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MANAGEMENT OF REAGENTS

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Management of Reagents

Introduction:
The aim of this guideline is to describe the management of reagents and volumetric solutions in the OMCLs.
The term "reagent" in this guideline covers solvents, media for microbiological use, solid, liquid and gaseous substances and preparations of substances that are not reference standards or reference materials, nor preparations of reference standards.

These reagents can be divided into five categories:

1. Purchased reagents in their original container
2. Purchased reagents which have been transferred into another container
3. In-house reagents
4. Water manufactured by the OMCL
5. Volumetric solutions

Management of the reagents covers the entire life-cycle of the reagents from purchasing/manufacturing (in the case of preparations) to use and disposal.

The major points to consider in the life-cycle of reagents are:

- Types of reagent and the quality, depending on their use.
  - This should be part of an SOP or an individual testing plan.
- Selection of the supplier based on the suppliers' qualification.
  - This qualification should be documented in a list of suppliers that is linked to the quality management system.
- Verification of reagents upon receipt.
  - This could be divided into an administrative part (documented checking of the invoice, delivery note and the integrity of the container, including storage temperature) and a scientific part (documented checking of the actual quality of the reagent given by the label or certificate against the requested quality). Specific in-house testing may be required for particular reagents.
- Ensuring that the reagent is not compromised in any way before being used.
  This is to be ensured by proper storage conditions, as suggested by the manufacturer or the OMCL.
- Checking the expiry dates of reagents before use (it is not necessary to document this verification)
- Avoiding misuse by misidentification of a reagent.
  - This is ensured by proper labelling and/or storage in dedicated areas.
- The reagents used in the analysis of a specific sample must be documented.

- Disposal of the reagent.
  - Reagents are disposed of after usage.
  - Reagents are disposed of when the expiry date is exceeded. The expiry date can be prolonged if it is justified and expired reagents can be used for a special, justified purpose. In this case the container has to be labelled appropriately.
- Labelling

  The main requirements for labelling are explained in the following chapters.

  The labelling can be partially replaced, provided that the reagents are registered in a way that ensures traceability of the individual containers to the required information. It is also possible to mark certain information directly on the container or on a flag label (useful for small containers).

1. Purchased reagents in their original container

Labelling:
The label has to include:

- Name of the substance.
- Expiry date (if it is not given on the label of the container, the supplier has to be asked to give this information; the expiry date is added to the label by the OMCL. If not available from the manufacturer, the OMCL has to determine and add an expiry date to the label.
- Storage conditions, if not stored at room temperature or if any specific conditions are required.
- Manufacturer or supplier of the substance.
- Batch number.
- Concentration and/or purity of the reagent, if applicable.

The OMCL has to add the following items on the label, some of which may not fit on the label so the information can be recorded elsewhere:

- Date of receipt by the laboratory section.
- Signature (initials) of the person responsible for performing checks on incoming reagents.
- Date packaging was opened (if package opening has an effect on the quality of the reagent).
- Other relevant information.

Expiry date:
The expiry date given by the manufacturer has to be considered valid. If opening has an effect on the quality of the substance, a new expiry date has to be determined by the OMCL and a justification for assigning the new expiry date must be documented. Should the reagent be modified in the original container (*e.g.* by dissolving a lyophilised material), it should be treated as described under point 3 below (Reagents made in-house).

2. Purchased reagents that are transferred into another container

Labelling:
The label has to include:

- Name or abbreviation/code of the reagent.
- Expiry date.
- Transfer date.
- Name/signature of the person who transferred the reagent.
- Batch number.

The label may include the following additional information:

- Concentration/purity of the reagent.
- Intended use of the reagent.
- Storage conditions if not stored at room temperature.

Expiry date:
The expiry date depends on the effect of the transfer on the quality of the reagent (*e.g*. humidity) and has to be fixed on a case-by-case basis or using a general approach, as is documented in SOP of the OMCL.

3. Reagents made in-house

Labelling:
The label has to include:

- Name of the preparation, if applicable.
- Name and quantity of the reagents in the preparation (can be replaced by a reference, *e.g*. project number).
- Expiry date (if the entire preparation is intended to be used in a short period, *e.g*. buffer solution for HPLC, the indication of an expiry date is not obligatory. This period must be defined in an SOP of the OMCL).
- Date of manufacture.
- Name/signature (initials) of the person who prepared the reagent.
- Storage conditions if not stored at room temperature.

Expiry date:
The expiry date can be fixed on a case by case basis or following a general rule which is documented in an SOP of the OMCL.

The expiry date, identity (e. g. batch number, name of manufacturer, article number) and quality of the used components have to be traceable, making sure that no expired reagent is used for the manufacture of a preparation.

4. Water manufactured by the OMCL

The label has to include:

- Name and quality grade (*e.g*. HPLC grade, distilled, *etc*.).
- Date of manufacture or transfer date from the production equipment.
- Name of the person who transferred the water from the production equipment.

If more than one production apparatus for processing of water is available, the identity of the apparatus used has to be documented.

Expiry date:
The expiry date has to be fixed by the OMCL, most appropriately in an SOP.

Storage:
The storage conditions depend on the quality and intended use of the water and should be described in an SOP.

5. Volumetric solutions

In general all requirements are the same as those described for reagents. Additional information required for the labelling of volumetric solutions is as follows:

- Titer.
- Date of the determination of the titer.
- Name of the person who determined the titer.
- Validity period of the titer (must be defined in an SOP of the OMCL).

The information concerning the titer could also be registered in a separate document which is kept close to the equipment. In that case an identification number or code has to be given on the label which ensures the traceability to the information in this document.