

Waste Management Aid to Compliance



Supporting Pharmacies Developing Systems

This document forms part of the Waste Management System developed on behalf of Health Boards by NHS Wales Shared Services Partnership – Primary Care Services (NWSSP-PCS). The contents herein, whilst non-statutory, are intended to reflect best practise to aid producers in complying with hazardous waste regulations and complement the monitoring process established by Health Boards in Wales discharging their duty of care.

October 2015

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Introduction

In accordance with The Hazardous Waste Regulations 2005, everyone involved in the waste management chain have a duty of care for the safe handling, storing, transporting and disposal of hazardous waste produced. An individual or group's duty of care continues from their initial involvement through to the point of the waste finally being disposed or rendered safe to human, plant, animal, water and the environment.

1. Pharmacy's Responsibilities

As a producer of waste a pharmacy has a duty of care for the safe handling, storing, transporting and disposal of hazardous waste produced. This duty of care extends to the point of the waste finally being disposed or rendered safe to human, plant, animal, water and the environment. A pharmacy's duty of care is a legal responsibility and does not form part of the Pharmacy Contract.

2. Health Board's Responsibilities

Health Boards (HB) provide and pay for the contract to collect and dispose of the waste. As a waste brokers, HBs play a part in the waste management chain and have a duty of care to ensure the safe handling, storing, transporting and disposal of hazardous waste produced. This is a legal responsibility which does not form part of the Pharmacy Contract.

In order to discharge their duty of care, HBs have implemented a programme to audit premises for which they provide the contract to collect and dispose of hazardous waste, namely, General Medical Practices and Pharmacies. In doing this, HBs can be satisfied that they have taken appropriate measures to ensure waste producers (pharmacies), waste contractors and others involved in the process are safely handling, storing, transporting and disposal of hazardous waste produced. The system adopted by the HB extends beyond an audit process to offering advice, information and monitoring where necessary.

3. Natural Resources Wales

Natural Resources Wales (NRW) act as enforcers of the Regulations. NRW Officers have powers to inspect and are warranted. In the event they identify breaches of the Regulations they will look at all those involved in the process, both directly and indirectly, to see who has failed to discharge their duty of care. Where failure to discharge a duty of care can be proven, NRW could seek to prosecute. This could involve one or more parties involved in the waste management chain.

4. Safe Management of Healthcare Waste

NHS Wales Shared Services Partnership – Facility Services published the Safe Management Healthcare Waste – Welsh Health Technical Memorandum (WHTM) 07-01 in March 2013.

The WHTM 07-01 provides:

- ✚ Updates to legislation;
- ✚ An emphasis on the waste hierarchy;
- ✚ A drive to address the carbon impact;
- ✚ An integration of primary care sector guides;
- ✚ Practical advice and guidance; and
- ✚ A review of terminology used for healthcare, clinical and non-clinical wastes.

Throughout this document the Safe Management of Healthcare Waste is referred to as 'the Manual'. The full document can be accessed using the following link:

<http://www.wales.nhs.uk/sites3/Documents/254/WHTM%2007-01.pdf>

The Manual provides practical advice and guidance using examples of best practice to comply with waste management legislation. The advice provided in both the Manual and this aid is not mandatory. Healthcare organisations or others choosing not to follow them are advised that alternative steps must be taken to comply with all relevant legislation.

The Manual incorporates relevant primary care sector guides; however these should not be read in isolation to the remainder of the Manual. This supporting aid to compliance has been developed with specific reference to Community Pharmacies to be used to develop internal systems.

5. Exemption from Registration as a Waste Producer

In accordance with the Regulations premises may only be exempt from registration if the "qualifying limitation is observed". This limit is 500kgs of hazardous waste in any 12 month period. If a pharmacy plans to, or actually produces, collects or removes more than 500kgs they will need to notify those premises. Waste medicines (with the exception of cytotoxic/cytostatic waste medicines) are not classified as hazardous and will therefore not contribute towards the 500kgs trigger for registration. However, waste producers must also include the weight of other hazardous waste items such as fridges, computers, batteries, fluorescent tubes, etc. Whilst these items will be subject to separate collection arrangements, their weight will contribute towards the 500kgs limitation for registration.

When considering the weight of the waste produced the following weights can be applied as a guide:

Type	Capacity (litres)	Weight (kgs)
Orange bag	50	2.5
Sharps box	7	1
Sharps box	24	5
Pharmi bin	30	10
Pharmi bin	50	15

Domestic fridge	Small	40
Fluorescent tube	Single	0.4

6. Registering as a Waste Producer

Where a pharmacy exceeds the limit of 500kgs of hazardous waste in any 12-month period they are required to register. The easiest way to register is on-line using the following link:

<http://naturalresources.wales/apply-for-a-permit/waste/register-as-a-producer-of-hazardous-waste/?lang=en>

NB: A registration fee is required at the time of registration.

Registration can take place at any time in a 12-month rolling period. A single registration is valid for 12 months and renewable thereafter providing more than 500kgs of hazardous waste per annum continues to be produced.

Once registered, the pharmacy will be issued with a registration code. This code will remain valid for the duration of the registration. In the event that there is a break in the registration period, a new code will be issued.

7. Site Register

Pivotal to the effective management of waste in any healthcare setting is record keeping. It is recommended that each premise develops a Site Register which includes:

- ✚ Consignment Notes (relating to the last 3 years);
- ✚ Producer Quarterly Returns (relating to the last 3 years);
- ✚ Current Policy;
- ✚ Exemption T28 registration details (for the process of denaturing controlled drugs;
- ✚ Waste producer registration information (if appropriate)
- ✚ Controlled Waste Transfer Notes (relating to the last 2 years);
- ✚ Current Pre-Acceptance Audit;
- ✚ Details of In-House Audits undertaken;
- ✚ Records of information, instruction and training delivered to staff/others; and
- ✚ Any other information relevant to the management of waste within the pharmacy (e.g., NRW registration information, if applicable).

8. Policy Documentation

To effectively manage healthcare waste, all those involved in the management of the waste stream should have access to an appropriate healthcare waste policy that identifies who is responsible for the waste and provides clearly written instructions on how it should be managed.

A template Policy can be found at Attachment One which could form basis of a bespoke site policy.

9. In-House Audits

The Manual identifies the vital role of regular producer waste audits in demonstrating compliance with regulatory standards.

It is considered that robust producer audits are the safest and most effective means of ensuring that the waste facility has sufficient information to comply with the waste acceptance conditions in their permits.

A suggested in-house audit template can be found at Attachment Two. This provides a monthly check sheet to record compliance observations; will inform the Pre-acceptance Audit; and promote effective record keeping.

10. Pre-Acceptance Audit

Waste contractors are permitted to process waste and are regulated by Natural Resources Wales. In order to comply with their permits, waste contractors must be satisfied that the waste they collect from the producer is appropriate for the designated disposal method, ie, incineration, alternative treatment, landfill, etc. Producers are required to undertake and provide the waste contractor with a 'Pre-acceptance Audit'.

The pre-acceptance audit must provide the waste contractor with specific information in order that the waste contract complies with their permit. From 1 July 2013 the waste contractor is in breach of their licence if they collect waste from a community pharmacy that has not provided an adequate pre-acceptance audit.

SRCL have provided a free on-line audit tool to complete the pre-acceptance audit.

The audit may be completed using this link: <http://srcl-audit.com/>

Pre-acceptance audits are to be completed every five years.

11. Training

It is important that all staff including temporary, locum, agency staff, receive appropriate information, instruction and training. Information, instruction and training should be periodically updated, or when changes to systems or legislation occur.

It is the Pharmacy's responsibility to deliver in-house training. This may take place in a number of formats, eg, practical demonstration, seminar, classroom style, etc. Details of any training should be documented and retained in the Site Register.

12. Further information

Natural Resources Website:

<https://naturalresources.wales/splash?orig=>

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XXXXXXXXXXXX PHARMACY

**WASTE MANAGEMENT
POLICY & PROCEDURE**

Pharmacy:

Date:

EXAMPLE

Review Date:

Waste Management Policy CONTENTS

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1. INTRODUCTION

- 1.1. In accordance with legislation the Pharmacy is required to have in place a policy and procedure to manage waste which ensures that the segregation, handling, transportation and disposal of wastes are properly managed so as to minimise the risks to the health and safety of patients, staff, the public and the environment.
- 1.2. This policy and procedure is directed to all aspects of waste management that occur as **XXXXXXX Pharmacy** fulfils its obligations to:
 - 1.2.1. provide primary healthcare services;
 - 1.2.2. maintain regulatory compliance; and
 - 1.2.3. maintain cooperation with partners, stakeholders and contractors.
- 1.3. For the purpose of this document the structures and means for fulfilling the above obligations is hereafter referred to as the Pharmacy.
- 1.4. The ownership for compliance with this policy is the responsibility of all persons who fulfil, cooperate with or utilise the Pharmacy's functions.

2. POLICY STATEMENT

- 2.1. This policy outlines the systems of work that will:
 - 2.1.1. enable the Pharmacy and its individuals to ensure that all wastes are disposed of correctly, without endangering human health and without using processes or methods which could harm the environment; and
 - 2.1.2. ensure that persons handling, producing, packaging, transporting and/or disposing of the Pharmacy's waste, exercise care to avoid injury or risk of harm to themselves or others, including the general public.

3. AIM & OBJECTIVES

- 3.1. This policy provides instructions on the classification, management, training and audit with respect to waste management. This will ensure that the storage, handling, transport, treatment and/or disposal of waste generated by the Pharmacy is managed to minimise the risks of harm to human health, damage to the environment or detriment of the local amenity.
- 3.2. To provide specific and detailed instructions to ensure the correct classification, management, training and audit with respect to waste management. This will ensure that the packaging, storage, handling, transport, treatment and/or disposal of waste generated by the Pharmacy is managed to minimise the risks of harm to human health, damage to the environment or detriment of the local amenity

4. WASTE DEFINITION AND CLASSIFICATION

- 4.1. Waste is defined in European Waste Framework Directive [75/442/EEC](#) as *"any substance or object, which the producer or the person in possession of it discards or intends to discard, or is required to discard"*.
- 4.2. Wastes must be classified and segregated in accordance with the regulations to ensure that each category of waste transported by or on behalf of the Pharmacy meets the waste acceptance criteria of the authorised waste receiving site/process.
- 4.3. All members of the Pharmacy have a responsibility to ensure that the waste generated/collected are segregated and identified.
- 4.4. Advice should be sought for any other waste substance or material that listed as part of this document and is not easily defined by the waste categories listed.

5. IDENTIFICATION, DESCRIPTION AND STORAGE OF SEGREGATED WASTE

- 5.1. It is the Pharmacy's policy to use coloured plastic safety containers for certain wastes and to store these and other wastes safely at the point of production while they await collection from designated waste hold/storage areas.
- 5.2. Sharps boxes or other rigid clinical waste containers must be sealed and identified prior to being stored for collection.

6. COLLECTION OF WASTE FOR TRANSPORT

- 6.1. Waste will be collected from waste hold/storage areas regularly in accordance with Pharmacy procedure.
- 6.2. Waste must be segregated in accordance with the requirements of the legislation such that description on the Controlled Waste Transfer Note or Hazardous Waste Consignment Note accurately reflects the waste load for transport.
- 6.3. All contracted waste carriers transporting waste on behalf of the Pharmacy must be in possession of a valid Waste Carriers Certificate and must comply with all regulatory transportation requirements.

7. RESPONSIBILITIES

- 7.1. The Proprietor(s) of the Pharmacy is ultimately responsible for ensuring that waste is managed in accordance with legislative requirements.
- 7.2. The Pharmacist is responsible to ensure that the staff and the services provided by staff meet the requirements of this policy and procedure and are compliant with the legislation.

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- 7.3. It is the responsibility of all staff to adhere to the legislation, this policy, and procedures to which it refers.
 - 7.4. The Pharmacy Manager/Pharmacist is responsible to ensure the registration status of the Pharmacy is maintained in accordance with legislation.
 - 7.5. The Pharmacist is responsible to ensure all waste records are maintained in accordance with the regulations, ie, Consignment Notes – 3 years, Waste Transfer Notes – 2 years.
 - 7.6. The Pharmacy Manager/Pharmacist will maintain the above records in a Site Register which will include Producer Quarterly Returns which have been checked against the appropriate Consignment Notes. Any irregularities will be pursued with the waste contractor to ensure waste was disposed and documented evidence is retained.
 - 7.7. The Pharmacy Manager/Pharmacist is responsible to undertake audits e.g. general and pre-acceptance audits to ensure that the Pharmacy is in compliance with this policy, procedure and legislation.
 - 7.8. The Pharmacy Manager/Pharmacist will undertake investigations and make recommendations for improvements as required where accidents and incidents are identified as non compliant with legislation.
 - 7.9. The Pharmacy Manager/Pharmacist has responsibilities to ensure that contractors who supply the Pharmacy with waste management services are compliant with policy and legislation. This includes disposal of other hazardous wastes such as fridges, fluorescent tubes, etc.
 - 7.10. The Pharmacy Manager/Pharmacist will be responsible to ensure that all staff employed by the Pharmacy is aware of the policy and that the mandatory training requirements of staff are fulfilled.

8. WASTE MANAGEMENT TRAINING

- 8.1. Waste Management training forms an integral part of the Pharmacy's mandatory training and staff induction programme that must be completed by all members of staff. Waste Management training will also be undertaken as part of the Pharmacy's staff induction programme.
- 8.2. Where possible waste management training will include the following:
 - 8.2.1. current waste legislation and penalties for non compliance;
 - 8.2.2. the responsibilities of individuals for the safe management of waste including 'Duty of Care' obligations;
 - 8.2.3. the practical methods and definitions that enable waste segregation;
 - 8.2.4. waste containers and storage arrangements;

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- 8.2.5. waste identification;
 - 8.2.6. a basic awareness of the transportation of waste; and
 - 8.2.7. a basic awareness of treatment and or disposal arrangements.

8.3. Persons handling waste should ensure that they:

- 8.3.1. are fully aware of any dangers which may arise in handling that waste;
- 8.3.2. have the necessary mechanical aids and equipment to handle that waste safely; and
- 8.3.3. are trained in the procedures associated with segregation and waste handling appropriate to their work environment.

9. IMPLEMENTATION

9.1. The policy shall be implemented throughout the Pharmacy from date of issue. Where adaptations are required to comply with changes the allocation of resources and training will be agreed.

10. PATIENT RETURNED MEDICINAL WASTE (INCLUDING CYTOTOXIC / CYTOSTATIC)

10.1. Medicinal waste returned to the pharmacy needing to be disposed of appropriately.

10.2. Patient returned medicinal waste is classified into two categories;

- 10.2.1. Cytotoxic and Cytostatic Medicines (EWC 20 01 31);
- 10.2.2. Medicines other than those classified as Cytotoxic and Cytostatic. (EWC 20 01 32).

10.3. A Cytotoxic and Cytostatic medicine is a medicinal product possessing any one or more of the hazardous properties;

- 10.3.1. H6: Toxic;
- 10.3.2. H7: Carcinogenic;
- 10.3.3. H10: Toxic for reproduction; and/or
- 10.3.4. H11: Mutagenic.

10.4. To establish whether a medicinal product has the above mentioned hazardous properties, pharmacists should refer to the products Material Safety Data Sheet, BNF publications or undertake a pharmaceutical assessment if required.

10.5. While these different classifications occur it is important to recognise that 'Incineration Only' is required to ensure safe disposal. It is an offence under the Hazardous Waste Regulations 2005 to knowingly mix and dispose of any

non hazardous waste e.g. residual (domestic) waste with the 'Incineration Only' clinical wastes.

11. SEGRAGATING & STORING MEDICINAL WASTE

11.1. Waste produced/collected must be safely contained only by the approved method as follows:

11.2. Non Hazardous Medicines Returned to Pharmacy must be segregated from other waste types, eg, obsolete NHS stock. It is acceptable to place this waste in a yellow container for incineration (EWC 20 01 32).

11.3. Waste medicines may be temporarily stored at the pharmacy for:

11.3.1. three months; if the waste has been returned to pharmacy from domestic households or by a healthcare worker (20 01 31/20 01 32);
and

11.3.2. twelve months; if the waste has been produced at the pharmacy (18 01 09/18 01 08).

Both waste streams must be segregated.

11.4. Cytostatic/Cytotoxic Medicines returned to Pharmacy must be separately packaged in purple lidded rigid plastic containers that clearly identify them as hazardous medicines (20 01 31).

11.5. Medicinal waste will come in two types for the purpose of transport regulations.

11.5.1. Solids (pills and powders); or

11.5.2. Liquids (ampoule contents etc).

11.6. Both solid and liquid waste must be packaged in suitable receptacles to ensure no accidental escape of the waste occurs and when necessary measures must be provided to minimise the breakage of primary packaging such as cushioning/absorbent materials.

11.7. Appendix A describes the colour code packaging required to ensure wastes receive appropriate treatment.

11.8. Pharmacy storage arrangements will be secure within the confines of the pharmacy. The classifications made during packaging should be clearly identified on the primary packaging to provide certainty that all subsequent handlers remain compliant with the regulations.

11.9. It is an offence under the Hazardous Waste Regulations 2005 to knowingly mix and dispose of any non hazardous waste e.g. domestic waste with 'Incineration Only' waste.

12. **TRANSPORTING WASTE**

- 12.1. It is normal practise to separate cytotoxic wastes from all other wastes at the point of production and this practice must continue. However regulation allows Cytotoxic and Cytostatic wastes to be transported jointly for incineration. This deliberate mixing of Cytotoxic and Cytostatic waste is permitted when pharmacies provide satisfactory primary packaging.
- 12.2. Given the effective separation of hazardous and non hazardous medicines at the point of production the waste will be transported in approved containers that will be accompanied by a completed Hazardous Waste Consignment Note and or Controlled Waste Transfer Notes that describe the waste in accordance with the regulations.

13. **RESIDUAL WASTE (DOMESTIC WASTE)**

- 13.1. Residual Waste for the purposes of this procedure is the non hazardous general waste for disposal into landfill. The majority of this waste is packaged inside black bags. Once waste enters the black bag waste stream the recycling potential is lost.

- 13.2. Domestic Waste is defined as;

EXAMPLE

Domestic Waste	<i>Non Hazardous Waste ONLY</i>	<i>Commercial waste, General factory waste, Floor Sweepings, Litter bin waste, General administration waste, General commercial waste, General industrial waste, General office waste, General catering and other residential waste</i>
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- 13.3. Disposal of Residual Waste (& recycle waste) into a container designated as Medicinal Waste is an offence under the Hazardous Waste Regulations 2005. Failure to separate hazardous and non hazardous waste effectively can result in regulators serving an improvement notice or penalty.
- 13.4. Containers for residual waste must remain closed and locked as far as conditions allow and must be accompanied by a completed Controlled Waste Transfer Note that describes the waste in accordance with the regulations.

Pharmacy	
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Please complete the monthly checklist by placing an '✓' or 'X' in the appropriate box. If the answer is X to any of the questions, details of the issue identified must be recorded on the attached sheet and remedial action taken as necessary.

MONTHLY CHECKLIST

Person completed the checklist to record their initials, date and time:

Month:	1	2	3	4	5	6	7	8	9	10	11	12
Initial:												
Date:												
Time:												

Pharmacy Returned Waste

Have containers been dated and signed on opening?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Has the waste been labelled with the Pharmacy address and appropriate EWC code?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Where containers have been closed, have they been dated and signed accordingly?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Is a purple lidded container available on the premise for the segregation of cytotoxic/cytostatic wastes?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Is a system in place to identify obsolete dispensary stock and patient returned medicines for disposal? (eg, segregation or if mixed a detailed list of items/quantities maintained)

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Is the date/initial of opening AND closing displayed on all containers in use/for collection?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

If yes to the above, are the dates within the storage for disposal limits, ie, 3 months for patient returned medicines and 12 months for obsolete NHS stock?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Are wastes being effectively segregated, ie, blister packs being removed from outer packaging?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Waste Storage

Is the storage area secure, ie, in a compound/stored internally or externally secured to an immobile object?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Is the storage area clean and free from debris?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Are the storage receptacles lockable and in working order?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

Signage

Is there signage displayed to facilitate effective waste segregation?

Month:	1	2	3	4	5	6	7	8	9	10	11	12
✓ or X												

QUARTERLY CHECKLIST

Record Keeping

Are all Consignment Notes being retained? (Must be retained for a minimum of 3 years)

Month:	3	6	9	12
✓ or X				

Are Consignment Notes being checked against the Producer Quarterly returns?

Month:	3	6	9	12
✓ or X				

ANNUAL CHECKLIST

Policy and Procedures

Is a Waste Policy with supporting procedures in place and current?

Month:	1
✓ or X	

Has the Waste Contractor been provided with a current Pre-Acceptance Audit? (ie, within the last 60 months?)

Month:	1
✓ or X	

Insert date/month of next submission date.

