# NHS_Grampian_faxlogoAppendix 1: Example: Refrigerator – Standard Operating Procedure (SOP) For Refrigerated Pharmaceutical Products (*customise as appropriate)*

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| --- | --- |
| **Practice/clinic name/site:** | XXX |
| **Responsible person:** | XXX |
| **Deputy:** | XXX |

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| SOP Number | 001 |
| SOP Title | Standard Operating Procedure for Refrigerated Pharmaceutical Products |
| Page(s) | 1 of 6 |
| Written by |  Signature |
| Approved by |  Signature |
| Date approved | xx.xx.xx |
| Review date | By xx.xx.xx (usually a maximum of 2 years) |

**Appliance Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Appliance identification | Appliance location | Use and limits | Fitness for purpose review |
|  |  | General refrigeration at +2°C to +8°C | Daily |
|  |  | Vaccine storage at +2°C to +8°C | Daily |

**Purpose:** To ensure the safe storage and handling of refrigerated pharmaceutical products.

**Scope:** This SOP applies to all departments/wards in NHS Grampian involved in the handling of refrigerated pharmaceutical products.

**Responsible Personnel:** Managers/Responsible persons should ensure that procedures/protocols are in place to ensure the correct storage of vaccines within their area of management and that staff have been appropriately trained in the importance of maintaining the cold chain and understand how to use the relevant equipment. The staff should be familiar with the procedure for the storage and stock rotation of refrigerated pharmaceutical products including, temperature recording in accordance with the **‘Policy** **for Handling Vaccines and Refrigerated Products For All Staff Working in NHS Grampian’.**

Every Department/Ward/clinic should have a designated registered nurse/health care professional and at least one deputy who has undertaken training and is overall responsible for overseeing the ordering, receipt, storage and monitoring of refrigerated pharmaceutical products.

**Information:**  All refrigerated pharmaceutical products must be stored in an approved pharmaceutical refrigerator, solely for the purpose of storing medicines and maintained within temperature range of +2oC to +8oC. Domestic refrigerators must not be used.

The refrigerator temperature must be monitored daily using a NHS Grampian approved maximum/minimum thermometer and recorded in the ‘Refrigerator Temperature Recording Logbook’.

**Storage of Refrigerated Pharmaceutical Products**

**Procedure**

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|  | ***Detail local department /clinic/ward process and staff responsible*** |
| 1. **The refrigerator must be locked at all times or sited in a secure room which must be locked when not occupied by a registered nurse/vaccinator.**
2. Ideally, the refrigerator should be directly wired (hard wired) to the mains supply to avoid accidentally being switched off. Where this is not possible apply a **‘Refrigerator – Do not Switch Off’** label to the plug. Consider if a ‘red’ socket, which will operate on generator in the event of a power failure is available.

Labels are available from your Department/Ward Pharmacy Technician/Pharmacy team.1. The refrigerator(s) should not be sited near a radiator or any other heat source.

There should be adequate space between compressor at the back of refrigerator and the wall to allow circulation of air. | *State location of refrigerator.***Pharmacy Team contact****Name:****Contact number:** |
| 1. An agreed list of products stored in the refrigerator should be available.
2. Detail ordering processes, who is responsible for checking and ordering stock, how orders and placed, how orders are received
3. The stock should be arranged systematically within the refrigerator ensuring:
* Effective stock rotation is practised and products with the shortest expiry date are used first.
* Medicines are in their original packaging.
* Adequate space between products and not touching the back or sides of the refrigerator to allow free flow of air.
* Medicines can be identified quickly.
* Medicines are not stored in solid/metal trays or in the plastic tray/basket at bottom of refrigerator
1. The refrigerator should not be more than two-thirds filled to capacity.
2. Ensure the temperature probe (green bottle) attached to the thermometer is **positioned** and secured in the centre of the refrigerator, i.e. middle of the middle shelf.
3. Food, drink and clinical specimens must never be stored in refrigerators used to store pharmaceutical products.
 | *Specify location of product list, e.g. front or top of fridge.**Specify ordering processes including responsible person**State when stock rotation occurs, e.g. when putting order away/on receiving an order from Pharmacy and staff responsible.**Specify shelf location of products, e.g. eye drops on top shelf, insulin’s on middle shelf.* |
| 1. Opening of the refrigerator door should be kept to a minimum. Should the door be open for an extended length of time and the alarm sounds, record reason in the ‘**Record of Possible Temperature Deviation and Actions Taken’** page of the Refrigerator Temperature Recording Logbook
 | *Staff responsible – details of who to report alarm to* |

**Monitoring of Storage Conditions and Temperature Recording**

**Information**

The refrigerator temperature must be monitored daily using the maximum/minimum thermometer to ensure the temperature range is between +2oC to +8oC and recorded in the **‘Temperature Recording and Checking Sheet’** of the ‘Refrigerator Temperature Recording Logbook’**.** At the start of each month, a new record sheet should be used for each appliance (a temperature log book is required for each separate appliance).

**Procedure**

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|  | ***Detail local department /ward process and staff responsible*** |
| 1. At an agreed time each day the refrigerator temperature must be checked as follows:
* Check the display screen of thermometer is showing ‘MIN-MAX’ If screen displays ‘LO-HI’ press mode button on front of thermometer to change to ‘MIN-MAX’
* Ensure the alarm on the thermometer is set at the ‘ON’ position
* Against the corresponding date line of the **‘Temperature Recording and Checking Sheet’**, enter the time and the actual, minimum and maximum temperature displayed on the thermometer screen
* If all temperatures are within range of +2oC to +8oC tick relevant column.

If the recorded temperatures are out with range, refer to the procedure, **‘Action to be taken when temperature out with range of +2oC to +8oC’** of this SOP below. * To clear readings press the memory clear button
* Tick relevant column for ‘Memory Cleared’.
* Sign for completing temperature recordings.
 | *State agreed time daily temperature recordings are checked and staff responsible.**Departments/clinics not operating 7 days a week specify any days temperature recordings will not be checked e.g. sat/sun**State location of logbook.**Staff responsible –staff completing daily temperature check.* |
| 1. At the end of every month, the responsible person must review all entries then date and sign for the completion of the monthly checks detailed in the **‘Refrigerator Temperature Recording Logbook’**  for the following:
* Expiry date check.
* Thermometer alarm settings check - refer to - **Standard Operating Procedure for Maximum / Minimum thermometer (Model No. 10368)**
* Recordings for month reviewed
 | *Staff responsible – registered nurse/health care professional completing checks.**Specify location of ‘***Standard Operating Procedure for Maximum/Minimum thermometer (Model No. 10368)***Recordings for end of month review should be signed by designated registered nurse/health care professional who has overall responsibility.*  |
| 1. Completed ‘Refrigerator Temperature Recording Logbooks’ must be kept for 25 years in a safe secure location within department/ward.
 | *State secure location.*  |

**Action to be taken when temperature out with range of +2oC to +8oC.**

**Information**

In all cases where the temperature has gone out with range of +2oC to +8oC, follow the flowchart **‘NHS Grampian** **Refrigerator Temperature Readings Procedure’** affixed to the refrigerator. If any part of the entry is out of range, then the person recording should try to identify any reason that could explain the discrepancy and act in accordance with agreed ward/clinic/area/room SOP for vaccine storage and handling. The flow chart should be referred to.

**All temperature deviations must be dealt with as soon as they are identified**.

**Procedure**

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|  | ***Detail local department /ward process and staff responsible*** |
| 1. If there is an explanation for temperature going out with range within the AMBER flow, e.g. cleaning refrigerator, short power cut (3 hours or less), document the following:
* Date
* Time
* Actual temperature
* Reason

in the ‘**Record of Possible Temperature Deviation and Actions Taken’** sheet.**N.B:** The exception to this is Lorazepam Injection – Lorazepam Injection is temperature sensitive and must be moved to another pharmaceutical refrigerator known to be working properly (if available) as soon as any temperature excursion occurs. Contact Vaccine Services for advice on the suitability of use if exposed to temperature out with +2oC to +8oC.1. Monitor the refrigerator temperature until it returns within range of +2oC to +8oC and document the time this happens along with the actual temperature on the **Record of Possible Temperature Deviation and Actions Taken’** sheet
 | *The**responsible person should be informed immediately to deal with temperature excursion. – Specify who to report to**State location of flowchart* *Incidents should be discussed with the appropriate team, e.g. vaccine clinic coordinator/ward or community hospital pharmacy technicians/pharmacotherapy teams as agreed within each Health and Social Care Partnership/area.* **Pharmacy Team contact****Name:****Contact number:***The vaccine services technicians at ARI should be contacted regarding complex incidents or those involving red flow***Vaccine Services - 01224 (5)53223** |
| 1. If a reason for the temperature deviation cannot be accounted for, **check:**
* Refrigerator door is closed properly
* Refrigerator not switched off at the plug
* The refrigerator is not overstocked
* There is adequate space between the back of the refrigerator and wall.
* Temperature probe is in the correct position.
1. Follow the flowchart **‘NHS Grampian** **Refrigerator Temperature Readings Procedure’** If directed to the red flow, contact Vaccine Services as soon as possible for further advice.
2. Quarantine all stock immediately and label ‘**Do not use’**. Store in an alternative pharmaceutical refrigerator known to be working properly and clearly set apart from **other stock.....,** as detailed on page 2 of the **‘Refrigerator Temperature Recording Logbook’** - see

Quarantined stock must not be used until authorisation has been given by Pharmacy.1. If the refrigerator is suspected to be faulty it must not be used to store pharmaceutical products.

Contact Vaccine Services who will advise and decide on a course of action. A note should be placed on the refrigerator - **Faulty Refrigerator – Do not Use. Use refrigerator in..........................**The Vaccine Service may decide to send out Temperature Loggers. These are portable electronically programmed devices to accurately record refrigerator temperatures. Instructions will be sent with the loggers on their use and when/how to return to Pharmacy ARI. The refrigerator must not be used to store pharmaceutical products until Vaccine Services have informed you if and when the refrigerator can or cannot be used.1. Record in the **‘Record of Possible Temperature Deviation and Actions Taken’** -
* Date
* Time
* Actual, minimum and maximum temperature
* Reason if known
* Action taken,
* Expert source consulted
* Advice given
1. Continue to monitor the refrigerator temperature. If it returns within range of +2oC to +8oC, document the time this happens along with the actual temperature.
 | *The appropriate person within the department/practice should be notified immediately.* *Incidents should be discussed with the appropriate team, e.g. vaccine clinic coordinator/ward or community hospital pharmacy technicians/pharmacotherapy teams as agreed within each Health and Social Care Partnership/area.* **Pharmacy Team contact****Name:****Contact number:***The vaccine services technicians at ARI should be contacted regarding complex incidents or those involving red flow***Vaccine Services - 01224 (5)53223***State location of alternative pharmaceutical refrigerator* *Specify local procedure if equipment or power failure occurs* |
| 1. After investigation your Pharmacist, Senior Vaccine Services Technician or Medicines Information will inform you of the outcome and further instruction.
2. Where **authorisation** has been given to return any quarantined stock to the refrigerator for use, refer to **‘Refrigerator Temperature Recording Logbook’** for further instructions. Stock must be marked with a red dot.
3. Quarantined stock that has been deemed unsuitable for use - return to Pharmacy ARI for destruction on advice from Vaccine Services.
 | *Specify process in place to inform staff.* |

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| **NB: All staff using this SOP must read and show understanding of the Policy for Handling Vaccines and Refrigerated Pharmaceutical Products For All Staff Working in NHS Grampian.** |