Guidelines for the Segregation, Packaging and Removal of Waste Medicines from HSE Pharmacy Departments and Aseptic Units 2022

Is this document a:

Policy [ ] Procedure [ ] Protocol [ ] Guideline [X]

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Guidelines for the Segregation, Packaging and Removal of Waste Medicines from HSE Pharmacy Departments and Aseptic Units

1.0 Introduction

The *Guideline for the Segregation, Packaging and Removal of Waste Medicines from HSE Pharmacy Departments and Aseptic Units* documents a system for disposal of waste medicines which complies with the Transport of Dangerous Goods Regulations (See Part B Section 1.7) while streamlining the process for Pharmacy Departments.

This Guideline applies to:

- Unused or expired medicines and related products from the pharmacy department
- Medicines including patient medicines returned from the wards provided there is no additional infection risk

  Note: Medicines that carry an infection risk should be disposed of in the appropriate infectious waste containers that are provided at ward level

- Waste generated in Aseptic Units i.e. wastes contaminated with residues of cytotoxic drugs to include used vials, syringes, needles, PPE, wipes and disinfectant bottles

  Note: This Guideline may also be applied to areas where monoclonal antibodies are prepared under aseptic conditions in laminar flow hoods

The Guideline adopts a worst-case approach to the classification of waste medicines as permitted under the Dangerous Goods Transport Regulations, thus obviating the need to determine the transport classification of individual medicines. In addition by availing of the exemptions associated with Limited Quantities, it avoids the need to identify the dangerous goods class on package labels (Refer to Appendix 1 for definition and further information on Limited Quantities).

2.0 Procedure

2.1 Procedure for the Segregation and Packaging of Waste Medicines and related products from General Pharmacies

Figure 1 Segregation and Packaging of Waste Medicines and related products from General Pharmacies

2.1.1 Segregation of waste medicines and related products from general pharmacies

Waste medicines and related products must be segregated into one of the following three waste streams. (Refer to Figure 1 above)

a) Medicinal products that are not pharmaceutically active (i.e. IV solutions with no added medicine).

Examples: IV sodium chloride, glucose, lactate solutions, water for injection, Intralipid®, plasma expanders.

b) Class 2 Aerosols

Note: Class 2 Aerosols are readily identified by the aerosol cans in which they are presented. Non-medicinal aerosols should also be included in this fraction. Pressurised inhalers are exempt from the transport regulations as they are only available in receptacles not exceeding 50 ml and hence can be disposed of in this waste stream or alternatively in (c) below.

c) All other medicines and related products not covered in (a) or (b) above (including medicines which are not classified as hazardous for transport).

2.1.2 Packaging and packing method

The packing and packaging methods are outlined in (a), (b) and (c) below:

a) Medicinal products that are not pharmaceutically active i.e. Intravenous solutions (with no added medicine), enteral and parenteral feeds

These products may be disposed of as non- hazardous waste in accordance with healthcare facility's waste management policy. No specific packaging requirements apply however Table 1 below provides options that should be considered:

Disposal of medicinal products that are not pharmaceutically active	
Non Risk Waste Type **LoW 180104** **LoW 200301**	**Instructions**
Non-pharmaceutically active and / or non-medicate product e.g. Non-flammable topical emollients, sodium chloride sterile water and glucose solutions.	**Subject to approval from relevant** non-risk waste contractor **:** Non-pharmaceutically active products and /or non-flammable topical emollients to be disposed of in the general waste. Any packaging that contains patient data should be disposed of in the confidential waste. Sodium chloride, sterile water and glucose solutions can be disposed of to drain subject to the waste water discharge license of the individual facility
Empty primary packaging from non-pharmaceutically active products and or topical emollients	Empty bottles (from non-pharmaceutical active products and/or non-flammable topical emollients) can be disposed of into general waste or if all residues are removed into a recycling bin. Remove all patients' details before disposal
Nutritional Supplements	Nutritional Supplements can be disposed of as food waste and/or to drain if permitted by the waste water discharge license of the individual facility
Uncontaminated cardboard outer packaging and inserts (without patient details)	Cardboard packaging and inserts can be disposed of in the recycling bin or be diverted to domestic waste when there is no access to recycling bin

Table 1 Disposal of medicinal products that are not pharmaceutically active

b) Class 2 Aerosols (Ventilated Limited Quantities Bin)

The waste aerosols must be packed in a packaging that provides adequate ventilation to ensure that any gas that may be released from an aerosol is not trapped within the package while the packaging must be capable of retaining any liquid that may be released from the aerosol. The Healthcare Risk Waste Contractor supplies a suitable packaging, which currently is a fibre drum. The aerosols may just be placed in the drum without the need to keep upright or secure against movement. When full,the drum lid should be closed according to the supplier's instructions.

c) All other medicines and related products (Limited Quantities Bin)

All other medicines and related products must be packaged as Limited Quantities in combination packaging consisting of an inner and outer packaging as outlined below.

(i) Inner Packaging

The medicines must be enclosed in an inner packaging. This can be the primary packaging that the medicine was supplied in such as ampoules, vials, bottles, blister packs or tablet containers. If necessary, a ziplock bag could be used to contain loose tablets.

Out of date/unwanted controlled drugs must be denatured prior to disposal[1]. Once denatured, drugs must be placed in an inner packaging (e.g. ziplock bag or commercial destruction kit container).

Note: To prevent the introduction of additional hazards, avoid the use of dangerous goods such as flammable liquids to render controlled drugs unusable.

Table 2 provides the practical upper limits that apply to the quantities of medicines allowed per individual inner packaging in Limited Quantities (LQ) packages.

Limited Quantities inner packaging limits to be applied to medicines	
Liquids	1 L
Solids	500 g

Table 2 Limited Quantities inner packaging limits to be applied to medicines

Note: Toxic liquid medicines have a more restrictive limit but due to their inherent risks, they are only available in small packaging that fall well within this limit.

Exception

A known exception that may not meet the Limited Quantities provisions is a **Betadine Alcoholic Povidone Iodine** product that can be supplied in either 500 ml or 5 L containers. In this instance the 500 ml container can be disposed of within the Limited Quantities package, whereas a 5 L container would have to be packaged separately as advised by the Healthcare Risk Waste Contractor or local Dangerous Goods Safety Adviser (DGSA).

(ii) Outer Packaging

30 L or 60 L yellow plastic rigid bins should be used as the outer packaging. The choice will depend on local circumstances such as the volume of waste generated and the ratio of liquid to solid waste.

[1] Controlled drugs must be put beyond use in line with Pharmaceutical Society of Ireland Guidelines

Absorbent material[2] must be present in the base of the bin. Bins are currently available with absorbent pre-installed.

Liquids present in excess of **120 ml** per inner packaging must be positioned upright within the bin unless they are in receptacles that are designed to be leak proof in all orientations, such as vials sealed with a rubber septum seal or infusion bags.

Note: Screw top bottles are not considered leak-proof in all orientations as they have the potential to leak should the caps work loose.

When full the bin should be closed with a purple-coloured lid. It is preferable to fill the bins right to the top as this restricts movement of the contents during transport. The manufacturer's fill lines are only relevant when the bins are used as a UN approved packaging for clinical waste so as to avoid any further contact with infectious waste once it is disposed of.

Note: One of the labels should be signed-off and traceability cable ties attached to the sealed bins as per existing standard practice.

The Transport Regulations limit the gross weight of each completed Limited Quantities package to 30 kg. However, weight restrictions associated with the packaging mean that a 30 L bin must not weigh more than **15 kg** and a 60 L bin must not weigh more than **25 kg.**

A Task Specific Manual Handling Risk Assessment must be carried out and control measures implemented to prevent the risk of musculoskeletal injuries. In practice a 60 L bin of mainly solids waste may weigh less than **10 kg.**

Note: Products not regulated as medicines, but associated with pharmacies may also be disposed of in this bin (outer packaging), provided any assigned transport hazards fall within the categories, flammable, toxic or environmentally hazardous and they are within the relevant inner packaging Limited Quantities limits for the substance concerned e.g. Phenol solution (80% w/w) is a Class 6.1 toxic substance with a Limited Quantities limit of 100 ml. Safety Data Sheets (SDS) are available for such products to determine their transport classification, if any, and the local DGSA should be consulted to confirm the relevant Limited Quantities limit for any such product that is regulated for transport.

Please refer to Appendix 3A Disposal of Waste Medicines in Limited Quantities Bin Checklist Guide.

2.1.3. Marking and Labelling of Packages

a) Class 2 Aerosols

The drums must be marked with the Limited Quantities mark and the text "UN 1950 WASTE AEROSOLS"

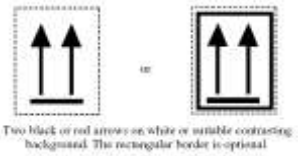
The aerosol bins are supplied pre-labelled.

b) All other medicines

[2] Sufficient absorbent or solidifying material to absorb or solidify all the liquid content present

The transport regulations require that the bins must be marked with the Limited Quantities mark on one side and orientation marks on two opposite sides;

Limited Quantities Mark



Orientation Mark

Bins are available pre-labelled with a combined Limited Quantities and Orientation Mark Label (as illustrated in Appendix 2, Figures 3 and 4) on one side and an orientation mark label on the opposite side.

2.2 Procedure for the Segregation and Packaging of Waste Medicines in the Aseptic Unit

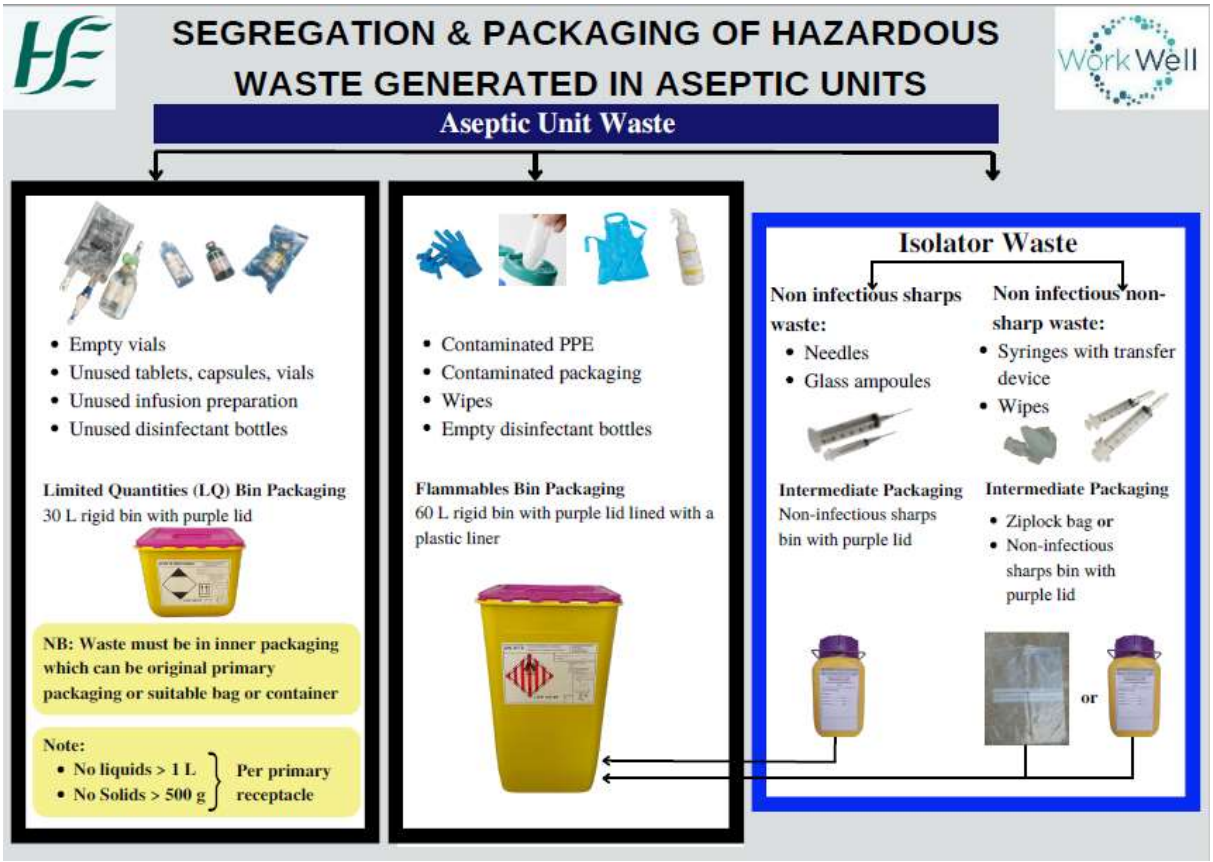


Figure 2 Segregation and Packaging of Hazardous Waste Generated in Aseptic Units

2.2.1 Segregation of waste medicines and related products from the Aseptic Unit

Hazardous waste must be segregated into one of the following three waste streams:(See Figure 2 above)

a) Unused medicines, infusion solutions, empty/part-used vials (Limited Quantities Bin)

b) Contaminated PPE, wipes, empty disinfectant bottles (Flammables Bin)

c) Needles, empty ampoules, syringes, closed transfer-devices (Isolator waste)

2.2.2 Packaging and packing method

The packing and packaging methods are outlined in (a), (b) and (c) below:

a) Limited Quantities Bin

This waste stream must be packaged as Limited Quantities in combination packaging consisting of an inner and outer packaging.

(i) Inner packaging

The medicines must be enclosed in an inner packaging before placing in the outer packaging (Limited Quantities Bin). This can be the primary packaging that the medicine was supplied in such as vials, blister packs or tablet containers or the sealed infusion bag in the case of unused infusion solution. If necessary, a ziplock bag could be used to contain loose tablets. Empty or part used vials with closed system transfer devices attached may still be regarded as inner packaging.

(ii) Outer Packaging

30L yellow plastic rigid bins should be used as the outer packaging. Absorbent material[3] must be present in the base of the bin. Bins are currently available with absorbent pre-installed.**Note:** To avoid potential manual handling issues, 60L bins are not recommended for this waste stream as it is likely to contain a high proportion of small glass vials. However, where a 60L bin is used, a Task Specific Manual Handling Risk Assessment must be carried out and control measures implemented to prevent the risk of musculoskeletal injuries.

It is not necessary to keep vials containing liquids upright as together with infusion bags, they can be considered leak proof in all orientations. However, if unused disinfectant bottles need to be discarded, they must be kept upright in the bin as their contents will exceed 120ml. The inner packaging limits of 1L for liquids and 500g for solids apply, but due to the anticipated nature of the waste, these limits will have no practical significance.

When full the bin should be closed with a purple lid.

Note: The manufacturer's fill lines are only relevant when the bins are used as a UN approved packaging for clinical waste.

Please refer to Appendix 3A Disposal of Waste Medicines in Limited Quantities Bin Checklist Guide.

b) Flammables Bin

Contaminated PPE, wipes, empty disinfectant bottles and waste from the isolator unit should be placed in a 60L yellow rigid bin, which has been pre-lined with a suitably sized plastic liner.[4]
(**N.B.**Do not use yellow clinical waste bags as they are supplied pre-labelled as infectious)

When the bin is full, seal the plastic liner with a cable tie, and close the bin with a purple lid.

Note: The label should be signed-off and a traceability cable tie attached to the sealed outer bin as per existing standard practice.

[3] Sufficient absorbent or solidifying material to absorb or solidify all the liquid content present

[4] Where there is a requirement to maintain a sterile environment the surface of the liner may need to be disinfected or alternatively sterile liners can be procured

Please refer to Appendix 3B Disposal of Flammables Waste Checklist Guide

Note: Subject to local policy, PPE and outer packaging that is judged as unlikely to be contaminated, such as hair nets or inner gloves, may be disposed of in the general waste stream.

This bin may also be used for outer packaging where, on the grounds of contamination risk, it is policy not to dispose of in the general waste stream.

c) Isolator waste

Syringes with needles and other sharp objects such as used glass ampoules must be placed in suitably sized Sharps Bins with purple lids/collars. Depending on local policy, syringes with closed transfer devices may also be placed in the Sharps Bin or alternatively collected in a suitable plastic bag eg. a ziplock bag.

When full the Sharps Bin should be closed according to the manufacturer's instruction and then placed in the Flammables Bin.

If using ziplock bags for non-sharps waste from the isolators, it is essential not to use bags that are pre-labelled as infectious/bio hazardous. Unlabelled bags are acceptable, as when full, these are placed in the Flammables Bin.

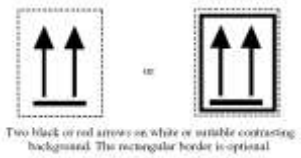
Please refer to Appendix 3C Disposal of Aseptic Isolator Sharps Bin Waste Checklist Guide.

2.2.3. Marking and Labelling of Packages

a) Limited Quantities Bin

The Transport Regulations require that the bins must be marked with the Limited Quantities mark on one side and orientation marks on two opposite sides, as outlined in 2.1.3 for general pharmacy waste medicines.

Limited Quantities Mark



Orientation Mark

Bins are available pre-labelled with a combined Limited Quantities and Orientation Mark Label (as illustrated in Appendix 2, Figures 3 and 4) on one side and an orientation mark label on the opposite side.

b) Flammables Bin

The bins must be marked with the UN number, UN 3175 and the proper shipping name, "SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S (Contains isopropanol, ethanol) and labelled with a Class 4.1 label.

Class 4.1 Label

Bins are available pre-labelled with a combined label as illustrated in Appendix 2 Figure 5.

c) Isolator waste Sharps Bins and bags

Sharps Bins must be marked with a label stating "NON-INFECTIOUS CYTOTOXIC-CONTAMINATED SHARPS" as illustrated in Appendix 2 Figure 6 and Figure 7. Existing infectious labels on the bins must be fully covered by the non-infectious label, to avoid penalties should the bins be subjected to regulatory inspection.The labels should be applied before the bin is put into use.

Labels

Pre-printed labels (7cm x 12cm) are available to order for small bins (<1.8L) that do not require assembly.

For larger Sharps Bins that require assembly, or where the pre-printed label does not fully cover the existing infectious label NON-INFECTIOUS CYTOTOXIC-CONTAMINATED SHARPS templates are available in word on https://healthservice.hse.ie/staff/benefits-services/health-and-safety/dangerous-goods.html.

If using ziplock bags for non-sharps waste from the isolators, it is essential to not use bags that are pre-labelled as infectious/bio hazardous. Unlabelled bags are acceptable, as when full, these are placed in the Flammables Bin.

3.0 Removal of Waste Medicines from HSE Pharmacies and Aseptic Units

3.1 Storage pending collection

3.1.1 Storage Area

The general requirements outlined in the "***Healthcare Risk Waste Management, Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste, November 2010***", apply to the storage of this waste. These advise that a central waste store or depot and related facilities should be provided for waste pending final removal for disposal. It should not be accessible to the public. Appropriate warning signs indicating the presence of healthcare risk waste/bio-hazard, restricting access to the public, should be prominently displayed at all entrances to any storage area.

The facilities for healthcare risk waste should include:

- A well ventilated, covered storage area for filled healthcare risk waste
- The waste marshalling area should be equipped with spillage kits and washing/cleaning and disinfection facilities for dealing with spillages etc. as well as all necessary services including lighting. Drainage, gradients and surfaces shall be such as to facilitate washing and cleaning
- Storage areas should conform to the following:
    - Well drained impervious hardstanding
    - Enclosed compound with lockable gates
    - Secure from interference by unauthorised persons, children or animals
    - Easily accessible to collection vehicles

Specifically in relation to the area designated for storage of Flammables Bins and Aerosol Bins, appropriate warning signs should include flammable and no-smoking warning signs as illustrated below

3.1.2 Presentation of Waste for collection

(i) There are no specific presentation requirements for Aerosol Bins. These are collected by arrangement with the Healthcare Risk Waste Contractor

(ii) Purple Lid Limited Quantities Bins, together with the purple and /or black lid bins bearing infectious labels, must be placed with the labels facing outwards in the existing special waste cages provided by the Healthcare Risk Waste Contractor

(iii) Flammables Bins must be placed in separate special waste cages, provided by the Healthcare Risk Waste Contractor, with the labels facing outwards

4.0 Documentation

4.1 Limited Quantities Bins

Transport documentation is not required under road transport regulations for the Limited Quantities Bins.

For export for final incineration, the medicines Limited Quantities Bins will be shipped under IMDG regulations as UN 3248 WASTE MEDICINE, LIQUID, FLAMMABLE, TOXIC, N.O.S., Class 3 (6.1), PG II and UN 3249 WASTE MEDICINE, SOLID, TOXIC, N.O.S. Class 6.1, PG II. The Healthcare Risk Waste Contractor will arrange for the necessary dangerous goods declaration to be prepared.

4.2 Flammables Bins

An ADR transport document showing the consignor and consignee name and address and the description of the goods, the packaging and the total quantity is required to accompany the movement of the Flammables Bin. The contractor will provide a suitable transport document (refer to 5.6 Role of Healthcare Risk Waste Contractor).

4.3 Waste Transfer Forms

Waste transfer forms are required under the waste regulations for all the bins and are arranged by the Healthcare Risk Waste Contractor. The waste aerosols will be identified under LoW160504* and the remaining bins will be identified under LoW180108*.

The Healthcare Risk Waste Contractor may also use an additional form as evidence of collection.

5.0 Roles and Responsibilities

With specific reference to this Guideline for the Segregation, Packaging and Removal of Waste Medicines in HSE Pharmacy Departments and Aseptic Units, the following responsibilities apply:

5.1 Chief Executive Officer (CEO)

The CEO has overarching responsibility to ensure, so far as is reasonably practicable the safety, health and welfare at work of all employees and others affected by HSE activities by:

5.1 Ensuring compliance with this Guideline.

5.2 Delegating operational responsibility for the day-to-day discharge of statutory duties under the ADR Regulations (i.e. duties of consignor[5] and packer), the Waste Regulations and the Safety, Health and Welfare at Work Act, 2005 to the Executive Management Team, Senior Management Team, Extended Senior Management Team, Senior Managers and Line Managers for all matters within their control.

5.2 Responsibilities of Hospital Group Chief Executive Officers, Chief Officers Community Health Organisations

5.2.1 Ensure there are adequate and appropriate arrangements in place for the successful implementation, monitoring, evaluation, audit and review of this Guideline throughout respective areas of responsibility (See Appendix 9).

5.2.2 Ensure necessary resources are allocated and are available for the implementation of this Guideline.

5.2.3 In accordance with the ADR, European Agreement concerning the International Carriage of Dangerous Goods by Road Regulations, ensure access is provided to competent dangerous goods advice.

5.3 Responsibilities of the Local Senior Managers e.g. Hospital GM, Head of Pharmacy

5.3.1 Ensure this Guideline is brought to the attention of, and implemented by all relevant employees and others as appropriate.

5.3.2 Ensure that all hazards and risks associated with the segregation, packaging and removal of waste medicines are identified and assessed, and appropriate measures put in place to eliminate or minimise the risk by responsible persons.

[5] With reference to the duties of the consignor, these exclude those assigned to the Healthcare Risk Waste Contractor under the agreed contract of carriage (Reference: Contract Book and User Guide Provision of Hazardous Healthcare Risk Waste Services to the Health Services Executive for the Acute Hospitals, Non Acute Locations. HSE Ref: HSE 2661)

Note: Detailed duties of the consignor are available in the ADR Carriage of Dangerous Goods by Road, A Guide for Business, available at https://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/New_ADR_Guide_for_Business.pdf

5.3.3 Ensure any written protocols for the segregation, packaging and removal of waste medicines are developed in line with this Guideline.

5.3.4 Ensure employees, contractors and agency personnel are trained commensurate with their delegated roles and responsibilities.

5.3.5 Ensure training records are maintained and are easily accessible.

5.3.6 Ensure systems are in place for the reporting and management of all incidents in line with the HSE Incident Management Framework.

5.3.7 Ensure accidents, incidents and near misses as defined in the following legislation, are notified to the locally appointed DGSA and managed in accordance with the following where appropriate:

- Notification of occurrences involving dangerous goods as per the provisions of ADR 1.8.5;
- Safety, Health and Welfare at Work (General Application) (Amendment) (No. 3) Regulations 2016

5.3.8 Engage with the relevant external contractor(s) to ensure compliance with this Guideline document as appropriate.

5.3.9 Monitor, Audit and Review the implementation of this Guideline.

5.4 Line Manager Responsibilities

Commensurate with your role:

5.4.1 Ensure this Guideline and any local written protocols are brought to the attention of, and implemented by all employees and others as appropriate (See Appendix 4).

5.4.2 Ensure all waste medicines from Pharmacy Departments and Aseptic Units are segregated packaged and removed in line with the requirements of this Guideline.

5.4.3 Ensure employees, agency personnel are trained commensurate with their delegated roles and responsibilities and training records are maintained.

5.4.4 Ensure all incidents are reported and managed in accordance with the HSE Incident Management Framework.

5.4.5 Monitor and review implementation of the Guideline and local protocol to ensure all measures are effective and continue to meet the requirements of the Guideline.

5.5 Responsibilities of Employees

5.5.1 Take reasonable care of their own safety, health and welfare and that of others.

5.5.2 Adhere to this Guideline, associated risk assessments and any local protocols.

5.5.3 Co-operate in the regular review of risk assessments and control measures to ensure that they are valid and are being effectively implemented and/or updated as required.

5.5.4 Attend relevant training as appropriate.

5.5.5 Report incidents in line with the HSE Incident Management Framework.

5.6 Responsibilities of Healthcare Risk Waste Contractor

In line with the contract of carriage, the following responsibilities are assigned to the Healthcare Risk Waste Contractor:

- The contractor to act as Carrier and Loader as defined in the current ADR regulations as per ADR 1.4.2.2 and 1.4.3.1
- The contractor on behalf of the HSE as consignor, to supply and complete the necessary paperwork to comply with all current Irish road regulations, as per ADR, chapter 5.4
- The contractor to sign the relevant documentation on behalf of the HSE when there is no available HSE person on site to do so

Appendix 1 Glossary of Terms/Definitions/Abbreviations

ADR	Agreement concerning the International Transport of Dangerous Goods by Road
Aerosol	Means an article consisting of any non-refillable receptacle made of metal, glass or plastics and containing a gas, compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected
Carrier	Carrier means the enterprise which carries out the transport operation with or without a transport contract
Class	Class refers to the hazard class to which dangerous goods are assigned for the purposes of transport. Dangerous goods are assigned to one of nine classes according to the hazard or the most predominant of the hazards they present[6] Class 1: Explosive substances and articles  Class 2.1: Flammable Gases  Class 2.2: Non-flammable, non-toxic gases  Class 2.3: Toxic gases  Class 3: Flammable liquids  Class 4.1 Flammable solids, self-reactive substances, polymerizing substances and solid desensitized explosives

[6] The detailed procedures and criteria for classification are presented in Part 2 of the ADR Regulations. See Section 1.7 of this guideline for information on how to access a copy of these regulations.

Class 4.2: Substances liable to spontaneous combustion

Class 4.3: Substances which, in contact with water, emit flammable gases

Class 5.1 Oxidizing substances

Class 5.2: Organic peroxides

Class 6.1: Toxic substances

Class 6.2: Infectious substances

Class 7: Radioactive material

Class 8: Corrosive substances

	 Class 9: Miscellaneous dangerous substances and articles 
Class 2: Gases	Covers all gases. Gases are defined as substances which: (a)at 50 °C has a vapour pressure greater than 300 kPa (3 bar); or (b)is completely gaseous at 20 °C under standard pressure of 101.3 kPa (1.013Bar)
Class 3: Flammable Liquids	Substances and articles containing substances of this Class which are liquids and have a flash-point of not more than 60°C
Class 4.1: Flammable Solids	Flammable solids are defined as readily combustible solids and solids which may cause fire through friction
Class 6.1: Toxic Substances	Substances (solids and liquids) which are known by experience or from experiments in animals to cause damage to health or death in humans within a short time, if relatively small quantities are ingested, adsorbed through skin or inhaled as a vapour, dust or mist
Competent person	A person is deemed to be a competent person where, having regard to the task he or she is required to perform and taking account of the size or hazards (or both of them) of the undertaking or establishment in which he or she undertakes work, the person possesses sufficient training, experience and knowledge appropriate to the nature of the work to be undertaken
Consignee	Consignee means any person, organisation or government which is entitled to take delivery of a consignment
Consignor	Consignor means any person, organisation or government which prepares a consignment for transport
Contractor	A person or firm who contracts to supply materials (any machinery, appliance, apparatus, tool or installation for use at work as defined by the Safety, Health and Welfare at Work (General Application) Regulations 2007 as amended) or labour (Collins Dictionary 2000). In this document the term "Contractor" is used broadly and is intended to cover Contractors, Agencies and Temporary Employment Businesses
Cytotoxic and Cytostatic Medicines	From a pharmaceutical chemotherapy perspective: A cytostatic medicine means a substance that slows or stops the growth of cells, including cancer cells, without killing them. These agents may cause tumours to stop growing and spreading without causing them to shrink in size. A cytotoxic medicine refers to anticancer drugs that kill cells, especially cancer cells. Ref:https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytotoxic-chemotherapy Under waste regulations cytotoxic and cytostatic medicines are designated as hazardous waste. The criteria used to determine if a waste medicine should be considered cytotoxic or cytostatic are not

	specified within the waste regulations, but guidance from various EU member states use the hazard properties Carcinogenic, Mutagenic or Toxic for Reproduction as defining criteria
Dangerous Goods	Dangerous Goods means those substances and articles that are capable of posing a hazard to health, safety, property or the environment and the carriage of which is prohibited or only authorised under the conditions prescribed in dangerous goods transport regulations
DGSA	Dangerous Goods Safety Adviser The principal duties of a DGSA are to advise, monitor and report on the transport of dangerous goods by road.
Employee	Means any person who has entered into or works under (or, where the employment has ceased, entered into or worked under) a contract of employment and includes a fixed-term employee and a temporary employee and references, in relation to an employer, to an employee shall be construed as references to an employee employed by that employer
Employer	In relation to an employee- (a) means the person with whom the employee has entered into or for whom the employee works under (or, where the employment has ceased, entered into or worked under) a contract of employment, (b) includes a person (other than an employee of that person) under whose control and direction an employee works, and (c) includes where appropriate, the successor of the employer or an associated employer of the employer;
Environmentally Hazardous Substance	Environmentally hazardous substances include, inter alia, liquid or solid substances pollutant to the aquatic environment and solutions and mixtures of such substances (such as preparations and wastes)
Flash Point	The lowest temperature of a liquid at which its vapours form a flammable mixture with air
Hazard	Something that has the potential to cause harm
Healthcare Risk Waste Contractor	Refers to the HSE approved contractors for the off-site collection and disposal of hazardous waste. For the purposes of this document the term waste broker and Healthcare Risk Waste Contractor are synonymous
IMDG	International Maritime Dangerous Goods Code
Inner packaging	Under the ADR means a packaging for which an outer packaging is required for transport
LD_{50}, LC_{50}	Represents the lowest level of a substance, which causes the death of 50% of the test animals within 14 days, when administered via the various routes of entry. The relevant thresholds for classification as toxic for transport are: LD_{50} (oral) ≤ 300 mg/kg LD_{50} (dermal) ≤ 1,000 mg/kg LC_{50} (Inhalation dust or mist) ≤ 4 mg/l, 1-hour exposure LC_{50} (Inhalation vapour) ≤ 5,000 ml/m^3, 1-hour exposure
Limited Quantities	Limited Quantities refers to dangerous goods which when packed according to restrictions on the quantity of dangerous goods per package and per primary receptacle are exempt from a number of provisions of the dangerous goods regulations. These include exemptions from the requirements to: Use UN certified packaging

<table>
<tr><td></td><td>Display UN numbers and Class labels on the packages
Provide a transport document when going by road
The worst-case Limited Quantities inner packaging limits for medicines are:<table><tr><td>TINCTURES, MEDICINAL UN 1293</td><td>1 L</td></tr><tr><td>MEDICINE LIQUID TOXIC, N.O.S. UN 1851</td><td>100 ml</td></tr><tr><td>MEDICINE LIQUID, FLAMMABLE, TOXIC, N.O.S. UN 3248</td><td>1 L</td></tr><tr><td>MEDICINE SOLID, TOXIC, N.O.S. UN 3249</td><td>500 g</td></tr></table></td></tr>
<tr><td>LoW</td><td>The list of waste (LoW) provides an EU- harmonized coding of all waste. The different types of waste in the list are fully defined by a six-digit entry</td></tr>
<tr><td>Medicine6[7] (human)</td><td>(i)Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(ii)Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis</td></tr>
<tr><td>Non-pharmaceutically active</td><td>Means a licensed medicinal product that is not pharmaceutically active and possesses no hazardous properties e.g. sodium chloride, sterile water, sugar solution</td></tr>
<tr><td>N.O.S.</td><td>Not Otherwise Specified, as encountered in some proper shipping names</td></tr>
<tr><td>Packer</td><td>Packer means any enterprise which puts dangerous goods into packaging’s, including large packaging’s and intermediate bulk containers (IBCs) and, where necessary, prepares packages for carriage</td></tr>
<tr><td>Packing Group PG</td><td>Is an indication of the relative degree of danger presented by various articles and substances within a class or division. Roman numerals I, II and III are used to represent “high danger”, “medium danger” and “low danger” respectively</td></tr>
<tr><td>PPE</td><td>Personal Protective Equipment</td></tr>
<tr><td>PPPG</td><td>Policy Procedure, Protocol, Guideline</td></tr>
<tr><td>Proper Shipping Name (PSN)</td><td>Proper shipping name refers to the standardized name assigned to a substance or article which in conjunction with its UN number is used to identify it during transport</td></tr>
<tr><td>UN approved packaging</td><td>Packaging which has been tested and certified to meet the construction and performance requirements as set out in the transport regulations for the relevant packaging type</td></tr>
<tr><td>UN Number</td><td>UN number means the four-digit identification number of a substance or article which is used to identify it during transport</td></tr>
</table>

[7] The definition of a medicinal product in Article 1 of Directive 2001/83/EC was amended by Directive 2004/27/EC. Additional guidance can be sourced at https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0003-guide-to-definition-of-a-human-medicine-v7.pdf?sfvrsn=30

Appendix 2 Illustrations of Labels for Medicines Bins

30 L Limited Quantities Bin Label

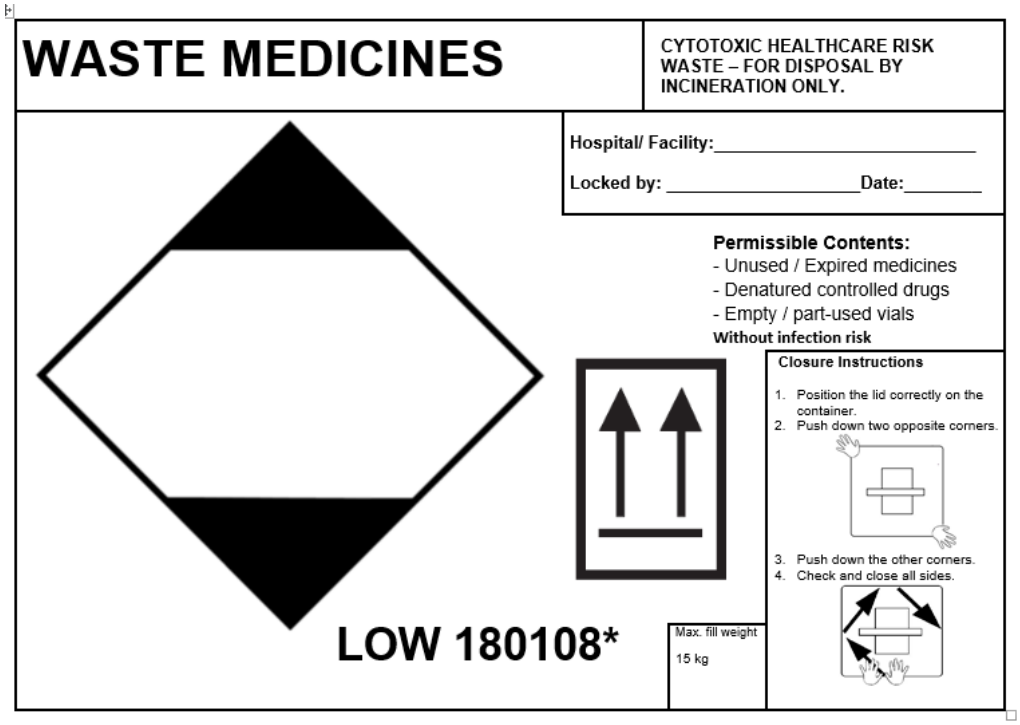


Figure 3. 30 L Limited Quantities Waste Medicines Labels

60 L Limited Quantities Bin Label

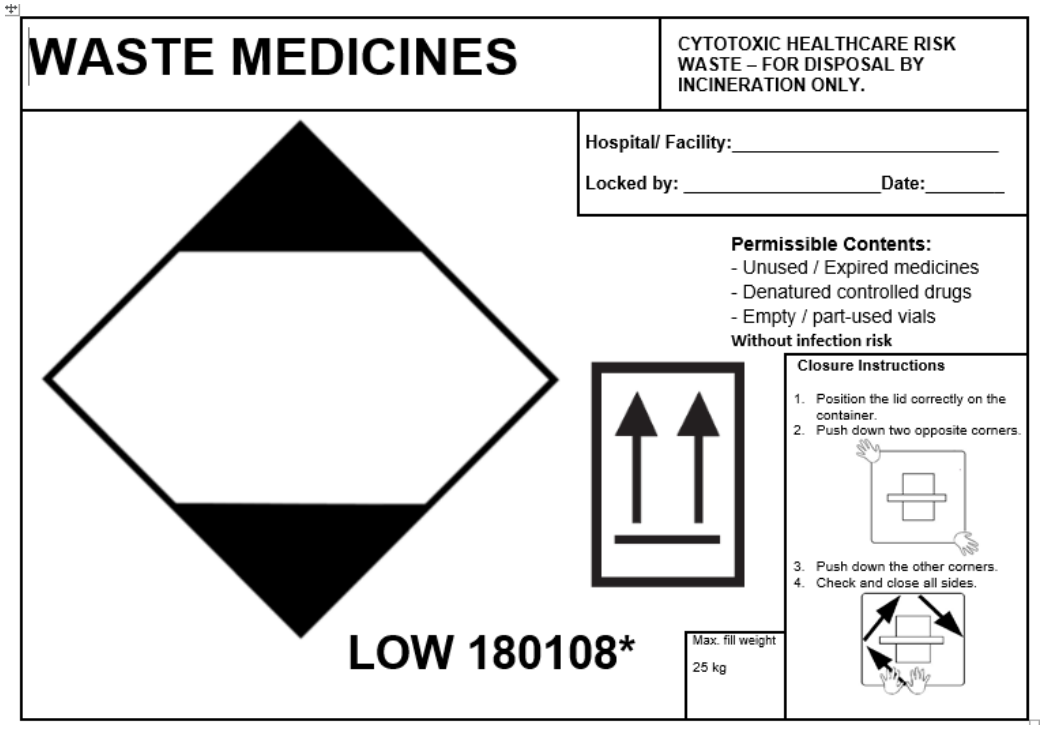


Figure 4. 60 L Limited Quantities Waste Medicines Labels

Flammables Bin Label

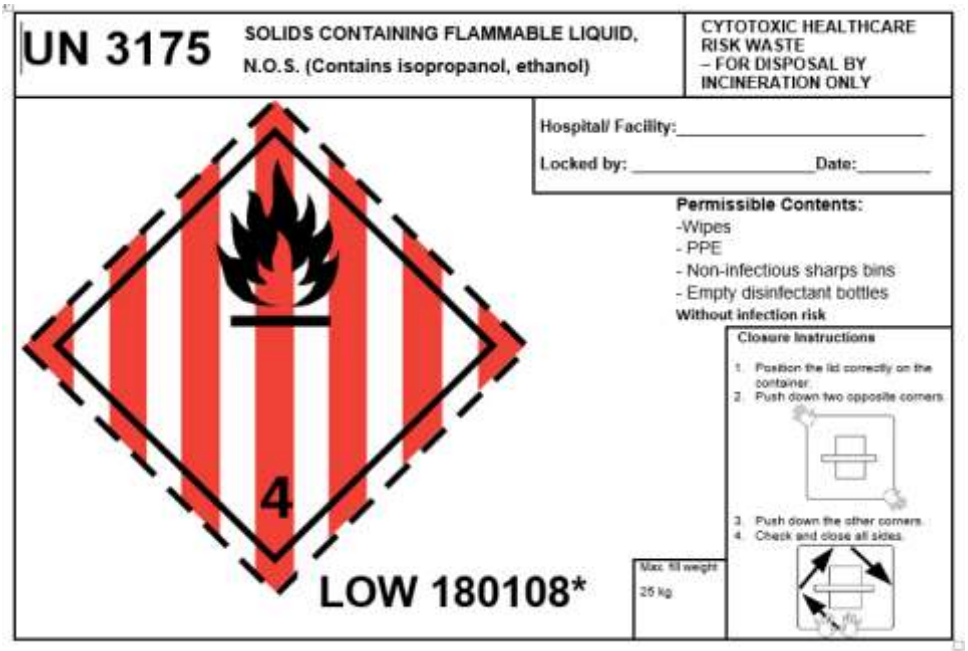


Figure 5. Flammables Bin Label

Non-infectious Sharps Bin Label (7 x 12cm Dimensions)

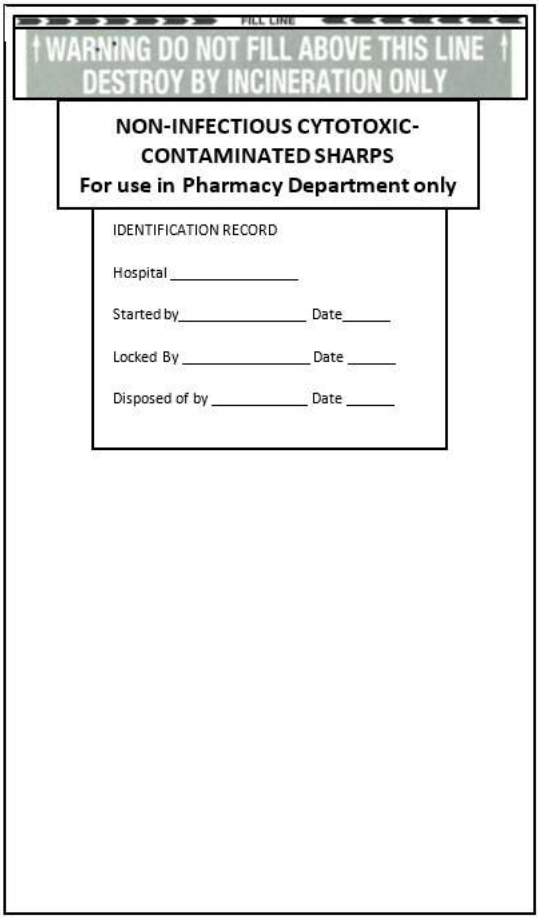


Figure 6. Example Non-infectious Sharps Bin label for bins not requiring assembly

Non-infectious Sharps Bin Label (for larger Sharps Bins that require assembly)

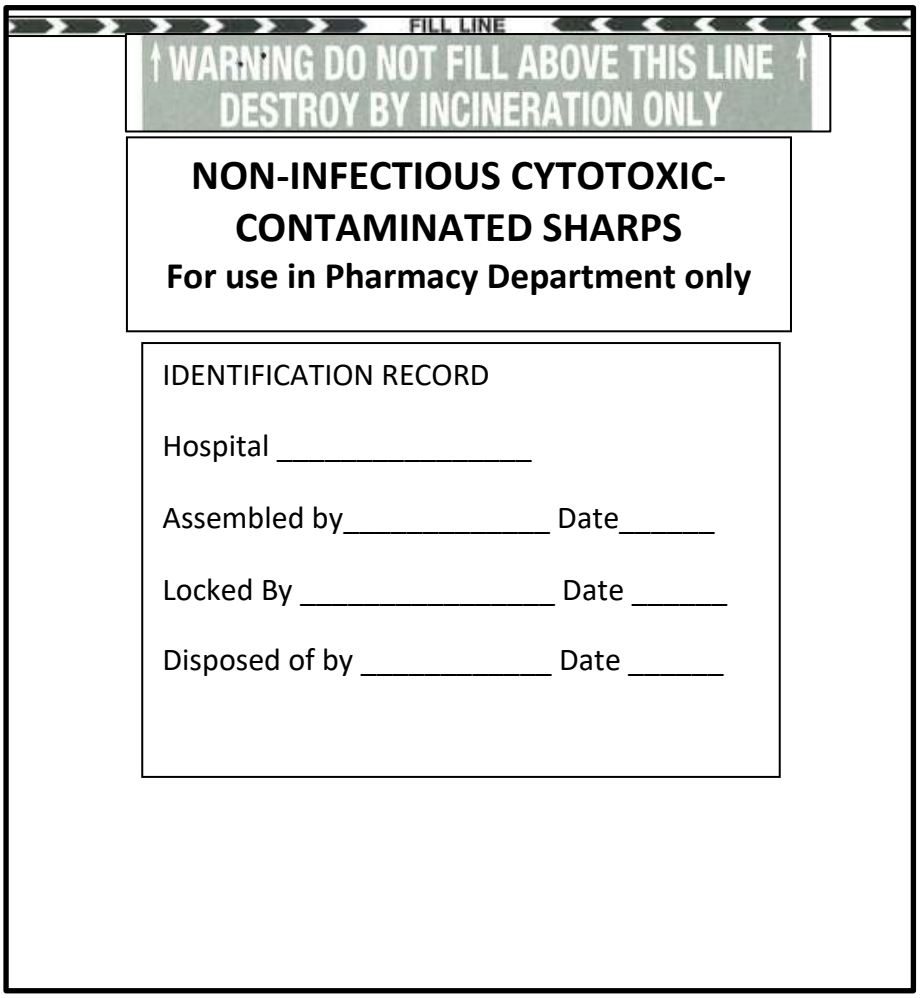
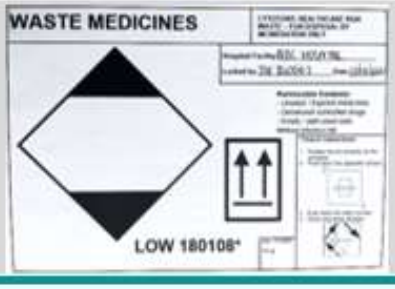


Figure 7. Example Non Infectious Sharps Bin label for bins requiring assembly

Appendix 3 Checklists

Appendix 3A Disposal of Waste Medicines in Limited Quantities (LQ) Bin Checklist Guide

Disposal of Waste Medicines in Limited Quantities (LQ) Bin Checklist Guide

1	Yellow 30/60 Litre rigid bin (with purple lid), pre-labelled with Limited Quantities Label **Note:** Absorbent material pre-installed in the base of the bin	
2	Permitted contents as inner packaging include: • Unused / Expired medicines • Denatured controlled drugs • Empty / part-used vials } Without infection risk **Note:** Solids ≤ 500g Liquids ≤ 1L } Per Inner Packaging Liquids > 120ml positioned upright (unless leak-proof in all orientations)	
3	Bin closed with the purple lid when full **Note:** Bin gross maximum weight 15kg (for 30L) and 25kg (for 60L)	
4	Traceability cable tie applied and secured	
5	Limited Quantities Label completed on closure with: • Hospital/Facility • Locked by • Date	

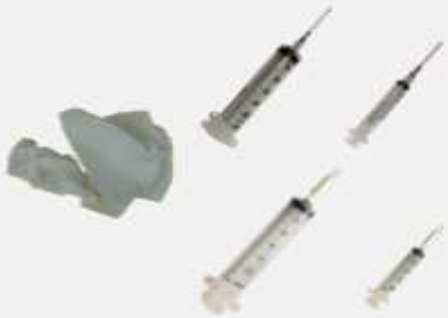
Appendix 3B Disposal of Flammable Waste Checklist Guide

Disposal of Flammable Waste Checklist Guide

1	Yellow 60 Litre rigid bin (pre-labelled) with Flammables Label	
2	Insert plastic liner and fold over sides **Note:** Do not use yellow clinical waste bags as come pre-labelled as infectious	
3	Place non-infectious sharps bin and/or zip lock bag into bin **Additional permitted contents:** Contaminated PPE, wipes, empty disinfectant bottles **Note:** No free liquid	
4	Liner closed with cable tie when full **Note:** Do not compress waste	
5	Bin closed with purple lid when full **Note:** Bin gross weight ≤ 25kg	
6	Traceability cable tie applied and secured	
7	Flammables Label completed on closure with: • Hospital/Facility • Locked by • Date	

Appendix 3C Disposal of Aseptic Isolator Sharps Bin Waste Checklist Guide

Disposal of Aseptic Isolator Sharps Bin Waste Checklist Guide

1	Purple Lid Sharps Bin of an appropriate size Purple Lid Sharps Bin assembled (if required) Non-infectious cytotoxic label applied **Note:** Non-infectious cytotoxic label completed with: • Hospital • Assembly by / Started by & Date	
2	**Permitted contents** Non-infectious sharps waste i.e. needles, glass ampoules, syringes with transfer devices, wipes **Note:** Alternatively syringes with transfer devices and wipes may be placed in a zip lock bag	
3	Bin locked when full and non-infectious cytotoxic label signed off with: • Locked by & Date • Disposed of by & Date	
4	Sharps Bin placed in Flammables Bin	

Appendix 4 Signature Sheet

I have read, understand and agree to adhere to this Guideline and Procedure:

Print Name	Signature	Area of Work	Date

PART B

1.0 Initiation

1.1 Purpose

The purpose of the Guideline is to provide guidance on the segregation, packaging and removal of waste medicines from Pharmacy Departments and Aseptic Units to ensure compliance with the applicable provisions of the relevant dangerous goods transport and waste regulations.

This Guideline applies to:

- Unused or expired medicines and related products from the pharmacy
- Medicines including patient medicines returned from the wards provided there is no additional infection risk. Medicines that carry an infection risk should be disposed of in the appropriate infectious waste containers that are provided at ward level
- Waste generated in Aseptic Units – wastes contaminated with residues of cytotoxic drugs to include used vials, syringes, needles, PPE, wipes and disinfectant bottles

The Guideline must be used if developing any local written procedures detailing the specific practices for a particular activity or facility.

1.2 Policy Statement

It is the Policy of the Health Service Executive (HSE) to reduce, so far as is reasonably practicable, the risks associated with the disposal of pharmacy wastes. In this regard the HSE as consignor[8] and packer[9] of waste medicines is committed to classify, segregate, package, mark and label, and present for collection pharmacy waste in line with dangerous goods and waste regulatory requirements as outlined in Section 1.7.

1.3 Scope

This Guideline applies to all personnel involved in the segregation, packaging and removal of waste medicines from both Acute and Non Acute HSE Pharmacy departments.

1.3.1 Out of Scope

This Guideline does not address waste medicines generated in ward/clinical areas which are deemed to have an infectious risk or waste medicines generated from High Street Pharmacies.

In line with the HSE Code of Governance (2021) Section 38 and Section 39 Agencies are to adopt this Guideline or develop a Guideline of their own which is consistent with this Guideline and provide assurance to the HSE regarding same.

[8] Consignor means any person, organisation or government which prepares a consignment for transport

[9] Packer means any enterprise which puts dangerous goods into packaging's, including large packaging's and intermediate bulk containers (IBCs) and, where necessary, prepares packages for carriage

1.4 Objectives

- To provide a simplified framework for HSE managers with responsibility for the disposal of waste medicines that complies with the relevant transport and waste regulation
- To ensure a standardised approach across the HSE and reduce variation in practice
- To outline the clear roles and responsibilities of responsible persons

1.5 Outcome

- A process to enable Managers to fully comply with the relevant dangerous goods transport and waste regulations
- A standardised approach across the HSE with regard to the disposal of waste medicines and reduce variation in practice
- Clear roles and responsibilities are outlined

1.6 Guideline Development Group

Members of the Pharmacy Waste Project Group, Pharmacy Waste Advisory Group and Pharmacy Waste Aseptic Group can be found in Appendix 5 of this Guideline. Conflict of Interest Declaration Forms were signed by members of the Development Group and are retained on file by the National Health and Safety Function (NHSF), Policy Team.

1.7 Approval Governance Group

Members of the Approval Governance Group can be found in Appendix 6 of this Guideline.

1.8 Supporting Evidence and Publications

The following legislation is pertinent and was referred to during the development of this guideline:

1. ADR: Agreement Concerning the International Carriage of Dangerous Goods by Road – a softcopy may be downloaded by navigating from the webpage at http://www.unece.org/trans/welcome.html
2. European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations, (current version) – apply the ADR regulations to national and international road transport within Ireland
3. IMDG Code: International Maritime Dangerous Goods Code
4. Commission Regulation (EU) No 1357/2014 on the properties of waste which render it hazardous
5. Commission Decision 2000/532/EC on the list of waste (LoW)
6. Regulation (EC) No 1013/2006 on the international movement of waste
7. The Waste Management Act 1996 and subsequent amendments
8. S.I. No. 324 of 2011 European Communities (Shipments of hazardous waste exclusively within Ireland) Regulations 2011
9. Safety, Health and Welfare at Work Act, 2005

The following documents were also consulted:

10. EPA Waste Classification Guide, June 2015
11. DOHC HSE: Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for Healthcare Risk Waste, November 2010
12. UK Dept. of Health: Health Technical Memorandum 07-01: Safe Management of Healthcare Waste, March 2013
13. French Ministries for Environment and Health: Practical guide on waste from healthcare settings (Pour une bonne gestion des déchets produits par les établissements de santé et médico-sociaux), March 2016
14. German LAGA guide on the disposal of healthcare waste (Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes), January 2015
15. Draft US NIOSH List of Hazardous Drugs in Healthcare Settings, 2020
16. Stericycle UK cytotoxic and cytostatic drugs list, 2013
17. UK Pharma cytotoxic drugs list, 2009

2.0 Development of Guideline

2.1 Literature Review

The objective of the literature review was to determine the legal requirements, establish current status and best practice in relation to the disposal of medicines and associated waste from hospital pharmacies.

What are the legal requirements and current status?

The ADR and IMDG dangerous goods regulations are the relevant regulations and require that any materials that fall within the scope of the regulations are correctly classified, packaged and marked/labelled as prescribed by the regulations (See Appendix 7 for further information on the classification of medicines for transport). The Healthcare Risk Waste Management, Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste, November 2010 recognised that some medicines are classified for transport and advised that appropriate classification, packaging and labelling should be determined with assistance from a Safety Adviser. In the absence of further detailed guidance and easily accessible information on transport hazards from medicine suppliers, the practice that evolved in many facilities was to ship waste medicines as infectious clinical waste of Class 6.2. This practice does not comply with the transport regulations or the guidance and the HSA as the competent authority for enforcement of the ADR transport regulations have also identified the practice as non-compliant.

Under European waste regulations, human medicines fall under either the absolute hazardous waste entry LoW 180108 for cytotoxic and cytostatic medicines or the absolute non-hazardous waste entry LoW 180109 for all other medicines. The regulations themselves do not provide a definition of what constitutes a cytotoxic or cytostatic drug and do not require that waste medicines are segregated into these two fractions. Both waste codes are currently used in waste transfer documentation.

Following on from the determination of the legal requirements and current status two other questions were considered:

What is the simplest and most practical way of complying with the transport regulations?

UK Department of Health (2013) Technical Memorandum **[12]** advised the use of an exemption from the road transport regulations that applies to medicines in finished retail packaging or application of exemptions that apply to dangerous goods packaged in Limited Quantities. The finished packaging exemption was not of benefit as the waste is exported for incineration and the exemption does not apply to sea transport. Consequently, it was concluded to develop a guideline based on application of Limited Quantities packaging provisions. To simplify the process further, it was also decided to adopt a worst-case strategy as allowed under ADR 2.1.3.5.2 and 2.1.3.5.5 and IMDG 2.0.5.4.3 of the transport regulations. Otherwise, it would be necessary to determine the transport class of each individual medicine, a task that is complex and challenging due to the fact that safety data sheets are not required to be supplied with medicines and the concentration of the Active Pharmaceutical Ingredient (API) in use may change. (See Appendix 8 for a worked transport classification example where a Safety Data Sheet (SDS) for the supplied medicine was available).

Was it necessary, practical or worthwhile to segregate medicines into LoW 180108 and 180109?*

UK national legislation requires that waste medicines are segregated into separate fractions in England and Wales, but this requirement does not exist in the legislation for Scotland and Northern

Ireland. Similarly, there is no explicit requirement to segregate the waste in Irish legislation **[9]**. From a practical perspective, there is a lack of agreed criteria for defining waste cytotoxic and cytostatic medicines. French **[13]**, German **[14]** and UK guidance **[12]** documents use common criteria of medicines that are either carcinogenic, mutagenic or toxic for reproduction (CMR), while the UK guidance similarly ascribes acute toxicity as a determining criterion. This was further illustrated when various lists of what are deemed hazardous drugs were compared (This list is available and can be accessed through the National Health and Safety Helpdesk at https://healthservice.hse.ie/staff/benefits-services/health-and-safety/health-and-safety-helpdesk.html). Thus, practicality would be an issue.

Finally considering that LoW 180109 is a non-hazardous waste code, the possibility of having such a fraction incinerated in the non-hazardous waste incinerators that operate in Ireland was explored as a potential cost saving. However, this was not acceptable to the operators due to the difficulties in ensuring clear segregation of medicines into the separate fractions.

The conclusion therefore, was not to segregate the medicines and use LoW 180108* as the worst-case designation.

Recommendation

It is recommended that the Guideline that has been developed and is presented in Part A is adopted as the most practical way of complying with the transport and waste regulations. The guideline is based on taking a worst case approach to the transport classification of waste availing of the exemptions allowed for Limited Quantities. This avoids the need to individually identify packages as regards the class of dangerous goods that they may contain.

2.2 Method of appraising evidence

The process outlined in this document is based on a review of the relevant legislation, codes of practice and relevant publications as documented in section 1.7.

2.3 Resources necessary to implement the PPPG recommendations

The Guideline document consolidates existing practices and service managers are required to review existing practices and procedures to ensure they are aligned to the requirements set out in this Guideline. Implementation of this Guideline will be supported through a series of briefing sessions and by the provision of on-site support from the local Dangerous Goods Safety Advisor (DGSA).

2.4 Guideline Steps/Recommendations

The recommendations are outlined in Part A of this Guideline.

3.0 Governance and Approval

3.1 Formal Governance Arrangements

Please refer to Appendix 6

4.0 Communication and Dissemination

4.1 The Guideline will be disseminated by the National HR Division for immediate implementation by relevant services, in line with the agreed HSE protocol. The Guideline will also be communicated through national and local newsletters; twitter and email notifications.

5.0 Implementation

5.1 Managers (Responsible Persons) are responsible for developing an implementation plan, including identification of responsible person(s), specifying the actions to implement the Guideline and timeframes for implementation.

5.2 **Education and Training**

Support for the implementation of this Guideline will be provided through:

- The use of an instructional video and
- On-site support from the local Dangerous Goods Safety Advisor (DGSA)

Additional support is available from the National Health and Safety Function, Policy Team and National Dangerous Goods Safety Advisor.

Please contact the National Health and Safety Function, Helpdesk on the link below:
https://healthservice.hse.ie/staff/benefits-services/health-and-safety/health-and-safety-helpdesk.html

6.0 Monitoring, Audit and Evaluation

6.1 Managers are required to monitor and audit the implementation plan supporting this Guideline using the audit checklist in Appendix 9.

6.2 Implementation of this Guideline shall be audited periodically at national level and by the local Dangerous Goods Safety Advisor (DGSA).

7.0 Revision/Update

7.1 This Guideline shall be reviewed at national level every three years or earlier if circumstances require it e.g. change in legislation etc.

Appendix 5 Membership of the Guideline Development Group to include: Pharmacy Waste Project Group, Pharmacy Waste Advisory Group and Pharmacy Waste Aseptic Advisory Group

	Pharmacy Waste Project Group
Bríd Cooney	National Health and Safety Advisor
Dr. JJ Tobin	National Strategic Dangerous Goods Adviser, Chemhaz Solutions
Fiona Dowling	Stericycle
Michael Joyce	Dangerous Goods Adviser, Chemhaz Solutions
Martina Hunt	Capital and Estates Department
Christopher Murray	Dangerous Goods Safety Advisor, Eco-online Department (who replaced James McHugh February 2022)
Sarah Ingle	Regional Dangerous Goods Safety Advisor, Eco-online representing Section 38 Hospitals (February 2022) who replaced Henry Mooney, August 2021)
Chairperson: Ms. Margo Leddy	National Health and Safety Manager

Pharmacy Waste Advisory Group	
John Given	Chief Pharmacist, Galway University Hospital
Eimear Heslin	Senior Pharmacist Technician, RCSI Hospital Group, Connolly Hospital (replaced Rebekah Corrigan, Senior Pharmacist Technician)
David Hobbert	Chief Pharmacist, University Hospital Kerry
James Kee	Liaison Chief II Pharmacist, CHO 7 Dublin South, Kildare and West Wicklow Community Healthcare
Aileen Maher	Senior Clinical Pharmacist, University Hospital Limerick
Pat Murphy	Pharmacist, CHO Area 8 Midlands Louth Community Healthcare
Claire O'Dwyer	Chief II Pharmacist, Louth County Hospital
Louisa Power	Chief II Pharmacist, CHO Area 3 Mid-West Community Healthcare
Mary Worrall	Chief II/Senior Pharmacist, Children's Health Ireland at Crumlin
Pharmacy Waste Aseptic Advisory Group	
Elizabeth Breen	Chief Pharmacist II, National Cancer Control Programme
Yvonne Cummins	Senior Pharmacist, Our Lady of Lourdes Hospital
Jane Fanning	Senior Pharmacist, Aseptic Unit, Children's Health Ireland at Crumlin
Olivia Flynn	Chair of the Aseptic Service Special Interest Group, University Hospital, Limerick
John Given	Chief Pharmacist, Galway University Hospital

Martina Keegan	Senior Pharmaceutical Technician, National Cancer Control Programme
Harold Lewis	Chief II Pharmacist, Galway University Hospital
Aileen Maher	Senior Clinical Pharmacist, University Hospital Limerick
Pat Murphy	Pharmacist, CHO Area 8 Midlands Louth Community Healthcare
Claire O'Dwyer	Chief II Pharmacist, Louth County Hospital
Mary Worrall	Chief II/Senior Pharmacist, Children's Health Ireland at Crumlin

Acknowledgements:

The Guideline Development Project Group would like to thank and acknowledge the contribution of:

- Pilot Sites:
  - Connolly Hospital, Blanchardstown
  - Our Lady's Hospital, Navan
  - Louth County Hospital, Dundalk
  - Our Lady of Lourdes Hospital, Drogheda
  - Cavan and Monaghan Hospital
  - CHI Crumlin

- Fionnuala King, Chief Pharmacist, Acute Hospital Drugs Management Programme

- Henry Mooney (EcoOnline and formerly DCM)

- Sarah Fagan, Chief Pharmacist, HSE

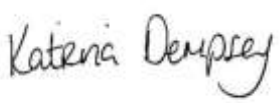
- James McHugh, Stericycle

- Health and Safety Authority

- Marine Surveys Office

- Environmental Protection Agency

Appendix 6 Membership of the Approval Governance Group

Anne Marie Hoey, National Director HR	Signature:  Date: 07.09.2022
Katrina Dempsey, Interim Head of the National Health and Safety Function	 Signature: Date: 31.08.2022

Appendix 7

1.0 Classification of Medicines for Transport (for information only)

Based on their hazardous properties all goods must be assessed against criteria in the transport of Dangerous Goods regulations (refer to Appendix 1 for relevant criteria) to determine if they classify as dangerous goods. Some medicines are classified as dangerous goods for transport and are assigned by Pharmaceutical suppliers to one of the following classes. The examples provided are for illustrative purposes only and are not meant as an exhaustive list.

Class 2 – Gases

These are encountered in the form of aerosol cans which use a compressed gas to expel the medicine.

Examples:
Sprilon® - for skin care (pressure sores) which is a flammable aerosol

Glytrin® - Sublingual Spray

Note: Nitrolingual Pumpspray is not a Class 2 medicine even though it also delivers 400 micrograms Glycerol Trinitrate per metered dose.

Cryogesic® -coolant aerosol spray – regulated as a medical device rather than a medicine.

Aerosol inhalers.

Notes:

- Pressurised aerosol inhalers are not subject to the transport regulations as they are only available in receptacles not exceeding 50 ml

- Trigger or pump action sprays that generate an aerosol via mechanical action do not fall into the category of aerosols under transport regulations as they do not contain a gas under pressure

Class 3 - Flammable Liquids

Some medicines are classified as Class 3 flammable liquids principally due to the use of ethanol or isopropanol as a solvent/excipients. Frequently, such medicines are encountered as either topical medicines or liquid concentrates for injection or infusion.

Examples:
Tincture of iodine- an over-the-counter medicine that falls into Class 3 because it contains approximately 98% Ethanol – Topical medicine 30 ml bottle with screw cap

Chloraprep®- is used in preparation for surgery and similarly belongs to Class 3 as it contains 70% Isopropyl Alcohol - Topical Medicine in sealed pouches

Betadine® Alcoholic Povidone Iodine products used in preparation for surgery – topical medicine can be supplied in 500 ml or 5 L containers
Note: non-alcoholic povidine iodine products also exist and are not classified as dangerous goods.

Dexketoprofen - contains ethanol – pain medicine by injection.

Ketorolac Trometamol 30 mg – eye drops for use after eye surgery – topical medicine.

Paclitaxel solution – chemotherapy drug for infusion – concentrate contains 50% (v/v) Ethanol – not flammable when diluted for infusion**.**

Paricalcitol -5 µg/ml solution for injection contains 20% (v/v) Ethanol - used in kidney dialysis patients - 1 ml or 2 ml ampoule.

Phenytoin for injection/infusion used in neural anti-seizure therapy contains 8% Ethanol – 5 ml ampoule.

Dalacin T® 10 mg/ml - topical solution (acne treatment).

Class 6.1 – Toxic Substances

These come as a mixture of toxic solids in tablet or capsule form for oral administration, transdermal patches, and powders that must be reconstituted for injection or infusion in addition to some toxic liquids.

Examples:
Voriconazole Powder - is an anti-fungal drug that is reconstituted to 10 mg/ml for injection. After reconstitution it is sufficiently dilute to be no longer classified as a dangerous good for transport.

Paliperidone palmitate – supplied in pre-filled syringes which is administered by injection to treat schizophrenia (LD50 Paliperidone = 65 mg/kg) – pre-filled syringes with ≥ 273 mg paliperidone palmitate are toxic liquids.

Ixazomib citrate – 2.3, 3 and 4 mg Ninlaro® capsules are Class 6.1 toxic solids.

Bortezomib - a chemotherapy drug that is supplied as a powder for reconstitution and infusion. After reconstitution to 2.5 mg/ml it is sufficiently dilute to be no longer classified as a dangerous good for transport.

Class 9 – Miscellaneous Dangerous Goods

A number of medicines are assigned to Class 9 due to their environmentally hazardous properties.

Examples:
Sudocrem® -as the active ingredient is Zinc Oxide which is environmentally hazardous

Pevisone® - topical cream contains econazole nitrate

Note: Medicines that are classified as environmentally hazardous are exempt from all other provisions of the dangerous goods transport regulations because they are always supplied, packaged in individual receptacles of not more than 5 L or 5 Kg.

Appendix 8 Worked Transport Classification

Example: Bortezomib Medicine

According to an SDS for a Bortezomib preparation, the active substance, Bortezomib has an estimated LD_{50} (oral) of < 2 mg/kg.

This would make it a Class 6.1 packing group I toxic substance under the transport regulations.

However, it is supplied as a powder mixed with mannitol at approximately 90% mannitol: 10% Bortezomib. The precise concentration in the powder is not indicated in the summary of product characteristics available to pharmacists.

At this concentration the estimated LD_{50} of the mixture = 2 x100 /10 = 20 mg/kg, which equates to Class 6.1 packing group II for transport.

In use, the powder is reconstituted with solvent to give a maximum concentration of 2.5 mg/ml = 0.25%.

The estimated LD_{50} of this concentrate = 2 x 100 / 0.25 = 800 mg/kg which is not classified as toxic for transport.

Appendix 9 Audit Checklist for the implementation of the Guidelines for the Segregation Packaging and Removal of Waste Medicines from HSE Pharmacy Departments and Aseptic Units 2022

Audit Checklist Questions		Guideline Clause	Yes	No	NA	Action Required	Action Owner	Timeframe
1	Is there a system in place for the appropriate circulation/communication of this Guideline and any local protocols to all relevant employees?	5.3.1 Part A						
2	Do all relevant departments have access to this Guideline?	4.1 Part B						
3	For General Pharmacy, is the segregation of waste medicines in line with requirements as set out in section 2.1.1 of this Guideline?	2.1.1						
4	For General Pharmacy, is the packaging and packing method for waste medicines in line with requirements as set out in section 2.1.2 of this Guideline?	2.1.2						
5	For General Pharmacy, is the marking and labelling of packaging in line with requirements as set out in section 2.1.3 of this Guideline?	2.1.3						
6	For the Aseptic Unit, is the segregation of waste medicines in line with requirements as set out in section 2.2.1 of this Guideline?	2.2.1						
7	For the Aseptic Unit, is the packaging and packing method for waste medicines in line with requirements as set out in section 2.2.2 of this Guideline?	2.2.2						
8	For the Aseptic Unit, is the marking and labelling of packaging in line with requirements as set out in section 2.2.3 of this Guideline?	2.2.3						
9	Is the storage of Pharmacy Waste in line with requirements set out in section 3.0 of this Guideline?	3.0 Part A						
10	Is assurance sought from the Healthcare Risk Waste Contractor that the appropriate transport documents are prepared?	4.0 Part A						
11	To support implementation of this Guideline, has appropriate information, instruction, supervision and training been provided?	5.0 Part B						
12	Has the ongoing provision of information, instruction and training been incorporated into the departments training schedule?	5.4.3 Part A						

Action Plan: Each criterion that scored 'no' must have a comment placed in the comment column – this comment will form the basis of your Quality Improvement Plan (QIP)/Action Plan