

Maintaining Cold Chain of Medicines Policy

This policy describes the requirements, processes and equipment for maintaining the cold chain of medicines

| | | |
|---|--|-------------------|
| Key Words: | Cold chain, medicines, fridge, refrigerator, thermometer, vaccines | |
| Version: | 6 | |
| Adopted by: | Quality Forum | |
| Date Adopted: | 19 June 2018 | |
| Name of Author: | Tejas Khatau | |
| Name of responsible Committee: | Medicines Management Committee | |
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| Target audience: | Any staff required to handle medicines requiring cold storage | |
| Type of Policy | Clinical √ | Non-clinical √ |
| Which Relevant CQC Fundamental Standards? | S4 – Medicines Management | |

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Version Control and Summary of Changes

| Version number | Date | Comments (description change and amendments) |
|-----------------------|-----------------------------|---|
| Version 1, Draft1 | 25/01/2010 | Adapted from Policy and Procedure for Maintaining Vaccine Cold Chain for staff employed by Leicestershire County and Rutland PCT |
| Version 1, Draft 2 | February 2010 | Changes made following comments from Teresa Scott (Child Health Operational Manager), Shelley Jacques (Clinical Governance Operations Lead, Adults) |
| Version 1, Draft 3 | 25 th March 2010 | Correct reference to the Incident reporting policy and sharps policy. |
| Version 2 | January – March 2012 | Policy reformatted to LPT standard and harmonised. Comments received from Policy Group on 14/3/2012 |
| Version 3 | March 2015 | Minor changes to section 5.4 and 5.6. Appendix 3 (staff signature sheet) removed in line with other policies. |
| Version 4 | February 2018 | Minor changes in sections 4.6, 4.7 and 4.10 |
| Version 5 | November 2020 | Minor changes to section 4.3 and 4.6. |
| Version 6 | November 2023 | Minor changes to 4.7 and 4.10. Footer added. Reference updated. |

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Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area.

This applies to all the activities for which LPT is responsible, including policy development and review.

Due Regard

LPT must have **due regard** to the aims of eliminating discrimination and promoting equality when policies are being developed (**see section 2 of the template for further information**)

Definitions that apply to this Policy

| | |
|-------------------|--|
| COSHH | Control of Substances Hazardous to Health |
| NPSA | National Patient Safety Agency |
| POM | Prescription Only Medicines |
| MHRA | Medicine and Health Care Products Regulatory Agency |
| Due Regard | Having due regard for advancing equality involves: <ul style="list-style-type: none">• Removing or minimising disadvantages suffered by people due to their protected characteristics.• Taking steps to meet the needs of people from protected groups where these are different from the needs of other people.• Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low. |

1.0. Purpose of the Policy

This policy stipulates the process, procedures and equipment required to ensure that medicines requiring cold storage are managed appropriately.

This policy applies to outcome 9 of the Care Quality Commission which asks that the organisation has clear procedures for medicines handling that include safe storage.

2.0. Summary and Key Points

In order to maintain safety, efficacy and manufacturer's expiry, certain medicines are required to be stored between 2-8°C at all times.

Failure to ensure appropriate storage can result in loss of NHS money and large scale recalls as the efficacy of the medicine cannot be guaranteed.

This policy applies to all medicines that require storage between 2-8°C.

This policy stipulates the process, procedures and equipment required to ensure that medicines requiring cold storage are managed appropriately.

3.0. Introduction

In order to ensure safety, efficacy and manufacturer's expiry date, the temperature range of certain medicines need to be maintained between 2-8°C during every stage of the medicines trail (e.g. storage, transport, packaging). This is often referred to as "maintaining the cold chain." If the cold chain is broken (i.e. if the medicines become too hot or too cold at any time), such medicines may lose their effectiveness quickly or become potentially dangerous. This also leads to waste of NHS money as they have to be disposed.

In addition to requiring a cold chain, many of these medicines are also Prescription Only Medicines (POM) and therefore need to be stored securely.

National Patient Safety Agency (NPSA) Rapid Response Report 008 identified a number of incidents related to vaccine cold storage. Themes identified from these reports included: delay in storage of vaccines (especially after delivery); storage at wrong temperature; fridge switched off (in error) or broken; power cut or fridge door left open; no temperature monitoring; inadequate or missing equipment; and inappropriate use of domestic fridges.

4.0 Maintaining Cold Chain of Medicines

The general principals of maintaining security and cold chain are detailed below.

It is good practice to have locally written and approved procedures for all activities concerning medicines. Such procedures should specify what should be done and by whom.

4.1 Ordering and Monitoring of Stock

Ordering and monitoring of stock levels must be carried out by authorised person(s).

Care must be taken to order the correct quantity. Some medicines present as single dose units whilst others may come as multiple packs or doses. Ordering excess amounts will make it difficult to house if refrigerator storage space is restricted. Each service area should have a stock list with desired quantities. Such stock lists should be reviewed at least annually.

Full documentation of all orders placed must be kept for at least 2 years.

It is good practice to carry out and document regular stock checks of the physical quantities against that recorded.

4.2 Receipt of Stock

Receipt of stock must be carried out by authorised person(s).

Staff must ensure that they check the following before signing for the medicines:

- Check the medicines and quantity received against the original order, dispatch note or invoice for any discrepancies;
- Check for any leakage or damage;
- Check that any required security seals are still intact;
- There is no reason to suspect that the cold chain has been disrupted

Medicines must be refrigerated immediately on receipt.

Stock with the longest expiry date must be put at the back. This ensures good stock rotation and prevents medicines from expiring.

All invoices or delivery notes for the receipt of stock medicines must be kept for at least 6 years after the end of the financial year to which they relate.

4.3 Refrigerator

Medicines requiring storage between 2-8°C must be stored in specialised medical refrigerators. These are generally of higher specification, lockable and may be equipped with an internal fan.

Ordinary domestic refrigerators should not be used for the day to day storage of medicines.

Annual servicing of refrigerators is desirable but the precise arrangements should be decided locally. Services that store vast quantities of medicines in the refrigerator

may opt to stipulate that this is done annually to mitigate against unforeseen refrigerator malfunction and wastage. Equally, services will opt to do this to meet their regulatory obligation. Records of such service must be kept.

All refrigerators should be cleaned and disinfected regularly to prevent mould growth.

Refrigerators should not be situated near a radiator or any other heat source that could affect their working, and should be appropriately ventilated.

Opening of the refrigerator door should be kept to a minimum in order to maintain required temperature.

The mains electrical lead should ideally be fitted in a spur point, which should be fused but not switched. If an on/off switch exists, there must be clear signage to ensure that the power supply is not accidentally switched off.

Ice should not be allowed to build up within the refrigerator, as this reduces effectiveness. Refrigerators that develop ice build-up must be defrosted regularly. Records of defrosting and cleaning should be kept. Contingency plans should be made for defrosting activities.

4.4 Thermometer

The temperature inside the refrigerator must be monitored at least once daily (or every working day that the area is occupied) with a maximum–minimum thermometer. Digital thermometers are the most reliable. The service can opt to use the integrated refrigerator thermometer or an external one.

Thermometers must be reset and replaced according to the manufacturer's guidance.

Temperatures must be documented on a chart. An example can be found in appendix 4.

The records should be readily accessible for easy reference and retained for one year.

Consideration should be given to servicing and calibrating thermometers to an appropriate standard annually to ensure that they are working to an expected level of accuracy. Note that this would be an essential requirement for a service holding a wholesaler dealer's license. Records of such service must be kept.

4.5 Storage and Security

Many medicines requiring cold storage and all vaccines are prescription only medicines, therefore they need to be stored securely, especially when not in use. Medicines must be stored in a locked refrigerator. The refrigerator must be located inside a lockable room which is not directly accessible by the public.

Keys to refrigerator must be kept on the designated person during normal operating hours. The keys must be locked in a draw or safe outside of working hours.

Medicines must be stored in their original container so that they retain their batch number and expiry date. The packaging also protects the product against light.

Medicines must not be stored in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator.

Sufficient space should be allowed in the refrigerator so that air can circulate freely and items can be easily removed.

Food, drink and clinical specimens must never be stored in the same refrigerator as medicines.

Regular expiry date checks must be carried out and documented.

4.6 Transport by Community Staff

Medicines requiring cold chain should be transported in validated cool bags to maintain the temperature conditions. Community staff must transport medicines in their original packaging, out of sight from the public (e.g. in the boot of the car or glove compartment) and take it to the patient for administration as soon as possible. Staff must ensure that they carry only the required quantity of medicines based on their perceived usage. Regular temperature monitoring, using a portable digital thermometer, must be carried out and documented. A locally approved procedure needs to be in place to cover all activities, including the return of surplus vaccines to a refrigerator.

Some medicines can remain potent and safe outside the cold chain for a given period of time. The precise details vary depending on the product, manufacturer and maximum temperature exposure so it is essential this is ascertained first. Every effort should be made to maintain the cold chain during transportation, however, if permissible, and necessary, staff can carry the medicines without a validated cool bag or outside the cold chain for short journeys (this also allows enough time for the medicine to warm up which reduces discomfort from an intra-muscular injection). The decision to do this must be made at an appropriately senior service level with consultation with pharmacy in order to mitigate risks. Staff must ensure that they are aware of how long the medicine can remain outside the cold chain, administer it within this time frame and carry a thermometer to ensure the maximum specified temperature or time period isn't breached.

4.7 Packing and Transport (for distribution to another provider/service)

Validated rigid cool boxes should be used to reduce risk of damage and ice packs from a recognised medical supply company should be used to maintain the cold chain. Individual manufacturers' instructions should be strictly adhered to.

A validation exercise must be done to ensure current provisions maintain the medicines within the required temperature range for the whole duration of the journey with additional contingency built in in case of unexpected delays.

Cool boxes must be prepared as late as possible before departure to minimise time medicines spend out of the refrigerator. Alternatively, cool boxes can be packed with medicines in advance and stored in the refrigerator if space allows (it will still need ice packs placing as per local SOP once taken out of the refrigerator).

Medicines must be kept in the original packaging. Bubble wrap (or similar insulation material) must be placed around ice packs in order to prevent direct contact with the medicines.

Sufficient space should be left in the cool box to allow air to circulate freely and items to be easily removed.

If reproducible validation has been carried out and the packing methodology can be assured, the temperature in the cool box need not be monitored regularly throughout its journey. The decision should be taken locally based on temperature sensitivity of the medicines, quantity being transported, staffing, length of the journey and any potential delays. It is good practice to have the evidence for this decision to be recorded in a risk assessment that is annually reviewed. However, minimum and maximum readings should be recorded at the end of the journey to demonstrate that the cold chain remains intact.

The opening of the cool box must be limited to ensure correct temperature is maintained.

When supplying medicines to another service, a delivery note must be supplied detailing:

- Name of medicine, strength and formulation being transported;
- Quantity;
- Batch number and expiry date;
- Destination;
- Signature of recipient;
- Minimum and maximum temperature at the end of delivery.

4.8 Spillages

Refer to Policy for Control of Substances Hazardous to Health (COSHH) for further information.

Staff must wear gloves when cleaning such spillages. Additional personal protective equipment such as aprons and face masks may be required depending on the nature of the medicine and manufacturer's recommendations. Spillages must be cleared up quickly using absorbent paper towels.

Spillages on skin should be washed with soap and water. Spillages coming into contact with the eyes should be washed with sterile sodium chloride solution 0.9% and immediate medical advice sought. When seeking such advice, it is helpful to know the name of the medicine.

Any waste created from cleaning spillages must be sent for incineration.

4.9 Disposal

All reconstituted and opened single and multi-dose medicine vials must be disposed of in an approved sharps bin if not used within the recommended time period. Expired medicines must be disposed in the same manner.

Temporary closure on the sharps bin must be used where available. Sharps bins which are two thirds full must be replaced. Refer to Infection Prevention and Control Policy for the Management of Sharps and Exposure to Blood Borne Viruses in Community Health Services, Inpatient Facilities and primary Care.

4.10 Disruption of Cold Chain

Medicines can remain safe and effective if stored outside of the cold chain for a given period of time. There can be a number of reasons why a cold chain is breached, ranging from a broken down refrigerator, power failure through to medicines being accepted after delivery and left outside. Regardless of the reason, medicines requiring cold chain can be immediately placed back in the (working) refrigerator but clearly marked and segregated so that they are not inadvertently used. If unsure, advice should be sought from pharmacy before using the medicine. Once information is ascertained and the medicine is suitable to use, it must be clearly marked and the expiry date stated if different from the manufacturer's expiry. This is so that these products are used as soon as possible. Any subsequent breach of the cold chain occurring for these medicines may have a cumulative effective which could affect their stability and efficacy. Often, data is lacking on stability of products that have had more than one temperature breach, requiring them to be disposed.

It is important to note that disruption of the cold chain will render the medicine "off label" as it has been stored outside of the manufacturer's recommendations.

In the event of disruption to the cold chain due to refrigerator breakdown/power failure, prompt immediate action needs to be taken followed by longer term considerations.

Prompt Immediate Action:

- Check the plug and power supply to the refrigerator in case it has been switched off or disconnected by mistake;

- Check other electrical appliances sharing the same power supply to ascertain if the failure is isolated to the refrigerator only or a more widespread problem;
- Check the minimum and maximum temperature inside the refrigerator and try to ascertain approximately how long it has been outside of the range. If this is difficult to establish, the safest approach is to look at the last time when the refrigerator temperature was recorded as being within range and assume that the period of time following this record till when the disruption of cold chain was discovered is the time period of disruption of cold chain;
- Immediately pack all the medicines in the affected refrigerator into transparent bag(s), stick a label to say “cold chain disrupted – do not use until further advice” along with the date, time and person’s name;
- Place all medicines in another working refrigerator;
- Inform the line manager or another designated person so that repairs to the refrigerator can be carried out as soon as possible;
- Contact the individual companies or pharmacy for advice on what to do with the medicines;
- Ascertain when the medicines are next required and immediately order replacement stock if needed.
- Complete an electronic incident form.

Once the refrigerator has been fixed and is working normally, ensure that the temperature within the refrigerator returns to between 2-8°C before using it.

Longer term considerations will focus on the cause(s) of the disruption and how this can be prevented in the future.

Services that keep large quantities of medicines must give due consideration to business continuity.

5.0 Duties within the Organisation

5.1 The Trust Board has a legal responsibility for Trust policies and for ensuring that they are carried out effectively.

5.2 Trust Board Sub-committees have the responsibility for ratifying policies and protocols.

5.3 Divisional Directors and Heads of Service are responsible for ensuring there are appropriate resources provided within their service area to implement and adhere to the policy.

5.4 Managers and Team leaders will be responsible for:

- Ensuring this policy is implemented in their area of responsibility.
- Ensuring that their staff are appropriately trained in line with the requirements of this policy;

5.5 Responsibility of Staff:

- It is the responsibility of the individual staff who manage such medicines to ensure that they follow the procedure described in this policy and additional local guidance.

6.0 Training

There is no training requirement identified within this policy. Individual services must ensure staff are trained to their local SOP.

7.0 Monitoring Compliance and Effectiveness

| Ref | Minimum Requirements | Evidence for Self-assessment | Process for Monitoring | Responsible Individual / Group | Frequency of monitoring |
|---------|----------------------|------------------------------|---------------------------------|--------------------------------|-------------------------|
| 4.3-4.5 | Full compliance | 4.3-4.5 | Part of Medicines Storage audit | Medicines Risk Reduction Group | Yearly |
| 4 | Full compliance | Whole of section 4 | Audit for Unit C18 | FYPC Group meeting | Yearly |
| 4 | Full compliance | Whole of section 4 | Inspection for Unit C18 | Responsible Person | On-going and regularly |
| 4 | Full compliance | Whole of section 4 | MHRA | MHRA | Every 2-3 years |

8.0 Standards/Performance Indicators

| TARGET/STANDARDS | KEY PERFORMANCE INDICATOR |
|---|---|
| Leicestershire Medicines Code and Care Quality Commission | Medicines are stored securely and at the correct temperature. Temperature is recorded and appropriate action taken if there is a deviation. |
| | |

9.0 References and Bibliography

Policy was drafted with reference to the following:

Immunisation Against Infectious Diseases – “The Green Book”; accessed from http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh_4097254

The Safe and Secure Handling of Medicines: A Team Approach; accessed from; <http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf>

Vaccine Cold Storage; NPSA Rapid Response Report 008; accessed from: <http://www.nrls.npsa.nhs.uk/resources/?entryid45=66111>

Leicestershire Medicines Code; accessed from: <https://www.areaprescribingcommitteeleicesterleicestershirerutland.nhs.uk/guidelines/secondary-care/medicines-code/>

Reporting and Management of Incidents Policy

Taylor, J. Recommendations on the Control and Monitoring of Storage and Transportation Temperatures of Medicinal Products; The Pharmaceutical Journal, volume 267, 2001, pp. 128-131.

Due Regard Screening Template

| Section 1 | | | |
|--|---|---|----------|
| Name of activity/proposal | | Maintaining cold chain of medicines | |
| Date Screening commenced | | 01/11/2023 | |
| Directorate / Service carrying out the assessment | | N/A | |
| Name and role of person undertaking this Due Regard (Equality Analysis) | | Tejas Khatau | |
| Give an overview of the aims, objectives and purpose of the proposal: | | | |
| AIMS: | | | |
| OBJECTIVES: | | | |
| PURPOSE: | | | |
| Section 2 | | | |
| Protected Characteristic | Could the proposal have a positive impact Yes or No (give details) | Could the proposal have a negative impact Yes or No (give details) | |
| Age | No | No | |
| Disability | No | No | |
| Gender reassignment | No | No | |
| Marriage & Civil Partnership | No | No | |
| Pregnancy & Maternity | No | No | |
| Race | No | No | |
| Religion and Belief | No | No | |
| Sex | No | No | |
| Sexual Orientation | No | No | |
| Other equality groups? | No | No | |
| Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please <u>tick</u> appropriate box below. | | | |
| High risk: Complete a full EIA starting click here to proceed to Part B | | Low risk: Go to Section 4. | X |
| Section 4 | | | |
| If this proposal is low risk please give evidence or justification for how you reached this decision: Following national best practice. Policy covers equipment and processes rather than people. | | | |

| | | | |
|--|--------------|-------------|------------|
| Signed by reviewer/assessor | Tejas Khatau | Date | 01/11/2023 |
| <i>Sign off that this proposal is low risk and does not require a full Equality Analysis</i> | | | |
| Head of Service Signed | | Date | |

Appendix 2

The NHS Constitution

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

| | |
|--|---|
| Shape its services around the needs and preferences of individual patients, their families and their carers | √ |
| Respond to different needs of different sectors of the population | √ |
| Work continuously to improve quality services and to minimise errors | √ |
| Support and value its staff | √ |
| Work together with others to ensure a seamless service for patients | √ |
| Help keep people healthy and work to reduce health inequalities | √ |
| Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance | √ |

Appendix 3

Stakeholders and Consultation

Key individuals involved in developing the document

| Name | Designation |
|---|---|
| City and County Health Services policies harmonised | Tejas Khatau (City Policy) Jenny Dowling (County Policy) |
| | |

Circulated to the following individuals for comment

| Name | Designation |
|---|-------------|
| Members of the LPT Medicines Management Group | |
| | |
| | |

If yes, what was the action?

Reviewed by: Date:.....

If the fridge temperature is outside of the stated range (+2°C and +8°C) then refer to Policy for Maintaining Cold Chain.

*taken from Royal Pharmaceutical Society of Great Britain

Appendix 5

Maintaining Cold Chain Audit Template

Name of Service Date.....

Name of Person Undertaking Audit

| Compliance Achieved? | | | | | |
|----------------------|---|--------------------------|--------------------------|--------------------------|----------|
| 1 | Ordering and Monitoring of Stock | Yes | No | N/A | Comments |
| 1.1 | Ordering and monitoring of stock levels carried out by authorised person(s) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.2 | Service has stock list with desired quantities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.3 | Stock list reviewed at least yearly | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.4 | Documentation of orders placed kept for 2 years | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.5 | Regular stock check is carried out and documented | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.6 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 1.7 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 2 | <i>Receipt of Stock</i> | Yes | No | N/A | Comments |
| 2.1 | Receipt of stock must be carried out by authorised person(s). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.2 | Staff check the following: | | | | |
| | medicines and quantity received against the original order or invoice | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | leakage or damage | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | any required security seals still in tact | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.3 | Medicines refrigerated immediately | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.4 | All invoices for receipt of stock medicines received must be kept for at least 6 years | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| | | | | | |
|-----|--|--------------------------|--------------------------|--------------------------|--|
| 2.5 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.6 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|-----------------------------|---|--------------------------|--------------------------|--------------------------|---------------------------------|
| 3 | <i>Refrigerator</i> | Yes | No | N/A | Comments |
| 3.1 | Specialised medical refrigerator used | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.2 | Refrigerator lockable | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.3 | Records of annual servicing as per manufacturer's instructions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.4 | Temperature mapping completed and satisfactory for each refrigerator | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.5 | Records of annual calibration of refrigerator thermometers to appropriate standard | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.6 | Temperature of refrigerator is monitored regularly | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.7 | Refrigerator situated away from heat source and well ventilated | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.8 | Opening of refrigerator door kept to a minimum | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.9 | Mains electrical lead fused but not switched | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Compliance required with either |
| | Main electrical lead with an on/off switch has clear signage indicating power supply is connected to refrigerator | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.10 | No ice build up | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.11 | Refrigerator defrosted regularly and records kept | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.12 | Contingency plans for defrosting activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.13 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.14 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|---|--------------------------|--------------------------|--------------------------|----------|
| 4 | <i>Portable Thermometer</i> | Yes | No | N/A | Comments |
| 4.1 | A digital minimum and maximum thermometer is used | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.2 | There is a 'master' calibrated thermometer which his less than 1 year old | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.3 | Thermometers calibrated annually against 'master' thermometer and records kept of such activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.4 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.5 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 5 | <i>Storage and Security</i> | Yes | No | N/A | Comments |
| 5.1 | Refrigerators are locked when not in use | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.2 | Refrigerators are located inside a lockable room which is not directly accessible by the public | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.3 | Medicines stored in their original packaging | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.4 | Medicines not stored in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.5 | Refrigerator not overfilled | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.6 | No food, drink or clinical specimens stored in the same refrigerator | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.7 | Keys to refrigerator kept on designated person during normal operating hours | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.8 | Keys locked in a draw or safe outside of working hours | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.9 | Regular expiry date checks carried out and documented | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| | | | | | |
|------|--|--------------------------|--------------------------|--------------------------|--|
| 5.10 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5.11 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 6 | <i>Transport</i> | Yes | No | N/A | Comments |
| 6.1 | Medicines are transported in validated cool boxes | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.2 | Cool boxes are packed in a consistent manner | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.3 | Medicines are kept in their original container | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.4 | Medicines are protected from coming into contact with ice packs | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.5 | Temperature in the cool box is monitored throughout the journey | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.6 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 6.7 | Other: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|---|--------------------------|--------------------------|--------------------------|----------|
| 7 | <i>Spillages and Disposal</i> | Yes | No | N/A | Comments |
| 7.1 | There is a locally written and agreed procedure describing how to deal with spillages | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 7.2 | Sharps bins are available for safe disposal of sharps | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|-----|----|-----|----------|
| 8 | <i>Disruption of Cold Chain and Emergency Plan</i> | Yes | No | N/A | Comments |
| | | | | | |

| | | | | | |
|-----|--|--------------------------|--------------------------|--------------------------|--|
| 8.1 | The emergency lighting is in working order | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 8.2 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 9 | <i>Pest Control</i> | Yes | No | N/A | Comments |
| 9.1 | Pest control measures have been implemented in the last year | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 10 | <i>Medicines Recall</i> | Yes | No | N/A | Comments |
| 10.1 | The medicines re-call systems have been tested in the last year | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 10.2 | There is a locally written and agreed procedure describing this activity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

| Compliance Achieved? | | | | | |
|----------------------|--|--------------------------|--------------------------|--------------------------|----------|
| 11 | <i>Education and Training</i> | Yes | No | N/A | Comments |
| 11.1 | Staff have had tailored training on medicines management in the last 3 years | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| 11.2 | Staff have read the most up-to-date SOP and signed the document | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

PRIVACY IMPACT ASSESSMENT SCREENING

| | | | |
|--|-------------------------------|--|-------------------|
| <p>Privacy impact assessment (PIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet individual’s expectations of privacy. The first step in the PIA process is identifying the need for an assessment.</p> <p>The following screening questions will help decide whether a PIA is necessary. Answering ‘yes’ to any of these questions is an indication that a PIA would be a useful exercise and requires senior management support, at this stage the Head of Data Privacy must be involved.</p> | | | |
| Name of Document: | | Maintaining Cold Chain of Medicines | |
| Completed by: | | Tejas Khatau | |
| Job title | Lead Pharmacist - FYPC | Date | 01/11/2023 |
| | | | Yes / No |
| 1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document. | | | No |
| 2. Will the process described in the document compel individuals to provide information about themselves? This is information in excess of what is required to carry out the process described within the document. | | | No |
| 3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document? | | | No |
| 4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used? | | | No |
| 5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics. | | | No |
| 6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them? | | | No |
| 7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private. | | | No |
| 8. Will the process require you to contact individuals in ways which they may find intrusive? | | | No |
| <p>If the answer to any of these questions is ‘Yes’ please contact the Head of Data Privacy Tel: 0116 2950997 Mobile: 07825 947786 Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, adoption n of a procedural document will not take place until approved by the Head of Data Privacy.</p> | | | |
| IG Manager approval name: | | | |
| Date of approval | | | |

Acknowledgement: Princess Alexandra Hospital NHS Trust