BARDA Standard Operating Procedure Receipt and Inspection Process for BARDA Contracted Products Delivered to SNS Facilities or Other Designated Storage Sites

SOP Number: ASPR-BARDA-SOP-025.02
Approval Date: 03/29/2017
Effective Date: 04/29/2017

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

1. PURPOSE AND SCOPE

1.1 The purpose of this Standard Operating Procedure (SOP) is to establish the Biomedical Advanced Research and Development Authority (BARDA), Regulatory and Quality Affairs (RQA) Division procedures for receiving and inspecting medical countermeasure (MCM) products being acquired by BARDA for storage by the Centers for Disease Control (CDC) Division of Strategic National Stockpile (DSNS) at a Strategic National Stockpile (SNS) site or Other Designated Storage Site (ODSS).

1.2 This SOP is applicable to any BARDA product designated for storage.

2. PERSONNEL ROLES AND RESPONSIBILITIES

2.1 SNS/ODSS

2.1.1 Responsible for receiving and storing BARDA contracted products in accordance with cGMP regulations and the procedures outlined in this SOP.

2.2 BARDA RQA/RQA Representative

2.2.1 Overall responsibility for determining the quality acceptability of BARDA acquired MCM product delivered to SNS or ODSS for storage.

2.2.2 Responsible for executing the receiving and inspection process described in this SOP although the CO and/or designated COR may choose to verify the receiving and acceptance process for delivery of product.

2.2.3 Responsible for providing the results of the quality review of the receipt and inspection process to the COR with a recommendation to accept or reject the shipment.

2.3 BARDA COR

2.3.1 Responsible in conjunction with the BARDA CO for proceeding with formal acceptance; and, in the event of rejection, will negotiate proper product disposition with the contractor.

2.4 BARDA CO

2.4.1 Responsible for all official communication with the contractor regarding product acceptance or rejection.

3. PROCEDURES

3.1 CO/COR request pre-delivery documentation.Pre –delivery documentation delivered to RQA for review.

3.2 Pre-delivery Documentation Review

NOTE: A pre-delivery documentation review is performed by the RQA representative prior to a shipment being initiated and the results of all steps in the procedure 3.1 through 3.5 are recorded on the BARDA RQA Product Receipt and Inspection Form (ASPR-BARDA-SOP-025.02.F02). The COR requests the documentation and information in steps (3.2.1 – 3.2.5) from the contractor and, upon receipt, sends it to the PCT supporting RQA specialist for review. The RQA specialist reviews and notifies the COR if information is inadequate or needs further clarification.

3.2.1 Certificate(s) of Analysis (CoA) – The document that lists the lot specific results of final release tests and certifies to be in compliance with established product specifications.

3.2.2 Quality Disposition Letter – Contractor authored letter stating that the product lot scheduled for delivery has been manufactured in accordance with cGMP regulations and has met all manufacturing acceptance and release criteria (ASPR-BARDA-SOP-025.02.F01). The letter should also state that the any deviations that occurred during manufacturing have been investigated, determined to have no negative impact on product quality, and have been closed by the contractor's Quality Assurance department. BARDA may request a listing of major deviations that occurred during manufacturing.

3.2.3 Sample Labels – Comparator or reasonable facsimile label for each lot of FDA unlicensed or unapproved product, that will appear on the primary, intermediate box, and the shipping case. In the case of a FDA licensed or approved product, the contractor is not required to provide a sample label.

3.2.4 Lot Data – Lot numbers and date of manufacture or expiry (licensed or approved products only) for each product lot to be included in the shipment.

3.2.5 Product Safety Data Sheets –Description of hazardous properties, if any, for the purpose of safe handling of the product during receiving, inspection, storage, and distribution.

3.3 Receiving and Inspection Process

NOTE: At the SNS point of delivery or ODSS the receiving and inspection process is performed by the RQA Representative as follows and records the corresponding results on the :

3.3.1 Verify the presence of an appropriate intact lock and seal on each delivery truck.

3.3.2 The RQA Representative will verify for each delivery truck that the seal number matches the seal number recorded on the Bill of Lading.

3.3.2.1 If the seal number is verified, the RQA Representative will signal for and observe the removal of the lock and seal.

3.3.2.2 If the seal number does not match that of the corresponding Bill of Lading, the RQA Representative shall follow the steps listed in section 3.4.

3.3.3 The RQA Representative will observe warehouse personnel off-load the product, and conduct a cursory examination during off-load for obvious physical damage.

3.3.4 The product must immediately be moved from the loading dock to the appropriate temperature specified storage area where the inspection process will be completed which includes a detailed examination of the physical condition of the products outermost long-term storage packaging.

3.4 Non-matching Seal Numbers or Missing Seal

3.4.1 The RQA Representative present will require an immediate investigation into the discrepancy.

3.4.2 As an initial step, the RQA Representative, and SNS or ODSS personnel will interview the truck driver regarding the discrepancy. If no acceptable explanation is provided, a formal investigation will be initiated.

3.4.3 The RQA Representative will initiate a formal investigation in the event that no acceptable explanation is provided for a non-matching or missing seal. The RQA Representative will simultaneously inform the COR and the CO of the discrepancy. The CO notifies the contractor discrepancy and request that the contractor launch an investigation. The contractor will be advised to treat this as a deviation and BARDA will require an investigation report. BARDA security will also be notified of the deviation by the CO.

3.4.4 The RQA Representative will recommend non-acceptance of product from transport with missing seals, tampered-with or non-matching seal numbers pending outcome of investigation.

3.4.5 Prior to off-loading, the RQA Representative will move away from the trailer to a safe distance and signal for SNS with site security to open the trailer. Once it determined that no immediate threat is present witin the trailer, the RQA Representative will return and examine the product or evidence of tampering or theft. If such evidence is found, photos will be taken to document and to support the impending investigation.

3.4.6 The product will be off-loaded and moved to the appropriate storage where the inspection process will continue.

3.5 Inspection and Verification Criteria

3.5.1 The inspection and verification criteria listed below will be used for each shipment of contracted product to an SNS site or ODSS.

3.5.2 All product deliveries are placed under quarantine status at the SNS or ODSS by site staff upon delivery. Product will remain in quarantine status until all the steps in the acceptance process have been completed satisfactorily, the Quality Acceptance Memo (ASPR-BARDA-SOP-025.02.F01) has been provided to the COR by BARDA RQA, and until the CO formally notifies the contractor that the product is accepted.

3.6 Shipping Temperature Exposure

NOTE: Verification that no temperature deviations occurred will be used for each shipment. The specific steps in the verification process are as follows:

3.6.1 The contractor will provide BARDA with the acceptable temperature parameters in advance of making the first shipment.

3.6.2 The TempTale or other acceptable temperature monitoring devices, if any, included with the shipment will be removed from the pallets by the BARDA RQA Representative or designated site staff under the observation of the RQA Representative, stopped, and examined for any alarm condition.

3.6.3 A preliminary reading representing temperature exposure of the shipment while in transit will be extracted from the temperature monitoring device.

3.6.4 Any temperature excursions identified will be noted on the BARDA Product Receipt and Inspection Form (ASPR-BARDA-SOP-025.02.F02) as a deviation.

3.6.5 The RQA Representative will notify the COR of the preliminary temperature excursion data advising that full temperature data logging device download data should be requested on an expedited.

4. RECORDS MANAGEMENT REQUIREMENTS

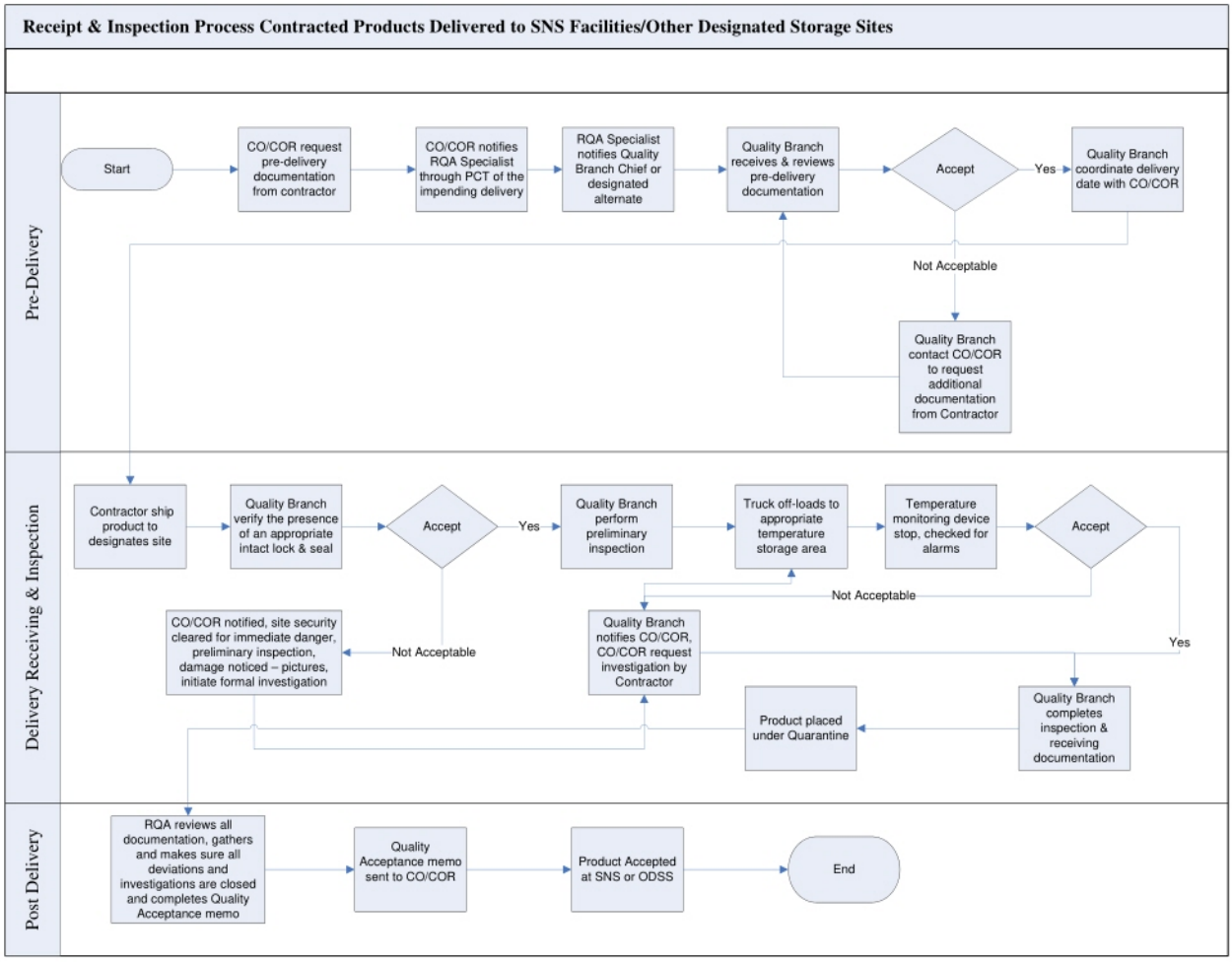
4.1 The records that may be produced as a function of the work outlined in this SOP are managed through the ASPR records schedule or the GRS, DAA-0468-2013-0003.

4.2 Authors of the SOP will work in coordination with the Chief, Records Management Branch to complete this section.

5. GRAPHICS

5.1 Process Flowchart

Figure 1: BARDA Standard Operating Procedure Flowchart



6. ATTACHMENTS

6.1 Quality Disposition Letter Template

Quality Disposition Letter Template

Company Letterhead

U.S. Department of Health and Human Services
300 Independence Ave., S.W.
Room G640
Washington, DC 20201
[dd MON yyyy]

Attn: [Name of BARDA Contracting Officer (CO)]

Dear [name of CO],

On [dd MON yyyy ship date] Lot(s) [lot number(s)] of [product name], containing [quantity shipped] was shipped from our facility in [facility location] and arrived at the Division of Strategic National Stockpile (DSNS) site [DSNS site code name] on [dd MON yyyy date received at DSNS].

This letter is to certify that [product name and product lot number(s)] produced at [insert company name and location of manufacturing facility] were manufactured under current Good Manufacturing Practices (cGMP) conditions and have met all acceptance and release criteria. Any deviations associated with the production of [this/these lot(s)] have been investigated and closed by the [insert company name] Quality Assurance Department and are determined to have no negative impact on product quality.

[Insert company name] Quality Assurance Department has reviewed the official temperature records for this product shipment. During shipment, the product [insert lot number(s)] was maintained within the required temperature of [_____ °F/C] as measured by calibrated temperature recording devices.

Sincerely,

Name of Responsible Quality Assurance Individual at the Company
Title, Quality Assurance
Company Name
Company Address
Telephone Number

6.2 BARDA RQA Product Receipt and Inspection Form

BARDA RQA Product Receipt and Inspection Form

Contract No.:	**Contractor:**	
Product:	**Delivery Date:**	
Lot No.:	**Quantity Delivered:**	**vials/bottles**

Pre-Acceptance Document Review	**Verification**	**Comments**
Certificate of Analysis	Reviewed ☐	
Product Safety Data Sheet	Supplied ☐	
Sample Labels and Lot # and Date of Mfg or Expiration Date	Supplied ☐	
Quality Disposition Letter	Reviewed ☐	
Documents reviewed by:		Date:

Receiving and Acceptance Criteria Checklist		
Locks and Seals Present Yes ☐ No ☐	Seal #s Agree with Bill of Lading Yes ☐ No ☐	
Number of TempTales _____	Temperature Deviations Yes ☐ No ☐	
Date of Manufacture: _____ or Expiration Date: _____	Labeling Comparison Acceptable Primary Yes ☐ No ☐ Secondary Yes ☐ No ☐	
Package Integrity	Acceptable	Not Acceptable
Accountability	Quantity	Unit of Measure
Units per full case	a	Vials/Bottles
Full Cases	b	Cases
Partial Case	c	Vials/Bottles
Total Quantity	(a X b) + c =	Vials/Bottles

BARDA RQA Product Receipt and Inspection Form

Enter TempTale information for all those used in the shipment.

TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped
TempTale#	Pallet #	Location	Time Stopped

Deviation(s): No _____ Yes _____ If Yes, describe deviation.

Contractor Notified? Yes _____ No _____

Delivery received by: _____ _____

RQA Representative (print) Signature

Cc: RQA File, COR, CO

6.3 Deviation Notification Form

Deviation Notification Form

Date:

To: **RQA Director *(Name)***

COR *(Name)*

CO *(Name)*

From: **RQA Reviewer (Name)**

Subject:

IND / Serial Number:

Background

Deviation

Comments

Submitted by:

_____

RQA Representative

6.4 Deviation Close-Out Memo

Product Acceptance Recommendation
Deviation Close-Out Memo

To: RQA Director *(Name)*

COR *(Name)*

CO *(Name)*

Product Description: _____

Manufacturer: _____

Lot Number: _____

Arrival Date/Site: _____

Deviation Notification Closure Action*

(Describe any disposition actions recommended by RQA, COR, or CO)

_____ Acceptance Recommend

_____ Acceptance Not Recommended

**ATTACH DOCUMENTATION FROM MANUFACTURER*

RQA REPRESENTATIVE _____ DATE_____

COMMENTS:

RQA MANAGEMENT CONCURRENCE:

NAME _____ DATE CLOSED _____

6.5 Quality Acceptance Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of the Secretary**

Office of the Assistant Secretary for
Preparedness & Response
Biomedical Advanced Research &
Development Authority (BARDA)
Washington, D.C. 20201

From: *(RQA Representative Name)*

Date: *(date sent)*

To: *(COR Name)*

Cc: RQA Director Name (HHS/ASPR/BARDA)

Subject: RQA review of *(date and product Name)* delivery

Dear (COR Name),

For the (contract number, product name) product lots listed below which were delivered to SNS or other designated storage site (site name) on (date), RQA has reviewed all product acceptance criteria. RQA has also reviewed the official shipment temperature data and Quality Disposition Letters received from the contractor certifying that all quality parameters of the lots in this shipment have been met.

Based on this review, RQA has determined that the product lots listed below are acceptable for placement into site inventory.

Four (4) pallets of (contract number, product name) product, total 722,500 doses delivered on (date) to SNS site (name):

Lot #	Total Doses in Product Lot	Expiration Date for Product Lot
XXXXX	180,690	4/2/2012
XXXXX	179,530	4/7/2012
XXXXX	181,470	4/14/2012
XXXXX	180,810	4/30/2012

(RQA Representative Name)

6.6 Packing Slip and Actual Count Worksheet

Packing Slip and Actual Count

Pallet #	Lot #	Lot Check	# Cases	Count Check	DOM	DOM Check	TempTale	TT Location	Time TT Stopped	Label Check
1										
2										
3										
4										
5										
6										
7										
8										

APPENDIX A: ACRONYMS AND ABBREVIATIONS

This section describes the acronyms used in this document.

Table 1: Acronyms and Abbreviations

Acronym	Literal Translation
AMCG	Office of Acquisitions Management, Contracts and Grants
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
cGMP	Current Good Manufacturing Practices
CO	Contracting Officer
CoA	Certificate of Analysis
COR	Contracting Officer Representative
DSNS	Division of Strategic National Stockpile
GRS	General Records Schedule
MCM	Medical Countermeasure
ODSS	Other Designated Storage Site
RQA	Regulatory and Quality Affairs Division
SNS	Strategic National Stockpile
SOP	Standard Operating Procedure

APPENDIX B: GLOSSARY

Table 2: Glossary

NOT APPLICABLE TO THIS SOP

APPENDIX C: REFERENCED DOCUMENTS

Table 3: Referenced Documents

Document Name	Document Number and/or URL	Issuance Date
Federal Acquistion Regulation Part 46	http://farsite.hill.af.mil/reghtml/Regs/far2afmcfars/fardfars/Far/46.htm	
U. S. Pharmacopeia Good Storage and Shipping Practices	http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1079.html	
U. S. Pharmacopeia Monitoring Devices – Time, Temperature, and Humidity	http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1118.html	

APPENDIX D: REVISION HISTORY

Table 4: Record of Changes

Revision Number	Effective Date	Author/Originator	Description of Change	Justification for Changes
00	12 Dec 2011	M. Waters	New SOP	Previous SOP BARDA-APMO-016.01 to be retired Updated SOP to reflect current practices
01	07 May 2012	D. Yeskey	Changed to BARDA-SOP-025.01	SOP number changed to accommodate a numbering realignment of the BARDA Core 20 SOPs
02	29 March 2017	P.Hylton	Document format change. Place in a step for CO/COR to receive pre-delivery documentation fron contractor. Process flow diagram added to procedure.	Updated to comply with Section 508 of the Rehabilitation Act of 1973, as amended in 1998 (29 U.S.C § 794 (d)).

APPENDIX E: APPROVALS

X Debra A. Yeskey -A

Digitally signed by Debra A. Yeskey -A
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2000085631, cn=Debra A. Yeskey -A
Date: 2017.04.12 10:09:51 -04'00'

Debra A. Yeskey, Pharm.D., Acting Deputy Director, Regulatory and Quality Affairs

Signature: _____ Date: _____

Print Name: Debra A. Yeskey, Pharm.D.

Title: Acting Deputy Director, Regulatory and Quality Affairs Division

Role: Approver for Dr. Rick Bright