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MANAGEMENT OF SAMPLES

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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 Samples

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

Sample management is critical to the accuracy and reliability of testing, and, therefore, for ensuring the validity of test results. This document describes archiving aspects for samples (initially mentioned in OMCL GL Archiving (PA/PH/OMCL (07) 105 DEF)) and provides requirements for management of samples in general.

Several chapters of ISO/IEC 17025:2017 deal with this topic 7.1 (Review of requests, tenders and contracts), 7.3 (Sampling), 7.4 (Handling of test or calibration items).

2. OBJECTIVE

The purpose of this guideline is to describe how samples tested by OMCLs are managed, in what concerns: receipt, handling, protection, identification, traceability, storage, archiving and disposal of the samples.

3. DEFINITIONS

Samples: Test items (ISO/IEC 17025: 2017), i.e. each item to be tested by the OMCL, as defined by the scope of the individual OMCL's activities (e.g. APIs, medicinal products, medical devices, cosmetics, samples for PTS studies etc.).

Retained sample: samples that are archived for legal or other purposes.

4. RESPONSIBILITIES

The OMCL should define the person(s) responsible for receipt, transport, identification, handling, testing, access (restricted), storage, retention and disposal of the samples. Written procedures shall be in place describing how the aforementioned activities are managed.

5. RECEIPT

The condition of the sample shall be inspected on arrival as per the agreement and following a clearly defined internal procedure, taking into account any legal or health and safety aspects which may apply. The outcome of the inspection (especially any deviation from standard conditions) shall be recorded. Where there is any reason for doubt as to the suitability of the received item, the responsible person, where appropriate, shall consult the sender and agrees on appropriate action before proceeding. The outcome of this agreement shall be recorded.

During receipt, care should be taken to ensure that the samples are stored in a designated area for unregistered samples, under the prescribed storage conditions.

The table below describes who may be contacted in case doubts arise or deviations are observed during receipt of a material:

Context of testing	Function/body with whom the testing order should be clarified
Samples submitted by the competent authority's sampling body (e.g. inspectorate)	Competent authority's sampling body
Quality defect samples (including samples sent directly to the OMCL)	Competent authority that is responsible for follow-up of quality defects (e.g. inspectorate)
MRP/DCP surveillance studies	The sampling OMCL
CAP testing	EDQM as coordinator of the study
OCABR	The manufacturer or marketing authorisation holder that requested batch release and submitted the samples
PTS samples	The OMCL should refer to the suppliers of the samples for the PTS in case doubts arise or deviations are observed
Samples that were taken by the OMCL (e.g. as part of an annual sampling plan)	The function responsible for carrying out the sampling plan or the scientific coordinator of the specific market surveillance project

Testing shall be carried out only after all deficiencies have been solved.

6. HANDLING AND PROTECTION

All the measures necessary to handle the sample and protect their integrity (to avoid deterioration, loss or damage) shall be documented and followed by the personnel (e.g. special handling procedures as cool/frozen, protected from light, humidity, health and safety requirements, etc. required during storage, pre-testing or testing). If appropriate, the samples should be accompanied by specific handling and storage instructions.

Restricted access levels should be defined for the samples received and to be handled under specific protection measures (e.g. narcotics, cancerogenic samples).

7. IDENTIFICATION

The OMCL shall have a system to ensure that samples are uniquely identified (e.g. code, reference) and marked. The type of identification system depends on the organisation, e.g. it may be linked to the analytical study. The identification shall be retained while the item is under the responsibility of the laboratory.

The identification system shall allow the sample to be traced back to a single source and transport conditions. A common identifier may only be given to several items if they are from the same batch and were sampled, transported and received together.

The identification of the samples may be ensured by generating a reference number or barcode etc. (by hand or allocated by the software), ensuring that each sample is identified correctly and that all individual samples are clearly marked (where the same sample is supplied in several packages/containers, appropriate identification (e.g. sample 1, 2, 3) can be indicated on the labels) or the samples are within a marked container when individual samples are too numerous or too small or when integrity of packaging is needed.

8. TRACEABILITY

The sample's unique identifier shall be recorded on all paper and/or electronic records generated by the OMCL, from receipt of the sample through to its testing and storage.

From the sample labels, it shall be possible to establish when a specific sample arrived at the OMCL and, likewise, it shall be possible to identify and locate the sample by the records available. Special care shall be taken to avoid any possible confusion (physically or when samples are referred to in records or other documents).

9. STORAGE OF SAMPLES DURING TESTING

Once the samples have been received and accepted and it has been confirmed that the testing order submitted is complete, the samples shall be placed in the appropriate storage area, under the prescribed storage conditions.

Samples that pose a safety risk and samples subject to special legal requirements (for instance, infectious substances, samples with high pharmacological activity, toxic substances and psychotropic drugs) should be stored in specially designated storage areas.

During testing, the samples shall be stored and handled in accordance with the OMCL's procedure and the manufacturer's requirements. Any other legal or known specific requirements should also be taken into consideration. If the manufacturer defines specific storage conditions for samples, the OMCL shall ensure that such conditions are maintained, monitored and recorded. All storage deviations from specified conditions shall be recorded. In case the customer requires testing after acknowledging a deviation from specified conditions, a disclaimer in the report, indicating which results may be affected by the deviation, shall be included.

10. STORAGE OF / ACCESS TO RETAINED SAMPLES

After being tested, samples should be retained until the report and all administrative actions have been finalised, according to the OMCL's policy. For samples from the legal supply chain that were found to be out of specification and samples for illegal products (falsified medicines, illegal supply chain), the sample retention period should include the period of time required for appeal procedures to the competent authority.

If applicable (or if requested), the OMCL should define retention times for samples (remained in their unopened primary packaging), in accordance with the requirements of an accreditation body or equivalent (e.g. an audit cycle), national regulations or equivalent and any agreements with the competent authority. The OMCL shall describe the location (depending on the prescribed storage conditions) and level of access to the retained samples. Particular attention should be paid to the storage rooms (or cabinets) to prevent damage, deterioration or loss (e.g., as a result of temperature, humidity, light).

11. DISPOSAL

The OMCL shall ensure that a proper disposal procedure in accordance with national legal requirements is in place and that any agreements with the competent authority are adhered to.

12. REFERENCES

ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories.