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Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-R502

General Equipment Maintenance

1. **Purpose:** To outline the general procedures and policies for ensuring that the major production equipment at the sites manufacturing radiopharmaceuticals remain in good working order.

2. **Scope:** To describe the written procedures and policies necessary for maintaining the major pieces of equipment in good working order at the sites manufacturing radiopharmaceuticals.

3. **Responsibilities:**

   3.1. *Manufacturing Sites*: To follow this procedure as written and to assure that production equipment and quality control measurement equipment, including mechanical, electronic, automated, chemical, or other equipment, are:
   - Suitable for the intended use in the manufacture and testing of components and final product;
   - Capable of producing valid results;
   - Operated by trained employees; and
   - Properly calibrated versus a suitable standard.

4. **References**

   USP 28 ‹821› Radioactivity
   USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding
   FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)

SOP**: GEN-R502** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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Service & Operation Manuals for the Major Pieces of Equipment at each manufacturing site
Nucleophilic Synthesis Module Service Manual

5. Forms

Form EQ-001, "General Equipment History Log"

6. Policies

Each manufacturing site must establish written schedules to maintain, clean, calibrate, and adjust the major pieces of equipment used in the manufacturing and testing procedures of radiopharmaceuticals at pre-specified intervals and records maintained. Establish these written procedures based on the recommendations in the manufacturer's operation and service manuals.

The maintenance activities, including the date and individual performing the maintenance activity, should be documented in an equipment history logbook. For the investigational sites, the logbooks for the different pieces of equipment may be developed on site and requires each entry be signed. Alternatively, each site may use logbooks and record the equipment maintenance on **Form EQ-001**, "General Equipment History Log." Regardless of other logbooks in existence, equipment maintenance for all TRACERLab equipment that is used for sites manufacturing radiopharmaceutical production must be recorded in lab books on the **Form EQ-001**, "General Equipment History Log."

The purpose of Calibration of test equipment is to assure adequate and continuous performance of the equipment's measurements with respect to accuracy and precision.

Precautions to minimize contamination should be taken during all processing stages, including the stages before sterilization.

7. Materials and Equipment

N/A

8. PROCEDURES

HPLC Columns should be cleaned as per the manufacturing sites' written procedures and replaced as necessary.

GC Columns should be cleaned and maintained as outlined in the manufacturer's manual, manufacturing sites' validated procedures and replaced as necessary.

Biosafety cabinets and Laminar Flow Hoods should be cleaned at least daily and receive maintenance and calibration on an annual basis.

Dosimeters and ion chambers should be calibrated according to the Nuclear Regulatory Commission (NRC) and Agreement States regulations and guidelines.

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Nucleophilic Synthesis Module:

General Maintenance of the Module is outlined in the Nucleophilic Synthesis Module Service Manual and will be incorporated into the batch record as part of the routine procedures.

The yearly maintenance or planned maintenance (PM) that is performed by the manufacturer is outlined in the service manual as well. Refer to the Planned Maintenance Checklist located in the service manual. It recommends that a CLEAN run is performed prior to initiating a planned maintenance.

Refer to Adjustment and Calibration Procedures in the service manual for the following:

- Adjustment of:
  - Helium Pressure Regulator
  - Compressed Air Regulator
  - Reaction Vessel Pressure Sensor
  - Relative Pressure Sensors
  - Fine Metering Valves (needle valves
  - Reactor Needles: Needle Control Value, The Needle
- Manual Calibration of GM Counter
- Automatic Calibration of GM Counter

8.4.4 Disassembly/Reassembly of the synthesis module—Refer to the service manual to assist in maintaining the equipment.

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