Template Provided By:

Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-M001

Writing & Revising Reagent & Supply Forms

1. **Purpose:** To outline the policies and procedures for generating a new specification sheet/form, or revising a current one for a reagent or supply.

2. **Scope:** The specification sheets or forms will be used to specify the exact characteristics and parameters necessary for a reagent or supply to meet for utilization at the *site of manufacture* radiopharmaceutical.

3. **Responsibilities:**
   3.1 *Manufacturing Site*: To follow this procedure as written and to ensure that all test results recorded on the certificates of analysis comply with the written specifications as outlined on the 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   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)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-Q003**, "Receiving, Handling, Quarantine, and Release of Reagent & Supplies"
   4.5 **GEN-Q015**, "Investigating Out of Specification QC Test Results"

5. **Forms**
   - **Form SS-GEN**, "General Reagent/Supply Specification Sheet"
   - **Form SR-GEN-001**, "General Shipping Receipt & Verification Form"

SOP**: GEN-M001** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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6. Policies

6.1 New Specification Sheets should not be generated without the authorization of the *Sponsor* as this may affect all sites.

6.2 Revisions of the existing specifications sheets should not be initiated without the authorization of the *Sponsor* as this will affect all sites and possibly cause conflict with the information as it is recorded in the *Sponsor's* IND.

6.3 Use Certificate of Analysis for reagents and Certificate of Quality for Supplies (e.g. filters, columns, etc.).

7. Materials and Equipment

7.1 Representative Certificates of Analysis (C of A's) from each of the Suppliers

7.2 Material Safety Data Sheets for any Chemicals (MSDS)

7.3 Representative Certificates of Quality (C of Q's) from each of the Suppliers

8. PROCEDURES

8.1 Writing a New Specification Sheet

8.1.1 In the **Reagent/Supply** blank, fill in the name of the reagent or supply that will be referenced **(SS-GEN)**.

8.1.2 If the reagent or supply have particular storage requirements that must be maintained, enter those in the **Storage Conditions** blank, otherwise enter **N/A**.

8.1.3 **Internal Tracking Code (ITC)**, this is a unique combination of letters and or numbers assigned to each supply and/or reagent. The Internal Tracking Code always begins with **SS-,** followed by the next three characters that are assigned by the *Sponsor* and based on the reagent and/or supply.

8.1.4 Determine whether an **MSDS is on File.** Circle "**N/A"** when the item is a supply. When this item is a reagent, circle "**Y"** after verifying that an MSDS is on file, either in hard copy. Circle "**N"** when the MSDS is not on file and obtain the MSDS from the manufacturer.

8.1.5 **Suppliers & Ordering Information:** Select at least one, and preferably two to three vendors that meet the specification criteria, and who will work well within the specifications of the manufacturing process. The appropriate information will be captured for each vendor and verified.

8.1.6 **Parameter, Test Methodology, Specification:** For supplies only parameter and specification are required, although not all supplies need these requirements. For non-USP reagents, complete the entire section using the specific specification criteria established for this reagent within the manufacturing process. These are the values required for a certificate of analysis, values such as, purity, the testing required, and the

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range of acceptable testing specification ranges required to meet. This section is not required for the USP reagents.

8.1.7 This specific Form is assigned the same combination of letters and numbers as the Internal Tracking Code (ITC).

8.1.8 The name of this specific Form becomes the name of the reagent or supply plus "**specification sheet**."

8.1.9 This newly created form is then reviewed for completeness and accuracy.

8.1.10 Once the new form is determined to be complete, and the release specifications for the reagent/supply are determined to be satisfactory, it is submitted to the *Sponsor* for approval.

8.1.11 The Form is approved with an effective date assigned by the sponsor.

8.2 Writing a New Shipping Receipt & Verification Form

8.2.1 In the **Reagent/Supply** blank, fill in the name of the reagent or supply that will be referenced **(SR-GEN-001)**.

8.2.2 **Assigned Internal Tracking Number (ITN)**, this is a unique combination of letters and or numbers assigned to each supply and/or reagent. The Internal Tracking Number always begins with **SS-,** followed by: (1) three assigned characters on the specification sheet (**ITC**), (2) a location code, d (3) the next sequential number beginning with "**0001**." The ITN is a unique number for each lot of reagent or supply received, however, for generating forms the next sequential number is left blank.

8.2.3 **Parameter, Test Methodology, Specification:** For this section, the information is transferred from the specification sheet onto this form. If there are no parameters or tests to check then this section is deleted from this form.

8.2.4 The Form is assigned the same combination of letters and numbers as the Internal Tracking Code (**ITC**), except that the prefix is "**SR-**," instead of "**SS**,".

8.2.5 The name of this specific Form becomes the name of the reagent or supply plus "**Shipping Receipt & Verification Form**."

8.2.6 The newly created form is then reviewed for completeness and accuracy.

8.2.7 Once the new form is determined to be complete is consistent with the specification sheet, and determined to be satisfactory, it is submitted for approval.

8.2.8 The Form is approved with an effective date assigned by the sponsor.

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8.3 Revising a Current Specification Sheet or Shipping Receipt & Verification Form

8.3.1 Revisions to a current specification sheet or shipping receipt & verification form must first be requested through the *Sponsor*.

8.3.2 The revision may require a teleconference with members of the *Sponsor's* team in attendance to ensure that the revision will not significantly impact the other manufacturing sites.

8.3.3 Other manufacturing sites may be invited to attend the teleconference as appropriate.

8.3.4 If the revision is accepted, the change will be made and the revision will be effective as off the date assigned by the sponsor.

8.3.5 The *Sponsor's* will update the Form and notify all appropriate personnel of the change. A copy of the updated Form will be distributed to all of the manufacturing sites.

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