STANDARD OPERATING PROCEDURE – MANAGING OF NON-FUNCTIONAL REFRIGERATORS / FREEZERS

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Site Maintenance		
OBJECTIVE	- To provide guidance in situations where refrigerators, freezers or cold rooms become non-functional		
SCOPE	- Managing of non-functional refrigerators, freezers, and cold rooms		
COMPILED BY		**ORIGINAL DATE:**	
AUTHORISED BY			
DEFINITIONS	**Long Term Power Failures** means power failures with a duration of greater than 12 hours. **Medium Term Power Failures** means power failures with a duration of between three and 12 hours. **Primary distribution site** means a depot, sub-depot, wholesale pharmacy or distributor which stores and distributes vaccines to vaccination sites and does not provide vaccination services to clients. **Short Term Power Failures** means power failures with a duration of up to three hours. **Vaccines** means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations. **Vaccination site** 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. **Vaccinator** means a person who administers a COVID-19 vaccine to a client. **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 **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).		
ABBREVIATIONS	- N/A		
POLICIES, REFERENCES, SOURCE MATERIAL	- Provincial medicine supply management policy and/or supply chain prescripts (as applicable) - Cold chain and Immunisation Operations Manual 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
RELATED SOPs	- Preparation of cold chain equipment at primary distribution sites and vaccination sites - Receiving of bulk stock of vaccines - Distribution of vaccines
PRINCIPLES	1. Effective and efficient management of the cold chain is mandatory, and all persons involved in the storage, distribution and use of vaccines must be trained and supported to follow correct procedures. 2. Continuous temperature monitoring is required to ensure that vaccines are stored at the correct temperatures and cold chain equipment is performing within specification. 3. Non-functional refrigerators, freezers and cold rooms must be promptly identified. 4. The necessary steps must be immediately undertaken to transfer vaccines to a storage area that is functional and is compliant with the manufacturer's specifications. 5. The required cold chain equipment must be present at primary distribution sites, and at all vaccination sites that store and distribute vaccines. 6. Cold chain equipment may include refrigerators, freezers and/or cold rooms. 7. The cold chain equipment must be suitable for the type and quantity of vaccines to be stored at the site. 8. Cold rooms must be mapped, and the equipment must be maintained, validated, and calibrated. 9. WHO approved/compliant temperature recording devices must be used to continuously monitor the temperature of refrigerators and freezers. The use of dial thermometers or minimum/maximum thermometers is not recommended. 10. Robust systems and processes must be implemented, monitored, and evaluated on a daily, weekly, and monthly basis to ensure maintenance of the cold chain. 11. Frozen ice packs must always be available for placement in cooler boxes when refrigerators or freezers are not functional or during a power failure.
FUNCTIONAL ROLES AND RESPONSIBILITIES	- 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	- Refrigerators - Freezers - Frozen icepacks - Cooler Boxes
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	- Monitoring of temperatures
RECORD KEEPING	- Recording of temperatures - Any temperature excursions and action taken

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
1	**Refrigerator/freezer breakdowns**	
1.1	Remove vaccines from the non-functional refrigerator/freezer as soon as the warning system indicates that the refrigerator/freezer is not functioning.	Vaccine controller
1.2	If no alternative equivalent storage is available, place vaccines in a cooler box with conditioned ice packs for transportation to another primary distribution site or vaccination site with sufficient 2-8°C storage capacity.	Vaccine controller
1.3	Once COVID-19 vaccines have thawed they may not be frozen again and should therefore be placed in storage between 2-8°C. If a change of storage from -70 or -20°C to 2-8°C is required, the expiry date should be updated accordingly.	Vaccine controller
1.4	Report event to the relevant responsible pharmacist, or site manager at the vaccination site.	Vaccine controller
1.5	Complete Incident form. Mark effected vaccines “USE FIRST”	Vaccine controller
1.6	Request urgent repair/replacement of refrigerator.	Vaccine controller
1.7	Follow up repair/replacement of refrigerator.	Vaccine controller
2	**Short Term Power Failures**	
2.1	Ensure that the refrigerator door/freezer door is closed.	Vaccine controller
2.2	Continue storing vaccines in the refrigerator or freezer as per manufacturer's specifications.	Vaccine controller
2.3	Monitor the temperature during the period including minimum and maximum temperatures.	Vaccine controller
3	**Medium- and Long-Term Power Failures**	
3.1	Place vaccines in a cooler box with conditioned ice packs for transportation to another primary distribution site or vaccination site with sufficient 2-8°C storage capacity	Vaccine controller
3.2	Organise transport to another refrigerator at the primary distribution site or another vaccination site.	Vaccine controller
3.3	Once COVID-19 vaccines have thawed they may not be frozen again and should therefore be placed in storage between 2-8°C. If a change of storage from -70 or -20°C to 2-8°C is required, the expiry date should be updated accordingly	Vaccine controller
3.4	Report event to the relevant responsible pharmacist, or site manager at the vaccination site.	Vaccine controller
3.5	Complete Incident form. Mark effected vaccines “USE FIRST”.	Vaccine controller

4	**Return of Vaccine to Refrigerator Once Functional**	
4.1	Place vaccines in a cooler box with conditioned ice packs for transportation to another primary distribution site or vaccination site with sufficient 2-8°C storage capacity	Vaccine controller
4.2	Once Covid-19 vaccines have thawed they may not be frozen again and should therefore be placed in storage between 2-8°C. If a change of storage from -70 or -20°C to 2-8°C is required, the expiry date should be updated accordingly	Vaccine controller
4.3	Record the start date and time of the cold chain storage on the label or the carton when the vaccine is moved from the -70 or -20°C to 2-8°C. Use the date/month/year and hours: minutes format. **The original expiry date should be made unreadable**.	Vaccine controller
4.4	Update the expiry date as per manufacturers recommendations, mark the vaccine “USE FIRST”.	Vaccine controller
4.5	Place vaccines in the functional refrigerator.	Vaccine controller
5	**Develop a contingency plan, task lists and maintenance schedules**	
5.1	Develop a list of actions to be taken in case of a power failure, or of equipment malfunction. The list must answer the following questions: - Who to contact and in which sequence? - What to do if the main power supply is interrupted? - What to do if all powers supplies are down? - What to do if a refrigerator fails? - What to do if all the refrigerators fail?	Vaccine Controller
5.2	Develop a checklist of tasks that must be carried out (every day, every week and every month) by the various people according to their responsibilities and supervised by the cold chain responsible. The basic content must include: - Name of the person responsible for each task - Check the temperature. - Check the equipment is in good condition. - Clean the room and equipment. - Maintenance Actions - Check that the contingency plan is up to date	Vaccine Controller

health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Managing of Non-Functional Refrigerators/Freezers	Next Revision [REVISION DATE]

ANNEXURES	None

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 provided to relevant responsible parties after each SOP revision

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			