
 <p><b>health</b> Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Routine Monitoring and Handling of Vaccines	Next Revision [REVISION DATE]

## STANDARD OPERATING PROCEDURE FOR ROUTINE MONITORING OF VACCINE HANDLING


<b>INSTITUTION</b>	National Department of Health		
<b>SECTION</b>	COVID-19 Vaccination – Routine Monitoring and Handling of Vaccines		
<b>OBJECTIVE</b>	To outline the daily monitoring of temperature and stock management at vaccination sites.		
<b>SCOPE</b>	- Routine monitoring of COVID-19 Vaccines Handling		
<b>COMPILED BY</b>		<b>ORIGINAL DATE:</b>	
<b>AUTHORISED BY</b>			
<b>DEFINITIONS</b>	<p><b>Current Stock Level</b> means the vial count in the main storage location (cold room/refrigerator) at close of business daily.</p> <p><b>Expiry date</b> means the date up to which a medicine will retain the strength and other properties as stated on the label.</p> <p><b>Stock issued</b> means the vial count issued out of the main storage location (cold room/refrigerator) for the day</p> <p><b>Stock lost</b> means the vial count of any wastage due to for example breakage, expiry, and pilferage.</p> <p><b>Stock received</b> means the vial count delivered since the last daily update.</p> <p><b>Stock transferred</b> means the vial count sent to another vaccination site or primary distribution site.</p> <p><b>Temperature recording device</b> means a device capable of monitoring the temperature reached during different stages of movement of a shipment in transit and provides a detailed reading either through a recorder chart or “downloading” of the information recorded through a software package</p> <p><b>Vaccines</b> means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer’s recommendations.</p> <p><b>Vaccination site</b> means a place where COVID-19 vaccination services may be provided to eligible populations and may include a primary vaccination site or a place where outreach services (fixed, temporary or mobile) are provided.</p> <p><b>Vaccine champion</b> means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist’s assistant or nurse and may also function as the vaccination site manager, or as a vaccinator.</p> <p><b>Vaccine controller</b> means a pharmacist or pharmacist’s assistant or other health care professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, outreach sites and/or the supply of vaccines to mobile teams (where applicable) and the updating of data on the Stock Visibility System (SVS).</p>		
<b>ABBREVIATIONS</b>	- GPP: Good Pharmacy Practice		
<b>POLICIES, REFERENCES, SOURCE MATERIAL</b>	<ul style="list-style-type: none"> <li>- Provincial medicine supply management policy and/or supply chain prescripts (as applicable)</li> <li>- Cold chain and Immunisation Operations Manual of 2015</li> </ul>		

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	<ul style="list-style-type: none"> <li>- Pharmacy Act 53 of 1974</li> <li>- Medicines and Related Substances Act 101 of 1965</li> <li>- Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974</li> <li>- National Environmental Management: Waste Act 59 of 2008</li> <li>- National Environmental Management Act 107 of 1998</li> <li>- Hazardous Substances Act 15 of 1973)</li> <li>- Hazardous Substances Act, 1973 (Act 15 of 1973)</li> </ul>
<b>RELATED SOPs</b>	<ul style="list-style-type: none"> <li>- Receiving of vaccines</li> <li>- Distribution of vaccines</li> </ul>
<b>PRINCIPLES</b>	<ol style="list-style-type: none"> <li>1. Cold chain maintenance is mandatory therefore temperature monitoring systems must be developed and implemented in a structured manner.</li> <li>2. Staff must be trained and mentored with conducting daily activities to ensure the maintenance of the cold chain and stock management systems as per GPP.</li> <li>3. Staff must continuously check temperature records to ensure that the cold chain is maintained and report instances of temperature excursions.</li> <li>4. WHO approved/compliant temperature recording devices must be installed in refrigerators/freezers. These devices must be connected to an alarm/warning system in the event of power failures or other events that may lead to temperature excursions.</li> <li>5. Refrigerators/freezers must be connected to standby generators.</li> <li>6. Staff must ensure that stock management systems (stock cards and ESMS) are functional as these will be subject to regular audits.</li> </ol>
<b>FUNCTIONAL ROLES AND RESPONSIBILITIES</b>	<ul style="list-style-type: none"> <li>- Vaccine controller</li> </ul>
<b>TOOLS/ MATERIALS/ EQUIPMENT</b>	<ul style="list-style-type: none"> <li>- Temperature monitoring charts</li> <li>- SVS/ESMS</li> <li>- Stock/bin Cards</li> </ul>
<b>SAFETY WARNINGS</b>	<ul style="list-style-type: none"> <li>- <b>N/A</b></li> </ul>
<b>MONITORING AND EVALUATION</b>	<ul style="list-style-type: none"> <li>- <b>TBD</b></li> </ul>
<b>RECORD KEEPING</b>	<ul style="list-style-type: none"> <li>- Temperature recording records must be kept for a period of five years</li> </ul>

## 1. PROCEDURE:


No	PROCEDURE	RESPONSIBLE
1	<b>Ensuring Power Supply</b>	
1.1	Check twice daily for electricity supply for the refrigerator/freezer/cold room.	Vaccine Controller

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1.2	Check for power supply to refrigerators/freezers/cold rooms after load shedding intervals as there may be power surges that cause the fridge/freezer to be non-functional.	Vaccine Controller
1.3	Check back-up generators daily, if present or ensure that gas is always available (if relevant).	Vaccine Controller
<b>2</b>	<b>Monitoring of Temperature</b>	
2.1	Check temperature monitoring/recording device. Monitor and record temperature on temperature recording chart attached to the outside of the refrigerator/freezer/cold room (Annexure 2) twice daily.	Vaccine Controller
2.2	Initial the appropriate column when updating the temperature chart.	Vaccine Controller
2.3	At the end of the month, remove temperature monitoring charts (Annexure 1a/b/c) from refrigerator/freezer. File temperature recording sheets in a labelled file for audit reviews.	Vaccine Controller
2.4	Report temperatures that are not within the required range to the vaccine champion and supervisory pharmacist.	Vaccine Controller
2.5	Take corrective measures immediately; either to restore the required temperature or transfer vaccines to another functional refrigerator/freezer.	Vaccine Controller
<b>3</b>	<b>Maintaining of Refrigerator/Freezer Cleanliness</b>	
3.1	Check that all vaccines are neatly arranged in batches.	
3.2	Clean and wipe fridge surfaces daily.	Vaccine Controller
3.3	Clean the radiator with a wire brush or other suitable brush	Vaccine Controller
3.4	Check the condition of the door gaskets and that the doors are aligned and close correctly. Clean door gaskets if necessary.	Vaccine Controller
3.5	Check if the freezer compartment needs defrosting and defrost if there is more than 5mm of ice on the sides.	Vaccine Controller
<b>4</b>	<b>Updating of Stock Management Systems</b>	
4.1	Capture vaccine stock on stock management systems as individual vials/ampoules.	Vaccine Controller
4.2	Record receipts, issues, expired and damaged stock on stock management systems. Stock cards must be signed by the designated vaccine controller after every receipt; issue/expired/damaged stock entry.	Vaccine Controller
4.3	Calculate stock balances when stock cards are being used.	Vaccine Controller

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4.4	Add quantity of stock received to existing stock balance to obtain stock on hand balance.	Vaccine Controller
4.5	Subtract quantity of stock issued/expired/damaged from existing stock balance to obtain stock on hand.	Vaccine Controller
4.6	Check that the stock on hand balance on stock monitoring systems (ESMS and stock cards) equals the physical stock in refrigerator/freezer.	Vaccine Controller
4.7	Report all discrepancies for further investigation by vaccine champion and supervisory pharmacist.	Vaccine Controller
4.8	Undertake stock takes when there is a change in vaccine controller and record the vaccine levels at hand over.	Vaccine Controller

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<b>ANNEXURES</b>	Annexure 1: Temperature monitoring chart
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### 2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved


#### TRAINING REQUIRED

- Training to be conducted post SOP sign-off and prior to the effective date as per above
- Training to be administered to relevant responsible parties after each SOP revision

Trainees	Type of training


### 3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			

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### Annexure 1: Temperature monitoring Chart

<b>District:</b>							<b>Health Facility:</b>				
<b>Month / Year:</b>											
<b>Equipment :</b>								<b>Fridge / Freezer Number</b>			
Day	AM	°C	Alarm/OK	Duration	PM	°C	Alarm/OK	Duration	Initials	Action	
1											
2											
3											
4											
5											
6											
7											
8											
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