Template Provided By:

Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-Q003

Receiving, Handling, Quarantine, and Release of Reagents & Supplies

1. **Purpose:** To describe the procedures for purchasing, receiving, handling, and releasing the reagents and supplies to be utilized for the manufacture of radiopharmceuticals.

2. **Scope:** To outline the procedures for procurement, handling, and release of the reagents and supplies to be utilized at sites manufacturing radiopharmaceuticals.

3. **Responsibilities:**
   3.1. *Manufacturing Sites*: To follow this procedure as written and to ensure that reagents and/or supplies are ordered from the specified suppliers/vendors listed on the corresponding specification sheets.

4. **References**
   4.1 USP 28 ‹821› Radioactivity
   4.2 USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding
   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)
   4.4 **GEN-M001**, "Writing & Revising Reagent & Supply Forms"
   4.5 **GEN-M120**, "Documentation of Manufacturing Variances"

5. **Forms**
   - **Form SS-GEN**, "General Reagent/Supply Specification Sheet"
   - **Form RSR**, "Requisition, Shipping and Receiving Log Form"
   - **Form SR-ACN-L**, **"**Acetonitrile Shipping Receipt & Verification" Form (example)
   - Certificates of Analysis (C of A's) from each of the Suppliers for all non-USP reagents

Cancer Imaging Program, *Confidential--Use and restriction of this document is set forth in Transfer Agreement executed with the National Cancer Institute (NCI).*

- Material Safety Data Sheets for any Chemicals (MSDS)
- **Form MVR-001**, "Manufacturing Variance Report Form"
- **Form SR-GEN-L**, "Reagent/Supply Shipping Receipt & Verification" Form
- **Form SS-ACN**, "Acetonitrile Specification Sheet" (example)

6. Policies

N/A

7. Materials and Equipment

- Quarantine Labels
- Return/Disposal Labels
- Released Labels
- Blank Labels

8. PROCEDURES

8.1 Purchasing and Receiving a New Reagent and/or Supply

8.1.1 Refer to the corresponding specification sheet (SS-XXX) for the reagent and/or supply to be ordered to determine the approved vendors and reagent/supply specifications required.

For Example: **Acetonitrile Anhydrous, 99.5%**
Specification Sheet: SS-ACN
Vendors: Sigma-Aldrich Cat. # 27,100-4
Mallinckrodt-Baker, Inc. Cat. # 9035-10

8.1.2 Place the order with the vendor of choice and record the order on **Form RSR**, "Requisition, Shipping and Receiving Log Form" as shown below and the internal shipping order. The example illustrated below is an order for acetonitrile (Form SS-ACN).

Form RSR

Internal Tracking Number	Requisition Date	Order Number	Manufacturer's Lot Number	Date Received	Shipment Number
SS-ACN-X0001	7-17-04	2013478			

8.1.3 Continue this procedure for each reagent and/or supply placed under the same order number. Request appropriate documentation from the vendor such as certificates of analysis, certificates of quality, MSDS, etc. as appropriate. Refer to the reagent/supply specification sheets for guidance on these requirements.

8.1.4 When the shipment arrives, reconcile the reagents and supplies against **Form RSR**.

8.1.5 Log the receipt of each individual reagent/supply on **Form RSR**, "Requisition, Shipping and Receiving Log Form" as shown below. Enter the Manufacturer's Lot Number, Date Received, and the shipment number for each item received.

Cancer Imaging Program, *Confidential--Use and restriction of this document is set forth in Transfer Agreement executed with the National Cancer Institute (NCI).*

Form RSR

Internal Tracking Number	Requisition Date	Order Number	Manufacturer's Lot Number	Date Received	Shipment Number
SS-ACN-X0001	7-17-04	2013478	**890898678**	**7-24-04**	**54426**

8.1.6 Complete **Form SR-GEN-L,** (for example, **Form SR-ACN-L**, for acetonitrile), "Reagent/Supply Shipping Receipt & Verification," Form as follows:

8.1.6.1 Enter the expiration date of the reagent. If a supply does not have an expiration date, simply enter "N/A" for not applicable.

8.1.6.2 Assign the reagent/supply the next unique sequential internal tracking number complete with the preceding location identifier **(L)** as shown below in the table, and record this number on **Form SR-GEN-L,** (for example, **Form SR-ACN-L** for acetonitrile)**.**

Example of Numbering for Acetonitrile:

Manufacturing Site	Location Identifier (L)	Internal Tracking Number
University X	**X**	SS-ACN-**X0001**
Company Y	**Y**	SS-ACN-**Y0001**

8.1.6.3 Record the manufacturer's assigned lot number from obtained the reagent/supply package or container.

8.1.6.4 For non-USP reagents, a certificate of analysis should be requested with the shipment as per the specification sheet, **Form SS-GEN**, "General Reagent/Supply Specification Sheet," (for example, **Form SS-ACN**, "Acetonitrile Specification Sheet."**)** The manufacturer should send the C of A with the shipment. Or the certificate of analysis may be obtained from the manufacturer prior to removing the reagent/supply from quarantine. For USP reagents or general supplies, C of A's are not required. Simply circle the N/A, for not applicable, when no further testing of the reagent/supply is required.

8.1.6.5 In the section entitled, "Inspection of Shipment," enter the values for the table. Record the following: Date of arrival, indicate whether or not the outer shipping package of the reagent/supply was intact or if it was damaged in any manner prior to arrival.

NOTE: If the package is leaking, do not open the package. Initiate the appropriate safety protocol for your site, according to the reagents/supplies contained within the package and secure the area.

Cancer Imaging Program, *Confidential--Use and restriction of this document is set forth in Transfer Agreement executed with the National Cancer Institute (NCI).*

8.1.6.6 Open the outer shipping package and visually inspect the contents of the shipment. Record on the appropriate **SR-GEN-L Form**, the condition of the reagent/supply package or container itself.

8.1.6.7 If the reagent/supply passed both visual inspections, note that it was acceptable and place a quarantine label on it. If the reagent/supply was not acceptable note this as well stating the reason why and place a return/disposal label on the package and/or bottle. Prepare the reagent for return to the manufacturer or disposal per agreement with the manufacturer.

8.1.6.8 Sign and date that the reagent/supply has been inspected.

8.1.6.9 Generate an internal label to place on the item for internal tracking purposes. Be careful not to cover the manufacturer's labels. The label should contain the following information:

Internal Tracking Number (ITN)
Date Received

8.1.6.10 If applicable, verify the certificate of analysis or certificate of quality against the internal specifications to determine if this lot of reagent/supplies can be released for use in product manufacturing. If it passes all of the verification checks then place a released sticker over the quarantine sticker to show its "released" status. Note whether the manufacturer's C of A is attached or if it is not attached, note where the C of A is stored. Sign and date for verification.

8.1.6.11 If the supply or reagent does not pass the verification checks, then place a return/disposal label over the quarantine label, and initiate a "Manufacturing Variance Report Form," **Form MVR-001**. Return this item to the appropriate vendor or dispose of the item as agreed with the manufacturer. Attach the variance report to **Form SR-GEN-L**. Do not sign the verified by or released by if it fails to meet the specifications.

Cancer Imaging Program, *Confidential--Use and restriction of this document is set forth in Transfer Agreement executed with the National Cancer Institute (NCI).*