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MANAGEMENT OF REAGENTS

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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 Reagents

Note: Mandatory requirements in this guideline 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.

INTRODUCTION

The aim of this Guideline is to describe the management of reagents at OMCLs.

For practical reasons, in this Guideline reagents are divided into five categories:

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

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

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

1. Types of reagent and the quality, depending on their use;
2. Selection of the supplier based on the suppliers' qualification;
3. Verification of reagents upon receipt;
4. Labelling of the reagent (avoiding misuse/misidentification);
5. Storage conditions;
6. Ensuring that the reagent is not compromised in any way before being used;
7. Checking the expiry dates of reagents before use (it is not necessary to document this verification);
8. Documenting the use of reagents used in analyses ensuring traceability at least to batch number and expiry date;
9. Disposal of the reagent.

More detailed information on the supplier selection, verification, labelling, storage, expiration and disposal are given in the Table below.

Activity	**Purchased reagents in their original container**	**Purchased reagents which have been transferred into another container**	**In-house reagents**	**Water manufactured by the OMCL**	**Volumetric solutions**
External provider selection	Suitable external providers should be used where possible and documented in the OMCL's quality management system.		N/A		
Verification on 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 on the label or certificate against the requested quality). Specific in-house testing may be required for some reagents. The level of verification should be decided by the laboratory.		N/A		
Labelling – general	*The labelling information (general and specific) is recorded on the container, or may be recorded in a leaflet, register, LIMS system (or equivalent)* **Name** of the substance/reagent. **Date** received/prepared. **Expiry date.** **Storage conditions**, if applicable, any specific protection measures (e.g. protect from heat/light/atmosphere). **Concentration and/or purity of the reagent**, if applicable.				

Activity	**Purchased reagents in their original container**	**Purchased reagents which have been transferred into another container**	**In-house reagents**	**Water manufactured by the OMCL**	**Volumetric solutions**
Labelling – specific	• Manufacturer or supplier of the substance. • Batch number. • Date opened. • Identification: where the same batch is supplied in several containers, appropriate identification (e.g. vial 1, 2, 3) can be indicated on the labels.	• Name/Initials of the person who transferred the reagent. • Batch number. • Transfer date. • Identification: in cases of transfer to several vials (aliquoted), appropriate identification (e.g. vial 1, 2, 3) should be indicated on the labels.	• Name/Initials of the person who prepared the reagent. • Name and quantity of the reagents in the preparation (can be replaced by a reference, e.g. project number).	• Name/Initials of the person who dispensed the water. • If more than one production apparatus is available, the identity of the apparatus used must be documented.	• Name/Initials of the person who prepared the reagent. • Name and quantity of the reagents in the preparation (can be replaced by a reference, e.g. project number). • Titre. • Date of the determination of the titre. • Name/Initials of the person who determined the titre.
Expiry Date	The expiry period policy must be documented by the OMCL (e.g. SOP). The expiry date (before opening) given by the manufacturer must be considered valid. In the following cases a suitable expiry date shall be determined by the OMCL and a justification for assigning the new expiry date shall be documented: a) no expiry data is provided by supplier; b) when after opening/transfer environmental conditions (e.g. air, humidity) or further operations (e.g. dissolving a lyophilised material) affect the quality of the reagent. The expiry date can be prolonged by providing scientifically sound and documented justifications, e.g. in cases where expired reagents can be used for a special purpose. In this case the container must be re-labelled appropriately.				
Storage	The storage conditions depend on the quality and intended use of the substance/reagent and should be based on the manufacturer's recommendations and known physico-chemical stability. Storage areas must be appropriate (e.g. temperature, ventilation, fire hazard) and maintained (e.g. organised, tidy, segregated).				
Disposal	Reagents are disposed of when the expiry date is exceeded, or when they are no longer required. Disposal may be done at defined intervals or when the expiry date is checked prior to potential use, as applicable. Reagents must be disposed of appropriately, safely and in compliance with legal requirements.				