Template Provided By:

Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-R008

Good Documentation Practices

1. **Purpose:** Good documentation practices are an essential aspect of the quality control system in manufacturing radiopharmaceuticals. These processes ensure the presence of a clear audit trail permitting the investigation of any batch of product as necessary.

2. **Scope:** Good documentation practices will be utilized at the sites manufacturing radiopharmaceuticals.

3. **Responsibilities:**
   3.1 Manufacturing Sites: To follow this procedure as written and to ensure that all results, control information, and raw data are documented as specified in dedicated Quality Control Laboratory Notebooks and recorded on the appropriate testing forms.

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   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)

5. **Forms**
   5.1 **Form R008**, "Authorized Project Personnel Form"

SOP**: GEN-R008** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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6. Policies

6.1 Manufacturing Sites: It is the responsibility of each manufacturing site to maintain an up-to-date "Authorized Project Personnel Form," **Form R008**, complete with the signatures and initials of all authorized personnel working on the project.

6.2 Documents should be approved, signed, and dated by appropriate authorized personnel.

6.3 It is the responsibility of each *manufacturing site* to update all manuals with the latest copies of the current SOPs, MPRs, MBRs, Forms, etc., once they have been notified of the change. The new changes become effective as of the effective date on page 1.

6.4 Absolutely **no white-out may be used**. It is not an acceptable practice, under any circumstances, to use white-out when following good documentation practices.

6.5 Do not leave blank spaces, especially within a form or batch production record.

7. Materials and Equipment

- Black or Blue Ballpoint Pen

8. PROCEDURES

8.1 Where documents require the entry of data, write clearly, legibly, and choose either blue or black ink. Using pencils, and/or colored pens, other than those with blue or black ink, are not acceptable.

8.2 Update records at the time the work is actually performed.

8.3 Where an entry error occurs, draw a single line through the entry maintaining visibility of the original entry. Write in the correct value either, above or to the side of, the original entry. Initial and date the corrected entry, recording the reason for the correction. The correction may also be captured on a variance report form as necessary.

8.4 Either write in "N/A" (for not applicable) or draw a line through all unused blank spaces. Initial and date to indicate that the space was not needed and/or the value was not necessary.

8.5 In records requiring two signatures, (i.e., "performed by" and "checked by"), the same person may initial and date both in the event adequate personnel are not available to cover both of these functions. If the same person initials and dates the "checked by", he/she must perform a second independent check on the original work to ensure a valid check.

8.6 Record any data that is obtained immediately in the appropriate laboratory notebooks or forms.

NOTE: Data must be recorded in the appropriate QC laboratory notebook or Form as it is obtained. Any test data that is recorded on arbitrary pieces of paper and/or post-it notes are now the primary sources of documentation and cannot be discarded. They must be included in the laboratory notebook as well.

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8.7 Data may be recorded by electronic data-processing systems, photographic techniques, or other reliable means.

8.8 Only authorized personnel can access documentation handled by electronic data-processing methods. A record of changes and deletions will be maintained for each revision. Access will be restricted and the entry of critical data will be independently checked. Records will be protected by a back-up system.

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