



Safe Use of Medication Refrigerator Procedure

1. GUIDING PRINCIPLES

Temperature-sensitive products (which include pharmaceuticals, clinical trials medicines and vaccines) require storage between +2°C and +8°C to ensure their viability and quality. [Department of Health Cold Chain Management guidance](#) and the [Vaccine Cold Chain Guidelines OD 0355/11](#) are aligned with the requirements of the National Safety and Quality Health Service Standard and meet recommendations outlined in the [National Vaccine Storage Guidelines – Strive for 5](#).

This procedure provides practical guidance for WACHS facilities to meet the requirements outlined in the related Operational Directive but also includes guidance on medication storage.

2. PROCEDURE

Purpose-built vaccine fridges that are connected to essential power are **strongly recommended**.

PHARMACY AND WARD LEVEL

- Medication fridges must have recorded daily temperature checks (unless the facility utilises a Building Maintenance System (BMS) with the individual fridge connected to this system).
- If the facility does have fridge temperature monitoring facilitated via a BMS, it is up to the individual site as to whether daily recording is required but nurses/midwives/ pharmacy must always remain aware of fridge temperatures when removing stock and act as appropriate.
- It is recommended that data loggers are used in all medication fridges that are not connected to a BMS.
 - In regions or hospitals where the BMS system is unreliable data loggers are to be utilised.
- Data from either the BMS or data loggers are to be reviewed once a week.
 - Wards – Nursing staff (including midwives) are responsible for the review and saving of weekly data logger readings. This may also be provided to the Pharmacy department based on regional / local requirements.
 - Pharmacy – Pharmacy staff are responsible for ensuring the review and saving of weekly data logger readings for fridges with the Pharmacy department.
- If transporting temperature sensitive medications between areas, the use of eskies, ice bricks and a temperature monitoring device is required if the product is going to be out the fridge for greater than 15 minutes. If transport time is less than 15 minutes, no additional packaging is required.
- The unit manager must ensure cleaning of the medication fridge in line with the [OD 0355/11](#).
- Only medications and diagnostic items as approved by the Chief Pharmacist are to be stored in the Medication fridges.

ENGINEERING

- Routine maintenance schedule of medication fridges by the engineering department is required.
- As fridges become defective, the replacement with purpose-built vaccine fridges is strongly recommended.
- An annual audit of the refrigeration temperature recording system for each individual fridge is required.

EQUIPMENT COORDINATOR / NURSE UNIT MANAGER

- An annual audit of the location, age and model of all medication fridges is recommended.
- Sites currently utilising domestic fridges should have a transition plan for the replacement of these fridges with purpose-built vaccine fridges.

TEMPERATURE ALARM

If the alarm on the temperature monitoring device sounds, attending staff (or delegate) are to:

- Check the medication fridge door is closed.
- Monitor the temperature to ensure the temperature is returning to within the appropriate temperature range then reset the fridge alarm.
- Relocate stock as appropriate to avoid a cold chain breach (as outlined below)
- Initiate the cold chain breach process if temperature and duration of excursion warrants it.
- Any temperature excursion to 0 degrees C, or below, should be treated as a cold chain breach due to the higher potential of stock damage.

COLD CHAIN BREACH

A cold chain breach (CCB) occurs when storage temperatures are outside the recommended temperature range for longer than 15 minutes (or if temperatures reach 0 degrees C or below).

Refer to Medication Fridge / Cold Chain Action Plan ([Appendix 1](#)).

3. DEFINITIONS

Purpose-built vaccine fridge	Specifically designed to store vaccines, and are the best-practice storage option for temperature-sensitive medicines and vaccines
Building Management System (BMS)	A centralised, electronic system, usually maintained by the Engineering Department that can potentially be used to monitor refrigeration networks.
Data logger	An electronic temperature recording device that can be downloaded to a computer to interrogate and store recorded temperature data. Data loggers should undergo routine maintenance as per Vaccine Cold Chain Guidelines OD 0355/11 .
Temperature monitoring device	Any proprietary device that can be utilised to indicate to the recipient of a package that the contents have remained within the specified temperature range.

4. ROLES AND RESPONSIBILITIES

All Staff

Adhere to the principles and aims of this procedure and ensure they understand how to maintain the cold chain requirements of temperature-sensitive medicines and vaccines.

Engineering Staff

Engineering staff are responsible for the overall maintenance of medication fridges and the BMS. This can be delegated to an appropriate contractor.

Nursing Staff

Nursing staff (including midwives) are responsible for the appropriate handling, storage and administration of refrigerated medications within their facility. They are responsible for ensuring the recording of daily temperature readings and the review and saving of weekly data logger readings. Nursing staff are responsible for appropriately responding to a fridge alarm and undertaking the medication alarm and cold chain breach process.

Medical Staff

Medical staff are responsible for appropriately responding to a fridge alarm and undertaking the medication alarm and cold chain breach process.

Pharmacy Staff

Pharmacy staff are responsible for the appropriate handling and storage of refrigerated medications within the Pharmacy. They are responsible for ensuring the review and saving of weekly data logger readings for fridges with the Pharmacy department. Pharmacy staff are responsible for appropriately responding to a fridge alarm and undertaking the medication alarm and cold chain breach process within the Pharmacy department.

5. COMPLIANCE

Depending on the circumstances, non-compliance with this procedure may constitute a breach of employment or contractual obligations, misconduct (under the Department of Health [Discipline Policy MP0127/20](#)), sexual harassment, discrimination, or some other contravention of the law.

Those who fail to comply with this procedure may face disciplinary action and, in serious cases, termination of their employment or engagement.

6. EVALUATION

Monitoring of compliance with this document is to be carried out by the Nurse Unit Manager at a ward level.

7. REFERENCES

[Department of Health Cold Chain Management guidance](#)
[Operational Directive 0355/11: Vaccine Cold Chain Guidelines](#)
[National Vaccine Storage Guidelines 'Strive for 5'](#)

8. APPENDICES

Appendix 1 [Medication Fridge / Cold Chain Action Plan](#)

9. RELATED DOCUMENTS

[Department of Health Cold Chain Management guidance](#)
[Operation Directive 0355/11: Vaccine Cold Chain Guidelines](#)
[National Vaccine Storage Guidelines 'Strive for 5'](#)

**This document can be made available in alternative formats
on request for a person with a disability**

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Appendix 1: Medication Refrigerator Cold Chain Action Plan

This Action Plan is a guide to help you manage medication fridges and alarms

Fridge	Actions	Outcomes
Audible Alarm Sounds	<ul style="list-style-type: none"> Examine fridge to determine the current fridge temperature. Examine fridge to determine cause of the alarm. Fix reversible causes (e.g. door open) Remain at fridge and monitor temperature to ensure it returns to the acceptable range (2°C – 8°C). 	Current fridge temperature is 0°C or less. Treat as a Cold Chain Breach. Quarantine all stock and contact the relevant parties.
		Data logger shows temperature excursion > 15 minutes. Save and print data logger graph. Treat as a Cold Chain Breach. Quarantine all stock and contact the relevant parties.
	<ul style="list-style-type: none"> For fridges not connected to a BMS – review the data logger to determine the duration of temperature excursion (if the alarm has occurred due to an unwitnessed event of unknown duration). If the alarm sounds in the course of general, witnessed use – e.g. restocking, and the known duration is < 15minutes the data logger does not need to be down loaded. 	BMS alarm not triggered OR data logger shows temperature excursion < 15 minutes. Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.
		BMS alarm not triggered OR data logger shows temperature excursion < 15 minutes. Reversible cause found and fridge back in temperature range. Reset min/max reading on fridge digital display.

WACHS Medication Refrigerator Cold Chain Action Plan

Fridge	Actions	Outcomes
<p>Fridge BMS Alarm Alert</p> <p>It is recommended that all BMS systems are set up with a minimum of two temperature alarms.</p> <p>The first alarm should be triggered when the fridge temperature has been outside of the acceptable temperature range (2°C – 8°C) for ≤ 7 minutes.</p> <p>The second alarm should be triggered when the fridge temperature has been outside of the acceptable temperature range (2°C – 8°C) for 15 minutes – this is a Cold Chain Breach.</p> <p>A third alarm should be considered.</p> <p>The “freeze” alarm should be triggered when the fridge temperature has been below 0°C – this is a Cold Chain Breach.</p>	<p>First Alarm (≤ 7 minutes).</p> <ul style="list-style-type: none"> Examine fridge to determine the current fridge temperature. Examine fridge to determine cause of the alarm. Fix reversible causes (e.g. door open) Remain at fridge and monitor temperature to ensure it returns to the acceptable range (2°C – 8°C). 	<p>Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.</p>
	<p>Second Alarm (> 15 minutes).</p> <ul style="list-style-type: none"> Cold Chain Breach. 	<p>Reversible cause found and fridge back in temperature range. Reset min/max reading on fridge (for fridges not connected to the BMS).</p>
	<p>‘Freeze’ Alarm (<0°C).</p> <ul style="list-style-type: none"> Cold Chain Breach. 	<p>Treat as a Cold Chain Breach. Quarantine all stock and contact the relevant parties.</p> <p>Treat as a Cold Chain Breach. Quarantine all stock and contact the relevant parties.</p>

WACHS Medication Refrigerator Cold Chain Action Plan

Fridge	Actions	Outcomes
<p>Cold Chain Breach</p>	<p>Actions</p> <p>Quarantine all stock. Remove stock from the affected fridge and place in an alternative medication fridge – maintain at refrigerated temperatures. Clearly separate quarantined stock and label “DO NOT USE – QUARANTINED. Date: ___/___/___ . By: _____”</p> <p>Do not discard any vaccines or medications at this time. Contact the relevant staff for advice.</p> <p>Inform ward nursing staff including Nurse Unit Manager of Cold Chain Breach.</p> <p>Report the Cold Chain Breach via DATIX.</p>	<p>Pharmacy Stock; Contact the Pharmacy Department. Provide Pharmacy with the data logger graph or BMS graph of the temperature excursion. Provide the Pharmacy Department with a list of affected products. Follow advice provided by the Pharmacist.</p> <hr/> <p>Vaccines; Contact the Immunisation Coordinator. Provide Immunisation Coordinator with the data logger graph or BMS graph of the temperature excursion. Provide the Immunisation Coordinator with a list of affected vaccines. Follow advice provided by the Immunisation Coordinator.</p>

WACHS Medication Refrigerator Cold Chain Action Plan

Documentation to be completed in the event of a Cold Chain Breach.

Date: _____ Hospital: _____ Ward: _____	Details of alarm; <input type="checkbox"/> Audible <input type="checkbox"/> BMS – First Alarm <input type="checkbox"/> BMS – Second Alarm <input type="checkbox"/> BMS – “Freeze” Alarm Outcome; <input type="checkbox"/> Returned to temperature range <input type="checkbox"/> Stock moved to alternative fridge <input type="checkbox"/> Cold Chain Breach	Staff Contacted / Informed; <input type="checkbox"/> Engineering <input type="checkbox"/> Pharmacy <input type="checkbox"/> Immunisation Coordinator <input type="checkbox"/> Nurse Unit Manager
		Final Outcome;

Completed by:

Name: _____ Signature: _____ Contact Number: _____

Nurse/ Midwife / Doctor / Pharmacist (circle)