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Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-R004

Assigning Batch & Compounding Record Numbers to Production Runs

1. **Purpose:** To outline the procedures for assigning new batch and compounding record numbers at each manufacturing site.

2. **Scope:** To describe the procedure for assigning new batch and compounding record numbers at the sites manufacturing radiopharmaceuticals.

3. **Responsibilities:**
   3.1. Manufacturing Sites: To follow this procedure as written and to ensure that each batch and/or compounding record number assigned is a unique number.

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   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)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 **MBR**, Master Batch Record
   5.2 **Form R004-L**, "General Log for Assigning Unique Batch or Compounding Record Numbers"

SOP**: GEN-R004** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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6. Policies

6.1 Use only one log for one type of record. Start a new log form when generating or beginning a different set of records. For example, when recording **MBR-[^{18}F]FMISO-X0001, MBR-[^{18}F]FMISO-X0002, MBR-[^{18}F]FMISO-X0003,** a single log should be utilized as these are all the same type of records. However a new log must be initiated when recording **HBS-X0001**.

6.2 Each batch record and compounding record must be assigned a unique identification code consisting of a prefix followed by a sequential number.

7. Materials and Equipment

7.1 Binders for the Log Forms

8. PROCEDURES

8.1 Assigning Batch Record Numbers to [^{18}F]FMISO Production Runs

8.1.1 Assign the batch record number as follows; first use the prefix, MBR-[NAME]**,** to designate the synthesis of a specific tracer. Second, append a dash, followed by a location identifier letter (to designate the specific site of manufacture). The location identifier is followed by a sequential number, starting with 0001.

8.1.2 Record the assigned batch record number on a new copy of the latest approved Master Batch Record and on **Form R004-L**, "General Log for Assigning Unique Batch or Compounding Record Numbers."

8.2 Assigning Compounding Record Numbers to Master Compounding Records

8.2.1 Assign the compounding record number as follows; first use the prefix to designate the solution or standard that will be compounded. For example if the HPLC Buffer Solution is being compounded, then use "HBS" as the prefix. Second, append a dash, followed by the location identifier (to designate the specific site of manufacture). The location identifier is followed by a sequential number, starting with 0001.

8.2.2 Record the assigned compounding record number on a new copy of the latest approved Master Compounding Record and on **Form R004-L**, "General Log for Assigning Unique Batch or Compounding Record Numbers."

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