Organisation name Site or unit		STANDARD OPERATING PROCEDURE **Medicine Storage and Temperature Monitoring**	
Document ID	PHM-SOP-001-EN	**Version**	1.2
Status	To be issued	**Issue date**	
Review date		**Replaces**	1.0
Owner	Clinical lead for this procedure	**Approved by**	
Classification	Internal	**Applies to**	All clinical areas
Signature			

This is a controlled copy when approved. Printed copies are uncontrolled; check the version against the document register before use.

Contents

1. Purpose 2
2. Scope 2
3. Definitions 2
4. Background 2
5. Responsibilities 3
6. Materials and equipment 3
7. Safety and exceptions 3
8. Procedure 3
9. Worked examples 4
10. Decision points 5
11. Escalation 5
12. Monitoring and compliance 6
13. Records 6
14. Training and competence 6
15. Related documents 6
16. References 6
17. Change history 6
Abbreviations 1
Annex A. Temperature audit record 7

Abbreviations

Abbreviation	Meaning
PHM-FRM-001	Temperature log (form)

Abbreviation	Meaning
TRS 961	WHO Technical Report Series No. 961
SOP	Standard operating procedure

Key points

- Store each medicine and vaccine at the temperature on its product label, in the dedicated medicine fridge.
- Read the fridge thermometer twice each working day and record the reading on PHM-FRM-001.
- If a reading is out of range, quarantine the stock at once and tell the pharmacist. Never use quarantined stock until the pharmacist releases it in writing.
- The pharmacist reviews the log every week and signs it.
- Stop and get help straight away if a reading is out of range and the pharmacist cannot be reached, or the fridge fails with no working backup.

1. Purpose

To keep medicines and vaccines at the temperature their manufacturers require, so that they remain safe and effective, and to act at once when that temperature is not maintained. A medicine that has been too warm or too cold can lose strength without any visible sign, so the check and the response must be routine. This SOP supports the cold-chain requirements of the facility's medicines policy.

2. Scope

Element	Coverage
Who	All staff who store, check, prepare or supply medicines and vaccines.
Where	All medicine and vaccine storage, including ward fridges, clinic fridges, emergency kits and transport boxes.
When	At all times; daily readings; on any fault; and on delivery of stock.
Not covered	Controlled medicines security, which follows the controlled drugs procedure.

3. Definitions

Term	Meaning
Storage temperature	The range on the product label or the manufacturer's data sheet. Many refrigerated medicines and vaccines are stored between 2 and 8 °C, but the label governs.
Excursion	Any period during which the temperature is outside the stated range.
Quarantine	Stock set aside, clearly labelled, and not used or supplied until released in writing by the pharmacist.
Time-sensitive product	A medicine whose safety or effect depends on being kept within its stated temperature range [1].

4. Background

The World Health Organization's model guidance on the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series No. 961, Annex 9, 2011) sets out the principal requirements for the safe storage and distribution of such products, and recognises that local legislation takes precedence [1].

This SOP applies those principles through the product labels and a daily check, so that an excursion is found and acted on the same day.

5. Responsibilities

Role	Responsibility
Clinical director	Approves this SOP and receives the quarterly temperature report.
Pharmacist	Assesses excursions, releases or destroys quarantined stock, reviews the log weekly and signs it.
Ward or unit manager	Ensures fridges, thermometers, the backup arrangement and the staff training are in place.
Nurse or staff member on duty	Reads the thermometer, records it, and quarantines stock out of range.
Estates team	Repairs faults and maintains the fridge and its alarm.

6. Materials and equipment

Item	Requirement
Dedicated medicine fridge	Used for medicines only, with a calibrated thermometer that shows the current and the minimum and maximum readings.
Temperature log PHM-FRM-001	The current approved form, with a column for the reading, the initials, and the action taken.
Quarantine label	Clearly marked, applied before the stock is moved out of the fridge.
Backup storage	Named for each unit, and checked as the fridge is.

7. Safety and exceptions

- Do not store food or drink in the medicine fridge. Do not store medicines in the door, where the temperature changes most when it is opened.
- Do not adjust the thermostat without the pharmacist’s approval.
- Where a fridge fails, move the stock to the backup storage named for the unit, record the move and the time, and call the estates team.

8. Procedure

Before you start

- Check that the thermometer is working and that the log is current for the day.
- Check the storage range for each product from its label, and keep the list of ranges with the fridge.

Step 1. Read and record

1. Read the thermometer at the start and the end of the working day, and record the reading on PHM-FRM-001 with the time and your initials.
2. Compare each reading with the range on the product label. A product with a narrower range than the fridge sets determines the action [1].
3. Reset the minimum and maximum thermometer after each reading, if the thermometer has that function.

Step 2. Act on an out-of-range reading

1. Quarantine the affected stock at once: label it, and move it to a quarantine area in the same fridge or the backup storage.
2. Tell the pharmacist immediately, and give the reading, the time, and the minimum and maximum since the last check.
3. Do not use the stock until the pharmacist has assessed the excursion and released it in writing.

Step 3. Pharmacist assessment

1. The pharmacist decides, with the manufacturer’s data and the excursion record, whether the stock can be released or must be destroyed.
2. The decision, the reasons and the disposal or release record are kept with the log.

Step 4. Weekly review

1. The pharmacist reviews the log every week, checks that readings were made twice daily, and signs it.
2. Gaps, unusual readings, and repeated faults are reported to the ward or unit manager.

9. Worked examples

Situation	What to do
Morning reading is 9.4 °C on a fridge that holds insulin and vaccines stored at 2–8 °C.	Reading is out of range. Quarantine all stock that has a 2–8 °C range, label it, tell the pharmacist with the reading and the time. Check the fridge for an open door, a blocked air vent or a fault. Do not use the stock until the pharmacist releases it in writing.
The fridge is found at 1.5 °C after a power cut overnight.	The reading is below the 2–8 °C range for the products stored, so treat it as out of range. Quarantine, tell the pharmacist with the minimum reading, and the pharmacist assesses each product.
The thermometer reads 5 °C, but the log for the previous day is blank.	Record the current reading. Tell the pharmacist that the previous day’s readings were missed, so that the weekly review records the gap and its cause.

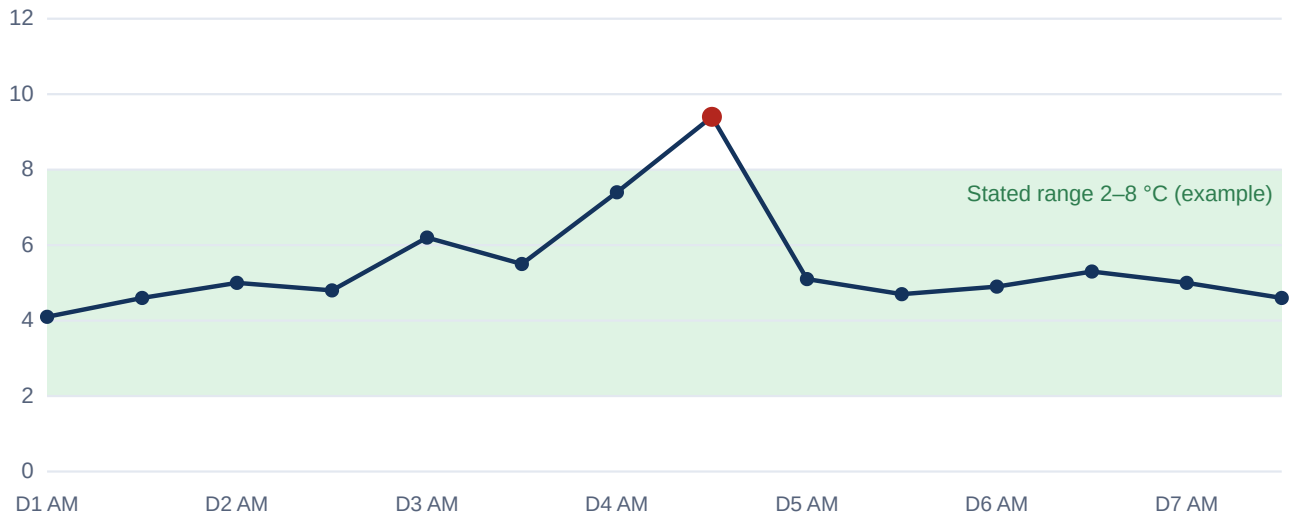


Figure 1. Example temperature record against the stated range

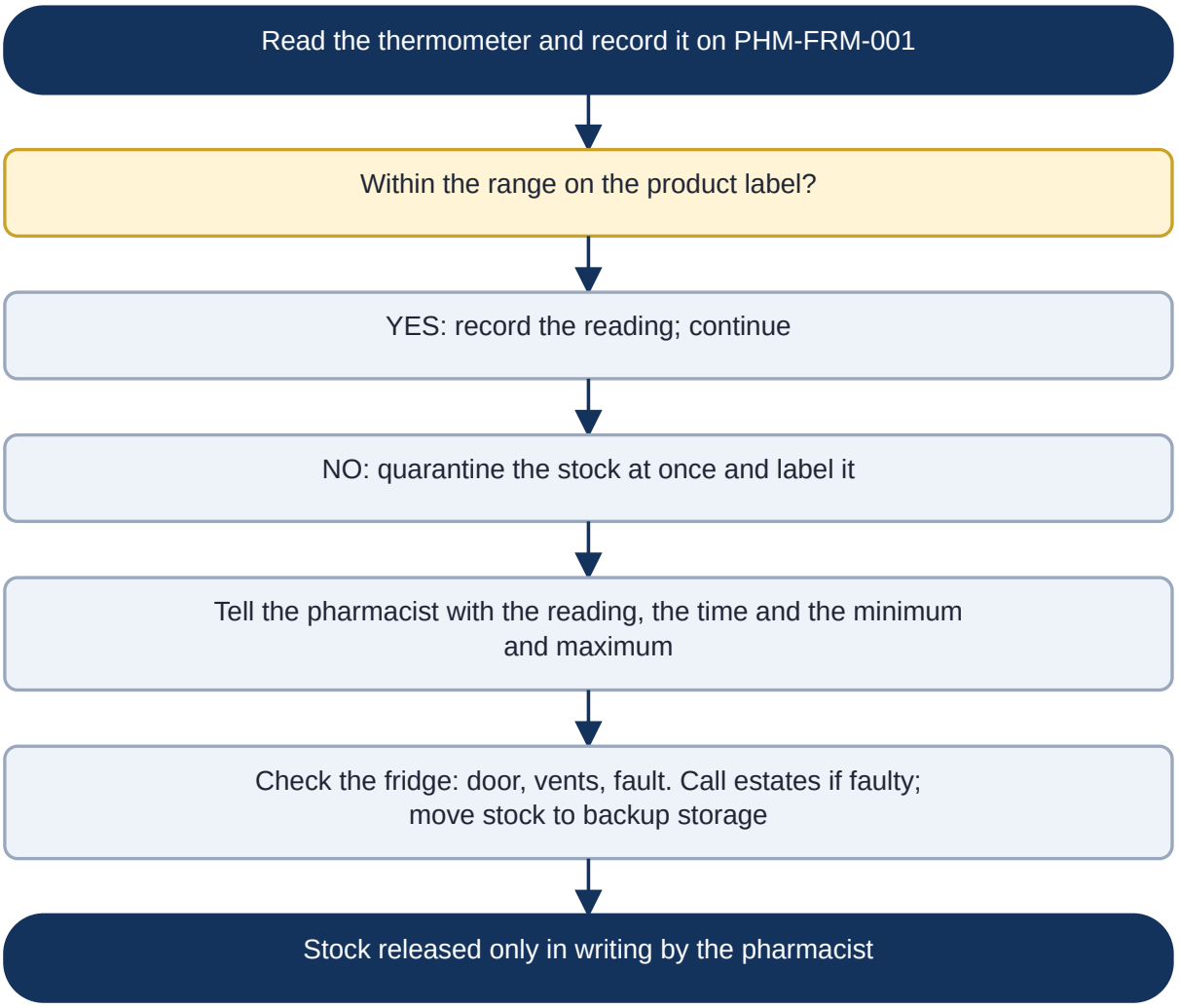


Figure 2. Response to a reading

10. Decision points

If	Then
Reading within range	Record it and continue.
Reading out of range	Quarantine, inform the pharmacist, and do not use the stock.
Fridge fault	Move stock to backup storage, record the move, and call the estates team.
Pharmacist cannot be reached and stock is out of range	Keep the stock quarantined; escalate to the clinician in charge.

11. Escalation

Event	Inform	Timescale
Out-of-range temperature	Pharmacist	Immediately
Fridge failure with no working backup	Clinician in charge, pharmacist and estates	Immediately

Event	Inform	Timescale
Stock used or supplied while quarantined	Pharmacist and risk team	Immediately; incident report within 24 hours

12. Monitoring and compliance

Indicator	Target	Method	Frequency	Owner
Readings recorded twice daily	100% of working days	Review of PHM-FRM-001	Weekly	Pharmacist
Out-of-range readings acted on the same day	100% of out-of-range readings	Review of log and incident reports	Monthly	Pharmacist

13. Records

Record	Kept in	Retention
Temperature log PHM-FRM-001	Unit file	As set by the institutional retention policy
Quarantine, assessment and release or disposal records	Pharmacy file	As set by the institutional retention policy

14. Training and competence

- **Induction:** reading the thermometer, using the minimum and maximum function, reading product ranges, quarantine, and escalation.
- **Annual update:** the response to a failed fridge, with a practical exercise.

15. Related documents

ID	Title	Relationship
STF-SOP-001-EN	Staff Credential Verification and Recheck	Staff authorised to handle medicines

16. References

1. World Health Organization. TRS 961, Annex 9: Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products. WHO Technical Report Series No. 961; 2011. Source read: the WHO publication page (scope). Specific temperature requirements must be confirmed from the full text before publication. Available from: https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

17. Change history

Version	Date	Summary of change	Approved by
1.0		First approved version.	ASF Expert Committee
1.2		Substantive revision: reading and minimum/maximum method, the narrower-range rule, excursion assessment by the pharmacist, fridge failure steps, worked examples and temperature chart.	

Annex A. Temperature audit record

Use this record for each audit session. Record one line per fridge for each day. Enter Y, N or NA as shown in the column heading.

Date	Fridge	Reading AM (within range Y / N)	Reading PM (within range Y / N)	Quarantined if out of range (Y / N / NA)	Pharmacist informed (Y / N / NA)	Pharmacist signed log weekly (Y / N)	Comment