

Title: Control of Purchased Standards, Chemicals, and Reagents

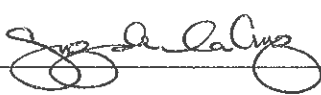
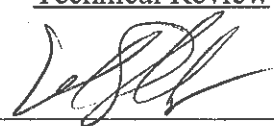
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- References: SOP 2100: Solutions, Standards, and Reagents Preparation and Documentation
SOP 270: Non-Conformance Reports and CAPA Management
SOP 110: Organization and Facilities
SOP 170: Sample and Waste Disposal
SOP 210: Controlled Sunstances

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	08-07-03	Original SOP
2.	08-18-09	Revised to comply with current version of SOP 101. System re-engineered to include QA oversight of reagent controls. Sec. 4.0: Moved from SOP 2100.
3.	SEP 14 2011	Minor rewording throughout. Sec. 3.3.4, 4.7, 4.8: added. Sec. 3.3: Clarified.

Uncontrolled when Printed

<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	08/26/11		8/27/11

QA Approval/Date:  09/14/11

1.0 SCOPE AND APPLICATION

This SOP describes the system for the control of purchased chemicals in the laboratory, including reagents and reference standards.

2.0 SUMMARY

- 2.1 An inventory of chemicals, standards, and reagents purchased from outside suppliers is maintained using a FoxPro database module called "Chem Track" in Job Tracking.
- 2.2 Incoming materials are quarantined until released for use by the Quality Assurance Unit (QAU). Original containers are labeled with date of receipt, initials of person receiving the material, and the assigned expiration date.
- 2.3 Chemicals, reagents, and standards are entered into the database when released for use by the QAU. Mechanisms are in place to facilitate deletion of consumed standards and to notify department managers of reagents approaching expiry.
- 2.4 Certain high-turnover chemicals, such as common solvents, concentrated acids, and single use organic stocks are not entered into the inventory individually. Each new lot is entered into the database.

3.0 RECEIPT OF MATERIALS

- 3.1 Incoming materials are quarantined in the Log-in area or in the back of the sample storage area until released by the QAU or their designee. Employees are not to remove quarantined materials until they have been labeled and released for use by QA.
- 3.2 Open the shipping box and observe the condition of the original container. If the integrity of the container has been breached or a material has been received outside the recommended tolerances for environmental controls, contain any spills in accordance with the Safety Manual and notify Purchasing and the employee/group that ordered the item. Do not release for use.
- 3.3 If a Certificate of Analysis (CofA) is included, review it for compliance with stated specifications, stamp it with the CofA stamp and record the date received, storage location, CAS number, expiration date (if noted on CofA), distributor, manufacturer, PO#, labeled weight and number of containers, and price. This information will be entered into the ChemTrack database.

- 3.3.1 The manufacturer should indicate the appropriate storage condition for the material on the label. The appropriate department manager or Technical Director should be consulted, if needed, to determine the storage location. If the storage condition is sub-ambient temperature, apply a blue 2-8°C or -10 to -25°C sticker.
- 3.3.2 If no CofA is received with the material, copy the packing list, stamp it with the CofA stamp, and record the appropriate information. Also record the lot number of the material, if not stated on the packing list.
- 3.3.3 The CofA should be obtained from the manufacturer, reviewed, and initialed/dated by QA, before the reagent is released for use. Pharmacopeial standards may not have a CofA.
- 3.3.4 If chemicals, reagents, or standards are expired or will expire within the next two months, notify the Purchasing department to arrange to have the item returned. Notify the person/group requesting the item.
- 3.3.5 If the CofA can not be obtained in a timely manner from the manufacturer, the analyst must qualify the reagent as appropriate for use in a scientifically sound manner (e.g. against an NIST traceable or other primary standard) and record this information in the data package. If the reagent fails the qualification, the analyst must return the reagent to the quarantine area and notify QA. QA will initiate a Non-Conformance Report per SOP 270.
- 3.4 The information recorded in the fields of the CofA stamp is used to enter information into ChemTrack.
- 3.4.1 At a minimum, all of the fields shaded in blue on the ChemTrack "Add" screen must be completed. These include: Chemical Name, Date Received, Expiration Date, Storage Location, Manufacturer, Grade, and Lot Number (see Fig. 1).
- 3.4.2 When entering compound names, enter the name exactly as it appears on the label. Do not use abbreviations or synonyms. If necessary, abbreviations or synonyms can be entered in the Notes field. If the compound name is too long to properly display, enter the complete name in the Notes field.

- 3.4.3 Designate the material location as follows:
- 3.4.3.1 Materials stored in refrigerators or freezers will use R or F, followed by the appropriate number, e.g. R-21 or F-6. GMP materials are stored in refrigerators designated RP-X, freezers designated FP-X, or the ultra-low freezer designated UFP-X.
 - 3.4.3.2 For materials stored in a cabinet within a room, use the room number. If stored in a flammable cabinet, hood or desiccator, use the room number followed by "Flam" "Hood" or "Des," e.g. 149 Flam. Refer to SOP 110 for the Laboratory Floor Plan.
 - 3.4.3.3 For controlled substances, use the location "RegSub." These are stored in the QA Office. Refer to SOP 210 for additional procedures for controlled substances.
- 3.4.4 A given entry may only have one storage location. If multiple containers are received for storage in multiple locations, multiple entries in ChemTrack are required.
- 3.4.5 CAS number should be entered without the use of descriptors (such as "CAS # xxx-xx-x"). Enter only the number, with dashes. If multiple CAS #'s apply, enter "various".
- 3.5 The MSDS and Certificate of Analysis are scanned into the database by opening the database entry for the associated reagent, loading the documents into the scanner, and clicking on the "Scan MSDS" button. Scan the MSDS first, the CofA second.
- 3.6 US Pharmacopeia standards are not labeled with expiration dates. They are given a five-year expiration date upon receipt, since the ChemTrack system does not allow this field to be blank. The quarterly Reference Standard catalog lists current lots for all materials, and periodically will give dates when previous lots become "no longer official." These catalogs will be reviewed by QA upon receipt to determine if any lots currently in-house have been given such dates. If so, the expiration field in ChemTrack will be updated, and the expiration date on the label updated. It is the responsibility of the analyst to verify, per SOP 2100, that the reference standard is current before use.
- 3.7 Client supplied standards are handled in the same manner as above, if they are to be retained for further use after a particular job is completed. The client or the manufacturer of the standard will be contacted for an MSDS, Certificate of Analysis, and stability information (expiration dating).

ChemTrack Form -- Edit 2,4-Disulfamyl-5-trifluoromethylaniline

List

Chemical Name: 2,4-Disulfamyl-5-trifluoromethylaniline

CAS No.: 654-62-6

Date Rec.: 01/19/1998

Date Exp.: 10/31/2009

Location: 153

Details

Manufacturer: USP

Grade: USP

Lot #: G

Catalog: 22300

Amount: []

Quantity: []

Price: []

Consumed?

Scan MSDS View MSDS

Notes

- No USP exp date given as of 10-29-03 MS
- No USP exp date given as of 08-10-04 MS
- No USP exp date given as of 03-31-05 MS
- No USP exp date given as of 1-09-05 TD
- No USP exp date given as of 06-05-06 TD
- No USP exp date given as of 09-12-07 MS
- No USP exp date given as of 07-16-08 LMS
- Exp date added 03/23/09 LMS

List Add Delete First Prev Next Last Save Cancel Close

Fig. 1: ChemTrack screen shot

4.0 EXPIRATION DATING

- 4.1 Purchased chemicals, reagents, and standards must be labeled with expiration dates, except for pharmacopeial standards as described above. If the manufacturer provides an expiration or retest date, this will be used as the expiration date. If the expiration date is one year or more from the date of receipt, the month and date may be used as the format, with expiration occurring on the last day of that month.
- 4.2 In the absence of a manufacturer's expiration or retest date, review the expiry history for the material. Assign the expiration date based on previous history. In the absence of this information, the expiration date for dry, stable inorganic chemicals, stable organics, solvents, and aqueous acids shall be 5 years from the date of receipt. Standards in solution and other aqueous solutions shall be given an expiration date 1 year from date of receipt.
- 4.3 If a reagent or solution, such as a buffer, is expected to degrade after opening, it will be labeled with the date opened and an adjusted expiration date given based on the date opened. Hygroscopic salts expire three months after opening.
- 4.4 After the expiration date, the reagent may be requalified according to USP, ACS, or other specifications. If appropriate, the expiration date may be extended for an additional year.
- 4.5 Purchased chemicals and reagents must be inspected prior to each use by the analyst. If the chemical or reagent appears discolored, forms hard lumps, or shows signs of decomposition, it must be discarded.
- 4.6 Reagents labeled "Protect from light" should be stored in amber bottles or otherwise protected from light exposure when not in use.
- 4.7 If a chemical or reagent is transferred to a container other than the one supplied by the manufacturer, it must be marked with identity, lot number, expiration date, and storage conditions.
- 4.8 If a chemical is found without a label, give the container to QA for relabeling. If a reagent is found without a label, notify the Technical Director or Group Leader who will determine appropriate disposal. If a label is found unattached to a container, notify QA and audit the containers in the immediate area to identify the unlabeled container.

5.0 ONGOING TRACKING

- 5.1 Monthly, QA will generate a list of chemicals which are expiring in the next month. This list will be distributed to each department manager, who must determine a disposition for each chemical.
- 5.1.1 The disposition may be disposal, re-qualification (with extension of the expiration date), or retention for research and development (R&D) use only.
 - 5.1.2 If an article is retained for R&D use, the container must be clearly marked, and the reagent segregated from in-dated reagents on a marked shelf or area. Red stickers labeled "R&D Use Only" are available from QA for this purpose.
 - 5.1.3 Disposal of expired reagents is the responsibility of the group. Periodically, QA will perform an internal audit for compliance.
 - 5.1.4 The lot number and expiration date of reagents is recorded in the raw data associated with the analysis, ensuring that only in-dated reagents are used.
 - 5.1.5 A "First-In/First-Out" system, common in manufacturing facilities, is not implemented in this laboratory. Any in-dated reagent that has been released by QA is considered acceptable for use.
- 5.2 Annually, QA or their designee(s) will perform a chemical inventory by generating a list of reagents by location from the ChemTrack database and auditing it against the reagents present in that location.

6.0 DISPOSITION

- 6.1 When a container is disposed of, either through complete consumption, rejection of the material, or expiration, it will be entered onto a Chemical Depletion Logsheet. These sheets are available in each storage area. An example is given in the Appendix.
- 6.2 These items will be periodically deleted from ChemTrack. The notation "Deleted" with the date and initials of the person deleting the entry will be added to the Comments section of the database entry. The entry will be deleted from view but not from the actual database. The complete database is archived on the server.
- 6.3 Whenever an item is consumed, whether completely or so that the amount left is not enough for the material's typical use, it is the responsibility of the last analyst to use the material to dispose of the container and its contents properly, in accordance with SOP 170. This is to avoid the presence of multiple, empty (or nearly empty) containers in storage.

