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**1.0 Purpose**

This SOP defines the procedure for dealing with rejected and expired material within the Biopharmaceutical Development Program (BDP), at NCI-Frederick, Frederick, MD.

**2.0 Scope**

This procedure is applicable to BDP personnel responsible for the monitoring, labeling and disposal of rejected and expired materials that may be found in either the MMIC warehouse or in the laboratory areas of the BDP.

**3.0 Authority and Responsibility**

3.1 Materials Management and Inventory Control (MMIC) is responsible for:

- 3.1.1 Monitoring expiration dates of materials in inventory.
- 3.1.2 Labeling materials in the Warehouse according to their designated status.
- 3.1.3 Segregating and securing rejected materials from all other materials.
- 3.1.4 Processing rejected materials in a timely manner.
- 3.1.5 MMIC prints the “Reject” labels, and/or provides them to production and Process Analytics (PA) upon request.

3.2 Production/PA is responsible for:

- 3.2.1 Labeling expired materials within their respective areas with an “Expired – Do Not Use” labels if they cannot be disposed of immediately.
- 3.2.2 Disposing of materials in accordance with the guidelines set in Material Specification.

3.2.3 Transferring expired materials to a segregated secured area for disposal, if disposal by an outside contractor is required.

3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for:

3.3.1 Reviewing and dispositioning of materials used in the manufacture and testing of product.

3.3.2 BQA is responsible for quality oversight of this procedure.

#### 4.0 Safety Precautions

Refer to the Safety Data Sheet (SDS) for precautions in handling and safety procedures for handling hazardous and non-hazardous waste. SDS are available through the NCI-Frederick Environment, Health and Safety (EHS) website: <http://home.ncifcrf.gov/ehs/ehs.asp?id=75>. Click on the individual collections to search for a specific MSDS.

#### 5.0 Procedure

5.1 Materials determined to be unacceptable upon initial receipt.

5.1.1 Shipment is refused and returned to vendor/supplier.

5.1.2 MMIC to notify BDP Business Operations Procurement Staff of return.

5.2 Materials determined to be unacceptable after visual inspection (carrier has left the premises).

5.2.1 MMIC segregates material by placing material into a "Rejected" Material storage location (if available) or will "Placard" material as "Rejected" using signs.

5.2.2 MMIC notifies BDP Business Operations Procurement Staff of the problem and requests return for credit/exchange.

5.2.3 If a credit/exchange is not allowed, MMIC disposes of the material in accordance with guidelines on Material Specification and/or SDS.

5.3 Materials determined not acceptable after Receipt and Quarantine.

5.3.1 PA forwards the document package for the material with a recommendation to BQA for disposition as "Reject".

5.3.2 The document package includes the:

- Material Specification sheet.
- Supplier's Certification documentation
- Test Records (if applicable).

**NOTE:** Test Records may not be included if the recommendation for reject is due to the Certificate of Analysis not meeting BDP specifications.

5.3.3 BQA reviews documentation and disposes the material as "Reject." MMIC is notified regarding the reject status of the material.

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- 5.3.4 MMIC segregates the material by placing the material into a "Rejected" Material Storage location (if available) or will "Placard" the material as "Rejected" using signs. MMIC labels material as "Rejected."
  - 5.3.5 MMIC notifies BDP Business Operations Procurement Staff and requests a return for credit/exchange. MMIC completes Section C of Form 21708-01.
  - 5.4 Expired Materials in All Areas
    - 5.4.1 Periodic review of inventory maintained in the warehouse, manufacturing area, and PA labs is to be performed to verify that housed materials are within expiration dating.
      - 5.4.1.1 Nightly, an email listing of all the items in MMIC which have reached their expiration date is automatically generated by the BDP SQL Server database server
    - 5.4.2 Materials that have expired are labeled as "Expired – Do Not Use" if they cannot be disposed of immediately or a line is drawn through the BDP applied label to indicate that they are now designated for R/D use. Expired materials not disposed of immediately are segregated until their disposition is determined.
    - 5.4.3 Expired materials may be extended per request by the BDP operation, ***SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.***
      - 5.4.3.1 Situations that may warrant extension of dating may include (but are not limited to):
        - 5.4.3.1.1 Revision of BDP specification after original receipt of material.
        - 5.4.3.1.2 Manufacturer's expiration date is longer than the expiration date indicated on the BDP Master Specification.
        - 5.4.3.1.3 Unopened chemicals that have not reached the manufacturer's expiration date.
    - 5.4.4 Any items that meet the above specifications may be submitted to PA for retesting (C and D items) or Release on COA (B items).
  - 5.5 Materials Rejected after Lot Investigation (previously released).
    - 5.5.1 BQA completes Section(s) A and B of Form 21708-01, Material Status Change Notification, and provides the appropriate departments with "Reject" labels.
    - 5.5.2 Department personnel label materials as "Reject," notifying BQA and complete section C of Form 21708-01.
    - 5.5.3 Department personnel will contact MMIC for transfer of the material to MMIC storage.
    - 5.5.4 The material is disposed of per EHS.



## 5.6 Disposal

5.6.1 Materials that can be disposed of by regular trash, per guidelines on the Material Specification or SDS, do not require issuance of "Reject" labels. This is annotated by the Requester in Section A of Form 21708-01. Disposal will be based upon local, State, and Federal Guidelines.

5.6.2 Hazardous materials will be picked up and discarded by EHS.

## 6.0 Documentation

6.1 Form 21708-01, Material Status Change Notification, is filed with the original raw material file for the specific lot number in BQA Documentation (BQAD).

## 7.0 Definitions

7.1 **Expired** – Any material or item remaining beyond the date which has been assigned as its shelf life.

7.2 **Rejected** – Any material or item that has been determined to be unacceptable for use (including expired materials).

## 8.0 References and Related Documents

8.1 **SOP 21902** *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*