SOP Title: Receipt and Inspection of Materials
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TABLE OF CONTENTS

1. PURPOSE

This Standard Operating Procedure (SOP) describes the steps required to receive and inspect all incoming materials to the Biopharmaceutical Development Program (BDP), either by Materials Management and Inventory Control (MMIC), or through BDP facilities management (in the case of receipt of bulk gases).

2. SCOPE

This procedure is applicable to BDP personnel who receive and inspect materials.

3. RESPONSIBILITIES

For all incoming materials that are managed within Computerized Materials Requirement Planning System (pcMRP) and which have valid part number requests and (where applicable) master specifications.

3.1 Materials Management and Inventory Control (MMIC), or designee

- Completes Section 1 of the Inspection and Receipt of Materials – Inventoried Materials, Form 20302-01 upon receipt of the materials.
- Records receipt of Inspection Level, A, B, C, D, E and F items in the Receiving Log (Form 20302-03).
- Notifies the BDP Purchasing Agent of damaged, incomplete, or incorrect orders.
- Prints and applies status labels (“Approved,” “Quarantine,” “Released,” “Rejected,” “For Research and Development Use Only,” etc.), as applicable.

- Quarantines of materials with Inspection Codes of B, C, D or F, which includes applying Quarantine Labels.
- Assigns unique BDP Lot Numbers.
- Removes/stores expired and rejected materials after disposition by Process Analytics/Quality Control (PA/QC) or Biopharmaceutical Quality Assurance (BQA).
- Transferring Approved and Released materials to appropriate areas.

3.2 For all incoming materials that are NOT managed within pcMRP, MMIC or Designee.

- Completes Inspection and Receipt of Materials – Non-Inventoried Materials, Form 20302-02 upon receipt of the materials.
- Stores the material at the appropriate temperature in a secure location.
- Arranges delivery or pick-up of the material with the intended recipient where applicable.
- Enters the material into the Freezerworks inventory software (SOP 20004 – Use of the Freezerworks Database) where applicable.

3.3 For all incoming bulk gases, BDP Facilities Management, or designee.

- Completes Inspection and Receipt of Bulk Gases, Form 20302-04 upon receipt of the materials.
- Obtains, compiles, and files all the pertinent certifications associated with the material and obtaining PA approval of those materials.

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

4. DEFINITIONS

- **Approve** – To designate a material as acceptable for use, without going through a quarantine and release process.
- **For Research and Development Only** – A status describing material that has been designated for R&D use only and has not been authorized for GMP use.
- **Inventory Materials** – Components/materials that have BDP Part Numbers and are maintained at a minimum level in the MMIC warehouse.
- **Quarantine** – To sequester material from distribution and use.
- **Receiving Report** – Printout generated by Building 1050 receiving personnel that documents initial receipt of materials.

- **Reject** – To designate a material as unacceptable for use.
- **Release** – To remove a Quarantine condition and subsequently designate a material as acceptable for use.
- **TBD** – Abbreviation for "To Be Determined." TBD is used by MMIC as the designation for the expiration date on raw material status labels until the actual expiration date has been determined. The expiration date is either determined by checking the shelf-life statement on the part number from the 'A' inspection level items or the master specification for B, C, and D inspection level items.

5. RECEIPT AND INSPECTION – INVENTORIED MATERIAL

5.1 NCI-Frederick ATRF Receiving personnel deliver materials to the designated receiving area within the BDP MMIC.

Shipments may be returned by MMIC staff if found to be damaged. Receiving personnel notify Acquisition and Logistical Services (ALS). BDP Purchasing personnel must also be notified immediately of any returns.

5.2 Temperature-sensitive materials are processed as a first priority or staged in the temperature-controlled quarantine area until processed.

5.3 The receiving document (receiving report or delivery ticket) delivered with the materials is verified to the actual materials received. MMIC personnel sign the receiving document after verification. A copy is returned to NCI-Frederick ATRF Receiving personnel, and a copy is retained by MMIC.

5.4 The original requisition form is then compared to the receiving document, and the Purchase Order is signed and dated at the bottom to indicate all items checked for the following.

5.4.1 Quantity.

5.4.2 Catalog number.

5.4.3 Description.

5.4.4 PR number/release number, or credit card number.

NOTE: If the original requisition form is not available, MMIC staff will notify BDP Purchasing to locate the form.

5.5 Each item received is checked off, initialed, and dated on the requisition form. A copy of the requisition form is maintained by MMIC with the yellow copy of the receiving document in a secured file.

NOTE: If a requisition form still has items open (i.e., not received), then the MMIC copy is kept in a Back-Order file until it is closed.

5.6 MMIC records receipt of item(s) in the Receiving Log, Form 20302-03

5.7 MMIC personnel complete an Inspection and Receipt of Materials - Inventoried Materials, Form 20302-01, for each item received.

5.7.1 Section 1 – Initial Receipt

Check off the appropriate response for each step.

NOTE: If "No" is checked off for any item, the MMIC Supervisor, or designee, must initial and date, indicating that it is okay to proceed.

5.7.2 Section 2 – Material Information

5.7.2.1 Record information off each package and verify against the Part Number Request Form.

5.7.2.2 Assign the BDP Lot Number.

- This is a unique, 10-digit alphanumeric string consisting of the letter R (for GMP) or D (for non-GMP), followed by month, date, year (two digits for each), and then three digits which are assigned consecutively. The last three digits start with 001 each day. This is the lot number MMIC assigns.

Example (for GMP material): R013120005
01 = January
31 = 31st Day
20 = Year 2020
005 = 5th item received/processed

- Record the request for additional documentation (if required).

5.7.3 If the order was for Research and Development, skip to Section 5 on the form.

5.7.4 Section 3 – Quarantine Information

5.7.4.1 If item is Inspection Level A or E, check box, initial/date and proceed to section 5 (5.7.6). Otherwise, complete and apply "Quarantine" labels for Inspection Level B, C, D or F materials. Labels shall be applied to the smallest deliverable size of material without compromising integrity of packaging. In addition, a label must be placed on the outermost packaging. A true and exact representative sample of the label must also be applied to the Form in Section 3.

5.7.4.2 Labels will have the following information.

- BDP Part Number.
- Item Description.
- BDP Lot Number.
- Manufacturer's Lot Number.
- Expiration Date: TBD.
- Amount/Size.
- X of Y.

NOTE: X indicates the label number. For example, 2 cases of an item containing 12 individual items per case would have a total of 27 labels. Labels 1 of 24 through 24 of 24 would be put on the individual items. Labels 25 of 24 and 26 of 24 would be put on the outer container, and Label 27 of 24 would be attached to the paperwork. Y indicates the container (or deliverable).

5.7.4.3 Transfer material to the Quarantine area at the temperature specified on the Master Specification or Part Number Request, as applicable.

NOTE: Temperature on specification should match information on the container label. If different, notify the Supervisor immediately. The Supervisor is to notify BQA.

5.7.4.4 If Inspection Level B, forward the original Inspection and Receipt of Materials Form to PA/QC with lot specific COA/COC/COO (if available) and Master Specification. MMIC may maintain a copy until final disposition is assigned.

5.7.4.5 If inspection Level C or D, forward the original Inspection and Receipt of Materials Form to PA/QC with lot specific COA/COC/ COO (if available), Master Specification and completed PA/QC Test Request (Form 22002-1), if required by the Master Specification.

5.7.4.6 If Inspection Level F, forward the original Inspection and Receipt of Materials Form along with any other documentation accompanying the shipment to QA. MMIC may maintain a copy until final disposition is assigned.

5.7.5 Section 4 – Release from Quarantine

The BDP assigned expiration is indicated in Section 4.1. A check that the information contained on the sample label (Section 3) is correct is recorded in Section 4.2. Raw material release is performed by PA/QC (Inspection Level B items) or by BQA (Inspection Level C, D and F items) and is indicated by signature and date in Section 5.1 of the form.

5.7.6 Section 5 – Final Disposition

5.7.6.1 Research and Development orders: Complete and apply "For Research and Development Use Only" labels. Labels will be applied to the smallest deliverable size of material without compromising integrity of packaging. In addition, a label must be placed on the outermost packaging. A true and exact representative sample of the label must also be applied to the Form in Section 5.2. These labels will only contain the text that denotes the material as "Research and Development Use Only."

5.7.6.2 Inspection Level A materials: Inspection Level A items are inspected by MMIC, verifying the vendor, catalog number and that the material was un-damaged upon receipt. Labels shall have the following information.

- BDP Part Number
- Item Description
- BDP Lot Number
- Manufacturer's Lot Number
- Expiration Date
- Amount/Size
- X of Y

NOTE: The expiration date for Inspection Level A items is determined by MMIC by reviewing the Part Number Request for the approved shelf-life and then calculating the expiration date for use on the release label. If the Part Number Request does not specify the expiration date and an item is labeled with an expiration or "use by" date, that date should be used, rather than not assigning one.

Complete and apply “Approved” labels. Labels will be applied to the smallest deliverable size of material without compromising integrity of packaging. In addition, a label must be placed on the outermost packaging. A true and exact representative sample of the label must also be applied to the Form in Section 5.2.

5.7.6.3 Inspection Level E materials: Inspection Level E items are inspected by MMIC, verifying the vendor, catalog number, the NDC number and that the material was un-damaged upon receipt. Labels shall have the following information.

- BDP Part Number
- Item Description
- BDP Lot Number
- Manufacturer’s Lot Number
- Expiration Date
- Amount/Size
- X of Y

NOTE: The expiration date for Inspection Level E items is obtained from the vendor label.

Complete and apply “Released” labels. Labels will be applied to the smallest deliverable size of material without compromising integrity of packaging. In addition, a label must be placed on the outermost packaging. A true and exact representative sample of the label must also be applied to the Form in Section 5.2.

5.7.6.4 Inspection Level B, C, D or F materials: Complete and apply final disposition labels. Labels will be applied to the smallest deliverable size of material without compromising integrity of packaging. In addition, a label must be placed on the outermost packaging. A true and exact representative sample of the label must also be applied to the Form in Section 5.2. Labels shall have the following information.

- BDP Part Number
- Item Description
- BDP Lot Number
- Manufacturer’s Lot Number
- Expiration Date:
- Amount/Size
- X of Y

NOTE: The assigned expiration date is determined by PA/QC per SOP 22714 - Sampling, Testing, and Review of CGMP Materials by Process Analytics/Quality Control and recorded on Form 20302-01 Section 4.1. MMIC uses this expiration date for the release label.

5.7.6.5 The label content, application and completion of Section 5.2 must be verified by someone other than the person who applied the labels.

5.7.6.6 Transfer material to its appropriate storage area (CGMP or R&D) at the temperature specified on the Master Specification.

6. RECEIPT AND INSPECTION – NON-INVENTORY MATERIALS

6.1 Refer to Steps 5.1 through 5.5.

6.2 MMIC personnel complete an Inspection and Receipt of Materials - Non-Inventoried Materials, Form 20302-02, for all items received.

6.3 Section 1 – Initial Receipt

Check off the appropriate response for each step.

6.4 Section 2 – Receiving Information

6.4.1 If the receiving document generated by NCI-Frederick ATRF Receiving is available, check the box, initial, and skip to Section 3 on the Form. Attach the receiving report to Form 20302-02.

NOTE: Some items, if ordered on a Government IMPAC card, may not be accompanied by a receiving document. If this is the case, the items received are checked against the original PR. A copy of the PR is then attached to the Direct Receiving Form that was delivered with the materials. This is returned to BDP Purchasing for reconciliation.

6.4.2 If the receiving document is not available, list all materials received in the space provided, and the sender information in the space provided.

6.5 Section 3 – Recipient Information

Record the intended recipient's name and building number.

6.6 Section 4 – Receiving Performed By

6.6.1 MMIC staff initials and dates in the space provided.

6.6.2 Upon delivery, MMIC will require a signature and date.

7. RECEIPT AND INSPECTION – BULK GASES

7.1 Bulk gas deliveries are arranged and coordinated by Facilities, Maintenance, and Engineering (FME).

7.2 Each gas delivery is accompanied by a batch-specific certificate (either a COA or COC) indicating the type of gas with its relevant quality testing and a delivery ticket.

7.3 These certificates are forwarded to the BDP cGMP Facilities Manager or designee by the delivery driver or FME. The certificates are reviewed, comparing the delivery lot to the certificate lot and comparing the certificate data against the established internal master specification,

7.4 Complete Form 20302-04, Inspection and Receipt of Bulk Gases. The form is signed by BDP cGMP Facilities Manager or designee and by PA/QC.

7.5 Attach the delivery ticket and the gas certificate behind the form and file the paperwork in MMIC.

7.6 Any discrepancies should immediately be brought to the attention of BQA, who will then evaluate the impact and determine appropriate action.

8. DOCUMENTATION AND RECORDS

8.1 BQA retain original files for all controlled materials released with inspection levels of C, D or F per SOP 21407 - Records Retention.

8.2 MMIC maintains files of all inventory (levels A through F) materials and non-inventory materials (no internal part numbers). After no less than one year, forms are sent to BQAD for archiving.

9. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
20004	Use of the Freezerworks Database
21407	Record Retention

Document Number	Title
21902	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials
22002	Request for Quality Control Testing
22714	Sampling, Testing, and Review of CGMP Materials by Process Analytics\Quality Control
20302-01	Inspection and Receipt of Materials, Inventoried Materials
20302-02	Inspection and Receipt of Materials, Non-Inventory
20302-03	Receiving Log
20302-04	Inspection and Receipt of Bulk Gases