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Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-Q108

Resterilization of Final Product in the Event of a Failed Filter Integrity Test

1. **Purpose:** To describe the procedure for resterilization of final product in the event of a failed filter integrity test.

2. **Scope:** This standard operating procedure explains the process for handling resterilization of final product in the event of a failed filter integrity test 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 the corresponding Master Production & Batch Records for a batch of final product.

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   4.3 FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—June 2002 (CDER)
   4.4 **GEN-M120**, "Documentation of Manufacturing Variances"
   4.5 **GEN-Q110**, "Filter Integrity Test by Bubble Point"

5. **Forms**
   5.1 **MVR-001**, Manufacturing Variance Report Form

SOP**: GEN-Q108** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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6. Policies

6.1 Always observe radiation safety rules.

6.2 Always observe aseptic technique when filtering final product for parenteral administration.

7. Materials and Equipment

7.1 Millex-OR Filter Unit; Millex-GS, 0.22 µm mixed cellulose esters, 25 mm 25 mm with luer outlet Ethylene oxide sterilized, Milli-fil GS, 0.22 µm, Sterile Filter Unit, Sterile [Millipore]; or Cellulose Acetate Membrane 0.22 µm (Costar or VWR), sterile and pyrogen free

7.2 Sterile Hood with Radiation Shielding for containers and syringe

7.3 Empty Sterile Vial with Gray Butyl Stopper

7.4 Final Product Label

7.5 Sterile Syringe with Needle and one extra sterile disposal needle (22G or less)

7.6 Venting Filter Needle

7.7 Alcohol Swab

8. PROCEDURES

8.1 Ensure that the surfaces of the hood are clean and ready for a sterile filtration.

8.2 Set up the empty sterile vial in the hood; also swabbing the vial septum in the hood. Use aseptic technique throughout the entire procedure.

8.3 First insert the venting filter needle in the vial septum. Next insert the extra needle with the sterilizing filter attached into the vial.

8.4 Using a sterile syringe with a needle, draw up the final product into the syringe.

8.5 Remove the needle from the syringe and attach the syringe to the filter.

8.6 Filter the final product into the vial.

8.7 Once the final product has been filtered, conduct an integrity test on the filter as per **GEN-Q110**, "Filter Integrity Test by Bubble Point."

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