Data and information management

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When referring to data…

we may think of the primary product of laboratory work i.e. figures and results of measurements and observations. These are indeed very important since they represent the basis on which results, reports and certificates can be issued and opinions and interpretations and statements of compliance can be reported.

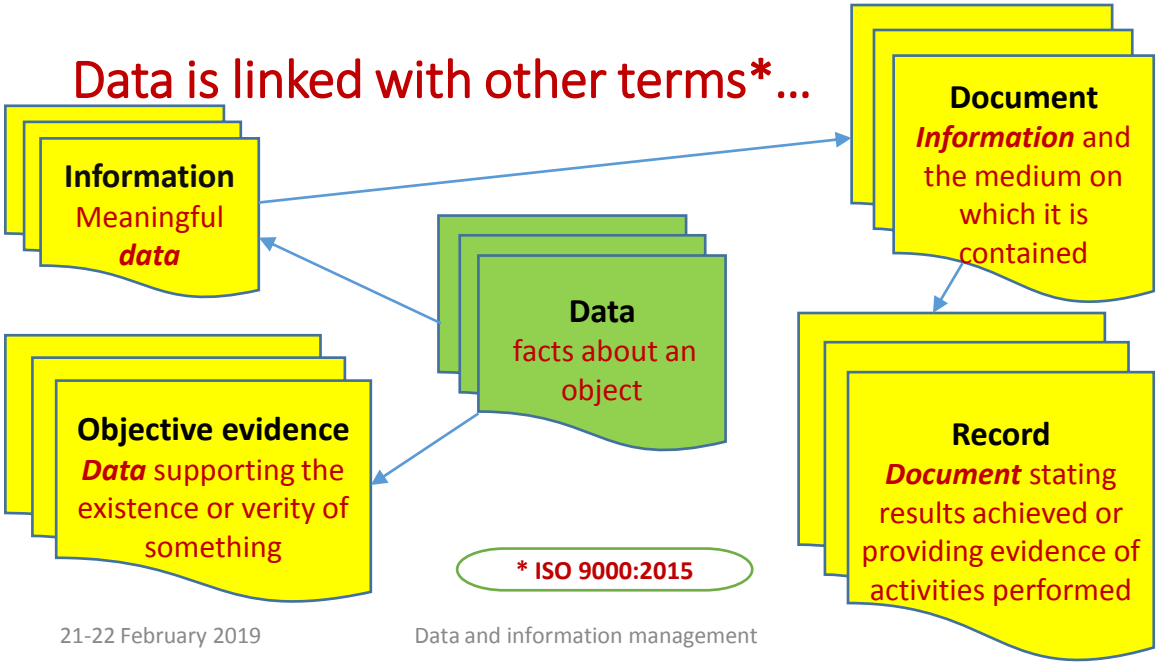
Is that all?

ISO 9000:2015 defines data as…

Facts about an object i.e. an entity, an item, anything perceivable or conceivable.
This may include among others a product, a service, a process, a person, an organization, a system, a resource.

Following the definitions for some other terms…

Data is linked with other terms*…



* ISO 9000:2015

To this end, when referring to data integrity…

we need to consider all other relevant elements in the management system, namely

- data
- information
- quality records
- technical records
- documents

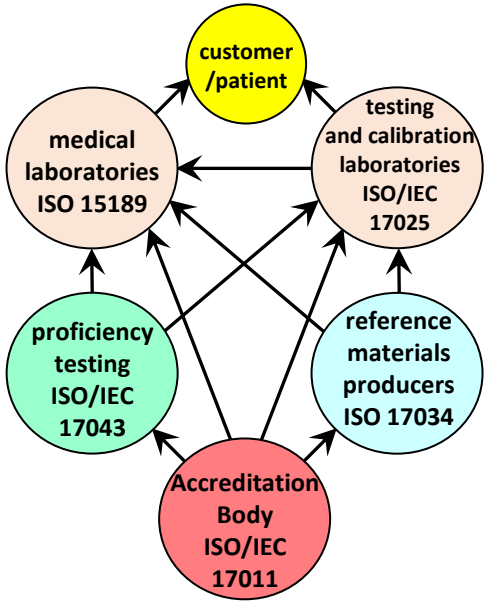
Requirements for the competence

of conformity assessment bodies (CABs) are included in a series of standards.

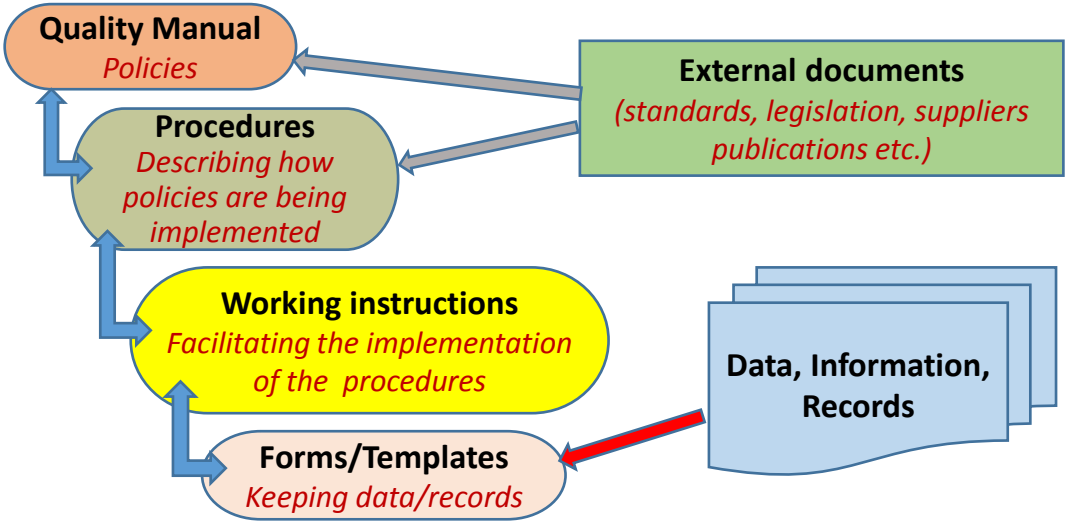
These standards are the ones used by accreditation bodies in the assessment of CABs for their accreditation.

This is why the term *“accreditation standards”* is used throughout this presentation. The requirements of these standards include specific references to data/information/documents/ records, their protection and integrity.

Interaction between a laborarory, other CABs, the users of the results and the Accreditation Body



The documentation of a management system



Quality records vs technical records

- What does each group of records include?
- The answer is given in ISO/IEC 17025:2005 , ISO/IEC 17043 and ISO 17034

➔ Each of these standards describes in detail the content of quality and technical records reflecting the specific needs of the type of CAB.

Similarly, this applies in the other standards as appropriate.

Quality records are records…

providing objective evidence of the extent of the fulfilment of the requirements or the effectiveness of the operation of the management system; they include reports from

- internal audits
- management reviews
- records of corrective and preventive actions

These elements are found in all accreditation standards with the exception of preventive actions not referred to in the new ISO/IEC 17025. Their task is now met by risk-based thinking.

Technical records are accumulations…

of data and information which result from laboratory activities and which indicate whether specified quality or process parameters are achieved; they include records from

- original observations
- derived data and sufficient information to establish an audit trail
- calibration records
- staff records
- a copy of each test report or calibration certificate

➔Records from sampling activities to be included (ISO/IEC 17025)

Important aspects in all cases

- The requirements of the standards are applicable to both handwritten and electronic records – Appropriate measures have to be taken in each case
- Thermally printed data have a limited life-time
- Data stored on “data server” need appropriate IT principles to be met i.e. controlled access, appropriate environmental conditions, regular backups, appropriate measures to prevent damage or deterioration

Integrity and confidentiality

- Integrity is directly related to confidentiality! They are two of the main pillars in accreditation process.
- This is why detailed requirements are set in all accreditation standards.
- All parties involved shall follow these principles and implement appropriate and documented policies to meet relevant requirements set in the accreditation standards.

Accreditation standards set requirements…

referring to the responsibility of each particular CAB to safeguard data, information, records and documents.

Similar requirements are also included in ISO/IEC 17011 regarding the operation of accreditation bodies...

Requirements of ISO/IEC 17011

are included mainly in the following clauses:

6.2 Personnel involved in the accreditation process (confidentiality)

6.3 Personnel records: qualifications, training, competence, results of monitoring, experience, professional status and affiliations for personnel managing or performing accreditation activities

6.4 Outsourcing (confidentiality)

7.14 Records on conformity assessment bodies

9.3 Document control

9.4 Control of records: identification, storage, protection, retrieval, retention time and disposition of records

Laboratory accreditation standards provide

for the laboratory information management system(s) used for the

- collection
- processing
- recording
- reporting
- storage or retrieval of data

➔ *ISO 15189 addresses these issues in a way that reflects the particular needs of the sector (personal data of the patients).*

The recently revised standard for laboratories

ISO/IEC 17025 :2017 refers to data, records and documents in the following clauses:

- Control of records in 8.4 and 7.5 (the latter refers to technical records)
- Control of data related to laboratory activities in 7.11
- Control of documents in 8.3

➔ Confidentiality in 4.2

7.5 Technical records

The laboratory shall ensure that technical records for each activity contain

- the results
- report and information to facilitate identification of factors affecting the measurement result and its uncertainty
- date and identity of personnel responsible for the activity and checking the results

➔Original observations, data and calculation shall be recorded at the time they are made and shall be identifiable with the task.

Amendments to technical records

shall be tracked to previous versions or to original observations.

Both the original and amended data and files shall be retained with relevant dates, the alterations and the personnel responsible for them.

“Laboratory information management system(s)”

includes the management of data and information contained in both computerized and non-computerized systems.

Some of the requirements can be more applicable to computerized systems than to non-computerized systems. (Note 1 to 7.11.1)

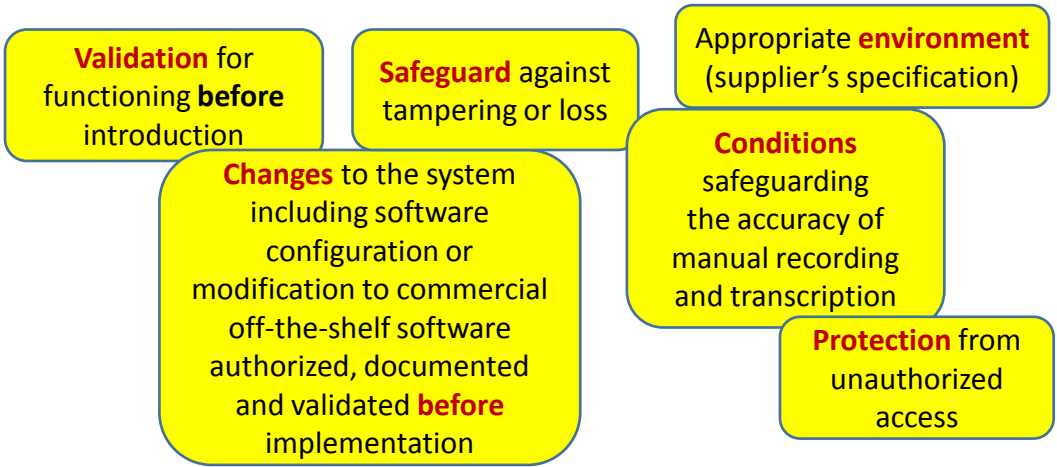
➔ *A similar definition is given in ISO 15189 for “information systems”.*

According to clause 7.11…

the laboratory shall have access to the data and information needed to perform laboratory activities (7.11.1).

The laboratory information management system(s) used for the collection, processing, recording, storage or retrieval of data shall operate within the following framework (7.11.2-7.11-6)…

Control of data and information management



Commercial off-the-shelf software…

in general use within its designed application range can be considered to be sufficiently validated (Note 2 to 7.11.2).

Changes to the system including software configuration or modification to commercial off-the-shelf software shall be authorized, documented and validated before implementation.

Furthermore…

Conditions ensuring the **integrity** of data and information

Recording **failures** – **immediate** and **corrective actions**

Instructions, manuals, and reference data **readily available** to personnel

Calculations and data transfers **checked** in an appropriate and systematic manner

Information system(s) managed/maintained off-site: responsibility of laboratory for ensuring **provider/operator's compliance** with requirements

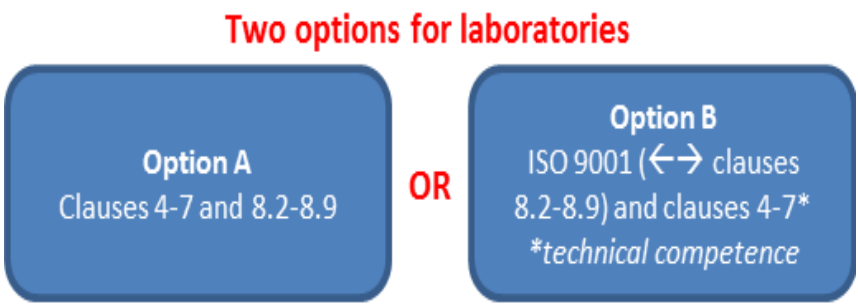


Figure 2: Management system options

from the Eurachem leaflet "A new ISO/IEC 17025 for laboratories"

Option B is of interest to laboratories already implementing a management system in accordance with ISO 9001 which need to comply with clauses 4-7 of ISO/IEC 17025 as well.

In the case of management system option A

further to clause 7.11 of ISO/IEC 17025, its clause 8.4 dealing with control of records also applies.

- 8.4.1 provides for the need to establish and retain legible records demonstrating the fulfilment of the requirements of the standard.
- 8.4.2 specifies that….

continued…

In the case of management system option A (2)

the laboratory shall implement the control needed for the

- ✓identification of its records and their
- ✓storage
- ✓protection,
- ✓back-up
- ✓archive
- ✓retrieval
- ✓retention time
- ✓disposal

Although not directly referred to…

the need to address risks and opportunities as provided in clause 8.5 is evident with regard to data and records as well.

In the medical sector…

the importance of data integrity is of decisive importance. The 2012 version has given higher importance to the Laboratory Information Management, introducing clause 5.10 instead of an Annex which was dealing with this issue in the previous version (2007).

According to the Note to clause 5.10.1…

“Information systems”

includes the management of data and information contained in both computerized and non-computerized systems.
The latter can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.

In the case of medical laboratories…

the accreditation standard ISO 15189 specifies the requirements as follows:

- 4.13 Control of records
- 5.10 Laboratory information management
- 4.3 Document control

Control of records

The laboratory shall have a documented procedure for

- identification of quality and technical records and their
- collection
- indexing
- access
- storage
- maintenance
- amendment
- safe disposal

➔Records shall be created concurrently with performance of each activity

continued…

Control of records (2)

- The date and the time of amendments to records shall be captured along with the identity of personnel making the amendments
- Records can be in any form or type of medium provided they are readily accessible and protected from unauthorized alterations
- The retention time shall be defined
- The environment shall be suitable for safe storage of records
- Records shall be retrievable for as long as medically relevant or as required by regulation

According to sub-clause 5.10.1…

- The laboratory shall have access to the data and information needed to provide a service which meets the needs of the user.
- The laboratory shall have a documented procedure to ensure that the confidentiality* of patient information is maintained at all times.

** also addressed in the ethical conduct specifying that laboratory management shall ensure (among others) that confidentiality of information is maintained (4.1.1.3.e)*

Authorities and responsibilities (5.10.2)

for the management of the information system, including the maintenance and modification to the information system(s) that may affect patient care; these authorities and responsibilities refer to all personnel who use the system, in particular those who

- access patient data and information
- enter /change patient data and examination results
- authorise the release of examination results and reports

Specific requirements

The system(s) used for the collection, processing, recording, storage or retrieval of examination data and information shall operate within the following framework (5.10.3)…

Information system management

Validation (supplier) and **verification** for functioning (laboratory) **before** introduction

Documentation (day to day functioning) **readily available** to **authorised** users

Appropriate **environment** (supplier's specification)

Changes to the system authorised, documented and **verified before implementation**

Protection from unauthorized access

Conditions safeguarding the accuracy of manual recording and transcription

Compliance with **national/ international** requirements for data protection

Safeguard against tampering or loss

Ensuring the **integrity** of data and information – recording **failures** – **immediate** and **corrective actions**

Furthermore…

Verification that the results of examinations, associated information and comments are **accurately reproduced** (e- or hard copies) **by external systems** directly receiving the information (computers, fax, e-mail, website, personal web devices)

Verification that changes (new examinations or automated comments) are **accurately reproduced**

Contingency plans to maintain services in case of failures or downtime in information systems

Information system(s) managed/maintained off-site: responsibility of laboratory for ensuring **provider/operator's compliance** with requirements

The Regulation (EC) No 679/2016 (GDPR)

on the protection of data of natural persons with regard to the processing of personal data and on the free movement of such data has been implemented as from 25 May 2018.

Accreditation standards address the protection of such data even if not in such detail.

Laboratories need to consider some address relevant issues to fully comply with it.

Medical laboratories dealing with patients' personal data may need to elaborate more extensively although in their case relevant national and international regulatory tools already apply.

Laboratories need to consider the following…

- is it ensured that the agreement for the collection of data and the permission for the particular use are given by the owner?
- what kind of personal data is retained, where and how?
- who has the responsibility and authority for access and use?
- what is the risk from loss, subtraction or unauthorized alteration?
- what are the measures taken to ensure that suppliers of relevant services are competent and what is their policy and practice?
- is the set retention time appropriate?
- is all data collected absolutely required?
- is the anti-virus protection adequate and efficient?

Thank you for your attention

….and your questions