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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:**

   *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**

   USP 28 ‹821› Radioactivity
   USP 28 ‹823› Radiopharmaceuticals For Positron Emission Tomography—Compounding
   FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—June 2002 (CDER)
   **GEN-M120**, "Documentation of Manufacturing Variances"
   **GEN-Q110**, "Filter Integrity Test by Bubble Point"

5. **Forms**

   **MVR-001**, Manufacturing Variance Report Form

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

| Printed Name | Signature | Date |
|---|---|---|
| **Author:** | | |
| **Regulatory Approval:** | | |

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## 6. Policies

Always observe radiation safety rules.
Always observe aseptic technique when filtering final product for parenteral administration.

## 7. Materials and Equipment

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
Sterile Hood with Radiation Shielding for containers and syringe
Empty Sterile Vial with Gray Butyl Stopper
Final Product Label
Sterile Syringe with Needle and one extra sterile disposal needle (22G or less)
Venting Filter Needle
Alcohol Swab

## 8. PROCEDURES

Ensure that the surfaces of the hood are clean and ready for a sterile filtration.
Set up the empty sterile vial in the hood; also swabbing the vial septum in the hood. Use aseptic technique throughout the entire procedure.
First insert the venting filter needle in the vial septum. Next insert the extra needle with the sterilizing filter attached into the vial.
Using a sterile syringe with a needle, draw up the final product into the syringe.
Remove the needle from the syringe and attach the syringe to the filter.
Filter the final product into the vial.
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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