	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC05
	STANDARD OPERATING PROCEDURE **Storage & Handling of Cold Chain Items**	Revision no.	05
		Effective Date	01-06-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
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1.0 PURPOSE

1.1 This document lays down the process requirement of Storage and Handling of cold chain items according to the cold chain requirement. Handling of returned cold chain items is also covered in this procedure. Other consumables, besides vaccines are non-returnable stock from customer.

1.2 Emergency recovery details are also included in this procedure for break in cold chain system.

1.3 The Warehouse Supervisor and Storage Team Leader shall be responsible for implementation and update for this procedure to fulfill operational and customer requirement

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	°C	Degree Celsius
3.2	EHS	Environment Health and safety
3.3	SOP	Standard Operating Procedure
3.4	Cold Chain System	The system for distributing product in a potent state from the manufacturers to the actual designated required sites
3.5	Cold Chain Item List	Items that are needed to abide the cold chain system
3.6	Cold Chain Temperature	Required temperature for cold chain items: 2°C to 8°C
3.7	Freezer Storage Temperature	Required -1°C to -17°Cor colder during storage
3.8	CCTV	Closed Circuit Television
3.9	PPE	Personal Protective equipment

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Reviewer (Process Owner)	M. J. M. Jareed Warehouse Supervisor	30/05/2025
Approving Authority	JASJIT SINGH MGR COL	30/5/2025

4.0 RESPONSIBILITY

4.1 The Warehouse Supervisor shall be responsible for the implementation and update for this procedure to fulfill operational and customer requirements.

4.2 The Safety & Security staff is required to record the temperature record twice a day during office hour by using the Temperature Record Form.

5.0 PROCEDURE

5.1 The process of storage and handling of cold chain items is summarized at Flow chart A.

5.2 Cold chain items are stored at the cold room and freezer room, are maintained by contractor on monthly servicing basis to ensure the effectiveness of the storage of the product.

5.3 The essential components of the cold chain system are:

5.3.1 People to organize the product's handling and storage of the product.

5.3.2 Equipment used for the storage and its monitoring of the temperature

5.4 Handling of Cold Chain Products.

5.4.1 Storage of Products:

5.4.1.1 Only pharmaceutical products that require cold chain are required to be stored at specific storage facility.

5.4.1.2 Cold room and freezer room are used for long term and short term storage.

5.4.1.3 Adopt "First-Expiry First-Out" issue system for new stock; for returned and reusable stock shall be returned into the system and also adopt "First-Expiry First-Out" the next customer order.

5.4.1.4 Place package with label facing front to allow visibility and stock check

5.4.1.5 Ensure sufficient space to permit air movement during storage

5.4.1.6 Product should not be stored at door way of the room and it should be stored sufficiently away from internal walls and rows to allow air to circulate within the storage area.

5.4.1.7 Keep doors closed at all times, except issue & receipt operations.

5.4.2 Handling issue and receipt of products at the designated storage area to ensure no break in cold chain environment.

5.4.3 Handling of returned cold chain items from customer as follows:

5.4.3.1 Check and ensure items are received in insulation boxes with chilled ice packs and thermometer to indicate the reading of the temperature meeting the specific temperature range of

+2°C to +8°C for Cold Chain and -1°C to -17°C for freezer items. If not meeting requirement, reject the returned items immediately.

5.4.3.2 Check and ensure the detail of the items: Quantity, Expiry Date, Lot/ Batch Number and reason for returned are provided by customer. Customer's instruction is needed if items are reusable and put to serviceable stock.

5.4.3.3 When vaccines are returned with reason stated to be quarantine and disposal. Vaccines are to be put under quarantine pending follow up instruction from customer.

5.4.3.4 Customer instructions are required for follow up disposal action. Arrangement has to be made with customer to witness the disposal.

5.4.3.5 Vaccine's returned to warehouse till its disposal is to be recorded on Vaccines Returned Form in Annex A.

5.4.4 Handling and monitoring of temperatures for the Cold Room and Freezer Room are as follows:

5.4.4.1.1 Check and record the temperature through the Data logger panel available in Cold and Freezer Room area and take the print out of temperature record every day for cold room and freezer rooms and file for record purpose.

5.4.4.1.2 Cold Room: +2 °C to + 8 °C

5.4.4.1.3 Freezer Room: -1°C to -17°C.

5.4.4.2 For the Cold Room where electronic Temperature Monitoring System (TMS) is available, the temperature readings are captured automatically and tracked 24/7. This will be the Primary monitoring system. Daily records of the TMS shall be printed and checked.

5.4.5 When the cold room/freezer room system breakdown, or there is power failure, the following should be carried out. The process is summarized at flow chart B.

5.4.6 Flow chart note:

5.4.6.1 During Breakdown of cold room /freezer room system or power failure:

5.4.6.1.1 Immediately record down the temperature that product has been exposed.

5.4.6.1.2 Record the maximum temperature reached during power failure.

5.4.6.1.3 Do not open the cold rooms / freezer room doors.

5.4.6.2 If power cannot be restored for cold rooms/ freezer and fault cannot be rectified within an hour:

5.4.6.2.1 Arrange to transfer the product with requirement of 2°C to 8°C to cold chain boxes required number of ice packs and data logger to monitor its temperature.

5.4.6.2.2 Arrange vendor to supply dry ice for the evacuation items in the freezer

5.4.6.2.3 Return product to the cold room or freezer room only when functioning normally and the internal temperature is within the range of +2°C+8°C and -1°C to -17° respectively.

5.4.6.3 If the product has been exposed to temperatures higher than recommended storage temperature, the customer must be notified.

5.4.6.4 If the product has been exposed to temperatures higher than recommended storage temperature, seek the advice of the manufacturer on whether the affected product can still be used. The following details should be given:

5.4.6.4.1 Name of the product, the manufacturer, batch number, expiry date and quantity affected.

5.4.6.4.2 The range of temperature to which the products have been exposed to and the duration of exposure. Then temperature recording chart, if available, should be included for verification.

5.4.6.4.3 While waiting for manufacturer's recommendations, the affected vaccines should be quarantined and kept at required temperature.

5.5 Entry into the cold & Freezer room shall follow the safety requirement in order to avoid negative impact on the health of the personal. This shall include the wearing of PPEs, Warm Jacket, Warm Hand gloves. Proper mask shall be used upon entry and working in those rooms.

5.6 Safety precaution are outlined and detailed in the SOP SMSA-08 shall be followed.

5.7 CCTV shall be closely monitoring the Cold Rooms and Freezer rooms by security staff during working hours. Security personal shall monitor the Cold & Freezer room doors opening and closing. If the door is open and no personal movement taken place more than 10 to 15 minutes this shall be considered as the possible Health concern and shall be checked the area physically.

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6.0 RECORD

Title of Record	Custodian	Retention Period
Cold Chain Item List	Storage Team Leader	3 years
Daily Temperature Recording Form	Storage Team Leader	3 years
Vaccines Returned Form	Storage Team Leader	3 Years

7.0 Attachment/Reference

7.1 Annexure A – Vaccines Returned Form

8.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No.
00	12-11-2016	New document	NA
01		Changes Made in the SOP as follows • SOP Format updated to uniform all SOPs. • SOP Document ID amended as SMSA-HC unique ID format for all SOP. • Incorporated new abbreviations under Section 3. • Amended the Point 5.4.1.3 by removing "first to be picked for issue" and added First Expiry First Out as a Standard. • Amended the point 5.4.3.1 by adding the temperature range of Freezer room together with cold room. • Amended point 5.4.4.1 by adding the temperature recording and monitoring through Data logger panel. • Amended the point 5.4.4.1.2 by adding freezer room correct temperature range. • Amended the point 5.4.6.2.3 by adding the temperature ranges for cold and freezer room • Freezer room temperature range is	

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03	16-01-2022	corrected in all SOP including Flow Chart as -1°C to -17°C. • Flow Chart A& B are corrected now for temperature ranges for cold and Freezer rooms. • From point 5.4.4.1 removed (If any break down in data logger system then Annexure A shall be used twice daily for record purpose).	

END OF THE DOCUMENT

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