SESLHD PROCEDURE COVER SHEET

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SUMMARY	This procedure provides clear processes for monitoring and managing refrigerated medication storage in clinical areas.

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

Medicine: Management of Refrigerated Storage of Medicines and Vaccines in Clinical Areas

SESLHDPR/300

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 Health Policy Directive PD2022_032 - Medication Handling - Section 5.4.1 outlines medication storage requirements in patient care areas. The registered nurse/midwife in charge of a ward or clinical area is responsible for ensuring that medications are stored in accordance with all legal requirements and that the correct provisions are met in relation to temperature control and that temperature storage is consistent with the specifications on the manufacturer's pack.

NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management provides mandatory requirements for the, monitoring and management of vaccines including procedures for managing cold chain breaches.

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 (+2º to +8º C).

Any deviation outside of this temperature range requires investigation and remedial action to be completed by the clinical area. Further advice on storage conditions for each medicine can be obtained via the facility Pharmacy Department or NUM.

To ensure appropriate temperature conditions for medicines requiring refrigeration, each ward or clinical area **MUST** have a medicine-dedicated*, appropriately sized, monitored and maintained refrigerator, purpose built for medicine and/or vaccine storage and on an essential power supply.

For non-vaccine refrigerated medicines, 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 containing refrigerators **MUST** also have continuous data logging. The data logging report is downloaded and reviewed at least weekly.

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:

- **DAILY or TWICE DAILY:** 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.
- **WEEKLY:** For vaccine-containing refrigerators (and where fitted, non-vaccine containing refrigerators), download and save data logger reports weekly and after any identified temperature deviations.
- **MONTHLY:** Before storing centrally, check and sign off;
    - SESLHD District Form – Refrigerated Medicine Storage Temperature Monitoring Form (NHSIS1191) at the end of each month for non-vaccine containing refrigerators
    - NSW Health Vaccine Refrigerator Temperature Chart (NH700227) at the end of each fortnight for vaccine containing refrigerators
- Be responsible for cold chain management of vaccines that are stored in the clinical area(s) they manage.
- **EVERY TWO MONTHS:** Report refrigerated medicine storage records and any remedial actions to the facility Director of Nursing (or delegate) every two months.
- **AT LEAST ANNUALLY:** Conduct a self-audit of vaccine storage within the clinical area they manage at least annually in March each year as per NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management: Section 6. Vaccine Management and Storage Self Audit.
- Plan and record maintenance of refrigerators used for storage of medicines, including external annual refrigeration mechanic/engineering review.

- 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.
- 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. An example is available in NSW Health Policy

Directive PD2020_028 - Vaccine Storage and Cold Chain Management: Section 13.1 Vaccine refrigerator and Cold Chain Breach Protocol.

- Plan and record maintenance of all cold chain equipment as per in NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management: Section 3. Equipment.

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 at least every 2 months.
- 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.

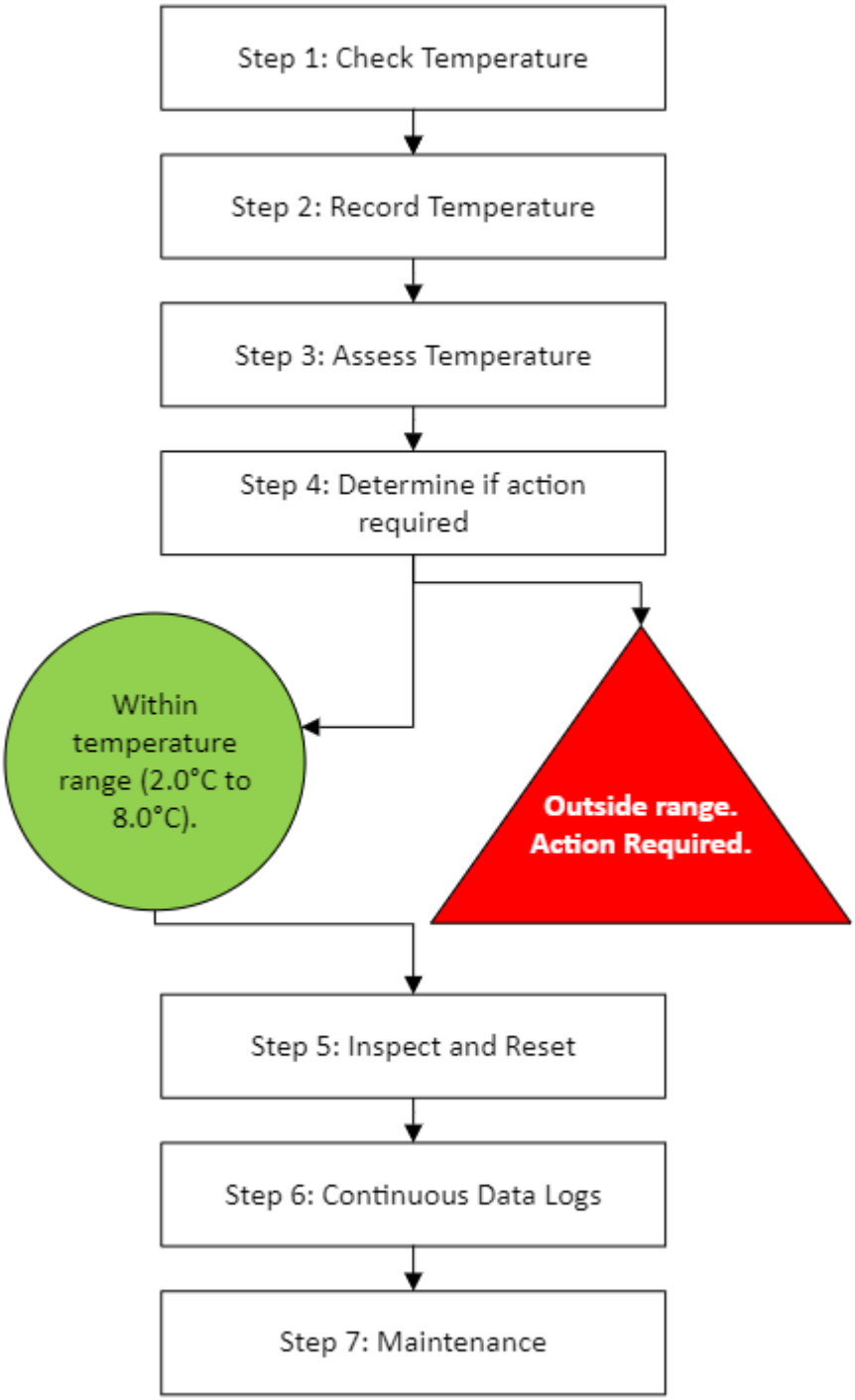
3.4 The Director of Pharmacy (or delegate) will:

- 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 or guidance on obtaining information 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.
- 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. This may include undertaking the HETI module on Vaccine Storage and Cold Chain Management.
- 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



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.

Step 2: Record Temperature

Record the temperature readings (current, maximum and minimum) and identity of the recorder on the relevant temperature monitoring form *ordered via the Print Catalogue as a POD item.*

- For non-vaccine refrigerators use SESLHD District Form – Refrigerated Medicine Storage Temperature Monitoring Form (NHSIS1191)
- For vaccine containing refrigerators use NSW Health Vaccine Refrigerator Temperature Chart (NH700227)

Step 3: Assess Temperature

Assess and record whether temperature range is acceptable for refrigerated storage (2.0°C to 8.0°C).

Step 4a: Action Required for Cold Chain Breach

Business Hours (Monday to Friday 8:00am- 5:00pm)

- In the event of any temperature deviation (*excludes fluctuations up to 12°C for less than 15 minutes to allow for stocktaking or re-stocking*) 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 “Do not 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.

If vaccines;

- Complete the Cold Chain Breach and Vaccine Wastage Reporting Form.
- **Contact the Public Health Unit (PHU) (Phone: 9382 8333) and obtain advice from the Immunisation Coordinator.** The PHU will require the cold chain breach reporting form, data logging and corresponding **twice** daily temperature readings to assess the breach.

If non-vaccine medicines; consult pharmacy for assistance and advice regarding the affected medicines.

- **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**

Do not discard any medicines until advice has been provided by the local PHU for vaccines, or pharmacy for other medicines.

- Action taken **MUST** be recorded on the NSW Health Vaccine Refrigerator Temperature Chart, for refrigerators storing vaccines, or on the SESLHD District Form – Refrigerated Medicine Storage Temperature Monitoring Form (NHSIS1191) for non-vaccine refrigerators.
- Where medications are wasted or a patient may have received inactive medicine as a result of the cold-chain breach, an incident report **MUST** be completed in IMS+.
    - If a cold chain breach is identified after patients have been vaccinated with potentially compromised vaccine(s) refer to NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management: Section 5.2 Patient Recall and Revaccination.
    - If a patient has received a potentially inactive non-vaccine medicine, contact the treating medical team.

Step 4b: Action Required for Cold Chain Breach

After-Hours / Weekends

- In the event of any temperature deviation after-hours, on weekends or public holidays, (*excludes fluctuations up to 12ºC for less than 15 minutes to allow for stocktaking or re-stocking*) 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;

- Complete the Cold Chain Breach and Vaccine Wastage Reporting Form.
- **Contact the Public Health Unit (PHU) (Phone: 9382 8333) and obtain advice from the Immunisation Coordinator.** The PHU will require the cold chain breach reporting form, data logging and corresponding **twice** daily temperature readings to assess the breach.

- **A message MUST 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.

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 the minimum / maximum temperature recorder.

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.
- 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 Step 4 **MUST** 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 **MUST** be stored centrally in a file by the NUM/MUM, or for pharmacy refrigerators, the Director of Pharmacy.

Step 7: Maintenance

- Inspection of all medication-dedicated refrigerators and cold chain monitoring equipment **MUST** be undertaken annually by the Maintenance/Engineering Department. This **MUST** be recorded on either the SESLHD District Form – Refrigerated Medicine Storage Temperature Monitoring Form (NHSIS1191) or the NSW Health Vaccine Refrigerator Temperature Chart (NH700227).

5. PROCEDURE FOR DELIVERY AND RECEIPT OF VACCINES

5.1 Receipt of vaccines from NSW Vaccine Centre*

- NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management
- On receipt of a vaccine supply from the NSW Vaccine Centre the following **MUST** be recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart: vaccine delivery date, time, cold chain monitoring (CCM) reading and staff initial. A record of the following is also recommended: vaccines received, quantity, and batch numbers.
- If a cold chain breach has been identified following a vaccine delivery from the NSW Vaccine Centre, the vaccines **MUST** be quarantined in a functioning refrigerator with a 'DO NOT USE' sign and the breach reported to the NSW Vaccine Centre on 1300 656 132.

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

5.2 Delivery of vaccines from pharmacy to clinical areas

- Vaccines **MUST** be transported from pharmacy to wards in a monitored cooler (Esky®) using a battery-operated minimum/maximum thermometer or data logger.
- The person who transfers the vaccine is responsible for ensuring the cooler is packed appropriately, the temperature of the cooler is recorded during transfer and at arrival to the ward. Vaccine temperatures can be recorded on the 'Vaccine Cooler Temperature Chart'.
- 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 medicine-dedicated*, vaccine-appropriate refrigerator on receipt.
- The nurse/midwife receiving the vaccines **MUST** record their receipt and that the cold chain was maintained during transfer 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 **MUST** be reported to the Director of Pharmacy (or delegate) immediately.

6. DOCUMENTATION

- SESLHD District Form – Refrigerated Medicine Storage Temperature Monitoring Form (NHSIS1191)
- 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 National Vaccine Storage Guidelines 'Strive for 5', Appendix 2 – Vaccine Storage Self Audit) 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 Health Policy Directive PD2022_032 - Medication Handling
- NSW Health Policy Directive PD2020_028 - Vaccine Storage and Cold Chain Management
- National Safety and Quality Health Service Standard 2nd Edition, Australian Commission on Safety and Quality in Health Care (Medication Safety Standard 4.14)
- National Vaccine Storage Guidelines – Strive for 5 3rd Edition, Commonwealth of Australia 2019
- Cold Chain Toolkit for Immunisation Providers August 2020, NSW Health
- Vaccine storage and cold chain management NSW Health
- Safe Vaccine Storage Checklist NSW Health

9. VERSION AND APPROVAL HISTORY

Date	Version No.	Author and approval notes
Aug 2013	Draft 0.1	Julie Thompson. D&QUMC Coordinator.
Sept 2013	Draft 0.2	Revisions from review of Draft 0.1 by: D&QUMC Pharmacy Directors Subcommittee SESLHD Policy Officer Nursing and Midwifery Directorate – initial consultation Approved by D&QUMC to release to Draft for Comment 12/09/2013
Oct 2013	Draft 0.3	Julie Thompson. D&QUMC Coordinator. Incorporating feedback from Draft for Comment Process Approved by D&QUMC 14/11/2013
Nov 2013	Draft 0.3	Final Draft submitted for CQC approval.
Jan 2014	1	Hyperlink to NSW Ministry of Health 'Medication Handling in Public Health Facilities' PD2013_043 has been updated.
Feb 2015	2	Revision at request of Clinical Governance Unit
March 2015	2	Approved by D&QUMC
September 2015	2	SESLHD District Form F209 - Refrigerated Storage Temperature Monitoring Form updated. Link to form inserted into SESLHDPR/300
June 2017	3	Revision to include information on a Cold Chain Breach after hours, on weekends or public holidays and the Strive for 5 Vaccine Fridge Temperature Chart.
August 2017	4.1	Katie Kerr, QUM Lead Pharmacist Revision to incorporate requirements of PD2017_014
November 2017	4.2	Revisions from review of Draft 4.1 by: Pharmacy Directors Subcommittee, Pharmacy Departments, SESLHD Policy Officer
November 2017	4.2	Processed by Executive Services prior to submission to DQUM for endorsement.

December 2017	4.2	Approved by Drug and Quality Use of Medicines Committee
December 2017	4.2	Approved by Clinical and Quality Council
August 2021	5.1	Review by Erica Wales, QUM Lead Pharmacist Draft for comment period. Revision to incorporate requirements of PD2020_028 and feedback from Draft for Comment Process.
September 2021	5.2	Final version approved by Executive Sponsor. To be tabled at QUMC for endorsement.
October 2021	5.2	Approved at Quality Use of Medicines Committee.
12 August 2024	5.3	Review by Erica Wales, QUM Lead Pharmacist Minor amendments and reformatting. Approved at SESLHD Drug and Therapeutics Committee.