

	SMSA	Document ID	SMSA-HC09
	P.O. Box 63259 Riyadh 11526, K.S.A.	Revision no.	05
	<b>STANDARD OPERATING PROCEDURE</b>	Effective Date	01-05-2025
	<b>Product Quarantine and Disposal</b>	Next Revision Date	31-05-2027
		Function	Warehouse
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## 1.0 PURPOSE

- 1.1 This document lays down the procedure for product subjected to quarantine.
- 1.2 This procedure is to provide a system for documentation and timely response to NUPCO or MOI products while it is unserviceable

## 2.0 SCOPE

- 2.1 This procedure is applicable to all SMSA Employee working with pharmaceutical Warehouse.

## 3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	NUPCO	National Unified Procurement Company for Medical Supplies
3.2	MOI	Ministry Of Interior
3.3	MOH	Ministry Of Health
3.4	SFDA	Saudi Food and Drug Administration
3.5	WMS	Warehouse Management System
3.6	NA	Not Applicable
3.7	Etc.	Etcetera

## 4.0 RESPONSIBILITY

- 4.1 The Warehouse Manager, and Pharmacist shall be responsible for update for this procedure, handles product while in quarantine, and follow up on necessary investigation, clarification with NUPCO or MOI, and processing of documentation requirement till products is disposed
- 4.2 The Storage Team Leader and his staffs are to handle the following types of items for quarantine:
  - 4.2.1 Expired
  - 4.2.2 Rejected/Damaged
  - 4.2.3 Unserviceable
  - 4.2.4 Condemned
  - 4.2.5 Complaint
  - 4.2.6 Returned from cold chain outside desire temperature range

Author/ Originator of Doc Change	Name & Designation <i>MOAYAD MOHAMEDAIN</i> <i>PHARMACIST</i>	Signature <i>25-05-2025</i>
Reviewer ( Process Owner)	<i>M. J. M. Javed</i> <i>Warehouse Supervisor</i>	<i>29-05-2025</i> <i>31/05/2025</i>
Approving Authority	<i>Director</i>	

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4.2.7 Recalled  
4.2.8 Counterfeit

## 5.0 PROCEDURE

- 5.1 On receiving of returned products from NUPCO or MOI and found during the stock take for items relating to product expired / damaged / unserviceable/ condemned returned outside cold chain / recalled and counterfeit items are to be placed under quarantine storage
- 5.2 Upon receiving of information source from Authorities (NUPCO/SFDA/MOH, MOI), Manufacturer, Authorized Vendors and NUPCO or MOIs, on counterfeit product, or product subjected to recall, the affected lot & batch of product is to be quarantined.
- 5.3 Storage area and racking identified for purpose of quarantine is to be clearly segregated to prevent mix up of stock including temperature sensitive products in the cold room.
- 5.4 Quarantine storage is caged up with locking device to enhance and restrict this area to be accessed by authorized personnel only, while pending further investigation or instruction for necessary follow up and instruction for product disposition or disposal.
- 5.5 Products under quarantine are to be marked under "quarantined". Name of NUPCO or MOI and reason for quarantine is to be labeled with the product respectively.
- 5.6 Storage Team Leader is to report to Warehouse Manager, and Pharmacist for such products so that he can process the necessary follow up NUPCO or MOI appropriately.
- 5.7 In general circumstances, quarantine items are mostly for condemnation to be followed up with processing the documentation for disposal.
- 5.8 NUPCO or MOI will be informed on the quarantine items and shall be inspected by them and witnessed for disposal.
- 5.9 The following summary table is for working reference for follow up on product quarantine.

Nature	Follow up	Remarks
Expired	Raised Condemnation Certificate	
Rejected/Damaged	Raised Condemnation Certificate after investigation	NUPCO or MOI's Letter of Authorization or endorsement on condemnation certificate and witnessed for disposal are required.
Unserviceable	Arrange for repair	
Condemned	Raised Condemnation Certificate	
Complaint	Pending investigation & outcome from Product Complaint Report.	Disposition of product to be advised by NUPCO or MOI.

Author/ Originator of Doc Change	Name & Designation MOAYAD MOHAMED AIN PHARMACIST	Signature
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Approving Authority	Patent Controller	

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Returned from cold chain outside desire temperature range	Pending investigation & consultation with manufacturer.	Disposition of product and follow up to be advised by NUPCO or MOI.
Recalled	Pending investigation & outcome from Product Recall Report.	Disposition of product and follow up to be advised by NUPCO or MOI.
Counterfeit	Pending investigation	Method of disposal to be advised by NUPCO or MOI.
Prior release	Pending release approval by NUPCO or MOI	Release of product to be advised by NUPCO or MOI.

- 5.10 Products under quarantine are to be blocked off from Central WMS pending further instruction.
- 5.11 Upon approval by NUPCO or MOI for the products for disposal management through written notification, such items stored in the warehouse Quarantine Bay will be checked and verified physically for its quantity, description. Batch number or/and serial, shelf life expired etc., whichever applicable. The list of items shall be prepared and checked and signed by NUPCO/MOI and SMSA before hand over to disposal contractor.
- 5.12 Warehouse Manager, and Pharmacist shall be making prior arrangement with authorized waste/Disposal contractor for appointment date to pick up the load for disposal. Inform NUPCO or MOI on the date of disposal for witnessing at designated disposal site. Disposal contractor shall sign the list of Items and shall provide the certificate of disposal after disposing of items.
- 5.13 Items that were disposed shall be updated as strike off / shipped away from the Central WMS.
- 5.14 All Quarantine Material shall be labelled/taped as Hazardous Waste before hand over to the disposal contractor.
- 5.15 Log/Manifest shall be kept for all Pharmaceutical waste which shall show the material, Quantity, Date and Recipient and shall be signed as kept as a record.

## 6.0 RECORD

Title of Record	Custodian	Retention Period
Written Notification	Pharmacist	5 Years
Certificate of Condemnation	Pharmacist	5 Years

Author/ Originator of Doc Change	Name & Designation MOAYAD MOHAMEDAN PHARMACIST	Signature Z... 20-05-2025
Reviewer ( Process Owner)	M. J. M. Tareq Warehouse Supervisor	Signature 31/05/2025
Approving Authority	Paint Sec. / Mr. ...	Signature T. ...

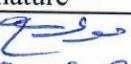
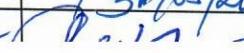
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## 7.0 Attachment/Reference

NA

## 8.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No.
00	28-11-2016	New document	NA
01	05-02-2018	<p>Changes Made in the SOP as follows</p> <ul style="list-style-type: none"> <li>• SOP Format updated to uniform all SOPs.</li> <li>• SOP Document ID amended as SMSA-HC unique ID format for all SOP.</li> <li>• SOP Title amended by adding Disposal in Product Quarantine. SOP title is "Product Quarantine and Disposal".</li> <li>• Incorporated abbreviations as used in SOP.</li> <li>• Amended all SOP for the terms Customer and Authority and replaced with NUPCO and MOI as actual customer and authority.</li> <li>• Amended point 4.1 for the responsibilities by adding Warehouse Manager Assistant manager and Pharmacist responsibilities and removed Warehouse supervisor responsibility as actual.</li> <li>• Amended point 5.2 by adding MOI as information source.</li> <li>• Amended the table under 5.9 sections by replacing Customer and authority with NUPCO and MOI as actual.</li> <li>• Point 5.6 brought down as point 5.10 to sequence the SOP.</li> <li>• Merged SOP-HC10 for disposal management in this sop and Point 5.11, 5.12, 5.13 and 5.15 incorporated for disposal of items.</li> <li>• Incorporated point 5.14 and 5.15 for labeling the as Hazardous waste and to keep the record for disposal.</li> <li>• Amended section 6 for the custodian from Warehouse Supervisor to Pharmacist.</li> </ul>	CR0211

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Reviewer ( Process Owner)	M. J. Javed Warehouse Supervisor	 30/05/2025
Approving Authority	A. A. A. C. / M. M. M.	 30/05/2025

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	<ul style="list-style-type: none"> <li>Flow chart amended by including more categories under product quarantine as explained in the SOP.</li> <li>Amended the Flow chart by deleting the terms resale and repair as not required as per process.</li> </ul>	
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END OF THE DOCUMENT

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Approving Authority	<i>M. A. C. / " "</i>	<i>31/05/2025</i>