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<th><strong>NAME OF DOCUMENT</strong></th>
<th>Medicine: Management of Refrigerated Storage of Medicines and Vaccines in Clinical Areas</th>
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| **EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR** | Kim Brookes  
SESLHD Director of Clinical Governance |
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| **KEY TERMS** | Refrigerator, refrigerated storage, temperature monitoring, thermometer, medicines, vaccines |
| **SUMMARY** | This procedure provides clear processes for monitoring and managing refrigerated medication storage in clinical areas. |
1. POLICY STATEMENT
This procedure outlines the processes to be followed by staff working in clinical areas to ensure that medicines and vaccines are stored within the correct temperature conditions.

NSW Ministry of Health Policy - PD2013_043 Medication Handling in NSW Public Health Facilities - Section 6.1 outlines medication storage requirements in patient care areas. The nurse in charge of a ward or clinical area must ensure medicines are stored within the correct temperature conditions.

NSW Ministry of Health Policy - PD2017_014 Vaccine Storage and Cold Chain Management provides mandatory requirements specifically in relation to the storage and management of vaccines.

National Vaccine Storage Guidelines – Strive for 5 and Immunisation Provider Kit provide information and advice specifically for vaccine storage management. These principles are relevant for other medicines requiring refrigerated storage.

2. BACKGROUND
To maintain the integrity and efficacy of medicines requiring refrigerated storage, they must be stored at all times within the range of 2.0 to 8.0 degrees Celsius (+2°C to +8°C). Any deviation outside of this temperature range requires investigation and remedial action. Further advice on storage conditions for each particular medicine can be obtained via the facility Pharmacy Department.

To ensure appropriate temperature conditions for such medicines, each ward or clinical area must have a medicine-dedicated*, appropriately sized, monitored and maintained refrigerator, purpose built for medicine storage and on an essential power supply. It is preferable the monitoring triggers an audible alarm in the event of temperature excursions, and must record minimum, maximum and current temperature.

All refrigerators used for vaccine storage must have an audible alarm set to activate when a temperature deviation occurs. Local risk assessments should determine the need for each refrigerator to have a back to base alarm. All vaccine refrigerators must also have continuous data logging.

2.1 Definitions

Medicines include all drugs, medications, diagnostics agents, vaccines and complementary medicines.

Refrigerated storage requires temperatures within the range 2.0 and 8.0 degrees Celsius (+2°C to +8°C).

Medicines requiring refrigerated storage are those that are labelled “Refrigerate” or “Store between 2°C and 8°C”.
Temperature deviations for refrigerated storage are either less than 2.0 degrees Celsius or greater than 8.0 degrees Celsius.

Medicine-dedicated means used only for medicines – no food or pathology permitted.

3. RESPONSIBILITIES

3.1 The Registered Nurse or Midwife in Charge of the ward will:

- Undertake responsibility for storage requirements of all medicines within the ward, including ensuring suitable refrigeration is available and functioning to temperature requirements of medicines and vaccines
- Undertake, escalate and document appropriate remedial action when temperature deviations occur.

3.2 The Nurse/Midwifery Unit Manager (NUM/MUM) (or delegate) will:

- Monitor and record compliance with refrigerated medicine storage requirements at least once daily (on each day the clinical area is open) or at least twice daily wherever vaccines are stored
- Where fitted, download and save data logger reports weekly and after any identified temperature deviations
- Be responsible for cold chain management of vaccines that are stored in the clinical area(s) they manage
- Ensure staff undertaking components of this procedure have read and are familiar with the procedure
- Ensure staff involved in the handling of vaccines have undertaken the HETI module on Vaccine Storage and Cold Chain Management: http://www.heti.nsw.gov.au/Courses/Vaccine-Storage-and-ColdChain-Management/
- Ensure that the current temperature monitoring form is located within proximity of the refrigerator, readily visible and accessible
- Ensure an information guide is displayed on every refrigerator storing vaccines for advice following a cold chain breach
- Plan and record maintenance of refrigerators used for storage of medicines, including external annual refrigeration mechanic/engineering review
- Plan and record maintenance of all cold chain equipment as per PD2017_014 (section 3)
- Report refrigerated medicine storage records and any remedial actions to the facility Director of Nursing (or delegate) every two months
- Ensure annual audits of vaccine storage within the clinical area they manage are attended.
3.3 The Director of Nursing (or delegate) will:

- Receive and review records of compliance with refrigerated medicine storage from all clinical areas within the facility
- Monitor and ensure compliance with this procedure throughout the facility, including ensuring appropriate training of nursing staff
- Maintain all related records and ensure availability of those records for accreditation purposes.

3.4 The Director of Pharmacy (or delegate) will:

- Ensure medicines supplied to clinical areas requiring refrigerated storage are clearly and appropriately labelled “Refrigerate” and/or “Store between 2°C and 8°C”
- Provide advice on the usability of medicines affected by temperature deviation
- Be responsible for cold chain management of vaccines that are stored in the pharmacy, including during their transportation to clinical areas
- Ensure pharmacy staff undertaking components of this procedure have read and are familiar with the procedure
- Ensure pharmacy staff involved in the handling of vaccines have undertaken the HETI module on Vaccine Storage and Cold Chain Management: http://www.heti.nsw.gov.au/Courses/Vaccine-Storage-and-ColdChain-Management/
- Ensure login and password details for vaccine ordering are only accessible by approved staff members.

3.5 All staff involved in management of refrigerated medicines (including storage, administration and cold chain management) will:

- Undertake appropriate training during their orientation
- Whenever accessing such medicines conduct visual checks of the temperature and report any variances
- Maintain the cold chain of vaccines at any time they are removed from a refrigerator
- Minimise refrigerator door opening to prevent the temperature rising above 8.0°C.
4. PROCEDURE FOR MONITORING OF REFRIGERATORS

4.1 Step 1: Check Temperature
Conduct temperature readings within the refrigerator on at least a daily basis (twice daily where vaccines are stored) at approximately the same time using an appropriate Min/Max thermometer or inbuilt device. For services that do not operate seven (7) days a week, the temperature should be checked immediately prior to the service closing and on re-opening of the service, before administration of any medications.

4.2 Step 2: Record Temperature
Record the temperature readings (current, maximum and minimum) and identity of the recorder on the relevant temperature monitoring form:
- For general medication fridges use SESLHD District Form F209 - Refrigerated Storage Temperature Monitoring Form
- For refrigerators where vaccines are stored use NSW Health Vaccine Refrigerator Temperature Chart (NH700227) (order via the Stream Direct Catalogue as a POD print item).

4.3 Step 3: Assess Temperature
Assess and record whether temperature range is acceptable for refrigerated storage (2.0°C to 8.0°C).

4.4 Step 4a: Action Required – Business Hours (Monday to Friday 8:00am- 5:00pm)
- In the event of any temperature deviation during business hours, notify the Nurse in Charge of the ward (or Director of Pharmacy for pharmacy refrigerators)
- Alternate refrigerated storage arrangements must be arranged immediately. The alternate storage must also be a medicine dedicated refrigerator. The medicines should be quarantined and marked “Not for Use” until advice is received regarding their stability
- The affected refrigerator must be taped shut and marked “Not in Use”
- Ensure there is communication to all staff in that area that no one is to use the affected refrigerator or medications
- If the refrigerator has a data logger download and review the data logging report.
- Consult pharmacy for assistance and advice regarding the affected medicines
- If vaccines supplied by the NSW Vaccine Centre are affected*, contact the Public Health Unit (PHU) (Phone: 9382 8333) and obtain advice from the Immunisation Coordinator
- Contact Maintenance/Engineering Department regarding refrigerator function
- Do not return medications to the affected refrigerator until it is functioning and stabilised within the required temperature range
- On the advice of pharmacy and/or PHU, discard any medications that have had their stability compromised
• Action taken must be recorded on the temperature monitoring form
• Where medications are wasted or patients may have received inactive medications as a result of the cold-chain breach, an incident report should be completed in IIMS.

Step 4b: Action Required – After-Hours / Weekends
• In the event of any temperature deviation after-hours, on weekends or public holidays, the staff member in charge of the clinical area should inform the after-hours supervisor of the issue
• Alternate refrigerated storage arrangements must be arranged immediately. The alternate storage must also be a medicine dedicated refrigerator. The medicines should be quarantined and marked “Not for Use” until advice is received regarding their stability
• The affected refrigerator must be taped shut and marked “Not in Use”
• Ensure there is communication to all staff in that area that no one is to use the affected refrigerator or medications
• If vaccines supplied by the NSW Vaccine Centre are affected*, contact the PHU (Phone: 9382 8333) and obtain advice from the Immunisation Coordinator
• A message should be left for the NUM/MUM to follow up on the issue on the next business day
• The NUM/MUM is responsible for ensuring the other actions (under step 4a) above are followed at the earliest opportunity.

* Refer to delivery records to determine whether the vaccines were obtained from NSW Vaccine Centre (see section 5)

4.5 Step 5: Inspect and Reset
• Undertake a visual and physical inspection to ensure refrigerator is clean, function is unhindered, with medicine safely stored
• Ensure medicine is stored safely and with appropriate circulation space
• Any required action should be documented on the temperature monitoring form
• Reset thermometer.

4.6 Step 6: Continuous Data Logs
• All refrigerators used to store vaccines must be continuously data logged. This may be either by use of a portable or built-in data logger, or a back to base data logger according to local risk assessment
• The data logging report must be downloaded and reviewed by the NUM/MUM (or delegate) weekly and following any identified deviations from the acceptable range (excludes fluctuations up to 12°C for less than 15 minutes to allow for stocktaking or re-stocking).
• Where the clinical area is accessed less frequently than weekly, the data logger report should be downloaded before each clinic, prior to the administration of any vaccines. A back-to-base alarm must be in use in these areas
Where temperature deviations are identified, the process described in section 4.4 should be followed.

Instructions on how to download the data logging report must be secured to the refrigerator.

A back-up hard copy of the data logging graphs should be stored centrally in a file by the NUM/MUM, or for pharmacy refrigerators, the Director of Pharmacy.

4.7 Step 7: Maintenance

Inspection of all medication-dedicated refrigerators and cold chain monitoring equipment must be undertaken annually by the Maintenance/Engineering Department.

5. PROCEDURE FOR DELIVERY AND RECEIPT OF VACCINES

5.1 Receipt of vaccines from NSW Vaccine Centre

On receipt of a vaccine supply from the NSW Vaccine Centre the following should be recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart:

- date received,
- vaccines received,
- quantity,
- batch numbers and
- the Cold Chain Monitor reading.

Any temperature deviation should be reported to the NSW Vaccine Centre immediately and stock quarantined until advice is received.

5.2 Delivery of vaccines from pharmacy to clinical areas

- Vaccines should be transported from pharmacy to wards in a cooler (Esky) accompanied by a battery operated minimum/maximum thermometer.
- The time from leaving the pharmacy refrigerator to reaching the ward refrigerator should be less than 15 minutes.
- Vaccines deliveries must be accepted by the Nurse in Charge of the ward (or delegate) and the stock must be transferred immediately from the cooler to the ward refrigerator on receipt.
- The nurse/midwife receiving the vaccines must record the following on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart: date received, vaccines received, quantity, batch numbers and the thermometer reading.
- Any identified temperature deviations should be reported to the Director of Pharmacy (or delegate) immediately.

6. DOCUMENTATION

- SESLHD District Form F209 - Refrigerated Storage Temperature Monitoring Form
- NSW Health Vaccine Refrigerator Temperature Chart (NH700227)
- Maintain documentation records for two years.
7. AUDIT
Temperature monitoring forms and, for vaccine fridges, data logging reports and delivery records must be submitted to the Director of Nursing (or delegate) every two months. A collated facility report must be provided to the facility medication safety committee annually.

Vaccine storage self-audits are to be conducted using the Quality Audit Reporting System (QARS) system (or where QARs is not used, manually using the NSW Health Cold Chain Audit Tool) at least every 12 months and results must be submitted to the facility medication safety committee for review.

Staff education records should be audited annually, preferably at the same time as the self-storage audits, and should be reviewed by the facility medication safety committee.

Compliance with this procedure will also be assessed as part of SESLHD Medication Safety Walk Arounds.

8. REFERENCES
- NSW Ministry of Health Policy - PD2013_043 Medication Handling in NSW Public Health Facilities
- NSW Ministry of Health Policy - PD2017_014 Vaccine Storage and Cold Chain Management
- National Safety and Quality Health Service Standard (Medication Safety Standard 4.10.3)
- Immunisation Provider Kit NSW Ministry of Health 2013
- NSW Health Cold Chain Audit Tool

9. REVISION AND APPROVAL HISTORY

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<tr>
<th>Date</th>
<th>Revision No.</th>
<th>Author and Approval</th>
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<tr>
<td>Aug 2013</td>
<td>Draft 0.1</td>
<td>Julie Thompson. D&amp;QUMC Coordinator.</td>
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<tr>
<td>Sept 2013</td>
<td>Draft 0.2</td>
<td>Revisions from review of Draft 0.1 by: D&amp;QUMC Pharmacy Directors Subcommittee SESLHD Policy Officer Nursing and Midwifery Directorate – initial consultation Approved by D&amp;QUMC to release to Draft for Comment 12/09/2013</td>
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<td>Julie Thompson. D&amp;QUMC Coordinator. Incorporating feedback from Draft for Comment Process Approved by D&amp;QUMC 14/11/2013</td>
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<td>Hyperlink to NSW Ministry of Health ‘Medication Handling in Public</td>
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<tr>
<td>Feb 2015</td>
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<td>Revision at request of Clinical Governance Unit</td>
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<tr>
<td>March 2015</td>
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<td>Approved by D&amp;QUMC</td>
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<td>SESLHD District Form F209 - Refrigerated Storage Temperature Monitoring Form updated. Link to form inserted into SESLHDPR/300</td>
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<td>Katie Kerr, QUM Lead Pharmacist Revision to incorporate requirements of PD2017_014</td>
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<td>4.2</td>
<td>Revisions from review of Draft 4.1 by: Pharmacy Directors Subcommittee, Pharmacy Departments, SESLHD Policy Officer</td>
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