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MANAGEMENT OF DOCUMENTS AND RECORDS

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N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

Management of Documents and Records

Guideline for OMCLs

Note: Mandatory requirements in this document are defined using the terms "shall" or "must". The use of "should" indicates a recommendation. For these parts of the text other appropriately justified approaches are acceptable. The term "can" indicates a possibility or an example with non-binding character.

1 INTRODUCTION

Management of documents and records (writing down what the OMCLs do and how they do it) is one of the pillars of a functioning quality management system (QMS).
Several chapters of ISO/IEC 17025 are dedicated to these topics (7.5 Technical records, 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).

2 OBJECTIVE

The purpose of this guideline is to help OMCLs in establishing and maintaining procedures:

- to control internal documents: identify, approve, issue, review, revise, identify changes and status or documents, ensure availability,
- to control external documents: access, distribute, ensure availability and implementation of current versions and track/archive previous versions, perform impact analyses on the QMS
- to control records: identify, store, protect, back-up, archive, retrieve, retain, and dispose quality and technical records,

in order to guarantee legibility, traceability and durability of documents and records. Approaches like ALCOA+ (attributable, legible, contemporaneous, original, accurate, complete, consistent, endurable and available) and audit trail can be applied.

3 SCOPE

This guideline is intended to address the management of internal and external documents, records and data related to the activities performed by the OMCLs.

4 DEFINITIONS

Documents: for the definition refer to the note in clause 8.3.1 ISO/IEC 17025:2017 (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.)

Internal documents – documents generated by the OMCL, see below (5.2).

External documents – documents generated by an external body/authority/company such as legislation, standards, guidelines, pharmacopoeias, EDQM's documentation, information from manufacturers, equipment supplier instructions, contracts, etc..

Records (quality and technical, internal and external) – registered evidence on OMCLs activities on the QMS and/or the process of performing tests (e.g. work sheets, logbooks, control graphs, records of equipment qualification, test requests, test reports, reports from audits, training records, records of corrective actions, etc.). A form or template containing data is considered a record.

Template – master version of the form

Form - individual instance of the template that is filled out

Review – checking of the suitability of a document.

Revision – changing the version of a document.

Data - information derived or obtained from registered evidence on OMCL activities**.** Data may be recorded on paper, electronically or using the hybrid system where both paper-based and electronic records constitute the original record.

ALCOA+. A commonly used acronym for "attributable, legible, contemporaneous, original and accurate", which puts additional emphasis on the attributes of being complete, consistent, enduring and available – implicit basic ALCOA principles.

Audit trail. The audit trail is a form of metadata that contains information associated with actions that relate to the creation, modification or deletion of records. An audit trail provides for secure recording of life-cycle details such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record regardless of its medium, including the "who, what, when and why" of the action.

5 MANAGEMENT OF DOCUMENTS

5.1 GENERAL REMARKS

It is advisable that the OMCL has an easily retrievable list of internal documents to facilitate their management and control, no matter whether they are managed through paper documents or through the computerized systems.

5.2 STRUCTURE OF INTERNAL DOCUMENTATION

The OMCL should define the structure of its internal documentation.
Internal documents may comprise the following:

- Management System documents: define the general organisation of the OMCL (including roles and responsibilities of personnel issuing, reviewing and approving the documents), Quality Manual (where applicable), QMS policies, SOPs (or reference to them), the structure of documentation and reference to other documents (e.g. Regulations on internal organisation, Job Description, etc.).
- Standard Operating Procedure (SOP): defines how a given activity related to the quality management system or to a technical task is performed and may contain or refer to operating details.
- Supporting documents: e.g. lists (equipment, personnel, premises, reference materials, reference standards), documents describing the premises, the organisation.
- Forms or Templates for quality and technical records: e.g. CA forms, templates for logbooks, work sheets for recording of raw data, test report templates, etc.

5.3 RESPONSIBILITIES

The OMCL shall define the responsibility of the personnel for approval before issuing, maintaining and periodically reviewing documents.
Each document should be approved by the most appropriate person(s) based on their competence and role.
The laboratory management shall ensure the consistency of the Quality Management System.

5.4 CONTROL OF ISSUING

The OMCL should describe its process for issuing of documents.

5.5 IDENTIFICATION

The OMCL shall ensure that documents are uniquely identified. Such identification can include following:

- the date of issue and/or revision
- page numbering, the total number of pages (e.g. page x of page y) or a mark to signify the end of the document

- changes and the current revision status of documents
- the issuing authority(ies)/ person(s) responsible for the issuing, reviewing, approving.

The type of identification system depends on the preferences of the OMCL (title, code, number, reference, etc.).

5.6 REVIEW, REVISION AND APPROVAL

The OMCL shall define a period for reviewing its documents in order to ensure continuing suitability. If the review process does not identify the need for changes, a new revision is not required. Nevertheless, evidence that the review was carried out must be recorded.
Review and approval of revised documents shall be performed prior to their issue. It may be done by the same function (position) that performed the original version (authorised the previous version).
The OMCLs shall evaluate the impact of new or revised external documents on the QMS. Whenever the internal document in the OMCL is revised, the laboratory should evaluate if the linked or referred documents are affected by the changes. Amendments by hand are not recommended, but if the OMCL allows this type of amendments it should be ensured that:

- the amendments are communicated to the responsible person to further proceeding to correct the documents for such amendments are defined;
- amendments are clearly marked, initialled and dated;
- a revised document is issued as soon as possible;
- amendments should be made to all controlled copies.

In revised documents, modifications shall be identified, where practicable, for example: track changes, comments, italics, bold, strikethrough, underlined or line in the margin. If not, a section or a specific record which describes all changes is acceptable.

5.7 DISTRIBUTION

The availability of both internal and external documents to all personnel involved in laboratory activities shall be ensured, as applicable to their responsibilities.
The OMCL shall describe how all staff concerned have access to the appropriate documents for controlled paper copies (e.g. record of issuing of all copies) or electronic documents (e.g. description of internal network or dedicated software).
Confidentiality shall be ensured in case of external distribution of documents.
If documents are distributed electronically, the OMCL shall ensure that the integrity of the information is maintained (e.g. preventing accidental change of SOPs).

5.8 OBSOLETE DOCUMENTS

The OMCL should promptly remove invalid/obsolete documents from all points of issue or use. Unintended use of invalid/obsolete documents shall be avoided (e.g. by marking the documents).
Obsolete documents may become records for traceability purposes.

5.9 ARCHIVING

The OMCL shall define retention times for obsolete documents considering the archiving requirements defined for quality and technical records (see section 6.4).

6 MANAGEMENT OF RECORDS

6.1 AVAILABILITY

The OMCL shall define rules to access, identify, collect and index records in order to ensure that they are readily retrievable.
The OMCL can index records by carrying out an inventory of the records. The inventory should contain the identity of the record, the person responsible for the type of record, the location, the archiving organisation (cabinet, shelf, folder, binder, box…), the retention time, etc.

6.2 CONTROL OF RECORDS

The OMCL shall ensure traceability, legibility and integrity of its records. This can be achieved by:

- recording observations, data and calculations at the time they are made;
- making sure that data on records are original (raw data), exact, clear, accurate and complete (records on thermal paper should be copied);
- identifying the person who performed the test or the activity and when the activity took place;
- prohibiting the use of pencil, eraser, correction fluid, sticky notes or similar;
- assuring that all kind of amendments should be crossed out, not erased, made illegible or deleted and the correct information entered alongside with the date and identification of the person making the correction and if appropriate, a reason for modification;
- crossing out empty fields to ensure they were not forgotten and to avoid filling-in afterwards (e.g. N/A), if applicable;
- signing across a paper that is attached or glued to a support paper (e.g. printout from the balance glued in the laboratory notebook), to clearly identify if a piece of information is lost.

For logbooks, pages should be marked sequentially to ensure that no page is removed.
Specific measures shall be in place for electronic records to avoid loss and trace changes of original data (e.g. by an electronic audit trail).
Protection and back-up of records are described in OMCL Guideline on Validation of Computerised Systems - Core Document and Annexes.

6.3 CONTROL OF DATA

The OMCL shall have access to data, which shall be safeguarded against tampering and loss. The integrity and confidentiality of data entry, collection, storage, transcription, transmission and processing of data must be guaranteed.
Calculations and data transfer shall be subject to appropriate checks (e.g. double checking when appropriate, avoiding the transcription of data or ensuring transcription is checked).

6.4 STORAGE AND ARCHIVING

The OMCL shall implement the controls for the storing and access of the quality and technical records to ensure confidentiality.
Records shall be easily accessible and readily available. For electronic records, legibility should be checked periodically, for example after software updates.
The OMCL shall define retention times to meet requirements from national regulations, accreditation body or equivalent (e.g. an audit cycle) as well as any other requirements (e.g. from customer). Records should be archived for at least 5 years after the date of issuing.
Records from Batch Release activities shall be archived in accordance with the EU Administrative Procedure for Official Control Authority Batch Release.
Particular attention shall be paid to the storage system to prevent damage, deterioration or loss of information.

6.5 DISPOSAL

The OMCL should describe the disposal of records after their retention time (destruction or long-term storage) according to national regulations or any other requirements.
Confidentiality shall also be considered.

7 REFERENCES

- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- OMCL Guideline on Validation of Computerised Systems - Core Document and Annexes, valid edition
- EU Administrative Procedure for Official Control Authority Batch Release, valid edition