Humber Teaching
NHS Foundation Trust

STANDARD OPERATING PROCEDURE
COLD CHAIN OF IMMUNISATIONS BY THE OCCUPATIONAL HEALTH DEPARTMENT

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VALIDITY – all local SOPS should be accessed via the Trust Intranet to ensure the current version is used

CHANGE RECORD

Version	Date	Change details
1.0	25/08/17	New SOP
1.1	01/06/20	Updated supply and delivery information, added electronic storage of consent forms, updated electronic method of storing data logger information
1.2	July 2023	Reviewed. Removed reference to contracted supplier. Updated contact information. Updated Occupational Health Manager job title throughout. Approved at DTG (27 July 2023).

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1. INTRODUCTION

These procedures describe the standard operating procedures for the safe and secure handling of immunisations including; Ordering, Receipt, Storage, Stock Management, Distribution, Administration, Returns and Waste in accordance with the current Humber Teaching NHS Foundation Trust Safe and Secure Handling of Medicine Procedures (SSHMP) and the Department of Health and Social Care's 'Green Book'.

2. SCOPE

These procedures must be adhered to by all staff employed by the Trust, who are involved with immunisations and associated processes.

This includes the Occupational Health Team.

3. DUTIES AND RESPONSIBILITIES

The -Occupational Health Manager has overall responsibility for the effective implementation of these procedures.

The Occupational Health Team is responsible for completing any task delegated by the Occupational Health Manager in accordance with the SOP for the Occupational Health Department.

4. PROCEDURES

4.1. Ordering, Receipt and Checking of Vaccines

4.1.1. Order Process

The Occupational Health Manager, or a nominated member of the Occupational Health Team, is responsible for ordering vaccines via hnf-tr.pharmacyprocurement@nhs.net . MMR vaccine is ordered via Immform.

4.2. Check of Delivery Consignment

Please note: This is an inspection of the outer carton only.

Staff accepting the vaccine delivery consignment must check the following:

- The consignment appears to be in good condition and all boxes are sealed.
- There are no signs of leakage on the packaging.
- Each box delivered is addressed to the Occupational Health Department accepting the consignment.
- If a consignment is not expected, damaged or the delivery driver has not got identification inform the Occupational Health Manager immediately.
- The consignment note is to be returned to the pharmacy department
- The consignment must be checked (refer to section 4.3) and transferred immediately into the immunisation refrigerator(s).

4.3. Checking Vaccine Order

- Stock received should be checked and confirmed against the order form and invoice.

All vaccine deliveries must be checked as follows:

- Open the consignment and remove any paperwork.
- Check the supplier details and the receiver details on the delivery note.
- Check the delivery note against the order confirmation to ensure the order received corresponds with the order placed.
- Remove the stock from the delivery box and check the products match the delivery note (ensure the accuracy of the item, e.g. quantity, pack size, form, strength etc.)
- Check stock is in good condition.
- Tick against each line on the delivery note as the items are checked.
- For each product listed write down the batch number and expiry date on a vaccine label and attach to the delivery note (if not already recorded – vaccine labels available from Occupational Heath admin).
- Sign and date the delivery note – delivery notes must be kept for two years from the date of issue. Refer to section 4.5.4.
- The information must be inputted in to the Vaccine Stock Record. Refer to section 4.5.4.

4.3.1. Discrepancies/Damaged stock

If there is a discrepancy with the order, stock is visibly damaged or the innermost container has been compromised the effected stock must be quarantined awaiting a decision from Occupational Health Manager. Refer to section 4.4.

4.4. Quarantining Stock

- Contact the Occupational Health Manager to alert them of the need to quarantine.
- Segregate the quarantined stock. Quarantine the affected vaccines as follows:
  Orders delivered to the Occupational Health Department
  - Retain in the clear plastic bag in which the order was delivered.

  Following an Immunisation Session
  - Retain in a clear plastic bag.

  Current Stock held in immunisation refrigerator
  - Place the quarantined stock in clear plastic bag.
- Complete quarantine stock notice(s) Appendix 2 and attach to the relevant container or clear plastic bag holding the quarantined stock.
- **Please note**: One quarantine notice must be completed for each product quarantined.
- If the quarantined stock is to be stored in the immunisation refrigerator it must be stored in a clear plastic bag with a quarantine stock notice attached. Appendix 2.
- Empty clear plastic bags are housed in the Treatment Room.
- If the immunisation refrigerator needs to be quarantined attach an Immunisation Refrigerator Quarantine Notice to the refrigerator door. Appendix 3.
- Occupational Health Manager to take appropriate action and advise the team accordingly.
- Following assessment by the Occupational Health Manager any quarantined vaccines that are deemed unsuitable to be returned to stock, will be disposed of in accordance with the Trust's SSHMP, section 16.

4.5. Stock Management

4.5.1. Storage of received orders

- Checked stock must be stored in the designated immunisation refrigerator(s)
- All vaccines of the same type must be stored together.
- Vaccines with the shortest expiry dates must be stored so they are selected first.

4.5.2. Stock rotation

- Vaccines with the shortest expiry dates must be stored so they are selected first.

- Returned vaccines that have been assessed as appropriate for use must be used at the earliest opportunity. These returned vaccines will be identified by a red dot sticker.

4.5.3. Stock checks of the immunisation refrigerators

Stock checks should be carried out when an order is placed and the stock balance confirmed with the Vaccine Stock Record. Any discrepancies must be reported to the Occupational Health Manager

4.5.4. Completion of Vaccine Stock Record

The Vaccine Stock Record accounts for vaccine activity. The information required can be obtained from the delivery note or the Vaccine Porter Cold Chain Compliance Form (Appendix 1). All records must be completed in a timely manner to ensure a true reflection of stock held

- Date
- Time
- Name of vaccine
- Batch number
- Expiry date
- Delivery note number
- Quantity received
- Quantity returned
- Quantity destroyed
- Sign and date the delivery note and or invoice to confirm the information has been inputted in to the Vaccine Stock Record.
- File the paper delivery note in the vaccine order folder.

4.6. Vaccine Distribution

4.6.1. Collating Immunisation Session Information

The occupational health nurse administering the vaccination will be responsible for completing the record of immunisation on the patient consent form. The patient consent form may be stored electronically on COHORT or placed in the patient's clinical notes.

4.6.2. Vaccine Porter Preparation

- Prior to vaccine porter preparation ensure that each immunisation refrigerator EasyLog data logger has been downloaded (this must be done am and pm) and check all temperature readings have remained between 2 and 8°C.
- Any deviation outside of the recommended temperature range must be reported to the Occupational Health Manager and the immunisation fridge quarantined. An immunisation refrigerator quarantine notice must be applied. Refer to Appendix 3 and Section 4.4.
- If the temperature readings have remained between 2 and 8°c, the vaccine porters can be prepared.
- Calculate the number of vaccine porters and gel packs required for the immunisation session.
- Check each vaccine porter and gel pack for visible damage – damage should be reported to the Occupational Health Manager
- Select the EasyLog data logger assigned to each specific vaccine porter.
- Prepare the Vaccine Porter Cold Chain Compliance Form (Appendix 1).
- Place in the clear window on the outside of the vaccine porter; one Vaccine Porter Cold Chain Compliance Form per porter.

Ensure any special instructions are added to the Vaccine Porter Cold Chain Compliance Form, e.g. use this porter first.

4.6.3. Vaccine Porters 9

- Add one MT28 gel pack to the bottom of the porter, add one MT28 gel pack to each side of the porter (5 packs in total)
- Pack the vaccines in their original packaging into the porter as per manufacturer's instructions.
- Leave enough space at the top of the porter for one further MT28 gel pack (making a total of six gel packs in accordance with manufacturer's guidance) and the lid.
- Start the Easylog data logger and place in the centre of the vaccine porter – update the Vaccine Porter Cold Chain Compliance Form.
- Re-set the digital thermometer and place the glycol vial in the centre of the vaccine porter. The digital thermometer must also be placed in the inside of the vaccine porter
- Any voids must be filled with bubble wrap.
- Securely fit the lid.
- The outer casing must be fastened in place.
- Vaccine porter **must** not be stacked.

More information regarding packing Vaccine Porters can be found at Vaccine Porter® Carrier System - Medical and Cleanroom Disposables - Helapet

4.7. Immunisation Sessions

4.7.1. Cold chain compliance within immunisation sessions

- Vaccine porters are to be used in numerical order.
- The glycol digital thermometer temperature reading must be checked and recorded on the Vaccine Porter Cold Chain Compliance Form, before administration to ensure that the vaccine porter temperature has remained within the recommended temperature range (2-8°C). If the temperature has not remained within range the Occupational Health Manager must be notified immediately.
- Immunisation staff are responsible for recording on the Vaccine Porter Cold Chain Compliance Form how many times the vaccine porter has been opened.
- Immunisation staff are responsible for recording the time the Vaccine Porter is emptied on the Vaccine Porter Cold Chain Compliance form, if emptied at the immunisation session.

4.7.2. Broken Cold Chain following Immunisation Session

Vaccines that have been removed from the Vaccine Porter during the Immunisation Session and not used must be destroyed.

- Record the destruction on the Cold Chain Compliance Form and a 'Record for the Destruction of Pharmacy Waste' form Appendix 4 and dispose of in accordance with the Pharmaceutical Waste Flowchart section 16 of the SSHMP.

Inform the Occupational Health Manager

4.8. Returned Vaccine Porters and Vaccines Following Immunisation Session

- **Vaccine porters containing immunisations must be returned to the Occupational Health Department, immediately following the immunisation session completion if within the eight-hour time scale recommended by the vaccine porter manufacturer.** If outside of the recommended eight-hour time scale – vaccines must be destroyed at the end of the immunisation session. Refer to the current SSHMP section 16.
- Destroyed Vaccines must be recorded on the Vaccine Cold Chain Compliance Form (Appendix 1), and the Record for Destruction of Pharmacy Waste (Appendix 4).
- Empty vaccine porters can be returned to the Occupational Health Department the following day if the immunisation session is off site
- Remove and complete the Vaccine Porter Cold Chain Compliance Form (Appendix 1) for each vaccine porter
- Remove and download the data logger; review the data and inform the Occupational Health Manager immediately if there have been any temperature excursions.

- The EasyLog data logger temperature graph are saved to the following folder on the V:drive at V:\Corporate\Pharmacy\Pharmacy Team\Public\Pharmacy Fridge Log\Occupational Health Vaccine Porters
- Returned vaccines must be placed in a clear plastic bag, quarantined from all other stock, and placed within the immunisation refrigerator until the EasyLog data logger temperature record has been reviewed by the Occupational Health Manager.
- The Occupational Health Manager will advise appropriate action to be taken.

4.8.1. Vaccine Porter Data Logger Data within Range 2-8°C

- Before vaccines can be returned to stock a visual check must be carried out to ensure that the stock is in good condition i.e. there are no signs of leakage on the packaging.
- A red dot sticker must be applied to all vaccines returned into immunisation stock.
- The returned vaccine should be placed on top of existing stock and used first at the next immunisation session.
- Record how many vaccines are returned to stock from each vaccine porter on the appropriate Occupational Health Department Temperature Monitoring Form.
- Update the vaccine stock record.
- Damaged stock; refer to section 4.4.

4.8.2. Vaccine Porter Data Logger Data out of Range below 2°C or above 8°C

- The Occupational Health Manager is responsible for investigating any breach in the cold chain involving storage or administration of vaccines.
- The Occupational Health Manager must inform the Trust Pharmacy and will be responsible for implementing any action to be taken. A Datix must be completed.
- **Vaccine Porters returned empty**: Check the exact time the vaccine porter was emptied; refer to the Vaccine Porter Cold Chain Compliance Form. If the temperature excursion has occurred after the vaccine porter was emptied, no further action is needed. If the temperature excursion has occurred during the immunisation session or whilst the vaccines are being stored in the vaccine porter the Occupational Health Manager must inform Trust Pharmacy who will advise on appropriate action. Any affected vaccines must be quarantined. Refer to 4.5
- Trust Pharmacy will instruct upon the safe handling of any vaccines that are approved for return to stock following a temperature excursion.
- Following instruction from Trust Pharmacy any quarantined vaccines that are deemed unsuitable to be returned to stock will be recorded on a ‘Record for the Destruction of Pharmacy Waste’ and dispose of in accordance with the Pharmaceutical Waste Flowchart section 16.

4.9. Immunisation Equipment

4.9.1. EasyLog Data Loggers

- When not in use the EasyLog data loggers must be stored within the immunisation refrigerators.
- Data Logger batteries must be changed annually. A message will appear on screen when the battery is running low; the data logger will have an amber flashing light.
- Refer to the data logger user guide
- Data logger batteries are available from Trust Pharmacy, email hnf-tr.pharmacyprocurement@nhs.net to request new batteries.

4.9.2. MediTray Cool Packs

- must be chilled for 24 hours before use
- must not be stored more than three gel packs high when normalising.
- must be stored flat
- must be replaced every 12 months

- must be weighed every three months and the information recorded on the MediTray Weight Record Chart. Refer to Appendix 5.
- If dropped visually inspect the cool pack for damage.

4.10. Training

Training will be provided by the Trust's Pharmacy Department.

5. REFERENCES

- Safe and Secure Handling of Medicines Procedures
- Immunisation Guidelines
- Immunisation against infectious disease: The Green Book https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book - the-green-book

Appendix 1: Vaccine Porter Cold Chain Compliance Form

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Appendix 1

Vaccine Porter Cold Chain Compliance Form

Date of Immunisation Session		Session Base	

Vaccine Porter Number				Vaccine Porter Packed		Date:	Time:
Data Logger Number				Data Logger Started		Date:	Time:
Data Logger Current Status?	Logging / Stopped (Delete as appropriate)	Warning Lights Visible?	Y / N (Circle)	Battery Replaced?	Y / N (Circle)	Date:	Time:

Name of Staff packing Vaccine Porter	Sign:	Print:	Designation:	Band:

Details of Vaccine (Include Batch Number and Expiry Date)	Quantity Packed	Quantity Returned	Quantity Destroyed following immunisation session	Comments:

Glycol Thermometer (Temperature readings **MUST** be recorded each time the vaccine porter is opened)								
Time								
Min Temp °C								
Max Temp °C								
Current Temp °C								
Vaccine removed from porter (inc. quantity)								

Number of times the vaccine porter is opened during the immunisation session		Vaccine Porter emptied at the session	Time:

Returned Vaccine Porter Information			
Data Logger downloaded, temperature graph printed and stapled to the relevant vaccine porter cold chain compliance form?	Yes/No Time:	Sign: Print:	Designation: Band:
Downloaded data logger temperatures within the recommended 2 to 8°C range?	Yes/No	Sign: Print:	Designation: Band:
Occupational Health Team: • If the Data Logger readings are not within the recommended 2 to 8°C range, contact the Senior Occupational Health Advisor immediately – Tel: 01482 383333			

Red Dot applied to authorised returned stock	Sign: Print:	Designation: Band:	Comments:
Returned to the vaccine fridge by	Sign: Print:	Designation: Band:	Comments:

Occupational Health Clinician use only.					
Datix Completed:	Yes/No	Date:	Time:	Datix Web Number:	Vaccine destroyed inc. quantity:

Completed Vaccine Porter Cold Chain Compliance Forms must be kept on the unit for 2 years from the last entry date. All forms must be scanned and stored in; V:\HMHTT\Medical Directorate\Pharmacy Fridge Log\Occupational Health\Completed Vaccine Porter Cold Chain Compliance Forms.

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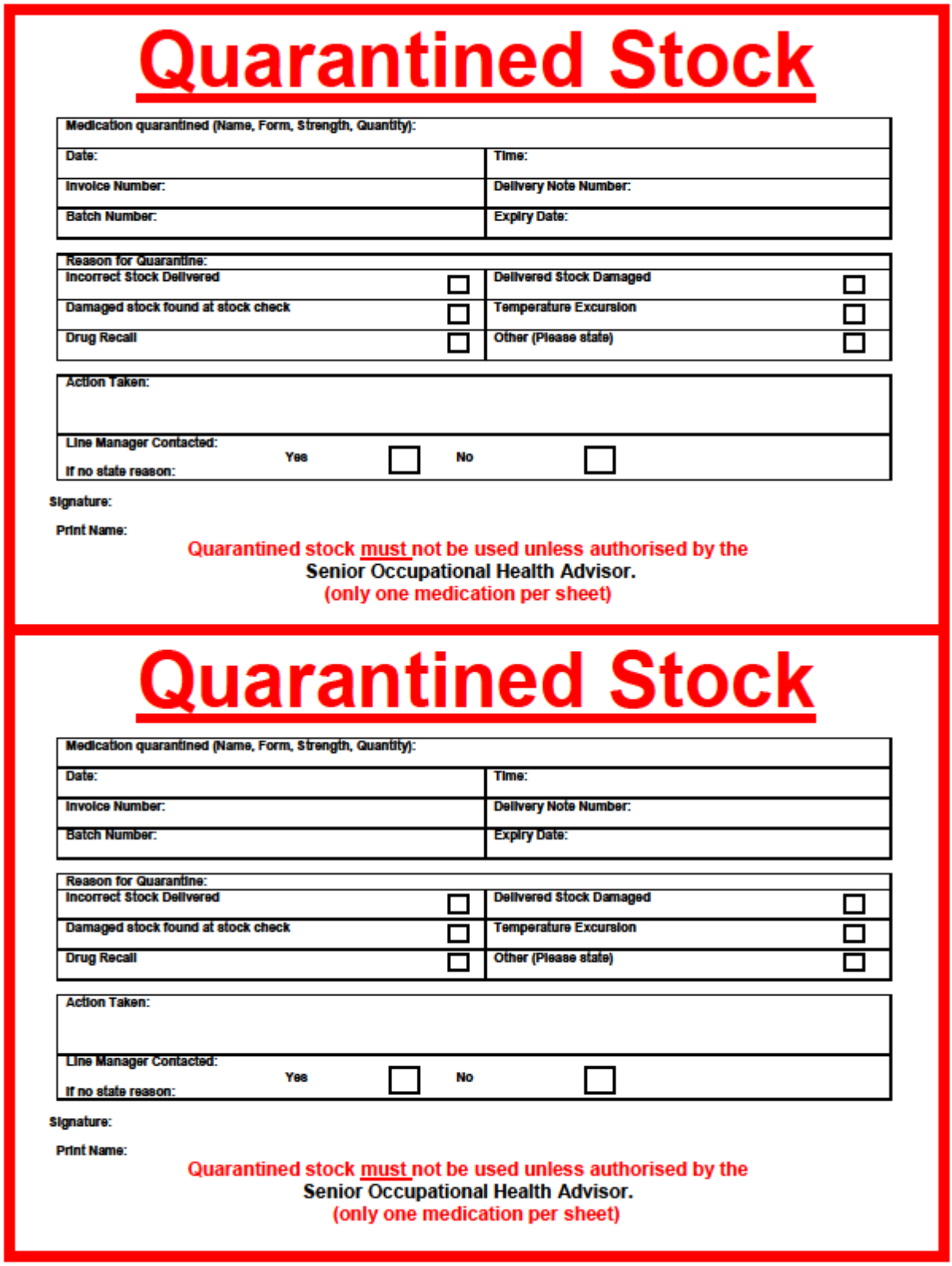
Standard operating procedure – Immunisation Cold Store
Version 5 - May 2017

Appendix 2: Quarantined Stock



Quarantined Stock

Medication quarantined (Name, Form, Strength, Quantity):	
Date:	Time:
Invoice Number:	Delivery Note Number:
Batch Number:	Expiry Date:

Reason for Quarantine:			
Incorrect Stock Delivered	☐	Delivered Stock Damaged	☐
Damaged stock found at stock check	☐	Temperature Excursion	☐
Drug Recall	☐	Other (Please state)	☐

Action Taken:			
Line Manager Contacted: If no state reason:	Yes	☐	No ☐

Signature:

Print Name:

Quarantined stock must not be used unless authorised by the
Senior Occupational Health Advisor.
(only one medication per sheet)

Quarantined Stock

Medication quarantined (Name, Form, Strength, Quantity):	
Date:	Time:
Invoice Number:	Delivery Note Number:
Batch Number:	Expiry Date:

Reason for Quarantine:			
Incorrect Stock Delivered	☐	Delivered Stock Damaged	☐
Damaged stock found at stock check	☐	Temperature Excursion	☐
Drug Recall	☐	Other (Please state)	☐

Action Taken:			
Line Manager Contacted: If no state reason:	Yes	☐	No ☐

Signature:

Print Name:

Quarantined stock must not be used unless authorised by the
Senior Occupational Health Advisor.
(only one medication per sheet)

Appendix 3: Immunisation Refrigerator Quarantine Notice

Appendix 4: Record for Destruction of Pharmacy Waste

RECORD FOR DESTRUCTION OF PHARMACY WASTE
(Retain completed sheet on Unit 2 years from date of last entry)
Refer to Disposal of Medicines Section 16, Safe and Secure Handling of Medicine Procedures (SSHMP)

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UNIT / TEAM NAME:.....

DATE	PATIENT ID OR STOCK (S)	**DRUG, FORM, AND STRENGTH** : refer to SSHMP 16.10 for disposal of CDs i.e.: - • Schedule 2&3, Midazolam, Temazepam, Tramadol • Medicines handled as Schedule 2&3 :- o Ketamine o Morphine Sulphate 10mg/5ml Oral Soln o High Strength Potassium Chloride (i.e. potassium content greater than 40mmol/L) • Schedule 4 part 1: all other benzodiazepines (e.g. Diazepam, Lorazepam etc.), Chlordiazepoxide, Zaleplon, Zolpidem , Zopiclone,	Quantity	Non-Hazardous Waste	Hazardous Waste	REASON (See Codes)	SIGNATURES (2 x SIGNATURES REQUIRED)	

CODES:

A= PATIENT'S OWN DRUGS (Brought into Unit)	**G**= DECLINED/WASTED INDIVIDUALLY PREPARED DOSES FROM MEDICINES ROUND. **NOTE: PATIENT ID, DRUG, FORM & STRENGTH does not have to be noted. Record as 'Medicine Round Waste' (MRW) + time of medicine round.**		
B= WARD STOCK – EXPIRED	**H**=	ENTER SPECIAL MEANING	
C= NON-STOCK MEDS(NSM)/ SELF ADMINISTRATION MEDS(SAM) – EXPIRED	**I**=		
D= NSM/SAM– NOT REQUIRED	**J**=		
E= NSM/SAM – NOT TRANSFERRED WITH PATIENT	**K**=		
F= DISCHARGE / LEAVE (TTOs)	**L**=		

RecordPharmacyWasteForm PWR5

Appendix 5: MT28 MediTray Weight Record Chart

MT28 MEDITRAY WEIGHT RECORD CHART

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MEDITRAY NUMBER:………

Date	Weight Recorded (Please refer to notes below)	Signature/ print name:	Comments:

MEDITRAY NUMBER:………

Date	Weight Recorded (Please refer to notes below)	Signature/ print name:	Comments:

MEDITRAY NUMBER:………

Date	Weight Recorded (Please refer to notes below)	Signature/ print name:	Comments:

MEDITRAY NUMBER:………

Date	Weight Recorded (Please refer to notes below)	Signature/ print name:	Comments:

Please Note:

- All MT28 MediTrays must be weighed every 3 months
- MT 28 MediTray manufacturers weight 0.6kg with a 10% allowance = 0.54kg. *MediTrays below 0.54kg must be replaced*
- MediTrays must be checked for any visible damage when weighed.