the order of the annual dose limit should not differ more than -33% to +50% (at the 95% confidence level) [13]. ICRP 103 [14] has superseded this document, but the statement is still valid and used in numerous guides and recommendations published in recent years.
- RP-160 [4] includes a chapter (6) on the accuracy of dose assessments that contains useful recommendations summarising the requirements established on this topic in international recommendations.

IMS should inform customers about measurement uncertainty. IMS could provide the relevant information by selecting an appropriate method, either on the measurement report, through a website, a leaflet, or in a contract.

Examples from accredited laboratories

Analysis of the uncertainty is provided in the Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation (RP-160) [4] and the technical standards IEC 62387:2020 [8] or IEC 61526:2010 [15] in the case of active dosemeters. Input quantities for the analysis might be, but not limited to, results of the tests proposed by above declared documents. IMS should use JCGM 100:2008 [10] as a basic guide. The technical report IEC TR 62461:2015 [16] gives guidelines for the application of the uncertainty analysis according to GUM. As an example, basic steps, for an analytical method might be:

- Identify major factors that significantly influence the measurement result (reader stability, element sensitivity (ECC), reference calibration, fading, blank value, energy and angular response, linearity, …).
- Define a mathematical model function which includes all input quantities defined as significantly influencing measurement. Different evaluators will use different input quantities and thus the consequence will be different model functions. This is related to the experience of the evaluator and/or the dosimetry system that the IMS uses.
- Assign a probability density function (PDF) to each of the input quantities. Exact knowledge of the distribution of the output quantity in relation to the possible range of values in each input quantity can significantly assist in the calculation of these quantities. Although, for the majority of input quantities an educated guess is the best available. In any case, a rectangular distribution will give the most conservative estimation. The assigning of PDFs to some of the input quantities can be based on statistical analysis. If the input quantities are mutually dependant a joint PDF must be used.
- For each input quantity the best estimation of the output quantity and the standard deviation (or other relevant quantity such as the difference between minimum and maximum value in the case of rectangular or triangular distribution) should be estimated.
- The impact of each quantity has to be calculated, so called sensitivity coefficients. These are partial derivatives of the model function with respect to each identified input quantity.
- For the calculation, essentially two methods are available:
    - The method based on the law of propagation of uncertainties and the central limit theorem [10].
    - The Monte Carlo method, which uses statistical sampling from the probability density functions of the input quantities to evaluate the convolution integral of the probability density functions [17].
- Using an analytical method [10].
- Calculate the uncertainty contribution to the output quantity due to each input quantity by multiplying the sensitivity coefficient and the standard uncertainty (with assigned PDF).

- Calculate the combined standard uncertainty which is the square root of squared uncertainty contributions.
- Using Monte Carlo method [17]:
  - Create a random sample using the PDF of each input quantity and calculate the value of model function for these input quantities.
  - Repeat previous step M times. A value of M between 10^4-10^6 could be satisfied.
  - Calculate the average value and the standard deviation for the created sample of M values of dose model function.
  - Use the above value of standard deviation as the standard uncertainty associated dose value.
- Calculate expanded uncertainty for a chosen coverage interval (usually 95%).

IMS have to evaluate the measurement uncertainty [4], [16], but report where applicable. The uncertainty should be reported to no more than two significant digits or in a term relative to measurand.

Audits

- **Possible auditor's questions**
  - Do you have a procedure for the estimation of your uncertainty budget?
  - How is your customer informed of the measurement uncertainty?
- **Showing evidence of compliance**
  - Type test results
  - A report with the estimation of the uncertainty of measurement
  - Calibration certificate with stated uncertainty budget
  - Excel calculations with identified sources of input quantities

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.3 Facilities and environmental conditions
- 7.1 Review of requests, tenders and contracts
- 7.2 Selection, verification and validation of methods
- 7.5 Technical records
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 8.8 Internal audits
- 8.9 Management reviews

3.4.7 Sub-clause 7.7: Ensuring the validity of results

New in ISO/IEC 17025:2017?

Partial (It expands the requirements of ISO/IEC 17025:2005 sub-clause 5.9 "Assuring the quality of test and calibration results").

Suggestions on how to interpret the requirement

The main objective of this requirement is to prevent incorrect results from being reported. The IMS shall implement monitoring activities to ensure the validity of reported results [1].

The standard requires the IMS:

- To have a procedure for monitoring the validity of results that includes:
  - Planning monitoring (some methods are listed, including *blind tests*).
  - Recording monitoring data in such a way that trends are detectable.
  - Reviewing monitoring results applying statistical techniques, where practicable [1].
- To participate in proficiency testing and/or interlaboratory comparisons [1].
- Analysing data from monitoring activities in base of pre-defined criteria and taking appropriate actions when criteria are not fulfilled [1].

Suggestions on how to implement the requirement

IMS usually have QC/QA procedures for the readers, dosemeters, ovens, irradiators, etc. It's important that those procedures include:

- Periodicity;
- Acceptance criteria;
- Records template;
- Actions to be taken when monitoring data are found to be outside pre-defined criteria;
- Analysis of results to detect trends and, when possible, improve the IMS activities.

For IMS, it is not easy to find a proficiency testing provider. Most countries do not offer that possibility. However, national regulatory authorities usually require a more or less complete type-testing of the dosimetry system based on the IEC 62387:2020 [8] standard before the IMS will gain approval. This type-testing can be considered as part of the validation of the method (see 7.2.2).

The regular participation of the IMS in dosemeter intercomparisons is required to get and maintain accreditation. The scope of accreditation usually includes: determination of $H_p(10)$ and $H_p(0,07)$ for whole body dosemeters, $H_p(0,07)$ for extremity dosemeters and $H_p(3)$ for eye lens dosemeters.

- The satisfactory participation in a dosemeter intercomparison for the tests included in the requested scope of accreditation is necessary before getting accreditation.
- If available, one participation at least for each of the tests included in the scope of accreditation is required in the period between reassessments. If not available, a laboratory comparison or a blind-test performed in a metrological facility is recommendable.

In some countries, the regulatory authority organises proficiency testing periodically and the participation of the IMS is often mandatory. There are also well known entities that provide dosemeter intercomparisons:

- Eurados regularly offers different type of dosemeter intercomparisons to all interested participants, upon payment of a participation fee.
- International Atomic Energy Agency (IAEA) offers different type of dosemeter intercomparisons usually for free upon invitation to selected IMS.

As part of the monitoring activities, the IMS participation in proficiency tests and interlaboratory comparisons shall be:

- Planned
- Reviewed according to predefined acceptance criteria
- Recorded

Actions shall be taken when interlaboratory comparison results are found to be outside predefined criteria in order to improve the IMS activities [1].

Examples from accredited laboratories

- Quality Control documents including periodicity and acceptance criteria for readers, dosemeters, ovens and irradiators.
- Quality Control records.
- Trend analysis of quality control results.
- Report of IMS participation in each intercomparison including the analysis of results. The performance limits defined in ISO 14146:2018 [18] can be used as pre-defined criteria by the IMS. (See Annex J)

Audits

- **Possible auditor's questions**
  - Does the IMS have quality control procedures for monitoring the validity of monitoring tests undertaken?
  - Is the resulting data recorded in such a way that trends are detectable?
  - Where applicable, are statistical techniques applied to the reviewing of the results?
  - Is the monitoring planned and periodically reviewed?
  - Are quality control data analysed and trends identified?
  - If they are found to be outside predefined criteria, is planned action taken to correct the problem and to prevent incorrect results from being reported?
  - Does the IMS use the data analysis to improve the IMS activities?
  - Are the intercomparisons planned?
  - Is the intercomparisons' plan enough to cover the scope of accreditation?
  - Is the intercomparison participation periodicity in line with other accredited dosimetry services?
  - Has the IMS recorded the analysis of its results with reference to the pre-defined criteria?

- If the results of IC participation are found to be outside pre-defined criteria, is planned action taken to correct the problem and to prevent incorrect results from being reported?
- Does the IMS use the results analysis to control and improve the IMS activities?

- **Showing evidence of compliance**
  - Quality control procedures or documents for readers, dosemeters, ovens and irradiators including periodicity, acceptance criteria and actions to be taken in the case that the they are not met.
  - Quality control records including results compared with acceptance criteria.
  - Quality control results tracking charts.
  - Examples of actions to improve the performance of the IMS as a consequence of the quality control results analysis, if possible.
  - Intercomparisons participation procedure or document including pre-defined acceptance criteria and foreseen periodicity of participation.
  - Intercomparison Participation Plan, that should be annually reviewed.
  - Report of each laboratory intercomparison participation including analysis of results.
  - Examples of actions to improve the performance of IMS as a consequence of intercomparison participation analysis, if possible.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 6.6 Externally provided products and services
- 7.2 Selection, verification and validation of methods
- 7.4 Handling of test or calibration items
- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 8.4 Control of records
- 8.8 Internal audits
- 8.9 Management reviews

3.4.8 Sub-clause 7.8: Reporting of results

New in ISO/IEC 17025:2017?

Partial.

Some changes are included regarding the requirements of ISO/IEC 17025:2005 sub-clause 5.10 "Reporting the results":

- 7.8.2 Common requirements for reports: Date of issue of the report is now required. Disclaimers regarding the information provided by the customer and regarding sampling when the IMS does not perform it have been included [1].
- A signature is not required, but the identification of the person authorising the report must be included [1].
- 7.8.6 Reporting statements of conformity: This sub-clause is new.
- 7.8.7 Reporting opinions and interpretations: Requirements are more detailed now.
- 7.8.8 Amendments to report: Changes in the information included in the report of results must be clearly identified [1].

Suggestions on how to interpret the requirement

- The reports of results must be clear and must contain all the necessary information so that the user can interpret the results correctly.
- This sub-clause includes the information required to be included in the test reports, calibration certificates or sampling reports, although generally IMS do not perform sampling.
- The standard sets requirements for results review and authorisation.

Suggestions on how to implement the requirement

- The results have to be provided accurately, clearly, unambiguously and objectively. A report format should be designed, including all information related to the test or calibration performed [1].
- The report of results can be issued by hardcopy or by electronic means, and all issued reports must be maintained as technical records.
- In the case of including opinions and interpretations, IMS have to officially authorise the personnel in charge of giving opinions and making interpretations. IMS have to document the basis upon the opinions and interpretations that have been made [1].
- In the case of reporting statements of conformity to a specification (for example: below to reporting level, exceeding investigation level, exceeding dose limits, etc.), IMS have to document the decision rule and link it with the evaluation of measurement uncertainty [1].

In the case of amendments to reports, any change of information has to be identified. If it is necessary to issue a new report, this has to be uniquely identified and a reference to the original that it replaces has to be included [1].

Examples from accredited laboratories

- The result report format must include the following information (required by the standard):
  - a title (e.g. "Dose Record" "Dose Results", "External Dosimetry Results");
  - the name and address of the IMS;
  - the location of performance of the IMS activities;
  - the page number and total number of pages;
  - the customer's name or identification and contact information;
  - an identification of the test or calibration method (code of the internal procedure or identification of the standardised method that applies. If a standardised method is used, the revision status and the year of approval must be included);
  - a description, unambiguous identification, and, when necessary, the reception condition of the dosemeters; (e.g.: type of dosemeter, identification code, etc.);
  - the reception date of the dosemeters is not essential for IMS purposes. Nevertheless, the exposure period is critical to the application of the results, so that it has to be included in the report;
  - the date of dosemeters reading;
  - the results with the units of measurement. In the case of test reports, measurement uncertainty (in the same units as that of the measurand or in relative terms) has to be included when it is relevant to the validity of the results, or a customer requires it, or the measurement uncertainty affects conformity to a specification limit. In other cases, a declaration of uncertainty (e.g. a sentence as "uncertainty is available to the customer") could be enough.
  - the date of issue of the report;
  - identification of the person(s) authorising the report;
- The results from external providers (subcontracting) should be clearly identified.
- A statement must be included that the results refer only to the tested dosemeters.
- The information provided by the customer must be clearly specified and it must be indicated that the IMS is not responsible for such information.
- Additional information which may be required by specific methods, by law, by customers or authorities (accreditation or regulatory bodies) should be included, for example: (e.g. reporting level, regulation, etc).
- As many notes or clarifications as may be considered appropriate must be included in order to facilitate the interpretation of the results by the customer.
- Accredited IMS have to include the accreditation mark according to their accreditation body instructions.

- In the case that opinions and interpretations are included in the report of results, they must be clearly identified as such on the report. IMS must document the basis on which those opinions or interpretations have been made. IMS must ensure that only authorised personnel issue such opinions or interpretations. The position that can express opinions and interpretations must be identified.
- In the case that statements of conformity are included in the report of results, the results to which the statement of conformity applies must be clearly identified. The specifications (or standards) that are met or not met, and the applied decision rule must be included.
- If an issued report needs to be changed or amended, a new report must be issued with new identification and a reference to the original report it replaces must be included. The changes or amendments made have to be clearly identified and, if appropriate, the reason for the change must be included in the report.
- If there is an agreement with customer in place, the results can be reported in a simplified manner. In that case all information related to the reported results should be readily available.
- A copy of all of the reports issued must be kept as a technical record. The storage time depends on the legal or contractual obligations. It can be defined by the regulatory authorities or by the client.
- Automatically controlled software with selective permissions for the staff to facilitate the implementation of requirements of 7.8.3 and provide accurate, clear and unambiguous results.

Audits

- Possible auditor's questions
  - Is all the information required by the standard included in each report of results?
    - (Title, name and address of the IMS, place where the activities are carried out, page and total number of pages, customer identification and contact address, identification of the method, description of the dosemeters to be read or calibrated, date of exposure of the dosimeter, date of the performance of the test or calibration, date of issue of the report, results with units, uncertainty or statement of uncertainty, identification of the results that come from external suppliers)
  - Is there a declaration that the results refer only to the tested or calibrated dosemeters?
  - Is the information provided by the client clearly identified? Is it indicated that the IMS is not responsible for such information?
  - Are the conditions of the test (if it is necessary for the interpretation of the results) included (e.g. environmental conditions)?
  - In the case of including declarations of conformity, is the reference to the decision rule included?

- Are opinions and interpretations identified as such in the report? Is the person authorised to issue opinions or interpretations identified in the management system?
- In the case of accredited laboratories, is the accreditation mark used correctly (according to the specifications of the accreditation entity)?
- In the case of modified or amended reports:
  - Has the new report of results been issued with unique identification?
  - Is the reference of the report that it replaces included?
  - Are the changes identified?
- How does the IMS review and authorise the report of results before it is issued?
- In the case of issuing simplified reports of results, is an agreement in place with with the customer?
- Are the reports of results retained as technical records?

- **Showing evidence of compliance**
  - Copy of the report of results containing all the required information.
  - Technical records to track all the information related to the test or calibration (personnel that has performed the test or calibration, equipment used, procedure followed, environmental conditions, etc.).

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 4.2 Confidentiality
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.5 Technical records
- 7.6 Evaluation of measurement uncertainty
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.4.9 Sub-clause 7.9: Complaints

New in ISO/IEC 17025:2017?

No (It replaces ISO/IEC 17025:2005 sub-clause 4.8 "Complaints").

Suggestions on how to interpret the requirement

- The IMS shall have a documented process for receiving, evaluating and making decisions on complaints, which shall include:
  - A description of the process for receiving, validating*, investigating the complaint and taking actions in response to the complaint;
  - A tracking system for recording complaints and actions taken;
  - Ensure appropriate action is taken in response to the complaint [1];
- The IMS itself shall be responsible for handling the complaint and a description of the process shall be available for interested parties e.g. customers or auditors if requested [1].
- The IMS is required to acknowledge receipt of complaints, provide complainants with progress reports on any resulting actions, communicate the final outcomes of the actions to the complainant and give formal notice of the end of the complaint to the complainant [1].

*All complaints require validating. Complaints that are found to not be valid after investigation should be noted by another means, such as a customer correspondence log.

Suggestions on how to implement the requirement

Procedure for handling complaints:

The IMS will produce a written procedure to receive, evaluate and make decisions on complaints. The process shall as a minimum contain all items listed in sub-clause 7.9.3 of the ISO/IEC 17025:2017 standard [1]. It is suggested to use a standard form for receiving complaints (See Annex K).

Complaints received by questionnaires shall be taken into account as well.

The procedure should also include a description of the communications to be used and how they are to be recorded when responding to the complainant to cover sub-clauses 7.9.5 to 7.9.7 (this can include written and verbal communications).

System to track complaints and actions:

The IMS should create a system where complaints can be registered. The following should be recorded:

- Date complaint raised
- Name of complainant
- Description of the complaint / issue
- Name of person within IMS responding to the issue
- IMS evaluation of the complaint
- Any actions taken to address the issue
- Dates of completion of actions and closure of complaint

- Recurring complaint: Yes/No

The results to be communicated to the complainant have to be made, reviewed and approved by persons not related to the activities that are the subject of the complaint.

Examples from accredited laboratories

- Procedure for handling complaints
- System to track complaints and actions

Audits

- **Possible auditor's questions**
  - Does the IMS process for handling complaints cover the following:
    - Description of receiving, validating and investigating complaints?
    - Tracking and recording of complaints?
    - Recording of actions to resolve the complaint?
- **Showing evidence of compliance**
  - The documented procedure for dealing with complaints.
  - A register of complaints received.
  - Questionnaires.
  - The raising, tracking and completion of actions.
  - Any communications sent to or received from complainants.
  - Internal audits and Management review report (including complaints).

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 7.5 Technical records
- 7.10 Nonconforming work
- 8.6 Improvement
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

3.4.10 Sub-clause 7.10: Nonconforming work

New in ISO/IEC 17025:2017?

No (It replaces ISO 17025:2005 sub-clause 4.9 "Control of nonconforming testing and/or calibration work").

Suggestions on how to interpret the requirement

- The IMS shall have a documented process that will be implemented when any aspect of its activities or results of this work do not conform to its own procedures or the agreed requirements of the customer [1].
- The process shall ensure the following:
  - A definition of the responsibilities and authorities for the management of nonconforming work is made [1].
  - Any actions taken are based upon risk levels established by the IMS [1].
  - An evaluation of the significance of the nonconforming work is made [1].
  - Decisions are taken on the acceptability of the nonconforming work [1].
  - The customer is notified and where necessary work is recalled [1].
  - The responsibility for authorising the resumption of work is defined [1].
- The IMS is required to retain records of nonconforming work and any actions taken [1].
- The IMS is required when the possibility of nonconforming work can recur has been identified or there is doubt about the conformity of the IMS with its own management system [1].

Suggestions on how to implement the requirement

- Create a written procedure for nonconforming work
  - The IMS should produce a written procedure to define the process to be followed when nonconforming work occurs. The process must ensure the requirements highlighted in section 7.10.1 of the ISO/IEC 17025:2017 standard are fulfilled.
- Retain Records
  - The IMS must create a system to retain records of any nonconforming work. This should include any corrective actions taken to avoid the recurrence of nonconforming work.

Examples from accredited laboratories

- Procedure for nonconforming work
- System to track nonconforming work

Audits

- **Possible auditor's questions**
  - Do you have a documented procedure for dealing with complaints?
  - How do you retain records of nonconforming work?
  - How do you record actions raised, the completion of actions and the effectiveness of the actions completed?

- Do you have an example of having to inform a customer of any nonconforming work?

- **Showing evidence of compliance**
  - The documented procedure for dealing with non-conforming work.
  - A register of non-conforming work detected.
  - The raising, tracking and completion of actions.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.3 Facilities and environmental conditions
- 6.6 Externally provided products and services
- 7.1 Review of requests, tenders and contracts
- 7.5 Technical records
- 7.9 Complaints
- 8.5 Actions to address risks and opportunities
- 8.6 Improvement
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

3.4.11 Sub-clause 7.11: Control of data and information management

New in ISO/IEC 17025:2017?

No (The requirements of ISO 17025:2005 sub-clauses 4.13 “Control of records” and 5.4.7 “Control of data” have been drafted differently and include specific reference to electronic information).

Suggestions on how to interpret the requirement

- This section is complemented by requirements of ISO/IEC 17025:2017 sub-clauses 7.5 “Technical records”, 8.2 “Managements system documentation” and 8.4 "Control of records".
- The main objective of this requirement is to ensure correct management of the information and data associated with the IMS activities.
- A laboratory information management system (LIMS) for collection, processing, recording, reporting storage and retrieval of data shall be established. This system shall also apply to information in any type of support.

Suggestions on how to implement the requirement

- All the data and information related to IMS activities shall be available [1].
- The IMS must have an information management system that also applies to information in electronic format.
- The laboratory information management system must be validated.
- Any change in the configuration or modification of the laboratory software must be validated and authorised before being implemented. These validations must be documented.
- Commercial software for general use such as Microsoft products can be considered sufficiently validated [6]. In this case validation by the IMS is not necessary. Other commercial software, such as instrument control and data manipulation software provided by instrument suppliers should be validated by the supplier. The IMS must ensure software purchased has been sufficiently validated by the supplier or provide their own validation.
- The IMS is required to implement measures in order to avoid the loss of information and unauthorised access. Protection measures and periodic backups are required to ensure the integrity of data.
- Corrective actions in the case of system failures shall be taken.
- The IMS shall ensure that an external provider for the management and maintenance of the laboratory information management system shall comply with applicable requirements.
- The staff shall have access to instructions or manuals for the laboratory information management system.
- Calculations and data transfers shall be checked by authorised personnel.

Examples from accredited laboratories

- Using conventional or specific commercial software or software developed internally by the IMS (templates, spreadsheets or similar) for the management of information.
- Documents describing the laboratory information management system.
- Validation: comparison of the results or values obtained by using the laboratory information management system with those obtained by manual calculations, calculator or other software.
- Protection measures to avoid loss of information and accidental changes: passwords, backups, personnel training in use of laboratory information management system, etc.
- Manuals, instructions or similar available to personnel and in the place where they are used.
- Corrective actions in the case of malfunctioning.
- Consideration of the risks associated with use, maintenance, access control and protection of laboratory information management system.

Audits

- **Possible auditor's questions**
  - Does the IMS have access to all data and information needed to carry out its activities?
  - Has the laboratory information management system (used to collect, process, record, inform, store or retrieve data) been validated before use?
  - In the case of changes in the laboratory information management systems (including software configuration or modifications in the commercial software), have these changes been authorised, documented and validated before their implementation?
  - Is the information management system protected against unauthorised access and manipulation?
  - Does the information management system meet the requirements of the provider or laboratory?
  - Is the accuracy of the manual transcriptions protected in the case of non-computerised records?
  - Is the integrity of the data and information maintained?
  - Are corrective actions taken in the case of malfunction of the laboratory information management system?
  - If the IMS has information management systems managed and maintained off-site or through an external provider:
  - How does the IMS ensure that the data control procedures of their administrators or external providers meets all the applicable ISO/IEC 17025:2017 requirements?
  - Are all the information management system instructions or manuals available to IMS personnel?
  - Does the IMS check the calculations and data transfers appropriately?

Additional questions: See section 7.5 "Technical records"

- **Showing evidence of compliance**
  - Documents describing the laboratory information management system.
  - Records of the laboratory information management system validation (initial and after changes).
  - Records of the corrective actions taken in case of information management system failure.
  - Records of calculations and data transfers checking.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 6.6 Externally provided products and services
- 7.5 Technical records
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.5 Clause 8: Management system requirements

3.5.1 Sub-clause 8.1: Options

New in ISO/IEC 17025:2017?

Partial (8.1 The entire sub-clause is new. Sub-clause 8.1.1 In the past there was no possibility of choice. Sub-clause 8.1.2 Option A Is new. Sub-clause 8.1.2 option B, In the past there was no possibility of considering ISO 9001) [19].

Suggestions on how to interpret the requirement

The IMS is requested to implement and maintain a management system to ensure the requirements of clauses 4 to 7 in both options are met. The competence of the IMS to produce technically valid data and results is accomplished only through compliance with clauses 4 to 7.

Moreover, IMS shall implement a management system in accordance with:

- 8.1.2 Option A: IMS shall address minimum requirements for the implementation of the management system which have not already been put in chapters 4-7.
- 8.1.3 Option B: the minimum requirements are considered fulfilled if the IMS has an ISO 9001 system and also fulfils requirements 4 to 7. In this case it also satisfies at least the intent of the requirements of the management system specified in 8.2 to 8.9.

Suggestions on how to implement the requirement

8.1.3 Option B

- Identify application asymmetries and common elements of which can benefit from the use of a management system.
- The system shall be adapted accordingly to ISO/IEC 17025:2017.
- It is necessary to verify that the activities of the IMS are implemented in compliance with clauses 4 to 7.

Examples from accredited laboratories

8.1.3 Option B

- A correlation table might be useful to verify compliance to ISO/IEC 17025:2017 requirements. E.g.

ISO/IEC 17025:2017	ISO 9001:2015
6 Resource requirements	7 Support
6.1 General	7.1 Resources
6.2 Personnel	7.1.2 People
6.3 Facilities and environmental conditions	7.1.4 Environment for the operation of process
7.7 Ensuring the validity of results	7.1.5.2 Measurement Traceability
8.5 Action to address risks and opportunities	6.1 Action to address risks and opportunities

Audits

- **Possible auditor's questions**

  8.1.1 General

  - Do the IMS, in the implementation of the system of management, choose option A or option B?
  - 8.1.2 Option A See questions in sub-clauses 8.2 through 8.9.

  8.1.3 Option B

  - What documents are in place that describe that the IMS management system appropriately meets the requirements from 4 to 7 of the ISO/IEC 17025:2017?

Cross reference with other ISO/IEC 17025:2017 sub-clauses

Annex B (Informative): Management system Option.

3.5.2 Sub-clause 8.2: Management system documentation (Option A)

New in ISO/IEC 17025:2017?

No (It replaces ISO/IEC 17025:2005 sub-clause 4.2 "Management system").

Suggestions on how to interpret the requirement

The IMS must establish, document, implement and maintain a management system capable of demonstrating compliance with the requirements of the standard, ensuring the validity of the results [1].

Suggestions on how to implement the requirement

- The IMS management is responsible for:
    - Implementation, documentation and maintenance of policies (in the case of having one) and objectives for the fulfilment of ISO/IEC 17025:2017 requirements. These policies and objectives have to be understood by IMS staff [1].
    - Definition of policies and objectives in order to address the competence, impartiality and consistent operation of the IMS [1].
    - Generating evidence of commitment to the development and implementation of the management system [1].
    - Continuous improvement of the effectiveness of the management system [1].
- All documentation related to compliance with the standard must be managed, included or linked to the management system [1].
- The personnel involved in the activities of the IMS must have access to the information that is applicable to their responsibilities [1].

Examples from accredited laboratories

- The IMS management must define and sign quality policies that demonstrate its commitment to the implementation and maintenance of the management system, as well as the allocation of the necessary resources. It must also define and sign policies of commitment to impartiality.
- These policies can be included as independent documents and can be signed by the IMS management or the upper organisation's management (where that exists).
- Actions for the continuous improvement of the management system must be established. These actions can be raised in the management review or in routine work. An evaluation of the effectiveness of the proposed actions must be carried out.
- All the documentation generated in the definition, implementation and monitoring of the management system must be identified and linked to the management system. This documentation can be documents, records, processes, etc. related to technical or managerial activities. Processes for the identification and control of the management system documents must be established.

- All personnel must know the management system and must have access to documentation and information related to the development of their activities. Direct communication with the IMS management and access to all applicable documentation is necessary. Participation of all IMS personnel in the management review is recommended.

Audits

- **Possible auditor's questions**
  - Are the policies and objectives documented? Do they address competence and impartiality? Are they coherent with the activity of the IMS?
  - Does the IMS management ensure that the policies and objectives are understood by staff and implemented at all levels of the organisation?
  - Does the IMS management demonstrate its commitment to the development and implementation of the management system?
  - Does the IMS management improve the effectiveness of the management system?
  - Is the documentation related to compliance with the standard included, referenced or linked to the management system?
  - Do the personnel involved in the activities of the IMS have access to the documentation of the management system and to the information applicable to their responsibilities?
- **Showing evidence of compliance**
  - Documents, signed by the IMS management, that include the policies and objectives.
  - Impartiality policies signed by the IMS management.
  - Records of attendance of IMS personnel to meetings related to the management system, policies and objectives.
  - Records of implementation and evaluation of effectiveness of actions to improve the management system.
  - Processes for control of documents that includes all the documentation related to compliance with ISO 17025:2017 and the management system.
  - Records of distribution of the management system documentation to the IMS staff. Records of reading confirmation.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.1 Impartiality
- 5 Structural requirements
- 6.2 Personnel
- 7.5 Technical records
- 7.11 Control of data and information management
- 8.3 Control of management system documents
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities

- 8.8 Internal audits
- 8.9 Management reviews

3.5.3 Sub-clause 8.3: Control of management system documents (Option A)

New in ISO/IEC 17025:2017?

No (This sub-clause includes, in a simplified way, the requirements of ISO/IEC 17025:2005 sub-clauses 4.3 “Document control”).

This sub-clause is complemented by requirements of ISO/IEC 17025:2017 sub-clauses 7.5 “Technical records”, 7.11 “Control of data and information management”, 8.2 “Management system documentation” and 8.4 "Control of records ".

Suggestions on how to interpret the requirement

The IMS has to control the documents, internal and external, related to compliance with the standard [1].

In this context, “document” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital [1].

Suggestions on how to implement the requirement

- The IMS has to establish processes for control of management system documents to demonstrate fulfilment of ISO/IEC 17025:2017 requirements.
- The established processes must ensure:
    - Designation of the position responsible for writing, reviewing and approving the documents.
    - Unique identification of the documents, indicating the version in use and the identification of changes with respect to previous version.
    - Controlled distribution of documents.
    - Documents are available at the places of use.
    - Periodic review of documents.
    - Identification of obsolete documents.
    - Prevention of the use of obsolete documents.

Examples from accredited laboratories

There are no requirements for documented procedures related to the management system and a quality manual is not required. The only documentation requirements related to the management system are: Policies and objectives; Evaluation of customer feedback; Non conformities and corrective actions records; Internal audits records (results) and Management review records.

The IMS must decide which documents are going to be part of its documentary system. Then, a process for control of documents has to be established in order to demonstrate compliance with the standard.

- Assignment of responsibilities for production (e.g. a document could be written by personnel with technical knowledge, reviewed by the quality manager (if any) and approved by the IMS manager.
- Identification of the documents and identification of the version in use .

- Definition of distribution lists to personnel involved in the activity described in the document.
- Controlled distribution of documents. Evidence of reception.
- Availability of documents in places of use.
- Definition of a maximum period for reviewing the documents and editing a new version (including identification of changes). All documents must be reviewed, even if there is no change in the considered period, it's necessary to have evidence of reviewing.
- Identification of obsolete documents to avoid inappropriate use.

The use of specific software for the control of documents can be valuable, since it reduces the workload of IMS personnel and it can simplify the process of review, approval, distribution, as well as the control of changes and control of obsolete documents.

There is commercial software for this purpose.

Audits

- **Possible auditor's questions**
  - Does the IMS control both internal and external documents involved in the management system?
  - Have the documents been approved by authorised personnel?
  - Are the documents uniquely identified?
  - Is the documents distribution controlled?
  - Are the documents available at points of use?
  - Are the documents revised and updated periodically?
  - Are changes and the current version status identified?
- **Showing evidence of compliance**
  - Management system documents.
  - Records of the control of documents process (review, approval, distribution).
  - Obsolete documents adequately identified.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 7.5 Technical records
- 7.11 Control of data and information management
- 8.2 Management system documentation
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.5.4 Sub-clause 8.4: Control of records (Option A)

New in ISO/IEC 17025:2017?

No (This sub-clause includes, in a simplified way, the requirements of ISO/IEC 17025:2005 sub-clauses 4.13 “control of records”).

This sub-clause is complemented by requirements of ISO/IEC 17025:2017 sub-clauses 7.5 “Technical records”, 7.11 “Control of data and information management”, 8.2 “Management system documentation” and 8.3 "Control of management system documents ".

Suggestions on how to interpret the requirement

Records are the evidence of the IMS performance of the activities included in the Management System.

The IMS has to control and maintain enough documents and records in order to demonstrate compliance with the requirements of the ISO/IEC 17025:2017 standard [1].

Both manual and electronic records are affected by the requirements of this section.

Suggestions on how to implement the requirement

- The IMS has to establish records to demonstrate fulfilment of ISO/IEC 17025:2017 requirements [1].
- These records must be recoverable and maintained in a legible way [1].
- Controls for identification, storage, protection, archive, retrieval, retention and disposal have to be implemented [1].
- Contractual obligations and applicable legislation have to be considered to establish storage time.
- All records have to be readily available.
- Confidentiality in access to records must be ensured.

Examples from accredited laboratories

- Definition of the records in which the information, technical and management, associated to the management system and to the compliance with the standard is collected.
- Maintaining all of these records under document control.
- Definition of a system for the identification of records.
- Records can be maintained in electronic or paper format.
- Maintaining control of access to records in order to ensure compliance with confidentiality requirements (restricted access to authorised personnel or passwords in the case of electronic records).
- Records must be kept easily legible and recoverable.
- Measures to prevent deterioration, damage, loss and improper access must be taken.
- In the case of electronic records, periodic backups must be made.
- Consideration of contractual obligations, applicable legislation and requirements of the regulatory body or the accreditation entity in order to define the period of storage.

Audits

- **Possible auditor's questions**
  - Has the IMS maintained records (evidence) of the performance of all technical and managerial activities to comply with the management system and ISO/IEC 17025:2017 standard?
  - Are the records easily legible and recoverable?
  - Has the IMS established processes to keep records protected against manipulation, deterioration and improper access?
  - Are backup copies made periodically?
  - Is the access to the records controlled and consistent with the confidentiality requirements?
  - Are the records stored during the period established by contractual obligations or current legislation?
- **Showing evidence of compliance**
  - Processes describing the management of documentation including control of records.
  - Records of all technical and managerial activities carried.
  - Records of backups.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 4.2 Confidentiality
- 6.2 Personnel
- 7.1 Review of requests, tenders and contracts
- 7.5 Technical records
- 7.7 Ensuring the validity of results
- 7.8 Reporting of results
- 7.11 Control of data and information management
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.5 Actions to address risks and opportunities
- 8.8 Internal audits
- 8.9 Management reviews

3.5.5 Sub-clause 8.5: Actions to address risks and opportunities (Option A)

New in ISO/IEC 17025:2017?

Partial (The sub-clause replaces the requirements of ISO/IEC 17025:2005 sub-clause 4.12 "Preventive actions").

Suggestions on how to interpret the requirement

Risk management is a process that consists of identifying, assessing, controlling, communicating and reviewing the risks that may affect the quality of results. The main objective of risk management is to anticipate situations that may affect the planned development of the activities and take appropriate preventive actions to avoid such events, minimising their consequences or achieving improvement.

Opportunities may occur from considering positive side of the risks. It is a potential enhancement or positive impact that could improve the laboratories ability to meet its performance, cost or other objectives (expanding the scope of IMS activities, addressing new customers, etc).

The IMS should consider the risks and opportunities associated with its activities in order to prevent or reduce problems and achieve improvement.

ISO/IEC 17025:2017 does not require a specific method for risk management or a documented process of risk management. The IMS can decide whether or not to develop a more comprehensive methodology for risk management than that required in the standard, for example, through the application of other guidelines or standards (e.g. ISO 31000:2018 *Risk management – Guidelines* can be useful [20]).

Suggestions on how to implement the requirement

- The IMS shall consider the risks and opportunities for improvement associated with the IMS activities in order to:
  - Give assurance that the management system achieves its intended results [1].
  - Enhance processes to achieve its purpose and objectives [1].
  - Prevent, or reduce, undesired impacts and potential failures in the activities [1].
  - Achieve improvement [1].
- Actions to address risks and improvement opportunities must be planned [1].
- These actions must be integrated and implemented into the management system [1].
- The effectiveness of these actions must be evaluated [1].
- Actions taken to address risks and improvement opportunities shall be proportional to the potential impact on the validity of IMS results [1].

Examples from accredited laboratories

To identify risks, it is useful to consider both the internal context of the organisation and its external context (risks related to the customer, the supplier, other stakeholders, etc.).

For risk assessment, a registry can be used (See Annex L) which includes the identification of the risk, the risk level (rating from 1 to 3); the probability of occurrence (rating from 1 to 3); risk classification (Risk level x Probability); actions to mitigate risk and other information such as (notes, risk owner, output / documents) as well as detailed explanations (See Annex M).

The IMS is responsible for deciding which risks and opportunities need to be addressed. In case of changes in processes, activities or working conditions the analysis performed has to be reviewed.

As a result of the risk assessment, remedial actions have to be implemented. These actions must be proportional to the potential impact of the risk on the validity of the results. The effectiveness of actions must be evaluated.

Review of risk assessment has to be done during the management review process.

Audits

- **Possible auditor's questions**
  - Does the IMS assess the risk and opportunities, associated with its activity?
  - Are actions to address risk and opportunities planned?
  - Are actions to address risk and opportunities integrated and implemented in the management system?
  - Does the IMS evaluate their effectiveness?
  - Are actions to address risk and opportunities proportional to the potential impact on the validity of the results?
- **Showing evidence of compliance**
  - Records of risk and opportunities assessment.
  - Records of actions related to addressing risk and opportunities.
  - Records of evaluation of effectiveness.
  - Records of management review including review of risk and opportunities assessment.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- All of the ISO/IEC 17025:2017 clauses could be involved in "Actions to address risks and opportunities", but the standard explicitly refers to the term risk in:
  - Foreword
  - Introduction
  - 4.1 Impartiality
  - 7.8 Reporting of results
  - 7.10 Nonconforming work
  - 8.6 Improvement
  - 8.7 Corrective action
  - 8.8 Internal audits
  - 8.9 Management reviews

3.5.6 Sub-clause 8.6: Improvement (Option A)

New in ISO/IEC 17025:2017?

No (This sub-clause includes the requirements of ISO/IEC 17025:2005 sub-clauses 4.7 "Service to the customer" and 4.10 "Improvement". Some of these requirements have been reduced).

Suggestions on how to interpret the requirement

The IMS has to identify opportunities for improvement, and introduce actions for their implementation.

Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. In addition, feedback from customers is useful to identify new opportunities for improvement [1].

Suggestions on how to implement the requirement

- Review of technical and operational processes for the identification of opportunities for improvement. This improvement can be related to the management system and also to the technical procedures or methodology.
- Implementation of actions for improvement defined
- Use of all types of communication (satisfaction surveys, communication records, review of results with customers, etc.) in order to obtain feedback from the customers.
- Evaluation of actions to improve the management system, IMS activities and customer service. The evaluation should include the implementation and effectiveness of the actions.

Examples from accredited laboratories

- All staff can propose actions for improvement in the framework of their activities.
- Use all the information related to the management system (technical and managerial) to identify areas for improvement.
- Definition and implementation of actions to improve the management system.
- Evaluation of the effectiveness of the actions implemented.
- Implementation of processes to obtain customer feedback (periodic satisfaction surveys, phone and e-mail communications, meetings to review results, etc.).
- Use the feedback to identify and to define actions for improvement.

Audits

- **Possible auditor's questions**
  - Has the IMS identified opportunities for improvement?
  - Has the IMS implemented the actions defined?
  - Has the IMS sought feedback from customers?

- Has the feedback from the customer been analysed in order to improve the management system, IMS activities and customer service?

- **Showing evidence of compliance**
  - Results of internal audits, management review.
  - Records of customer communications (satisfactions surveys, communication via e-mail, phone, etc.) and agreed actions.
  - Records of the improvement actions:
  - Improvement action definition and implementation.
  - Monitoring and evaluation of effectiveness.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 6.2 Personnel
- 7.5 Technical records
- 7.9 Complaints
- 7.10 Nonconforming work
- 8.5 Actions to address risks and opportunities
- 8.7 Corrective action
- 8.8 Internal audits
- 8.9 Management reviews

See Annex N: Example of Corrective action / Action for improvement report.

3.5.6 Sub-clause 8.7: Corrective action (Option A)

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clause 4.11 "Corrective actions" have been rewritten).

Suggestions on how to interpret the requirement

Corrective actions are useful tools for management systems improvement. The IMS must implement the appropriate actions to prevent the recurrence of non-conformities and take measures against their consequences.

Suggestions on how to implement the requirement

In cases of nonconformity:

- Analysis of causes and consequences have to be done.
- Implementation of corrections (actions to correct an error) and/or corrective actions in order to prevent the recurrence of nonconformities [1].
- Revision of the effectiveness of corrective actions taken [1].
- Introducing changes to the management system and assess risk and opportunities if necessary [1].
- Corrective actions shall be appropriate to the effects of the nonconformities.
- Records of causes and consequences analysis, descriptions of the corrective actions taken and their results have to be retained.

Examples from accredited laboratories

- In the case of the detection of a nonconformity, the IMS has to implement corrective actions:
    - Evaluation of all potential causes has to be done in order to define the root cause (cause analysis). All circumstances should be considered (processes, methods, environmental conditions, equipment, providers, personnel, training, etc.).
    - Analysis of non-conformity impact and consequences.
    - Evaluation of the possibility of recurrence.
    - Updating the risks and opportunities if necessary.
    - Definition and implementation of corrective actions.
    - Monitoring of corrective actions and evaluation of their effectiveness.
- Monitoring of recurrences of nonconformities after the implementation of corrective actions. In some cases, additional audits are necessary.
- Complete Information of the corrective actions has to be recorded (causes and consequences analysis, corrective action definition and implementation, evaluation of effectiveness).

Audits

- **Possible auditor's questions**
  - In the case of nonconformities, does the IMS take actions to control and correct them?
  - Does the IMS evaluate the causes and consequences of these non-conformities?
  - Does the IMS analyse the occurrence of similar nonconformities affecting the management system?
  - Does the IMS implement the corrective actions defined?
  - Does the IMS evaluate the effectiveness of the corrective actions taken?
  - Derived from the corrective actions, has the IMS introduced changes in the management system or update the risk and opportunities, if necessary?
  - Are the corrective actions appropriate for the effects of the nonconformities?
  - Are records of the corrective actions kept (cause and consequences analysis, corrective action definition and implementation, evaluation of effectiveness)? Are they complete?
- **Showing evidence of compliance**
  - Records of the entire corrective actions cycle:
  - Cause and consequences analysis (derived from a nonconformity).
  - Corrective action definition and implementation.
  - Monitoring and evaluation of effectiveness.
  - Monitoring the recurrence of nonconformities after corrective actions implementation.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- 5 Structural requirements
- 6.2 Personnel
- 7.5 Technical records
- 7.9 Complaints
- 7.10 Nonconforming work
- 8.5 Actions to address risks and opportunities
- 8.6 Improvement
- 8.8 Internal audits
- 8.9 Management reviews

A non-compliance of any ISO/IEC 17025:2017 clause may require the implementation of a corrective action.

See Annex N: Example of Corrective action / Action for improvement report.

3.5.7 Sub-clause 8.8: Internal audits (Option A)

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clause 4.14 "Internal audits" is rewritten in a more flexible way).

Suggestions on how to interpret the requirement

The IMS has to perform internal audits to verify the fulfilment of the management system requirements. In addition, an evaluation of the effectiveness and adequacy of the management system has to be done in this process. Internal audit is one of the most important tools to identify strengths, weaknesses and opportunities for improving the management system.

It is no longer necessary to complete the cycle for internal auditing in one year.

Suggestions on how to implement the requirement

- An internal audit programme has to be established, including frequency and responsibilities [1].
- The importance of the activities, changes in the IMS and the results of previous audits have to be taken into account in the internal audit programme [6].
- The internal audits have to cover all of the items of the management system.
- Fulfilment of the IMS requirements and the ISO/IEC 17025:2017 requirements has to be evaluated in the internal audit process. In addition, the adequate implementation and maintenance of the management system has to be analysed.
- Audit criteria and scope for the audit have to be defined [1].
- The results of the audits have to be reported to the IMS management [1].
- Corrections and corrective actions have to be implemented within reasonable timescales in order to avoid repetition of any deviation found.
- Records of the audit process have to be retained (audit programme, audit results, evidence of implementation of corrective actions, etc.) [1].

Examples from accredited laboratories

- Audits can be carried out by the quality manager (if the post exists) or any other qualified person as lead auditor, alone or assisted by an audit team. External auditors can be contracted if necessary.
- Auditors have to be trained to perform internal audits. The auditor should have sufficient technical knowledge about the activities to be audited.
- The auditors should not audit their own activities.
- ISO 19011:2018 [21] can be useful as a guide for internal audits.
- Results of the internal audits have to be reported to the management laboratory.
- An internal audit report, signed by the audit team leader, should include:
    - Report reference, title and report date.
    - Audit team and audit team leader.
    - Auditee and people present during the audit process.
    - Audit scope and objectives.

- Audit criteria.
- Strong points and improvement opportunities detected during the audit.
- Detected deviations.

Audits

- **Possible auditor's questions**
  - Is there a process to carry out internal audits?
  - Is there a programme to carry out internal audits (including frequency and responsibilities)?
  - Are the internal audits carried out in accordance with the programme?
  - Do these audits cover all of the items of the management system, including testing and calibration activities?
  - Are the internal audits carried out by trained and qualified personnel and, whenever resources permit, independent of the activity to be audited?
  - When a deviation is detected during the internal audit have adequate corrective actions been implemented? Have the affected clients been informed about the scope of the deviation?
  - Are the audit records kept (audited activity areas, the results of the audit and the corrective actions taken)?
  - Is an adequate follow-up of the deviations detected in previous audits?
  - Has the monitoring of deviations from previous audits been adequate?
  - Has the IMS management been informed about the audit results?
- **Showing evidence of compliance**
  - Internal audit programme (frequency, responsibilities).
  - Internal audit plan (dates and audit scope, objectives, criteria).
  - Auditor training and qualification.
  - Audit report.
  - Evidence of communication of audit results to IMS management.
  - Corrections or corrective actions derived from the detected deviations.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- All of the ISO/IEC 17025:2017 clauses are involved in Internal Audits.

See Annex O: Example of Template for Audit report.

3.5.8 Sub-clause 8.9: Management reviews (Option A)

New in ISO/IEC 17025:2017?

No (The requirements of ISO/IEC 17025:2005 sub-clause 4.15 "Management reviews" have been rewritten. Some inputs of Management reviews have been changed or added).

Suggestions on how to interpret the requirement

The IMS has to periodically review its management system to ensure its suitability and effectiveness, including policies and objectives [1].

Management review is, with internal audits, one of the most important tools to identify strengths, weaknesses and opportunities to improve the management system.

Suggestions on how to implement the requirement

- The IMS shall review its management system in order to ensure its suitability, adequacy and effectiveness [1].
- Management reviews shall be programmed at planned intervals [1].
- Policies and objectives of the management systems shall be reviewed related to the fulfilment of the standard [1].
- Management review shall focus on the following items:
    - changes in internal and external issues that are relevant to the IMS;
    - fulfilment of objectives;
    - suitability of policies and procedures;
    - status of actions from previous management reviews;
    - outcome of recent internal audits;
    - corrective actions;
    - assessments by external bodies;
    - changes in the volume / type of the work or in the range of IMS activities;
    - customer and personnel feedback;
    - complaints;
    - effectiveness of any implemented improvements;
    - adequacy of resources;
    - results of risk identification;
    - outcomes of the assurance of the validity of results; and
    - other relevant factors, such as monitoring activities and training [1].
- Results and records of management reviews shall include all decisions and actions related to at least:
    - the effectiveness of the management system and its processes;
    - improvement of the IMS activities related to the fulfilment of the requirements of this document;
    - provision of required resources;
    - any need for change [1].

Examples from accredited laboratories

- Management reviews should be programmed at planned intervals.
- Participation of a representative portion of the staff (where possible) is recommended.
- Revision of all of the technical and managerial processes developed by the IMS.
    - Revision of changes affecting the management system (considering internal and external influences; changes in the organisation; new legislation, impartiality; etc.).
    - Evaluation of quality policies and objectives.
    - Analysis of the risks and opportunities.
    - Evaluation of data on quality control activities and their results (interlaboratory comparisons or proficiency tests, trend analysis of the results, etc.).
    - Evaluation of the adequacy of resources (personnel and equipment).
    - Evaluation of training activities.
    - Analysis of complaints and customer's feedback.
    - Evaluation of the adequacy of suppliers.
- Results of management reviews should be kept as records (minutes of the meeting, decisions and actions related to the evaluated items, action plan, etc.).
- IMS management has to be informed about the results and conclusions of management reviews.

Audits

- **Possible auditor's questions**
    - Is the process to carry out reviews of the Quality System well defined?
    - Are management reviews programmed at planned intervals?
    - Has the management review been carried out according to the established programme?
    - Have all of the items referred to in the standard been evaluated and analysed?
    - As a result of the management reviews, have objectives and action plans been established?
    - Are records of management reviews (minutes of meetings, actions to be carried out, etc.) kept? Are they complete?
- **Showing evidence of compliance**
    - Management reviews programme.
    - Records of management review results.
    - Action plan derived from the results of the management reviews.
    - Communication of results to the IMS management.

Cross reference with other ISO/IEC 17025:2017 sub-clauses

- All of the ISO/IEC 17025:2017 sub-clauses are involved in management reviews.

References

[1] International Organization for Standardization, "ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories," 2017.

[2] International Organization for Standardization, "ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories," 2005.

[3] International Organization for Standardization, " ISO/IEC 17000:2004, Conformity assessment — Vocabulary and general principles," Geneva,Switzerland, 2004.

[4] European Commission, "Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation, RP 160, Directorate-General for Energy and Transport," Luxembourg, 2009.

[5] European Commission, "Basic Safety Standards Directive," Brussels, 2014.

[6] EUROLAB - The European Federation of National Associations of Measurement, Testing and Analytical Laboratories, "Handbook ISO/IEC 17025:2017," 2018. [Online]. Available: http://www.eurolab.org.

[7] Official Journal of the European Union, "Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (Data Protection Directive)," 2016.

[8] International Electrotechnical Commission, "IEC 62387:2020 2ed edition Radiation protection instrumentation – Dosimetry systems with integrating passive detectors for individual, workplace and environmental monitoring of photon and beta radiation," 2020.

[9] Joint Committee for Guides in Metrology, "JCGM 200:2012,International vocabulary of metrology- Basic and general concepts and associated terms," BIMP, Sèvres, 2012.

[10] Joint Committee for Guides in Metrology, "JCGM 100:2008, Evaluation of measurement data – Guide to the expression of uncertainty in measurement," Sevres, 2008.

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, "General Safety Requirements Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards," Vienna, 2014.

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, "General Safety Guide No. GSG-7: Occupational Radiation Protection," 2018.

[13] International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection," vol. 60, 1991.

[14] International Commission on Radiological Protection, "The 2007 Recommendations of the International Commission on Radiological Protection," vol. 103, 2007.

[15] International Electrotechnical Commission, "IEC 61526 Radiation protection instrumentation – Measurement of personal dose equivalents Hp(10) and Hp(0,07) for X, gamma, neutron and beta radiations – Direct reading personal dose equivalent meters," 2010.

[16] International Electrotechnical Commission, "IEC TR 62461:2015, Radiation protection instrumentation - Determination of uncertainty in measurement," 2015.

[17] Joint Committee for Guides in Metrology, "JCGM 101:2008, Evaluation of measurement data — Supplement 1 to the "Guide to the expression of uncertainty in measurement" — Propagation of distributions using a Monte Carlo method," Sevres, 2008.

[18] International Organization for Standardization, "ISO 14146:2018 Radiological protection - Criteria and performance limits for the periodic evaluation of dosimetry services.," Geneva,Switzerland, 2018.

[19] International Organization for Standardization, "ISO 9001:2015,Quality Management Systems," Geneva,Switzerland, 2015.

[20] International Organization for Standardization, "ISO 31000:2018, Risk management – Guidelines," Geneva,Switzerland, 2018.

[21] International Organization for Standardization, "ISO 19011:2018, Guidelines for auditing management systems," Geneva,Switzerland, 2018.

[22] International Organization for Standardization, "ISO 15382:2015, Radiological protection — Procedures for monitoring the dose to the lens of the eye, the skin and the extremities," Geneva,Switzerland, 2015.

[23] International Organization for Standardization, " ISO 21909-1:2015, Passive neutron dosimetry systems -- Part 1: Performance and test requirements for personal dosimetry," 2015.

[24] International Organization for Standardization., "ISO 15690:2013, Radiological protection -- Recommendations for dealing with discrepancies between personal dosimeter systems used in parallel," Geneva,Switzerland, 2013.

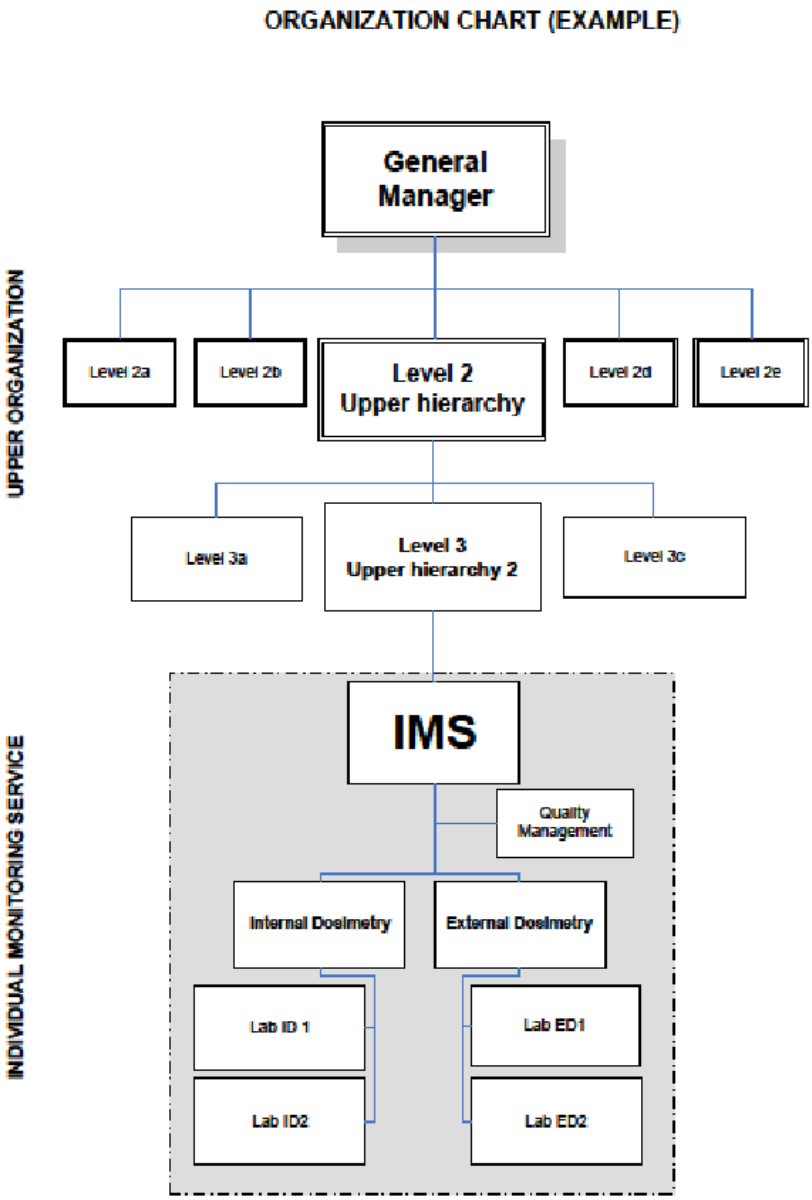
[25] International Organization for Standardization, "ISO 20553:2006, Radiation protection -- Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material," Geneva,Switzerland, 2006.

[26] International Organization for Standardization, "ISO 16637:2016, Radiological protection -- Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources," Geneva,Switzerland, 2016.

[27] International Organization for Standardization, "ISO 27048:2011, Radiation protection -- Dose assessment for the monitoring of workers for internal radiation exposure," Geneva,Switzerland, 2011.

Annex A: Organisation Chart Example

Clause 5 and sub-clause 6.2: Organisation Chart Example



Annex B: Position description form example

Sub-clause 6.2.2: Position description form example

Position Description

Position	Quality manager
Status	1 Full Time Equivalent
Direct supervisor	Laboratory manager
Replaced by	

Responsibilities/duties
Qualification/ education/training
Possible other remarks or requirements important to this position

Drafted by:		Date:		Signature	

Annex C: Example for "Evaluation of significance of deviations"

Sub-clause 6.2.3: Example for "Evaluation of significance of deviations"

An efficient management system (MS), should implement a mechanism to discriminate events based on their relevance and to objectively categorise them, concentrating resources and efforts in good quality investigations of the root causes of relevant deviations.

The manner on how personnel react in the presence of an event largely depends on their level of training, qualification, commitment, and support from upper management. As a basic requirement, personnel are expected to be alert and aware of possible undesirable events and clearly know what to do in terms of documenting and communicating them.

The way personnel react and make decisions can be systemised and improved based on risk and impact of event in order to (evaluate) categorise, record, and investigate them as needed.

A possible categorisation could be as follows:

i. Incident

e.g.: Temporary power failure in a laboratory supported by a UPS system

ii. Minor deviation

e.g.: Power failure (in a laboratory supported by UPS system) lasts more than few minutes. (Workers shall react in order to prevent loss of equipment and/or measurements)

Some other examples could be:

- Misspelling a worker's name during the registration process
- Dosimeter without ECC calibration has been shipped to customer

iii. Major deviation

e.g.: Power failure and auxiliary power supply failure. Measurement information has been lost.

Some other examples could be:

- Inadequately trained personnel to perform quality tests or measurements
- Measurements were performed without required calibration tests
- Irradiated Dosimeter has been shipped to the customer

iv. Critical deviation

e.g.: Power failure causes damage to main equipment (TLD or OSL reader)

Some other examples could be:

- Measurements were performed without required calibration tests
- Removal of the cover of film (Film dosimetry) outside of a dark room
- No traceability to National Measurement Institute

Annex D: Authorisation Matrix Example

Annex: 6.2.5: Authorisation Matrix Example

Authorisation Matrix

Key A: Authorised to perform task

R: Responsible for task being performed

Abbreviations:

- LM: Laboratory Manager
- QO: Quality Officer
- LT: Laboratory Technologist
- IA: Internal Auditor
- Secr: Secretariat
- ……..

TASK	LM	QO	LT		Secr.	Other
General						
Personnel and Organisation						
Equipment						

Drafted by:		Date:		Signature	

Annex E: Supervision of Personnel Form Example

Sub-clause 6.2.5: Supervision of Personnel Form Example

EVALUATION REPORT FOR THE YEAR …….

A. Personal information	
Surname:	Name:
Specialty:	e.g. Technician
Other details:	

B. Evaluator information	
Surname:	Name

C. EVALUATION	
CRITERIA	*Rating* (rating*: 1 = inadequate, 2 = moderate, 3 = good, 4 = very good, 5 = excellent).*
1. Knowledge and implementation of the procedures.	
2. Knowledge and application of relevant standards	
3. Identification of problems in MS or from performing procedures and respective solutions improvement/ suggestions / actions	
4. Performing tests, maintenance of equipment, and keeping all relevant records	
5. Initiatives for: selection or renewal of equipment / development and validation of new methods or improvement of already used	
Total Score:	

D. COMMENTS - DOCUMENTATION

Evaluator/ Supervisor _____

(Date, Name and Signature)

Worker _____

(Date, and Signature)

Annex F: Comparison of environmental conditions of different standards

Sub-clause 6.3.2: Comparison of environmental conditions of different standards [4]

Influence quantity	Passive dosimetry systems			Direct reading dosimeters
	ISO 1757:1996*	ISO 12794:2000*	IEC 62387:2020	IEC 61526:2010
Type of detector and type of dosemeter	Film, whole body	TLD, extremity	All passive, TLD whole body	All active, whole body
Environmental conditions	Temperature up to +50°C: 0.8 ≤ response ≤ 1.2 Humidity up to 90%: 0.9 ≤ response ≤ 1.1 Fading: 0.9 ≤ response ≤ 1.1	Temperature up to +40°C and humidity up to 90%: 0.9 ≤ response ≤ 1.1 Light exposure: 0.9 ≤ response ≤ 1.1	Temperature: -10 to +40°C, Humidity 10% to 90%, 0.83 ≤ response ≤1.25 Fading, light, reader stability and power supply combined: 0.91 ≤ response ≤ 1.11	temp. -10°C to +40°C 0.83 ≤ response ≤1.25 humidity 40% to 90% 0.90 ≤ response ≤ 1.10 power supply: 0.90 ≤ response ≤ 1.10 atmospheric pressure: 0.90 ≤ response ≤ 1.10 dose rate for dose meas.:0.80 ≤ response ≤ 1.20

*Standards withdrawn

Annex G: Report on Fulfilment of Requirements for Environmental Conditions Example

Sub-clause 6.3.3: Report on Fulfilment of Requirements for Environmental Conditions Example

	Reader parameters[1]						Environmental parameters[2]				
Date	N_2 flow	PMT Temperature [°C]	Dark counts	LED k-counts	Vacuum level	Warming up stabilisation of 30 min Yes / No	Temperature [°C]	Relative humidity [%]	Dose rate H*(10) µSv/h	Comments (Visual defects, malformation or dirt)	Signature of individual responsible

[1] Reader parameters are recorded directly from reader software

[2] Environmental parameters are recorded from thermo-hygrometer and dose-rate meter placed in laboratory. Equipment calibrated in accredited laboratory.

Annex H: A list of standards applicable to IMS capable of evaluating personal doses

Sub-clause 7.2: A list of standards applicable to IMS capable of evaluating personal doses:

- IEC 62387:2020 Radiation protection instrumentation - Passive integrating dosimetry systems for personal and environmental monitoring of photon and beta radiation. This standard applies to all kinds of passive dosimetry systems [8]
- ISO 14146:2018 Radiological protection - Criteria and performance limits for the periodic evaluation of dosimetry services [18]
- IEC TR 62461:2015 Radiation protection instrumentation - Determination of uncertainty in measurement [16]
- ISO 15382:2015 Radiological protection -- Procedures for monitoring the dose to the lens of the eye, the skin and the extremities [22]
- ISO 21909-1:2015 Passive neutron dosimetry systems -- Part 1: Performance and test requirements for personal dosimetry [23]
- ISO 15690:2013 Radiological protection -- Recommendations for dealing with discrepancies between personal dosimeter systems used in parallel [24]
- ISO 20553:2006 Radiation protection -- Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material [25]
- ISO 16637:2016 Radiological protection -- Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources [26]
- ISO 27048:2011 Radiation protection -- Dose assessment for the monitoring of workers for internal radiation exposure [27]

Annex I: Bad results as a consequence of improperly handled dosemeters

Sub-clause 7.4: Bad results as a consequence of improperly handled dosemeters

In the Eurados 2018 Annual Meeting, during the Learning Network, a discussion group tried to focus on the possible causes of bad results in personal dosimetry. The basic outcome is reported here, just as a hint, without any intent of statement that this could be a complete list fitting any IMS. Many of these might be included in procedures for the correct handling of dosemeters:

- Dosemeters exposed for internal calibration dosemeters wrongly sent to customers
- Confusion between measured values (readings) and dose values. In general, the dose measurement is accredited not the 'dose to the person' value
- Malicious exposures
- Late returned dosemeters: can give bad results, e.g. if stored incorrectly?
- Wrong background subtraction, strongly dependent on how background is evaluated (dosemeters sent to client, mean annual value, raw results without BG subtraction…)
- Instruments 'bad results': transient event during readout, mechanical shock, electronic noise
- Bad identification (dosemeter identification vs attribution to person)
- Data loss during data transfer
- Software problems (shift of dose results)
- Lost data after power shutdown
- Loss of data due to wrong backup
- Wrong instrument settings

Annex J: Report on IMS Participation in Personal Dosemeters Intercomparison Example

Sub-clause 7.7: Report on IMS Participation in Personal Dosemeters Intercomparison Example

Record ID

REPORT ON IMS PARTICIPATION IN PERSONAL DOSEMETERS INTERCOMPARISON (example)

Authors

Date

Information provided by organisers in the announcement

Organiser	
Scope	
Radiation qualities	
Radiation energy range - Photon - Beta - Neutron	
Dose range	
Angular range	
Number of dosemeters required	
Year	

Information of IMS participation

Dosemeter model	
Hanger	
Reader	
Files and dates: - Annealing - Readout	
IMS secret ID	
IMS public ID (if applies)	

Radiation qualities and doses imparted

Quality	$H_p(10)$ imparted (mSv)	$H_p(0,07)$ imparted (mSv)	Number of irradiated dosemeters

Irradiation laboratories and accreditation information

Results of IMS participation

Analysis of the results

- ✓ Performed by the organiser
- ✓ Performed by the IMS
  - Pre-defined criteria (ISO-14146:2018)

IC supplier evaluation

1. Accreditation and/or experience
2. Information about participants: number of participants, general results if available, etc.
3. Evaluation of IC supplier performance and reporting
4. Utility of participation

Corrective actions (in case results out of the acceptance criteria are found)

Conclusions

Annex K: Quality Report Example

Sub-clause 7.9: Quality Report Example

QUALITY REPORT | Quality Report Reference Number:

Section 1: To be completed by the Initiator

Quality Report raised to:		Quality Report raised by:	
Name:		Name:	
Job Title:		Job Title:	
Description of the problem:			
Name:	Date: DD Month YYYY	Signature:	

Section 2: To be completed by the IMS responsible person

Inform IMS quality manager to assign Quality Report reference and entry onto tracking spreadsheet
Is this a recurring issue? Yes / No Minor / Serious / Major & Implications Has the work been stopped, if so why?

Detail immediate corrective actions undertaken: What was the root cause and contributory cause(s)? Detail any further improvements, target dates, and those responsible for the actions: Detail any notifications to the customer: (*N/A if not applicable)* Authorisation of resumption of work required? Yes / No (*N/A if not applicable)*
Agreed deadline to meet: DD Month YYYY *Typically one month from raised date, however the date can be flexible and this should be discussed with your Quality Manager to ensure that a reasonable close out date is assigned*

Name:	Group / Team:	Signature:
Actions required: Yes / No	Actions Complete: Yes / No	Action Tracking Reference number:

Section 3: To be endorsed by the IMS Manager

Name:	Group / Team:	Signature:

Section 4: To be endorsed by the IMS Quality Manager

Name:	Date:	Signature:

Annex L: Risk Register Example

Sub-clause 8.5: Risk Register Example

HAZARD	Haz	L'hd	Risk	Notes	Mitigation	Risk owner(s)	Output / document
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				
			0				

Annex M: Risk Register Notes Example and explanations

Sub-clause 8.5: Risk Register Notes Example and explanations

Risk Register Notes								
Severity Impact rating (Hazard)								
		Quality						
1	Low	Minor quality issue; Work can continue or requires minor improvement action; Work stops until improvements is implemented						
2	Medium	Medium quality issue; investigation into issue required; work stops until investigation is complete and remedial actions are completed; potentially requires customer to be notified.						
3	High	Major quality issue; full investigation required into issue; work stops until issue understood, remedial actions taken and validation completed; customer informed; previous results re-called or verified as valid.						
Probability rating (Likelihood)								
1	Low	Remote	Unlikely to occur and would be an unusual event or a total surprise					
2	Medium	Occasional	Likely to occur once but would not be common					
3	High	Probable	Likely to occur repeatedly unpredictably or with some certainty					
Residual Risks:								
	Description				**Action**			
GREEN	Low: The risk associated with a particular hazard have been reduced or mitigated to an acceptable level.				Record for reference in quality documentation / risk register			
AMBER	Manageable Risk: The risks require controls or minor remedial actions to achieve acceptable level.				Record in quality documentation and residual risk register together with suggested controls or remedial actions.			
RED	Unacceptable: risk unacceptable, issue requires full investigation; improvement plan required to reduce the risk to an acceptable level; quality manager requires informing; potential requirement to inform customer				Full quality investigation required to identify and resolve issue. Improvement plan implemented. Investigation report written and agreed with quality manager.			

Risk level (severity impact rating (hazard)): LOW, MEDIUM, HIGH.

The risks evaluated with LOW level (1 point) are those in which it is estimated that the development of the activity can be continued without performing any action or requiring minor improvement actions.

The risks evaluated with the MEDIUM level (2 Points) are those in which it is estimated that they should be subject to a more thorough review and analysis.

The risks evaluated as HIGH (3 points) are those in which the appropriate treatment should be studied, adopting preventive actions including their implementation, monitoring and evaluation.

Probability of risk (Probability rating (likelihood)): LOW, MEDIUM, HIGH

LOW (1 point): Remote. Unlikely to occur and would be an unusual event or a total surprise

MEDIUM (2 Points) Occasional. Likely to occur once but would not be common

HIGH (3 points): Probable. Likely to occur repeatedly unpredictably or with some certainty.

Furthermore, a classification and evaluation of risks must be carried out. This assessment can either lead to the initiation of measures or the acceptance of the risk as such. It is possible that a risk is acceptable.

In order to determine the level of risk, a risk / probability matrix (see below) can be used to perform the risk classification. Identification of which are those risks that need priority treatment, or require more detailed analysis can be useful. The criteria for assessing risks can be the following:

Level of risk = severity impact rating x probability rating

		LIKELIHOOD		
		LOW (1)	MEDIUM (2)	HIGH (3)
HAZARD	HIGH (3)	3	6	9
	MEDIUM(2)	2	4	6
	LOW (1)	1	2	3

Risk classification:

Green (≤2): Low. Can be classified as an acceptable risk. Action needed: Record for reference in quality documentation / risk register.

Amber (3 to 6): Manageable risk. It is necessary to decide whether it is still acceptable or if measures need to be taken The risks require controls or minor remedial actions to achieve acceptable level. Action needed: Record in quality documentation and residual risk register together with suggested controls or remedial actions.

Red (9): Unacceptable: risk unacceptable, issue requires full investigation; improvement plan required to reduce the risk to an acceptable level; potential requirement to inform customer.

Annex N: Corrective Action / Action for Improvement Report Example

Sub-clause 8.6 and 8.7: Corrective Action / Action for Improvement Report Example

Corrective action / Action for improvement Report

TITLE:	CODE: (Identification code)
	Type: ☐ Corrective Action ☐ Action for improvement

DEFINITION

Date:	
Job title:	Name /Signature: Employee who defines:
Description:	
Origin	Identification code (of Non-conformity, complaint, etc.):
Origin description	Causes:
Related Processes	
Expected time:	Expected cost:

PRELIMINARY ANALYSIS

Date:	
Job title:	**Name:** **Employee who analyses:**
Analysis	
Term and responsible for implementing	
Term expected:	
Job title:	**Name:**
Term and responsible for the evaluation of the effectiveness	
Term expected (from the end of the implementation):	
Job title:	**Name:**

IMPLEMENTATION

Implementation date:	
Job title:	**Name /Signature:** **Employee who implements:**
Result of the implementation:	

EVALUATION OF THE EFFECTIVENESS

Evaluation date:	
Job title:	Name /Signature: Employee who evaluates:
Result of the evaluation:	
Evaluation:	Degree of effectiveness:
	Effective
	Not effective
	Partial effectiveness

CLOSING

Closing date:	
Job title:	Name /Signature: Employee who closes:
Closing information:	

Related Documents:

Annex O: Internal Audit Report Template (Example)

Sub-clause 8.8: Internal Audit Report Template (Example)

REPORT ID:

INTERNAL AUDIT REPORT

Audit Code:	
IMS / organisation audited:	
Audit Date:	
Standard of reference:	ISO/IEC 17025:2017
Other documents of reference:	(e.g. Quality Manual, Technical and managerial procedures, etc.)
Audit objective:	
Audit scope:	
Audit team:	(Identification of audit team leader)
Identification of staff present during the audit process:	
Audited items / Findings: (Detailed description of the items, documents and evidence reviewed during the audit process and of the relevant findings, according to the ISO standard clauses and sub-clauses. Detailed description of deviations has to be included) *use as many pages as necessary*	
Conclusions: (Deviations, weaknesses and strengths of the management system, opportunities for improvement, etc.)	

Deviations:			
	Deviation id.	Description	ISO/IEC 17025 Related Requirement

Date:

Signature: (audit team)

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