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Cancer Imaging Program

National Cancer Institute

Standard Operating Procedure

GEN-R005

Drug Product Complaints

1. **Purpose:** To describe the procedure for handling a radiopharmaceutical drug product complaint.

2. **Scope:** This standard operating procedure explains the process for handling radiopharmaceutical drug product complaints 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   - **4.3** FDA Draft Guidance PET Drug Products—Current Good Manufacturing Practice (CGMP)—September 2005 (CDER)
   - **4.4** **GEN-Q015**, "Investigating Out of Specification QC Test Results"

5. **Forms**
   - **5.1** **Form DPC-L**, "Drug Product Complaint Log"
   - **5.2** **Form DCI-L**, "Drug Product Complaint Investigation Form"
   - **5.3** **Form IOS-001**, "Investigating Out of Specification (OOS) QC Test Results Form"

6. **Policies**
   - **6.1** A PET drug product that is returned because of a complaint may not be reprocessed and must be destroyed in accordance with applicable Federal and State Law.

SOP**: GEN-R005** Date:_____

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

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7. Materials and Equipment

N/A

8. PROCEDURES

8.1 Receipt of Radiopharmaceutical Drug Product Complaints

8.1.1 Upon receipt of a radiopharmaceutical drug product complaint, initiate a **DCI-L Form**, "Drug Product Complaint Investigation Form."

8.1.2 Record the following:

- Manufacturing Batch Number
- The name and Dose/Strength of the Product
- Name of the Complainant
- Date the Complaint was Received
- Nature of the Complaint

8.2 Assigning Drug Product Complaint Numbers

8.2.1 Assign the drug product complaint the next consecutive drug product complaint number in the **DPC-L Log**, "Drug Product Complaint Log,"

8.2.2 Record the assigned drug product complaint number, manufacturing batch number, date the complaint was received, and product name on the **DPC-L Log**.

8.2.3 Record the assigned drug product complaint number on the **DCI-L Form**, "Drug Product Complaint Investigation Form."

8.3 Investigation and Follow-up

8.3.1 Review the complaint and determine if an investigation is warranted. If an investigation is not necessary, proceed to **Step 8.3.5**, and document the reason why an investigation was not conducted. Otherwise continue to **Step 8.3.2**.

8.3.2 Investigate to determine if the drug product's failure can be attributed to out of specification results.

8.3.3 Once the investigation is complete, document the findings from the investigation on the "Drug Product Complaint Investigation Form," **DCI-L Form.**

8.3.4 Document an investigation that was inconclusive or failed to demonstrate that the drug product was out of specification.

8.3.5 Respond to the complainant and report the response on the **DCI-L Form**.

8.3.6 File the completed **DCI-L Form** and any supporting documentation in the dedicated product complaints files.

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