Template

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Not Responsible for Investigator's Use

Standard Operating Procedure

) RLP -R009
General Equipment Maintenance for ^{89}Zr-Protein Production

1. **Purpose:** To outline the general procedures and policies for ensuring that the major production equipment at the site and the manufacturing sites remain in good working order and that any work on the equipment is clearly documented.

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 under [insert your institution name here] INDs.

3. **Responsibilities:**
   3.1. 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**
   4.1 USP 28 ‹821› Radioactivity
   4.2 USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding FDA Draft Guidance PET Drug

SOP**:) RLP -R009**	Supersedes**: none**	
Effective Date:	Version**: V1**	
Printed Name	**Signature**	**Date**
Author:		
Regulatory Approval:		

Procedure becomes effective on latest date of the two approval signatures above. Procedure applies to all IND drugs.

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Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)

4.3 Service & Operation Manuals for the Major Pieces of Equipment at each Site

5. Forms

5.1 **Form EQ-001**, "General Equipment History Log"

6. Policies

6.1 Each 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.

6.2 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 equipment that is used for [insert your institution name here] IND radiopharmaceutical production must be recorded in lab books on the **Form EQ-001**, "General Equipment History Log."

6.3 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.

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

7. Materials and Equipment

7.1 N/A

8. PROCEDURES

8.1 HPLC System Suitability Check

8.1.1. Columns should be cleaned as per the contracting sites written procedures and replaced as necessary.

8.1.2. Pumps, auto-injector, and system controller of HPLC system will be maintained following the user manuals.

8.1.3. Annual maintenance of this equipment will be performed by the vendor.

8.1.4. Standard protein solution will be injected (Form Q320) before each production to check the system suitability by checking the retention time and overall profile of the HPLC chromatogram.

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

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

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