

 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Preparation of Cold Chain Equipment	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – PREPARATION OF COLD CHAIN EQUIPMENT AT STORAGE, PRIMARY DISTRIBUTION AND VACCINATION SITES

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Site Preparation		
OBJECTIVE	- To provide guidance on the minimum standards for preparation of cold chain equipment at primary distribution sites and vaccination sites where COVID-19 vaccines are stored.		
SCOPE	- Cold Chain Equipment		
COMPILED BY		ORIGINAL DATE:	
AUTHORISED BY			
DEFINITIONS	<p>Conditioned Ice Packs means ice packs that are removed from the freezer/fridge and allowed to remain at room temperature until the ice can be heard to “rattle” in the ice pack.</p> <p>Digital Data Logger (DDL) means a device that continuously monitors and records ultra-low temperatures in freezers and can display and store temperature recordings for a specific period of time.</p> <p>Passive Containers/Cooler Boxes means insulated cooler boxes or containers with no active temperature control.</p> <p>Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer’s recommendations.</p> <p>Vaccination site means a place where COVID-19 vaccination services are 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>Vaccine Champion 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>Vaccine Controller 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>		
ABBREVIATIONS	- DDL- Digital Data Logger		
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> - Provincial medicine supply management policy and/or supply chain prescripts (as applicable) - Cold chain and Immunisation Operations Manual of 2015 - Pharmacy Act 53 of 1974 - Medicines and Related Substances Act 101 of 1965 - Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 - National Environmental Management: Waste Act 59 of 2008 - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973 		


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RELATED SOPs	<ul style="list-style-type: none"> - Receiving of bulk stock of vaccines - Distribution of COVID-19 vaccines
PRINCIPLES	<ol style="list-style-type: none"> 1. The required cold chain equipment must be present at primary distribution sites, and all vaccination sites that store and distribute vaccines. 2. Cold chain equipment may include refrigerators, freezers and/or cold rooms. 3. The cold chain equipment must be suitable for the type and quantity of vaccines to be stored at the site. 4. Cold rooms must be mapped, and the equipment must be maintained, validated, and calibrated. 5. WHO approved/compliant temperature recording devices must be used to continuously monitor the temperature of refrigerators and freezers. Minimum/maximum, stem and dial thermometers are not recommended. 6. Doors of refrigerators, freezers and cold rooms must only be opened when necessary, for example to remove or replace vaccines. 7. Storage of food is not permitted in a refrigerator, freezer or cold room where vaccines are stored. 8. Picking and packing of vaccines for distribution must occur within the specified temperature environment. 9. Access to cold rooms must be restricted to authorised personnel.
FUNCTIONAL ROLES AND RESPONSIBILITIES	<ul style="list-style-type: none"> - Vaccine controller - Responsible pharmacist (as defined in the Pharmacy Act 53 of 1974) - Supervising pharmacist - Professional nurse (responsible for medicine supply management)
TOOLS/ MATERIALS/ EQUIPMENT	<ul style="list-style-type: none"> - Refrigerators - Freezers - Cooler boxes/Passive Containers - Ice packs
SAFETY WARNINGS	<ul style="list-style-type: none"> - Wear waterproof insulated (cryogenic) gloves and safety glasses with side shields or safety goggles to remove the dry ice pod from the shipper - Do not leave dry ice in an unattended area - Do not place dry ice in a drain or flush down a toilet - Do not place dry ice in a closed area
MONITORING AND EVALUATION	<ul style="list-style-type: none"> - KPIs to be Defined
RECORD KEEPING	<ul style="list-style-type: none"> - Recording of temperatures - Any temperature excursions and action taken

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1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
1	Preparation of Refrigerators and Freezers	
1.1	Identify designated refrigerator/s and/or freezer/s suitable for the storage of vaccines taking temperature requirements and the volume of storage space required into account.	Vaccine Controller
1.2	Ensure that vaccine refrigerators/freezers/ultra-freezers are lockable or access controlled. Access should be limited to the pharmacy manager or vaccine controller.	Vaccine Controller
1.3	Display notices on designated refrigerator/s and/or freezer/s "for vaccine storage only".	Vaccine Controller
1.4	Position vaccine refrigerator/freezer away from windows, doors, and sunlight, preferably against an inner wall in the facility.	Vaccine controller
1.5	Use dedicated separate power points for electrical refrigerators and/or freezers.	Vaccine controller
1.6	Ensure WHO approved/compliant temperature recording devices are used/installed in the refrigerator/s, freezer/s and/or cold room/s.	Vaccine controller
1.7	In the case of refrigerators ensure that the thermometer hangs from the middle shelf of the refrigerator.	Vaccine controller
1.8	Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures in freezers.	Vaccine controller
1.9	Ensure temperature monitoring devices are connected to an alarm and/or warning system that will be triggered in the event of a power failure or other event/s that may lead to temperature changes.	Vaccine controller
1.10	Where applicable, display a temperature monitoring sheet on the outer door of the fridge/freezer/cold room. (Annexure 2).	Vaccine controller
1.11	Ensure that the refrigerator/freezer/cold room is connected to an alternate source of power e.g a back-up generator or inverter to sustain electricity in the event of a power outages.	Vaccine controller
1.12	Ensure that activities 1.1 to 1.12 are completed before storing vaccines in the refrigerator /freezer/cold room.	Vaccine controller
2	Preparation of Cooler Boxes/Passive Containers and Ice Packs	
2.1	Clean and disinfect cooler boxes/passive containers before and after use.	Vaccine controller
2.2	Store ice packs in the freezer for contingencies and use conditioned ice packs for transportation of the vaccines.	Vaccine controller

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ANNEXURES	Annexure 1: Process Flow Annexure 2: Temperature monitoring tool
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2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved


TRAINING REQUIRED	
<ul style="list-style-type: none"> • Training to be conducted post SOP sign-off and prior to the effective date as per above • Training to be provided 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: Process Flow

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Annexure 2: Temperature Monitoring Tool

District:							Health Facility:			
Month / Year:										
Equipment :							Fridge / Freezer Number			
Day	AM	°C	Alarm/OK	Duration	PM	°C	Alarm/OK	Duration	Initials	Action
1										
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