| [COMPANY X]<br>STANDARD OPERATING PROCEDURE | PROCEDURE NUMBER:<br>SOP-AAC-003 | |
|---|---|---|
| DEPARTMENT: QUALITY CONTROL | EFFECTIVE DATE: | |
| SOP TITLE: REAGENTS AND TEST SOLUTIONS RECEIVING AND MAINTENANCE | SUPERSEDES:<br>SOP-AAC-002 | PAGE: 1 OF 4 |

## I. OBJECTIVE

1.0 The purpose of this Procedure is to describe the receiving, maintenance, inventory control, and review of reagents and test solutions in the Quality Control (QC) Laboratory.

## II. SCOPE

1.0 This SOP is applicable to all reagents and test solutions in the Quality Control Laboratory at [COMPANY X]

## III. REFERENCES

1.0 SOP 60-027 – Procedure for Handling Laboratory Hazardous Waste and Expired Material

## IV. DEFINITONS

1.0 Reagents and Solutions: Chemicals which are used for compendial or manufacturer's test methods.
- 1.1 Reagents are either ACS Reagent grade or may be a commercially available suitable grade such as HPLC grade as specified by their Certificate of Analysis (CoA).
- 1.2 Test Solutions (TS): A reagent solution of a specified concentration used in a test or assay. These are generally used for qualitative purposes or as reagents in a chemical reaction where extreme precision of the concentration is not the primary factor.
- 1.3 Volumetric Solutions (VS): A solution of an accurately known concentration used for quantitative analysis. These solutions must be standardized against a primary standard or a previously standardized volumetric solution. The exact molarity or normality must be recorded and used in all subsequent calculations.

2.0 Laboratory Notebook: An officially issued, bound, and paginated document used to record the raw data, weights, volumes, and calculations for the preparation of all in-house reagents and solutions.

## V. ATTACHMENTS

1.0 Attachment #1 – QC Reagent and Solution Inventory Log (Inventory Log)
- 1.1 Attachment #1.1 – QC Reagent and Solution Inventory Log – Active Inventory
- 1.2 Attachment #1.2 – QC Reagent and Solution Inventory Log – Archive
- 1.3 Attachment #1.3 – QC Reagent and Solution Inventory Log – Monthly Review

## VI. PROCEDURE

1.0 **Reagents**:
- 1.1 The reagents must be accompanied by a Safety Data Sheets (SDS).
- 1.2 The chemist or designee is to refer to the SDS for information on handling, toxicity, proper container, etc. of the material.
- 1.3 Upon receipt of the material, the chemist or designee shall write on the label the date it was received and the expiration date.
  - 1.3.1 Expiration Dates: The expiration date of a reagent shall be the date specified by the manufacturer on the original container or the accompanying Certificate

of Analysis (CoA). If no expiration date is provided by the manufacturer, a default expiration date of one (1) year from the date opened shall be applied, unless otherwise documented by stability data or internal quality requirements.

1.4 Inventory Maintenance: An inventory list containing the reagent name, CAS#, lot number, and expiration date shall be documented and maintained digitally within the QC Reagent and Solution Inventory Log (Attachment #1)

1.4.1 All active materials stored in the QC laboratory must be logged in the "Active Inventory" tab (Attachment #1.1) of the Inventory Log.

1.4.2 The QC Manager or designee shall periodically review the Active Inventory to ensure the digital record accurately reflects the physical stock and that automated status indicators are addressed.

1.4.3 Any materials identified as "Consumed" or "Expired" during periodic checks must be updated in Active Inventory at the time of discovery.

1.4.4 Once the list has been reviewed and updated, click the UPDATE button to update the Archive and Monthly Review lists.

1.5 Monthly Review (Physical Check): On a monthly basis, the QC Manager or designee shall perform a physical "shelf-to-sheet" review of all reagents and solutions.

1.5.1 To facilitate this review, the QC Manager or designee shall print a copy of the inventory using the Monthly Review tab (Attachment #1.3), which mirrors the data from the Active Inventory list.

1.5.2 Using the printed inventory list, physically confirm that every reagent on the shelf is listed on the inventory and that no materials have reached or exceeded their expiration date.

1.6 Documentation: Results of the monthly inventory review shall be finalized on the printed Monthly Review (Attachment #1.3).

1.6.1 A Quality Assurance designee shall review the finalized Monthly Review log to ensure all fields are complete, signed by Quality Control, and that any expired materials noted have been appropriately documented and removed from the shelf and the Active Inventory list.

1.6.2 The printed review serves as the official record of the monthly review and must be signed and dated. The "Reviewed By" section shall be completed by the Quality Control Manager or designee who performed the physical check. The "Verified By" section shall be signed and dated by the Quality Assurance designee to provide objective oversight and confirm completion.

1.6.3 If any additional expired items are identified during the physical inventory check, they must be updated in Active Inventory and moved via the "UPDATE" button as described in Section 1.4.4 to ensure the digital and physical records match.

1.6.4 Signed logs shall be maintained in the designated QC inventory binder for a period defined by corporate retention policies.

1.7 Non-Conformance: If an expired reagent is found on the shelf outside of a routine check, then it must be reported to the QC Manager immediately. It may be required to determine if any previous test results were impacted by the use of expired material.

1.8 Expired and Consumed Materials: Refer to SOP [SOP NUMBER] for information on proper handling and disposal of hazardous waste and expired materials.

**2.0 Test Solutions (TS) and Volumetric Solutions (VS)**

2.1 Preparation and Acquisition: Test solutions shall be prepared according to the specific instructions provided in the compendial test method or the manufacturer's approved test method. The Test Solution is to be kept in a suitable glass or plastic reagent bottle. An amber reagent bottle is recommended to protect the solution from light unless the test method calls for otherwise.

2.1.1 Test solutions may also be purchased prepared from an approved vendor.

2.2 Labeling Requirements: Each container must be clearly labeled immediately upon preparation or receipt with the following information:

2.2.1 Name and concentration of the solution.

2.2.2 Date prepared (or date received, if purchased prepared).

2.2.3 Expiration date (or "Discard By" date).

2.2.4 Initials of the preparer/analyst.

2.2.5 Reference to the laboratory notebook and page number.

2.3 Expiration and Stability: The expiration date of a Test Solution is primarily determined by the stability period specified in the governing test method.

2.3.1 In the absence of a specific stability period in the method, the expiration date shall be one (1) year from the date it was prepared, received, or opened.

2.3.2 Component Limitation: The expiration of a test solution cannot exceed the expiration date of any individual reagent or raw material used in its preparation.

2.3.3 Analysts must check the label for the expiration date before every use; if the solution is expired, it must be disposed of immediately and appropriately. Refer to Section 1.7 for materials found non-conformant.

2.4 Monthly Inventory and Disposal:

2.4.1 All Test Solutions and Volumetric Solutions shall be subject to the Monthly Review (Physical Check) as described in Section 1.5 of this SOP.

2.4.2 Documentation of these checks and any subsequent disposal must be recorded on the Monthly Review and signed by both Quality Control and Quality Assurance as per Section 1.6 of this SOP.

## VII. RESPONSIBILITIES

1.0 It is the responsibility of the Quality Control Laboratory to properly execute this SOP.

2.0 It is the responsibility of the Quality Assurance Department to verify the monthly reviews and provide objective oversight.

## VIII. IMPLEMENTATION

1.0 This SOP shall be implemented on or before the effective date appearing on this document.

## IX. REASONS FOR REVISION

**(11/04)**

1.0 Corrected sign-off area in footer.

**(11/07)**

2.0 No changes.

**(03/16)**

3.0 Updated SOP to include SOP "Usage, Handling and Inventory of Alcohol".

4.0 Added HPLC grade to Section III, 1.2.

5.0 Added to Section IV, 1.3 "unless specified by an accompanying Certificate of Analysis or label claim."

6.0 Added to Section IV, 2.1 that test solutions may be purchased prepared.

**(08/23)**

7.0 Revised format. No content changes.

**(03/26)**

8.0 Updated Attachment #1 and made into a digital Inventory Log.

9.0 Added Attachments #1.1, 1.2, and 1.3 for each sheet of the Inventory Log.

10.0 Changed "4 Years" to "1 Year" in section 1.3.1 of VI. Procedure.

11.0 Removed "Material" in the updated title of "Safety Data Sheets" in Section 1.1 of Procedure and changed MSDS to SDS in sections 1.1 and 1.2.

12.0 Changed the expiration date to include "date opened" in sections 1.3.1 and 2.3.1 of section VI. Procedure.

13.0 Added Reference 1.0 – Procedure for Handling Laboratory Hazardous Waste and Expired Material

14.0 Changed "Verified By" section to be completed by Quality Assurance to provide objective verification.

15.0 Added section 1.6.1 to outline Quality Assurance role in the documentation and verification of the Monthly Review

16.0 Added 2.0 to Responsibilities to include Quality Assurance