

**WAS-G-05**

**SEPA Guidance: Storage and treatment of healthcare waste**

August 2025

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## Introduction

This document provides guidance for anyone carrying out the storage and treatment of healthcare waste under The Environmental Authorisations (Scotland) Regulations 2018 (EASR). It should be read alongside the overarching guidance on Waste Storage and Treatment.

Most permit and registration conditions are objective-based: SEPA defines the objective but it’s up to the Authorised Person to determine how best to meet that objective. This guide will help Authorised Persons work out how to meet these objectives.

If the activity is listed in Schedule 20 of EASR, it may also be subject to the [Waste Treatment Best Available Techniques (BAT) Conclusions](https://www.sepa.org.uk/media/594490/bat-conclusions.pdf).

If the activity includes waste incineration, it may also be subject to the [Waste Incineration Best Available Techniques (BAT) Conclusions](https://eippcb.jrc.ec.europa.eu/reference/waste-incineration-0). This document does not provide guidance on the incineration process or on emissions from incineration.

Producers and transporters of healthcare waste should follow the sections on classification and segregation and waste pre-acceptance.

The guidance provided in this document is not definitive, and it does not replace the general obligation to manage each operation in the context of its specific location and characteristics. In certain situations, a higher standard of environmental protection may be necessary, for example, where there are local sensitive receptors.

## Healthcare waste

### Definition of healthcare waste

Healthcare waste is waste produced during the provision of human or animal healthcare, or related research activities. It includes both clinical and offensive waste.

Healthcare wastes arise from hospitals, GP surgeries, dental surgeries, veterinary surgeries etc. Healthcare wastes also arise in the community, and from some non-healthcare activities, for example:

* Cosmetic body piercing and body art.
* Non-medicinal procedures in the hair and beauty sector.
* Substance abuse crime scene clean-up.

Healthcare wastes are generally listed in Chapter 18 of the List of Waste and from municipal sources listed in Chapter 20.

In this guidance ‘clinical waste’ is healthcare waste that may pose a risk of infection (e.g. swabs, bandages and dressings) or which may otherwise prove hazardous, (e.g. medicines) unless rendered safe.

‘Offensive waste’ is healthcare waste produced from human or animal healthcare activities that:

* Is not clinical waste.
* Contains body fluids, secretions or excretions.
* Falls within waste codes 18 01 04, 18 02 03 or 20 01 99.

In general, offensive waste includes:

* Sanitary towels and tampons.
* Panty liners.
* Feminine wipes.
* Incontinence products and nappies.
* Catheter and stoma bags.
* Animal faeces and animal bedding etc.

Offensive waste is also commonly referred to as ‘hygiene’ waste and both terms are interchangeable for the purposes of this guidance.

‘Medicine’ is a drug or other preparation for the treatment or prevention of disease. Medicines may also include diagnostic agents.

‘Cytotoxic and cytostatic medicine’ is medicine that possesses hazardous properties which are toxic, carcinogenic, mutagenic or toxic for reproduction.

A ‘sharp’ is an item that could cause cuts or puncture wounds. This includes needles, hypodermic needles, scalpels and other blades, knives, infusion sets, saws, glass, and nails.

### Classification and segregation of healthcare waste

Correct classification and segregation of healthcare waste at source makes sure the right waste goes to the right place for storage and treatment. Segregating healthcare waste at source based on types and properties means it can be treated effectively and helps divert certain healthcare wastes (for example, offensive wastes) away from more costly and energy intensive processes.

The most important step is for healthcare waste producers to make sure wastes are rigorously segregated at source. Healthcare waste producers must check and confirm through audit that they are doing this on an ongoing basis. Annex 1 provides an example of a waste audit and summary report.

SEPA recommends that the system in Table 1, based on current industry best practice, is implemented for the management of healthcare wastes.

The system identifies and segregates healthcare waste based on waste classification and the suitability of treatment and disposal options. It describes the waste and, in most cases, gives an indication of the chosen disposal method.

**Table 1:** Types of healthcare waste by packaging colour, list of waste code and activity

| **Colour of packaging** | **Waste types** | **List of waste (LoW) codes from EWC** | **Activities** |
| --- | --- | --- | --- |
| Orange: Infectious waste, not contaminated with chemicals or medicines. | Human healthcare (may contain sharps). | 18 01 03\* | * Storage.
* Alternative treatment.
* Incineration.
 |
| Orange: Infectious waste, not contaminated with chemicals or medicines. | Animal healthcare (may contain sharps). | 18 02 02\* | * Storage.
* Alternative treatment.
* Incineration.
 |
| Orange: Infectious waste, not contaminated with chemicals or medicines. | Municipal, separately collected fractions, not from healthcare or research-related sources (may contain sharps). | 20 01 99 | * Storage.
* Alternative treatment.
* Incineration.
 |
| Orange: Infectious waste, not contaminated with chemicals or medicines. | Commercial, separately collected fractions of absorbents, wiping cloths and protective clothing contaminated by infectious substances. | 15 02 02\* | * Storage.
* Alternative treatment.
* Incineration.
 |
| Yellow: Infectious waste, contaminated with chemicals or medicines (not cytotoxic or cytostatic). | Human healthcare (may contain sharps). | 18 01 03\*  | * Storage.
* Incineration.
 |
| Yellow: Infectious waste, contaminated with chemicals or medicines (not cytotoxic or cytostatic). | Animal healthcare (may contain sharps). | 18 02 02\* | * Storage.
* Incineration.
 |
| Red: Infectious anatomical, chemically preserved. | Human healthcare. | 18 01 03\* | * Storage.
* Incineration.
 |
| Red: Infectious anatomical, chemically preserved. | Animal healthcare. | 18 02 02\* | * Storage.
* Incineration.
 |
| Red: Infectious anatomical, not chemically preserved. | Human healthcare. | 18 01 03\* | * Storage.
* Incineration.
 |
| Red: Infectious anatomical, not chemically preserved. | Animal healthcare. | 18 02 02\* | * Storage.
* Incineration.
 |
| Red: Non-infectious anatomical. | Human healthcare. | 18 01 02 | * Storage.
* Incineration.
 |
| Red: Non-infectious anatomical. | Animal healthcare. | 18 02 03 | * Storage.
* Incineration.
 |
| Purple: Cytotoxic and cytostatic medicines. | Human healthcare. | 18 01 08\*20 01 31\* | * Storage.
* Incineration.
 |
| Purple: Cytotoxic and cytostatic medicines. | Animal healthcare. | 18 02 07\*20 01 31\* | * Storage.
* Incineration.
 |
| Blue: Pharmaceuticals, medicines, and controlled drugs.  | Human healthcare. | 18 01 0920 01 32 | * Storage.
* Incineration.
 |
| Blue: Pharmaceuticals, medicines, and controlled drugs.  | Animal healthcare. | 18 02 0820 01 32 | * Storage.
* Incineration.
 |
| Yellow/Black: Offensive.  | Human healthcare. | 18 01 04 | * Storage.

Incineration. |
| Yellow/Black: Offensive.  | Animal healthcare. | 18 02 03 | * Storage.
* Incineration.
 |
| Yellow/Black: Offensive.  | Not from healthcare or research-related sources. | 20 01 99 | * Storage.
* Incineration.
 |
| Colour not specified. | Amalgam waste from dental care. | 18 01 10\* | * Storage.
 |
| Colour not specified. | Infectious gypsum wastes (for example, plaster casts and molds). | 18 02 02\*18 01 03\* | * Storage.
 |
| Colour not specified. | Non-infectious sharps, not contaminated with chemicals or medicines. | 18 01 0118 02 01 | * Storage.
 |
| Colour not specified. | Non-infectious gypsum wastes (for example, plaster casts and molds). | 18 01 0418 02 03 | * Storage.
 |

Not all healthcare waste is clinical waste. Table 2 details the most common non-clinical waste produced at healthcare facilities. There is no recommended colour coded packaging for non-clinical waste.

Where these wastes are stored prior to onward transport, it is recommended they are stored separately from those in Table 1. This will ensure that any wastes not suitable for treatment by alternative treatment will not be processed alongside those that are suitable.

**Table 2: Common non-clinical wastes produced during healthcare activities.**

| **Waste type** | **List of waste (LoW) codes**  | **Activities** |
| --- | --- | --- |
| Non-infectious sharps, not contaminated with chemicals or medicines. | 18 01 01 or18 02 01 | Storage. |
| Water-based developer and activator solutions. | 09 01 01\* | Storage. |
| Water-based offset plate developer solution. | 09 01 02\* | Storage. |
| Solvent based developer solutions. | 09 01 03\* | Storage. |
| Fixer solution. | 09 01 04\* | Storage. |
| Bleach and bleach fixer solutions. | 09 01 05\* | Storage. |
| Photographic film and paper containing silver or silver compounds. | 09 01 07\* | Storage. |
| Photographic film and paper free of silver or silver compounds. | 09 01 08 | Storage. |
| Lead foils from dental care. | 15 01 04 or 15 01 10\* | Storage. |
| Non-infectious gypsum wastes (for example, plaster casts and molds). | 18 01 04 or 18 02 03 | Storage. |

Where the colour of packaging for a particular type of waste is not specified, use the most appropriate colour that considers the nature of the waste and treatment or disposal route. For example, it should be:

* Yellow if the waste requires waste incineration.
* Orange if alternative treatment is appropriate.
* Black and yellow if municipal incineration is appropriate.
* Or (if possible) an additional non-conflicting colour code.

## Additional pre-acceptance procedures for healthcare waste

Implement waste pre-acceptance procedures so enough is known about the waste before it arrives to confirm it is suitable for acceptance.

Advice provided to waste producers about segregating waste must follow table 1.

Where receiving waste from a country that does not use the same waste segregation process or colour-coded packaging as set out in table 1 of this guidance, confirm the segregation practices and colour-coding to understand the waste stream and determine the appropriate treatment.

### Pre-acceptance audits

Obtain and assess a waste Pre-Acceptance Audit (PAA) before first accepting waste from a producer and then at regular intervals, as set out in this guidance. This applies whether the producer is in Scotland or not. Annex 2 sets out the minimum criteria for a PAA.

PAA reports are not required for:

* Waste produced at domestic premises.
* Waste produced at care homes that do not provide nursing care.
* Healthcare wastes from non-healthcare activities – as classified under chapter 20 of the List of Wastes.

Pre-acceptance audits must be undertaken through physical presence at the producer’s premises. Those carrying out PAAs must be able to demonstrate they are appropriately trained and/or experienced and have the necessary knowledge and skills for the task.

PAA reports received from waste producers should contain the following information:

* Waste producer information including name, address, type of premises.
* Audit start and end dates.
* A description of the audit including the procedures employed, the auditors, their affiliation, and their competence.
* A description of the different, departments, wards or functional areas that exist within the premises highlighting the specific processes that produce relevant wastes.

The PAA report must include information to show which waste types are produced by each department, ward or functional area. The waste types the audit must include:

* Cytotoxic and cytostatic contaminated material.
* Other pharmaceuticals or pharmaceutically contaminated material – such as medicinally contaminated syringes, intravenous (IV) therapy bags, tubing, bottles, vials, ampoules.
* Waste chemicals – such as laboratory agents, auto-analyser bottles, diagnostic kits, disinfectants.
* Human or animal tissue and associated chemical preservatives.
* Sharps, and whether they are contaminated with medicines (even if fully discharged).
* Other infectious wastes.
* Dental amalgam.
* Non-hazardous offensive wastes - an offensive waste stream must be in place for offensive hygiene healthcare waste.
* Other non-hazardous wastes, including municipal waste and autoclaved wastes.
* Gypsum wastes other than the limited quantities correctly described as infectious.

For each waste type identified the PAA report must detail:

* A written description, type and classification, including List of Waste (LoW) codes.
* Physical form and composition.
* Hazardous properties.
* The type and colour-coding of the container or packaging the waste is placed in.
* How the packaging is labelled.

The PAA report must also include information about:

* The segregation practices for wastes placed in storage areas, bulk containers or bins.
* Specific storage requirements for the wastes.
* The contents of a representative number of each type of bulk container that were checked visually.
* Discussions held with staff that establish the validity of the segregation and storage standards, and the observation and recording of actual practice.

The PAA report must include:

* The findings made for each waste stream, and where applicable, the changes made because of this or previous audits.
* Information on the waste producer’s policies, staff training, internal audit regimes, and management systems.
* The estimated quantity of each waste expected to be delivered to the site from the waste producer per year and in a typical load.
* Confirmation that waste does not contain a radioactive source or, when there is a risk of radioactive contamination, confirmation that the waste is not radioactive, unless the authorisation allows acceptance of these materials.
* Safety data sheets for single stream product chemicals, laboratory chemicals or pharmaceuticals (if available).

A PAA will be deemed unsatisfactory if it:

* Does not contain the information set out above.
* Highlights potential unacceptable risks to process safety, human health and the environment including odour and other emissions.
* Shows that acceptance of the waste is likely to cause non-compliance with the conditions of the authorisation and/or prevent any waste from being treated to the desired standard i.e. rendered safe.

If a PAA is unsatisfactory:

* Stop accepting waste from the relevant producer unless it is only being immediately transferred for appropriate treatment or disposal elsewhere.
* Do not recommence accepting waste from the relevant producer until such time as they are able to provide a satisfactory PAA.

If a PAA is satisfactory, but highlights non-conformances or inappropriate segregation practices:

* Obtain information from the relevant waste producer which demonstrates they have put in place measures to resolve these issues.
* Stop accepting waste from the relevant producer from the date the PAA was received if they cannot demonstrate this after a period of 3 months.

The PAA report will no longer be valid for pre-acceptance purposes, and a new report is required if the:

* Time intervals (minimum frequency of audits) detailed in Table 3 are exceeded.
* Waste producer makes significant changes to its on-site practices.
* Waste changes.
* Waste received contains significant non-conformances to the pre-acceptance information.

Keep records that relate to pre-acceptance audits for a minimum of 6 years in a computerised process control system. This includes:

* PAA reports.
* Assessment of the reports.
* Additional information received.
* The assessment that the waste is acceptable.

Carry out appropriate pre-acceptance checks and subsequent assessments on the waste received from each producer.

Be able to obtain (without unreasonable delay) a copy of the PAA and assessment about any individual producer. This may be needed for operational reasons or because an officer from SEPA asks to see it.

Obtain and assess representative waste PAA reports on an ongoing basis following the minimum frequencies and scope detailed in Table 3.

**Table 3: Frequency and scope of pre-acceptance audit reports.**

| **Frequency** | **Scope** |
| --- | --- |
| 12 months for each healthcare waste producer premises that produces 5 tonnes or more of clinical waste in any calendar year. | The first audit must cover the whole premises. Where the audit is satisfactory and identifies consistent good practices and appropriate segregation, the scope of subsequent annual audits can be reduced to cover one third of the units, departments and wards. Each annual report must clearly identify which parts of the premises have been audited. The whole premises must be audited over the 3-year audit cycle. |
| 2 years for each medical practice, veterinary practice, dental practice and laboratory that produces less than 5 tonnes of clinical waste in any calendar year. | Each audit must cover the whole premises. |
| 5 years for other producers of clinical waste. | Each audit must cover the whole premises. |

## Additional waste acceptance procedures for healthcare waste

Implement waste acceptance procedures to ensure the characteristics of the waste received matches the information obtained during waste pre-acceptance. This is to confirm the waste is as expected and can be accepted. If it is not, reject it or, where that is not possible, accept it as a non-conforming waste.

Other than in an emergency (for example, taking waste resulting from an emergency incident clean-up), only receive pre-booked healthcare wastes that have undergone pre-acceptance assessment and are consistent with the pre-acceptance information.

When deciding whether to accept waste, check the relevant storage areas and treatment processes have the physical capacity needed to handle the waste. Do not accept if waste capacity is not available or if the limits in the authorisation would be breached.

Check and validate all transfer documentation and resolve discrepancies before accepting the waste. If the incoming waste classification or description is incorrect or incomplete, then address this with the original waste producer or waste carrier (or both) during waste acceptance. Record any non-conformance.

Carry out a thorough visual check of all loads (for example, in bulk containers, or on pallets) to identify any non-conforming items that may be:

* Unknown.
* Undocumented.
* Unexpected packaging types or colours.
* A waste type that the facility is not authorised for.

For example, this could be a cytotoxic or cytostatic sharps box, or rigid yellow bin of unknown content, buried at the bottom of a 770-litre wheeled bin or similar bulk container under orange clinical waste bags received for alternative treatment.

Initially, inspect the contents of each 770-litre wheeled bin or similar bulk container and check that the contents match those expected. If a specific customer has no non-conformances for three months or six consecutive collections (whichever is the longer period) it is possible reduce the visual inspection of their waste to a spot check of one 770 litre wheeled bin, or similar bulk container, or pallet in ten.

If non-conforming waste is identified later during a spot check, take measures to prevent a recurrence (including contacting the customer). Reinstate thorough visual checks on all loads from that customer until there are no non-conformances for the period as stated above.

Typically, waste is visually checked during bulk container-to-bulk container transfers or unloading or tipping operations. It is either directly inspected by the trained operative or via a surveillance camera and screen. If using the latter, the camera and screen should operate in colour and have a resolution and clarity that is good enough to easily and reliably identify any non-conforming items so they can be removed.

Healthcare wastes are potentially infectious; therefore, it is difficult to open each container or bag to check that they contain only the correct waste. Where pre-acceptance requirements set out above are followed, SEPA will not expect the contents of individual containers or bags to be checked at the facility. In these instances, check and confirm that the healthcare waste is appropriate for storage and treatment at the facility based on its colour-coded packaging.

Minimise the manual handling of waste. Use mechanical unloading technologies where it is possible and practicable to do so. Where manual handling is undertaken, physical assessment may be used to support visual checks of the waste. This process can be enhanced using backlights.

On arrival, bagged waste should be in, or unloaded into, bins or other rigid, leak proof bulk containers for storage and handling around the site. Securely close the lid of the bin or other bulk container when not loading waste into or out of it.

On arrival, rigid containers (bins and boxes) should be put in, or unloaded onto, enclosed bulk containers (for example 770 litre wheeled bins) or pallets for storage and handling around the site. To prevent spillages, store and handle rigid containers and packaging that contain waste in an upright, stable and controlled manner, as far as it is practicable to do so.

Waste packages should be in sound condition. All containers (boxes and bins) should have well-fitting lids or other secure closing mechanisms. Deal immediately with any non-conforming packages or put them in a bulk container. Put non-conforming packages into quarantine to be dealt with appropriately. Record all non-conformances.

Have clear and unambiguous criteria to reject non-conforming wastes and a written procedure for recording, reporting and tracking non-conforming wastes, including notifying the relevant customer or waste producer and requiring their timeous feedback on action taken to prevent reoccurrence.

All waste packages received must be labelled or marked with a unique identifier. The unique identifier must allow the waste to be tracked and easily identify the producer of the waste, its type and hazardous properties, and its receipt date.

When receiving waste in a bulk container (for example, a wheeled bin), then provided they are from the same producer, all received at the same date and time, and contain a single waste stream, it is possible to mark or label on the bulk container with the unique identifier for as long as the waste remains in there. Similarly, waste is received on a pallet, provided they are from the same producer, all received at the same date and time, and contain a single waste stream, the pallet can be marked or labelled with the unique identifier for as long as the waste remains on it. If splitting a bulk or palletised load, mark or label each container with the unique identifier so each can be tracked.

If there is a known risk of radioactive contamination (for example, a site is thought to use radioactive materials, but it is not clear if all the suitable systems are in place to manage and segregate the wastes produced), check the waste to determine that it does not include radioactive material, unless authorised to accept these materials.

## Quarantine storage

A dedicated waste quarantine area must be in place to temporarily store waste being rejected, or non-conforming waste whilst it is being assessed.

Quarantine storage must be indoors and separate from all other storage and clearly marked.

Quarantine storage must be for a maximum of 5 working days. Have written procedures for dealing with wastes held in quarantine, including a maximum storage volume. For some limited and specific cases (for example, the detection of radioactivity), the quarantine storage time can be extended if SEPA agrees.

The waste offloading, reception and quarantine areas must have an impermeable surface with self-contained drainage to prevent any spills entering the storage systems or escaping off site. All surfaces must be of a type and quality that can be disinfected effectively.

## Waste Tracking

Use a computerised tracking system to hold up-to-date information about the available capacity of the waste quarantine, reception, general and bulk storage areas.

Use a pre-booking system to make sure there is sufficient waste storage and process capacity for the incoming waste.

The waste tracking system should hold all the information generated during:

* Pre-acceptance.
* Acceptance.
* Storage.
* Repackaging.
* Treatment.
* Removal off site.

Create records and update them to reflect deliveries, on-site treatment and despatches. The tracking system will also operate as a waste inventory and stock control system and include the following information:

* The date the waste arrived on site.
* The original producer’s details (or unique identifier).
* Details that link each healthcare waste container accepted to its consignment or transfer note.
* Details of all previous holders.
* A unique reference number.
* Waste pre-acceptance and acceptance information.
* The package type and size.
* The intended treatment or disposal route.
* Accurate records of the nature and quantity of wastes held on site, including all hazards – and identifying the primary hazards.
* Where the waste is physically located on site.
* Where the waste is in the designated disposal route.
* The names of staff who have taken any decisions about accepting or rejecting waste streams and who have decided on recovery or disposal options.
* Details of any non-conformances and rejections.

The tracking system must be able to report:

* The total quantity of waste present on site at any one time.
* A breakdown by type of the waste quantities stored pending treatment, incineration or transfer.
* An indication of where a batch or consignment of waste is located based on a site plan.
* The quantity of waste on site compared with the limits authorised by the authorisation.
* The length of time the waste has been on site.

If receiving loose, packaged items (for example, bags or boxes of waste not in labelled bulk containers) collected from multiple premises (for example, collections from smaller producers such as doctor surgeries, dental practices, tattoo parlours) systems and procedures must allow:

* The waste to be tracked back to the original load received at the facility.
* Access to associated waste acceptance information and records.

If adding individual packages of waste (for example, bags or boxes) to a bulk container or pallet at the facility, the labelling and tracking system (including barcode systems) should be able to record this along with the date of the earliest package received. For example, by marking or labelling the container or pallet with the unique identifiers of the packages it holds and the earliest receipt date.

Keep tracking records for a minimum of 6 years after waste has been treated or removed off site. Store back-up copies of computer records off site. Records must be readily accessible in an emergency.

## Waste Storage

To reduce the environmental risk associated with waste storage and handling, use a combination of the following techniques.

**General**

Where possible, locate storage areas away from watercourses and sensitive perimeters, for example those close to housing. If storage options are limited, consider taking extra precautions to limit any impact on the receptors.

Store waste within a secure area of the facility to prevent unauthorised access and vandalism.

**Capacity**

Document the maximum storage capacity of the facility and its designated storage areas. Monitor the quantity of stored waste against the allowed maximum capacities, and do not exceed them. Take account of factors like seasonal changes in inputs and in markets for outputs and the impact this will have on the stored waste.

### Waste Segregation

Store different healthcare wastes according to waste type and destination. The following waste types must be stored in separate storage areas or containers. This is to prevent physical contact or a leak from one waste type contaminating another or its packaging:

* Clinical waste bags for incineration.
* Clinical waste bags for alternative treatment.
* Offensive hygiene waste.
* Cytotoxic and cytostatic medicines, including contaminated sharps.
* Other waste medicines, including contaminated sharps.
* Non-medicinally contaminated sharps.
* Dental amalgam.
* X-ray photographic fixer.
* X-ray photographic developer.
* Other photographic waste (for example, film).
* Other chemicals, stored in accordance with the relevant measures set out in [HSG 71 Chemical warehousing: The storage of packaged dangerous substances](https://www.hse.gov.uk/pubns/books/hsg71.htm).
* Anatomical waste and animal carcases.
* Non-infectious gypsum wastes (for example, plaster casts and moulds).
* Infectious gypsum wastes.

### Storage Duration

The maximum storage times of wastes held on site must be clearly established. Treat wastes or remove them from the site as soon as possible. Treat the oldest waste first, unless it is necessary to prioritise more recently received wastes because they pose a higher risk of environmental harm, such as odorous waste.

The following is a summary of standard maximum storage times for different types of healthcare waste at transfer stations and alternative treatment facilities:

* Infectious clinical waste (orange or yellow packaging)
	+ Transfer station (storage facility) – 7 days if awaiting direct transfer
	+ Alternative treatment (outside) – 7 days
	+ Alternative treatment (total onsite) – 14 days
* Treated waste from AT plant (e.g. autoclave floc)
	+ Alternative treatment (outside) – 7 days
	+ Alternative treatment (total onsite) – 14 days
* Offensive non-infectious waste (yellow & black packaging) – 7 days
* All anatomical waste and animal carcasses (red packaging):
	+ If 5 oC – 14 days
	+ If -18 oC – 28 days
* Cytostatic and cylotoxic medicinal waste (purple packaging) - 6 months
* Other medicinal waste (blue packaging) – 6 months
* Hazardous or non-hazardous chemical waste – 6 months
* Amalgam waste from dental care – 6 months
* Photographic processing wastes – 6 months

### Site Surfaces and Drainage

Unless specifically authorised by the permit or registration, store waste on an impermeable surface with sealed drainage.

For new sites, infrastructure should be designed and installed in line with CIRIA C736. Use a chartered civil or structural engineer to provide construction quality assurance and validate the construction of all facilities.

Storage areas should:

* Contain contaminated run off.
* Prevent incompatible wastes from coming into contact with each other.
* Be designed to allow access for inspection and cleaning.

Impermeable surfaces must have sealed construction joints and be designed to prevent spillage escaping off site.

Design bunkers, bays and pits so that waste and debris does not build-up in inaccessible areas such as corners. Regularly clean bunkers, bays and pits.

Where possible, keep clean rainwater separate from wastes and waste waters to limit storage and treatment requirements.

Drainage should be accessible to allow cleaning and maintenance. Inspect drainage channels, aeration channels and collection sumps to identify blockages. Remove debris and clean the channels and sumps to prevent odour, pest infestations and maximise drainage.

Have a documented inspection and maintenance programme for impermeable surfaces and containment facilities.

### Storage of healthcare waste

Store individual bags and containers (for example, bins and boxes) of waste loose.

Store and handle bagged waste on site in fully enclosed, lockable, rigid, leak-proof and weather-proof bulk containers (for example, bins).

Rigid waste containers (bins and boxes) should be sealed and in good condition. Store and handle them in an upright position (as far as possible) to prevent or, where that is not practicable, to minimise the risk of spillages.

Palletised containers should be stable and stacked upright no more than 2.2m high. The containers should not extend beyond (over-hang) the sides of the pallet. Pallets should be secured with clear or transparent shrink-wrap so that waste types, damaged containers, leaks or spillages and incorrectly stacked containers can be identified.

If waste contains free liquid (for example, chemical wastes such as fixer and developer solutions) store the pallets in a dedicated area of the facility that has self-contained drainage.

Bulk containers should have a lid which is kept closed, except when waste is being loaded into or unloaded from them.

Store and handle all pharmaceutical, chemical, anatomical and palletised wastes within designated areas of a secure building.

Store anatomical waste and animal carcasses in designated refrigerated units (operating below 5°C) or freezer units (operating below -18°C) unless storing them on site for less than 24 hours. Freezer units must be used if storing waste for longer than fourteen days.

Store and handle infectious wastes that are not pharmaceutical, chemical, anatomical or palletised wastes in a secure building. These wastes may be stored outside at existing facilities provided that:

* It is not technically or economically feasible to store them in a building.
* Alternative storage arrangements provide an equivalent level of environmental protection to storage in a building.
* There is an appropriate site-specific environmental risk assessment which includes (but is not limited to) an assessment of fugitive emissions to air, land and water (including odour), pests and flood risk.
* The waste is in bulk containers that remain closed and always locked, except when waste is being loaded or unloaded from them.
* The site that has impermeable surfacing and sealed drainage.

Store and handle offensive wastes in a secure building or in secure, fully enclosed, rigid, waterproof and leak-proof bulk containers. If stored externally in bulk containers, the containers should always remain closed, except when waste is being loaded or unloaded from them.

Do not store or hold wastes on site in vehicles or vehicle trailers, unless specifically authorised.

Store floc produced by alternative treatment plant in fully enclosed, waterproof and leak-proof containers.

Always maintain the integrity of waste packaging. Design and operate the facility in a way that minimises waste handling. Do not offload, throw, walk on or handle healthcare wastes in a way that might damage the packaging.

Store waste in a way that protects its integrity and prevents or, where that is not possible, minimises the risk of packaging failing. Pay particular attention to items at or near the bottom of bulk containers and avoid, for example, overloading, compressing or puncturing waste.

Store all bulk waste containers in a way that allows safe and easy access for inspection and minimises the need to remove others that may be blocking access. Maintain safe access to at least one side of palletised wastes. Handle and store containers so that labels and markings are easy to see and continue to be legible.

Do not stack bulk containers, bins and pallets that contain waste whilst they are being stored on site, unless they are held in purpose-built racking systems.

### Cleaning and disinfection

Storage areas must be suitable for effective disinfection with a broad-spectrum agent. Ensure that surfaces are regularly cleaned and disinfected.

Once emptied, check bulk containers to make sure all waste has been removed. Bulk containers should be cleaned inside and out as soon as possible. Containers that have held infectious waste must be disinfected.

Inspect bulk containers (for example, 770 litre wheeled bins) used to transport waste before each reuse to make sure that:

* They have been cleaned and disinfected.
* They are physically sound.
* The locking mechanism works.
* They meet the relevant requirements of the [Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations](https://www.gov.uk/government/collections/transporting-dangerous-goods).

The methods used for cleaning and disinfecting surfaces and containers should:

* Physically remove contamination.
* Be capable of achieving disinfection across the broad spectrum of micro-organisms with the parameters used (time, concentration, temperature, quantity).
* Not produce emissions of pathogenic bioaerosols or chemical agents, or must make sure these emissions are contained and managed appropriately.

Cleaning and disinfection processes must:

* Contain wash-waters within an impermeable area and either discharge them to foul sewer or dispose of them appropriately off site.
* Prevent run-off into external areas or to surface water drains.
* Prevent healthcare waste items from being discharged to the water environment (including to sewer).

Inspect storage areas, containers and infrastructure daily and deal with any issues immediately. Keep written records of the inspections and log any spillages of waste.

### Repackaging

Do not open and repackage (bulk) individual waste packages and containers (for example bags, bins, boxes and blister packs), unless the packaging is designed to be reused. If waste is received in damaged packaging, record this as a non-conformance. Transfer the contents to a new, clearly labelled container or package of the appropriate type and condition.

Repackaging must take place inside a building to prevent potential emissions. For example, use an automated process in a contained environment with air extraction and abatement. Record the transfer of waste from individual packages or containers to bulk containers and update the tracking system accordingly.

Unless specifically authorised, do not mix hazardous waste with other categories of hazardous waste, or with other wastes or materials.

## Waste Treatment

### Overarching Concept

Treatment must have a clear and defined benefit. Treated output material should meet expectations and be suitable for its intended disposal or recovery route.

Have up-to-date details of the treatment activities set out in the written environmental management system. Include information about the characteristics of the waste to be treated and the waste treatment processes, including:

* Simplified process flow sheets that show the origin of any emissions.
* Diagrams of the main plant items where they have environmental relevance, for example, storage, tanks, treatment and abatement plant design.
* Details of the treatment stages.
* The processing capacity of composting pad or treatment equipment or process.
* The control system philosophy and how it incorporates environmental monitoring information.
* A summary of operating and maintenance procedures.

The extent of the information about the treatment activities will depend on the nature, scale and complexity of the facility and the range of environmental impacts it may have.

### Treatment and disposal of healthcare waste

Incineration is the appropriate method of treatment for all anatomical, chemical and medicinal wastes, including wastes that are medicinally or chemically contaminated. Wastes containing cytotoxic or cytostatic medicines require high temperature incineration (that is at temperatures greater than 1,000°C).

For segregated infectious healthcare wastes it is possible to use ‘alternative treatment’ (non-incineration) such as chemical or heat-based disinfection. These wastes are put into orange bags, or orange-lidded rigid yellow containers.

Exclude the following wastes from alternative treatment activities unless specifically authorised:

* Waste medicines and chemicals.
* Wastes contaminated with or containing residual medicines or other chemicals, including syringes that are fully discharged, partially discharged or undischarged (for example 18 01 03\* infectious waste contaminated with 18 01 09 medicines).
* Non-infectious wastes (for example 18 01 04 offensive hygiene wastes).
* Anatomical waste.
* Dental amalgam.

Justification for the alternative treatment of these wastes must assess any impact on emissions to air and the water environment from the facility and demonstrate that the treatment:

* Is effective (including validation of worst-case challenge load and conditions).
* Is an efficient use of energy and raw materials.
* Enhances the recovery or recycling of the waste where possible.
* Does not impede the treatment of any other wastes.

Justification for the alternative treatment of any waste containing or contaminated with medicines or chemicals or anatomical waste must demonstrate that:

* All pharmaceutically active substances (hazardous or non-hazardous) will be destroyed.
* Chemicals will be fully treated and not diluted and released to the environment.
* Anatomical waste will be fully destroyed, and any chemicals (for example, preservatives) will be fully treated.

Exclude biohazard waste from alternative treatment activities, unless SEPA has specifically authorised the process for the treatment of these wastes and it can be demonstrated through the pre-acceptance procedures, that the waste is suitable for alternative treatment. ‘Biohazard waste’ is:

* Any waste known or likely to contain Advisory Committee on Dangerous Pathogens hazard group (HG) 4 biological agents.
* Any waste from a containment level 3 laboratory.
* All microbiological cultures from any source.
* Any potentially infected waste from pathology departments and other clinical or research laboratories (unless autoclaved before leaving the site of production).

Energy from waste (municipal waste incineration) or landfill are acceptable disposal methods for carefully segregated offensive hygiene wastes. It is best practice to put these wastes into yellow bags with a black stripe, otherwise known as ‘tiger-stripe’ bags.

### Pre-treatment at the site of production

The following wastes should be treated (inactivated) at the site of production:

* Class 2, 3 and 4 genetically modified microorganism cultures or contaminated material.
* HG 2, 3 and 4 pathogen cultures or positive specimens.

However, there may be very exceptional (emergency) circumstances when such waste can be receives for treatment at an authorised waste facility. For example, when the treatment process at the site of production has broken down. If receiving waste under these circumstances:

* Do not shred or macerate untreated wastes before the disinfection step.
* The treatment process must demonstrate a higher level of treatment (IStAATT level 4 criteria).
* Have waste pre-acceptance and acceptance procedures that make sure this waste is only accepted in exceptional circumstances, for example as a ‘one off’ because on-site treatment has malfunctioned.
* Submit a written justification in advance to SEPA addressing all these requirements and have the appropriate procedures in place.

### Compaction

Do not compact or compress infectious clinical waste by mechanical or manual means.

Offensive waste can be compacted if specifically authorised by the environmental authorisation, subject to the following:

* Have detailed procedures and appropriate measures in place to fully capture, contain and abate (if required) all emissions, such as odorous emissions to air, micro-organisms and release of liquids.
* Carry out monitoring to demonstrate that procedures and associated measures are effective.
* Use ‘light compaction’ where there is a risk of bags splitting.

### Shredding

The treatment must not shred or macerate untreated infectious wastes before the disinfection step. The exception is if the plant used is specifically designed and built to provide full bioaerosol containment.

This would be provided by operating the plant under negative pressure, with air extracted from the feed hopper and passed through high efficiency particulate air (HEPA) filters. Feed hoppers must have doors on the opening to contain bioaerosols and other potential emissions. The doors must be closed whilst the shredder or macerator plant is operating, with process interlocks or equivalent measures to prevent the plant operating when the doors are open.

Have appropriate containment measures to prevent microbial emissions from pre-shredded or pre-macerated waste before its disinfection. Assess and demonstrate the effectiveness of these measures through microbial emissions monitoring.

### Rendered safe

Treatment must make sure that clinical waste is ‘rendered safe’. For clinical waste to be considered rendered safe, the treatment process must:

* Reduce the number of infectious organisms present in any infectious waste to a level that no additional precautions are needed to protect workers or the public against infection.
* Destroy any anatomical waste (human or animal tissue) so that it is no longer recognisable.
* Make any clinical waste (including any medical equipment and items) unusable and unrecognisable.
* Destroy the component substances of any chemical, or medicinal and medicinally-contaminated waste.
* Make any patient information within the waste unrecognisable.

For infectious waste, the treatment process must, as a minimum, meet the level 3 criteria provided by the International Society on Analytical Assessment of Treatment Technologies (IStAATT). Certain bio-hazardous waste must be treated to level 4 criteria (for example, some laboratory waste).

**Level 3**

Inactivation of the following organisms at a 6 log10 reduction or greater:

* Vegetative bacteria.
* Fungi.
* Lipophilic or hydrophilic viruses.
* Parasites.
* Mycobacteria.

Inactivation of the following organisms at a 4 log10 reduction or greater:

* *Geobacillus stearothermophilus* spores.
* *Bacillus atrophaeus* spores.

Level 4

Inactivation of the following organisms at a 6 log10 reduction or greater:

* Vegetative bacteria.
* Fungi.
* Lipophilic or hydrophilic viruses.
* Parasites.
* Mycobacteria.
* *Geobacillus stearothermophilus* spores.
* *Bacillus atrophaeus* spores.

### Treatment Outputs

Correctly describe, classify and code waste from alternative treatment using the appropriate LoW code to make sure that it reflects the residual characteristics and properties.

Below are some examples of different treatment scenarios and the LoW codes to use for the wastes produced.

Example 1 - Waste hazardous by ‘infectious’ property only

If treating (rendering safe) waste that is hazardous by ‘infectious’ property only (orange stream waste – 18 01 03\*, 18 02 02\* and 20 01 99) use these waste codes:

* 19 02 10 (if combustible).
* 19 02 06 or 19 02 99 depending upon nature of output material.

Example 2 - Waste contaminated with or containing hazardous chemicals or medicines

If treating infectious waste containing or contaminated with hazardous chemicals or medicines, which are not specifically treated (removed or destroyed) by the treatment process, use the waste code 19 02 04\*.

Only use waste codes 19 02 06, 19 02 10, or 19 02 99 if the treatment plant validation demonstrates that the process renders the waste safe and treats all chemical and medicines (including pharmaceutically active substances).

Example 3 - Process failures

If there has been a process failure where waste has not been fully treated or rendered safe, use the waste code 19 02 04\*. This applies if the wastes have been mixed and not fully treated or rendered safe.

Wastes must keep their original waste code and classification if they have not had any form of treatment.

Sterilisation of waste at producer premises

For infectious healthcare waste (18 01 03\*) sterilised at a producer site, for example, in a laboratory autoclave, use the waste code 18 01 04. The waste must be rendered unusable and unrecognisable unless it is subsequently incinerated.

Treatment of offensive waste to produce a waste derived fuel

If treating non-hazardous offensive waste (18 01 04) to produce a waste derived fuel, and it has only had mechanical treatment such as shredding, use waste code 19 12 10. For waste that has been subject to physico-chemical treatment (such as heating or drying), use code 19 02 10.

## Plant commissioning and validation

As part of plant commissioning, carry out performance validation tests to demonstrate the treatment plant will render safe each of the waste types the facility is authorised to treat. Written proposals detailing the validation tests must be submitted to SEPA for prior approval.

Validation tests must be supervised by a suitably qualified, experienced and independent person. An appropriately accredited laboratory must do the analysis. For the treatment of infectious wastes, tests must be supervised by an appropriately qualified microbiologist. Analysis carried out at an accredited microbiological laboratory.

Submit the results of plant validation tests in a written report to SEPA for approval. We must approve this before waste treatment operations can commence at the facility.

The validation report must detail the operating conditions and parameters of the plant. Include the type and composition of waste stream(s) treated, and batch quantity or throughput rate. We will base our approval of the validation report on these validated plant operating conditions and parameters. The subsequent operation of the plant will be limited to these operating conditions and parameters.

Waste produced by an alternative treatment plant that has not passed a validation test, or received approval from SEPA, must be considered untreated until rendered safe by a validated and approved plant.

Repeat plant validation and send a written validation report to SEPA periodically throughout the operational life of the plant and at intervals of 4 years or less. Also repeat validation if:

* Any process parameters or conditions (for example, treatment duration, temperature, pressure, mass or type of waste) change from those assessed and approved during site commissioning or validation.
* Changes are made to the design or engineering of the treatment plant.
* Changes to the waste types accepted for treatment mean that the challenge load considered during plant commissioning or validation is no longer the worst-case scenario.
* The plant fails routine treatment efficacy testing.

If the results of periodic plant validation do not demonstrate that treated waste will be rendered safe (for example, they do not demonstrate the required microbial disinfection efficacy for the treatment of infectious waste) stop plant operations until the cause can be identified and recommission the plant. Before restarting operation, plant validation must be approved in writing by SEPA.

## Validation tests for treating infectious wastes

Use an appropriate certified test organism for the tests.

Use spore strips to validate thermal treatment plant if their integrity can be guaranteed. That is, if they can be inserted into the waste after the pre-shredding or maceration process and before the disinfection step. Or, if there is no pre-shredding or maceration, they can be inserted into the waste before the disinfection step.

Use spore suspensions to validate chemical treatment plant or thermal treatment plant the integrity of spore strips cannot be guaranteed.

Use *Bacillus atrophaeus* to test chemical treatment processes, and those involving dry heat technologies, and *Geobacillus stearothermophilus* for wet heat treatment.

*Bacillus atrophaeus* may be used to test certain steam treatment technologies providing sufficient justification is provided for its use.

Test organisms must be agreed in writing with SEPA prior to their use.

When using spore strips or suspensions:

* Use spore strips or suspensions from the same batch number in the tests.
* If using spore strips, they must be certified as containing ≥1 x 106 spores.
* If using spore suspensions, add sufficient suspension to each load to ensure ≥1 x 106 spores are present per gram mass of the total load.

For thermal treatment plant, the spores used must have a minimum certified D-value ≥1.8 minutes at either:

* 121°C wet heat for *Geobacillus stearothermophilus.*
* 160°C dry heat for *Bacillus atrophaeus.*

The D-value is the time at the temperature required to achieve a log (or 90%) reduction in relevant micro-organisms. For chemical treatment plant, where the D-value for the chemical disinfectant is not available, determine the D-value and demonstrate it is comparable to the values reported in available literature.

For thermal processes, the spores must be supported by the parallel use of either:

* Thermal indicator strips which indicate time and temperature of exposure.
* Multi-point thermal data loggers co-located in the waste load.

The time and temperature combination of the indicator strips must be indicative of the plant operating parameters needed to achieve microbial inactivation.

Base the validation of plant performance for disinfection on:

* The treatment of a worst-case challenge load – in terms of spore strip containment or insulation and presence of interfering or inhibiting substances or items.
* The maximum quantity of waste that will be treated – that is the maximum batch size or throughput of the plant.

The worst-case challenge load used must reflect the type and design of the treatment plant, specifically whether the:

* Treatment process provides thermal or chemical disinfection.
* Waste is pre-shredded or macerated prior to disinfection, or not.

Detail and justify the worst-case challenge load used in the validation report.

Here are example challenge loads for 3 test scenarios.

Example 1: Spore strips – thermal treatment with pre-shredding or maceration

Each spore strip is placed in a separate carrier designed to mimic normal conditions in the waste being treated. Examples used include net bags, tennis balls, socks, punctured plastic or alloy containers. If metal containers are used, the spore strips must be insulated, for example using cotton wool or equivalent, to prevent direct heat conduction. Each spore carrier containing a spore strip must be inserted loose into the bulk of the pre-shredded or macerated waste and distributed throughout the waste load. Only use fixed carriers or test reports for routine monitoring where it has been demonstrated through additional parallel testing that there is no significant difference between the results from these and loose carriers.

Example 2: Spore strips – thermal treatment without pre-shredding or maceration

Spore strips are fixed in the centre of filled, sealed items of varying size. These are representative of the toughest and most resistant items commonly found in healthcare waste, such as suction canisters and chest drains. Items should be filled with fluid and thermally stable gel. Consider using other items that could inhibit heat penetration and include them in the load. The items should be placed in worst case packaging, for example, sealed rigid bins or containers and bags, and distributed throughout the waste load.

Example 3: Spore suspensions – assumes pre-shredding or maceration before or during treatment

At least 6 small glass vials or bottles containing spore suspension are securely attached to the outside of suction canisters containing fluids (for example blood) and placed inside worst-case packaging (for example, sealed rigid bins). The waste load should contain other substances present in the waste stream that could inhibit the disinfection process, for example, organic matter, chemicals, blood and items that could inhibit heat or chemical penetration. For a typical waste load we recommend that a minimum of 5% heavy organic load (for example, blood) is added by weight. If a process is authorised to treat waste with a significantly higher organic load (for example, blood bags) then a higher organic content should be considered.

### Validation test format for infectious wastes

Use an appropriate validation test format, which will depend on whether spore strips or suspensions are used, as follows.

Spore **strips**

Test each plant over 3 separate treatment cycles, retrieving the treated test packages before starting the next cycle. In total, hold a minimum of 6 untreated spore strips outside of the device to use as controls to compare with the treated strips.

The minimum number of spores strips recovered is set out in Table 4 below.

**Table 4: Minimum number of spore strips.**

|  |  |  |  |
| --- | --- | --- | --- |
| Plant load (kg) or throughput (kg/hour) capacity | Recovered per cycle or collection | Total recovered (assuming 3 runs) | Retained as controls |
| 0 to 10kg | 3 | 9 | 6 |
| 11 to 50kg | 4 | 12 | 6 |
| 51 to 250kg | 6 | 18 | 6 |
| 251 to 500kg | 8 | 24 | 6 |
| 501 to 750kg | 10 | 30 | 6 |
| Over 750kg | 12 | 36 | 6 |

Analyse the entire test sample except for the control samples which will require serial dilution. Preserve samples appropriately and send to an accredited laboratory for analysis in a timely manner.

Analysis must be quantitative and based upon the number of spores per spore strip. Achieve the required log reduction (the number of spores recovered from control strips compared with those recovered from the test strips) with 95% confidence. All thermal indicator strips must also show that the required time and temperature parameters were achieved.

Spore suspensions

Test each plant over 3 separate treatment cycles, taking representative samples from the treated material before starting the next cycle. The test must include a control run, where waste (treated clinical waste or a suitable surrogate waste material) is passed through the plant without activating the treatment process. Add the same total quantity of spore suspension to each control and test run.

The minimum number of samples taken from the treated material is set out in Table 5 below.

**Table 5: Minimum number of samples.**

|  |  |  |  |
| --- | --- | --- | --- |
| Plant load (kg) or throughput (kg/hr) capacity | Recovered per test run | Total recovered (assuming 3 runs) | Recovered per control run |
| 0 to 10kg | 3 | 9 | 3 |
| 11 to 50kg | 3 | 9 | 3 |
| 51 to 250kg | 4 | 12 | 4 |
| 251 to 500kg | 4 | 12 | 4 |
| 501 to 750kg | 5 | 15 | 5 |
| Over 750kg | 5 | 15 | 5 |

If the mass of the waste differs between each control and test run, correct the test data for each run (spores present per kg of sample) to account for this difference.

Each sample should be at least 0.1% of the waste load, with a minimum sample of 50g for smaller units. Preserve samples appropriately and send them to an accredited laboratory for analysis in a timely manner.

The entire test sample should be analysed, except the control samples. Achieve the required log reduction (the number of spores recovered from control samples compared with those recovered from the test samples) with 95% confidence. Samples should be preserved appropriately until received by the laboratory for testing.

### Assessment methodology for infectious wastes

Follow an appropriate assessment methodology, which will depend on whether spore strips or suspensions are used, as follows.

Microbial **disinfection** efficacy – spore strips

For the control data, calculate and record the following:

* Number of spores (colony-forming units (cfu)) recovered from each individual control spore strip.
* Mean number (XC) of spores recovered from the control strips.
* Log10 of XC.

Then subtract 4 from the log10 of XC to generate the pass criteria.

Subtracting 4 provides the 4 log10 reduction for IStAATT Level 3 criteria. For the treatment of certain biohazard wastes a 6 log10 reduction is needed, in which case 6 must be subtracted from the log10 of XC to generate the pass criteria.

Using the combined test data from each test run calculate the following:

* Number of spores recovered from each individual test strip.
* Mean (XT) number of spores recovered.
* Standard deviation (σ) of spores recovered.
* Upper 95% (Lu) confidence interval of XT (this will be approximated by XT + 1.96 σ).
* Log10 of the upper 95% (Lu) confidence interval of XT (log10 Lu).

Note, if Lu = 0, then use ‘0’ for log10 Lu.

The test data used must include all the recovered test strips. If contamination is suspected, either retest the sample or, if that is not possible, include the results in the data analysis.

The following criteria represent the minimum standards that must be achieved:

* The log10 Lu for each run must be less than or equal to the pass criteria.
* Log10 XC must be equal to or greater than 5.
* For thermal processes all thermal indicator strips must indicate that the required temperature time parameters have been achieved.

Where these criteria are passed then it is more than 97.5% probable that the worst-case items present in any clinical waste will be treated to the minimum standard.

Here is a worked example:

Control data

Step 1.

Six control strips are analysed and give results of:

81, 93, 107, 121, 79, 119 cfu from analysis of the 1 in 10,000 dilution.

This equates to:

0.81, 0.93, 1.07, 1.21, 0.79 and 1.19 x 106 cfu respectively (X)

Step 2.

The mean (XC) of spores recovered from each control strip = 1.0 x 106

Step 3.

The log10 of XC = 6

Step 4.

The pass criteria = log10 of XC – 4 = 2 (Level III criteria)

Test data

Three test runs were done, each with three test strips. All were recovered and analysed.

Step 5.

The following results were obtained from each run and spore strip:

* run 1 – 0, 0 and 9 cfu
* run 2 – 0, 5 and 22 cfu
* run 3 – 0, 0 and 39 cfu

Step 6.

The mean (XT) of colonies recovered from each spore strip = 8.33 cfu

Step 7.

The standard deviation (σ) of the results = 13.63 cfu

Step 8.

The upper 95% (Lu) = 8.33 + (1.96 x 13.63) = 35.04 cfu

Step 9.

The log10 of Lu (log10 Lu) = 1.54

Interpretation

We have determined in step 4 that the pass criteria = 2

We have determined in step 9 that the log10 of the upper 95% confidence interval (log10 Lu) of the spores recovered from the test runs = 1.54

In this case:

* The results from the test runs show that the log of the upper 95% confidence interval for recovered spores (1.54) is less than the pass criteria (2).
* Log10 (XC) is greater than 5 so sufficient spores have been recovered for the results to be valid.
* For the purposes of this example, we will assume that all 9 data log points recorded that a temperature of 121°C had been achieved for 15 minutes.

The IStAATT level 3 criteria have therefore been successfully demonstrated.

Microbial disinfection efficacy – spore suspensions

If using spore suspensions correct the data to allow for any differences in the total mass of waste used in each control and test run.

Determine the results from the control samples using the procedures given for spore strips.

Instead of determining how many spores are present in each control spore strip determine how many are present per kg of control sample.

Record the mass of waste used in the control run (MC) in kg.

Determine the results from the test samples using the procedures and example given for spore strips with the following exception.

Record the mass of waste used to load each of test runs in kg (for example, mass of test 1 (MT 1), MT 2, MT 3).

Determine the individual results (as cfu per kg) for each test sample taken (equivalent to step 5 of the worked example provided for spore strips).

Multiply each of the test results by the mass of the corresponding test (for example, MT 1, MT 2, MT 3) divided by the MC. This is to correct any differences in mass between the tests and control run. Do this before proceeding to the next steps of the calculation (equivalent to steps 6 to 9 of the worked example provided for spore strips).

## Validation tests treating waste contaminated with or containing medicines

Validation tests must demonstrate that the plant can destroy the range of pharmaceuticals and active ingredients that may be present in the waste stream.

Base the identification of potential substances (including potential breakdown products), and assessment of their thermal stability and decomposition, on an initial review of available literature supported by laboratory scale trials, where appropriate, to define a worst-case challenge load.

Dilution of pharmaceuticals is not a valid form of treatment. If proposing a chemical treatment process, consider and assess the potential for reactions between the chemical agents used and the pharmaceutical chemicals that may be present in the waste.

Validation tests must assess and demonstrate the efficacy of each plant. These must involve:

* A control run.
* A minimum of three test runs.
* Considering at least three worst case substances.

The three worst-case substances are those that literature reviews and trials have identified as being the most thermally resistant. Dose the waste with the substances, so the concentration is significantly higher than the limit of detection and the background level of any potentially interfering pharmaceuticals or other chemicals.

Introduce chemical tracer dyes resistant to the treatment process with the pharmaceuticals to demonstrate the treated waste is homogenous and material sampling is appropriate.

Consider and assess any effect on plant emissions that may result from the treatment of the pharmaceuticals.

## Validation tests for the treatment of wastes contaminated with or containing chemicals

Validation tests must demonstrate that the plant is capable of fully treating the range of chemical contaminants that may be present in the waste stream. Clearly define the objectives of the treatment process, along with any reaction chemistry.

Provide an assessment of the efficacy of the treatment, demonstrating the fate of the substances in question. Simple physical dilution or absorption, without any concurrent chemical change, is not an acceptable treatment process in itself.

Validation tests must assess and demonstrate the efficacy of each plant. These must involve a control run and a minimum of 3 test runs. Take representative samples from the treated material resulting from each test run.

Consider and assess any effect on plant emissions that may result from the treatment of the chemical contaminants.

## Validation tests for the treatment of anatomical wastes

Anatomical waste must be made unrecognisable – this generally means that it is incinerated. It is not appropriate or acceptable to shred and treat anatomical waste by alternative treatments involving chemical or heat-based disinfection. Novel technologies like alkaline hydrolysis that dissolve and totally destroy the tissue could be used for such wastes.

Validation tests must demonstrate that the treatment process achieves the equivalent level of tissue destruction as incineration. The tests must also consider any chemicals present in or with the anatomical waste (for example preservatives). The tests must demonstrate that the plant is capable of effectively treating the range of chemicals that may be present.

## Routine plant efficacy testing

Test and assess the treatment efficacy of each waste treatment plant regularly throughout its operational life to make sure that its performance is maintained, and all waste is rendered safe. Follow an appropriate testing methodology, which for infectious wastes will depend on whether spore strips or suspensions.

The methods used for routine efficacy tests must be the same as those used for site commissioning validation. Only use alternative methods if parallel tests carried out during commissioning validation demonstrated that an alternative method met both these criteria:

* It was appropriate (accurate, reliable and repeatable).
* It produced the same results as those produced following the methods described in this guidance.

For thermal processes, use thermal indicator strips or multipoint data loggers in parallel.

Spore strip tests

The minimum frequency of efficacy tests and number of control strips used is specified in Table 6 below. Schedule the efficacy tests and evenly space them throughout the calendar year.

**Table 6:** Routine monitoring of microbial inactivation using spore strips.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Continuous hourly throughput or batch cycle load (kg) | Test frequency (first 6 months of operation) | Test frequency (operational, after the first 6 months) | Minimum number of spore strips or sub-samples | Minimum number of control strips |
| 0 to 50 kg | Monthly | Quarterly | 3 | 1 |
| 51 to 500 kg | Fortnightly | Every 2 months | 3 | 1 |
| 501 to 1,000 kg | Weekly | Monthly | 3 | 1 |

Test spore strips quantitatively (population of >1 x 106) or qualitatively (population of >1 x 104).

Controls and certificates from the test batch must accompany each set of samples.

The criteria for success are as follows:

* Investigate each individual ‘fail’ result as soon as possible.
* 95% of the individual spore strips in the first 6 months of operation, and each subsequent calendar year, must demonstrate 4 log10 inactivation or higher (quantitative), or no growth (qualitative).
* Thermal indicator strips must accompany each spore strip and indicate the minimum time and temperatures for 99% of spore strips is achieved.
* For each calendar year prepare a summary report that indicates the results obtained and any failures.
* The data in the summary report must be referenced to the validation report to demonstrate the treatment efficacy achieved during plant commissioning are met, rather than minimum standards.
* If more than 5% (or 1, whichever is greater) of qualitative spore strips exhibit growth in any calendar year, use quantitative testing for the next calendar year.

These criteria must include all scheduled monitoring results. Do not include additional investigative results. The percentage success criteria allow for both potential contamination and the uncertainty of microbial data.

If at any point during the calendar year the number of failures exceeds the annual 5%, stop operations at the plant until the causes have been identified and recommission the plant. In any circumstances, if one or more batches of waste may not have been treated to the required standard, take appropriate action and manage the waste as untreated.

Spore suspension tests

The minimum frequency of monitoring, number of test runs and sub-samples per test run is specified in Table 7 below.

**Table 7:** Routine monitoring of microbial inactivation using spore suspension.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Continuous hourly throughput or batch cycle load (kg) | Test frequency (first 6 months of operation) | Test frequency (operational, after the first 6 months) | Minimum number of sub-samples per test run | Minimum number of test runs |
| 0 to 250 kg | 6 monthly | Annually | 3 | 1 |
| 251 to 750 kg | 6 monthly | Annually | 3 | 2 |
| Over 751 kg | Quarterly | 6 monthly | 3 | 3 |

Carry out quantitative enumeration of spore suspensions with a certified population.

Carry out a single control run.

In other respects, the procedures and quantitative criteria for success in the section on spore strips will apply, including the actions to take if a plant fails the test requirements, or waste is not treated to the required standard.

## Emissions

A wide range of pharmaceuticals and chemicals are used in healthcare.

Identify and record all sources of emissions in the environmental management systems (or working plan). This includes all emissions to air and water (including emissions to sewer).

For larger facilities at Permit level, SEPA may set emission limits and monitoring requirements in the authorisation, based on the emissions inventory and environmental risk assessment.

## Point source emissions to air

Contain waste treatment plant (including shredders) and collect, extract and direct all process emissions to an appropriate abatement system for treatment before release.

To reduce point source emissions to air from the treatment of waste (for example, dust, volatile organic compounds and odour), use an appropriate combination of abatement techniques.

Have operating procedures to identify, prevent and control potential emissions of pathogens.

Use HEPA filters to prevent bioaerosol emissions from relevant point sources and ensure they are:

* Monitored (for example, by measuring the pressure drop across the filter) and maintained to achieve a minimum particle removal efficiency of 99.97% for particles ≥0.3μm diameter.
* Maintained annually in accordance with an appropriate standard.
* Safely removed and disposed of appropriately.

## Fugitive emissions to air

Design, operate and maintain storage and treatment plant in a way that prevents fugitive emissions to air, including dust, organic compounds and odour. Or where that is not possible, minimise these emissions. Storage and treatment plant includes associated equipment and infrastructure such as:

* Shredders.
* Conveyors.
* Skips or containers.
* Building fabric, including doors and windows.
* Pipework and ducting.

To make sure fugitive emissions are collected and directed to appropriate abatement, treatment plant should use high integrity components (for example, seals or gaskets).

Treatment plant should be fully enclosed, with air extraction systems located close to emission sources where possible.

Where necessary, to prevent fugitive emissions to air from the storage and handling of such wastes, consider a combination of the following measures:

* Store and handle the waste within an enclosed building.
* Use fully enclosed material transfer and storage systems and equipment, for example, conveyors, hoppers, containers, tanks and skips.
* Keep building doors and windows shut to provide containment, other than when access is required for loading or unloading.
* Keep enclosed buildings and equipment under adequate negative pressure with an appropriate abated air circulation or extraction system, where possible, locating air extraction points close to potential emissions sources.
* Use fast-acting or ‘airlock’ doors that are by default closed.

Establish a leak detection and repair programme and use it to promptly identify and mitigate any fugitive emissions from treatment plant and associated infrastructure (for example, pipework, conveyors, tanks).

Regularly inspect and clean all waste storage and treatment areas, equipment (including conveyor belts) and containers or bins.

Prevent the corrosion of plant and equipment (for example, conveyors or pipes). This includes selecting and using appropriate construction materials, lining or coating equipment with corrosion inhibitors and regularly inspecting and maintaining plant.

Have an appropriate regular maintenance programme covering all buildings, plant and equipment. This should also include protective equipment such as air ventilation and extraction systems, curtains and fast-action doors used to prevent and contain fugitive releases.

When washing containers, design and operate the washing process and associated equipment in a way that prevents fugitive emissions to air. For example, carrying out this activity in a contained or enclosed system.

Fully enclose and contain pre- and post-treatment shredder plant to prevent emissions. Design and operate the shredder plant using appropriate process interlocks so that it cannot operate unless it is enclosed and contained. For example, only when the loading door on the hopper has been closed or sealed. Dust and microbial emissions from the shredder plant should be contained and extracted to an appropriate abatement system, for example HEPA air filtration.

Have procedures to minimise the amount of time odorous wastes spend in storage and handling systems (for example, pipes, conveyors, hoppers, tanks).

Have measures to contain, collect and treat odorous emissions, including using contained buildings and plant or equipment with appropriate air extraction and abatement. We do not consider masking agents to be appropriate measures for the treatment of odorous emissions.

Monitor odour abatement systems to ensure optimum performance. For example, by making sure that scrubber liquors are maintained at the correct pH and replenished or replaced at an appropriate frequency.

Failures in containment at microwave facilities might result in non-ionising radiation leaks. Operational procedures must include checking for these leaks at regular intervals.

## Point source emissions to the water environment and sewer

Identify the main chemical constituents of the site’s point source emissions to the water environment and sewer as part of the site’s inventory of emissions.

Assess the fate and impact of the substances emitted to the water environment and sewer.

Discharges to the water environment or sewer must comply with the conditions of an environmental authorisation or trade effluent consent. Relevant sources of wastewater include:

* Process water or condensate collected from treatment processes.
* Waste compactor runoff.
* Vehicle washing.
* Vehicle oil and fuel leaks.
* Washing of reusable sharps bins.
* Washing of healthcare waste 770 litre wheeled bins or similar bulk containers.
* Spills and leaks in waste storage areas.
* Loading and unloading areas.

Direct waste compactor runoff to foul sewer or a sealed drainage system for on-site reuse or off-site disposal. Discharges to surface water or storm drains are not acceptable.

Do not discharge sharps or medicines (for example, resulting from the washing of reusable sharps bins) to surface water, storm drainage or foul sewer.

Direct wash waters from cleaning healthcare waste containers to foul sewer or a sealed drainage system for off-site disposal. Wash waters may require treatment to meet any discharge limits.

The contents of healthcare waste containers (bags, bins and boxes) must not enter foul, surface or storm drainage systems. Clean up spilled or leaked material (including fluids) and dispose of them at a suitably authorised waste management facility rather than disposing of them to sewer.

For chemical treatment processes, consider whether effluent (disinfectant) should be neutralised before discharging to the water environment or sewer.

## Fugitive emissions to land and the water environment

Use appropriate measures to control potential fugitive emissions and make sure that they do not cause environmental harm.

Have the following in operational areas of the facility (where appropriate):

* An impermeable surface.
* Spill containment kerbs.
* Sealed construction joints.
* A sealed drainage system.

Have measures in place to prevent overflows and failures from tanks and vessels, including where relevant:

* Overflow detectors and alarms.
* Directing over-flow pipes to a contained drainage system.
* Locating tanks and packaged liquids in suitable secondary containment (bunds).
* Providing isolation mechanisms (for example, closing valves) for tanks, vessels and secondary containment.

Collect and treat separately each water stream generated at the facility, for example, surface runoff water or process water. Separation must be based on pollutant content and treatment required. Segregate uncontaminated water streams from those that require treatment.

Have design and maintenance provisions in place to detect and repair leaks. These should include regularly monitoring, inspecting and repairing equipment and minimising underground equipment and infrastructure.

Provide appropriate buffer storage capacity at the facility to store waste waters, taking into account:

* Potential abnormal operating scenarios and incidents.
* The nature of any polluting substances and their impact on the downstream wastewater treatment plant and receiving environment.

Have procedures in place to monitor, treat and reuse the water held in the buffer storage before discharging.

Take measures to prevent emissions from washing and cleaning activities, including:

* Direct liquid effluent and wash-waters to foul sewer or collecting them in a sealed system for off-site disposal – do not discharge them to surface or storm drains.
* Where possible, use biodegradable and non-corrosive washing and cleaning products.
* Store all detergents, emulsifiers and other cleaning agents in suitable bunded or containment facilities, within a locked storage area, or in a building away from any surface water drains.
* Prepare cleaning or disinfection solutions in contained areas of the site and never in areas that drain to the surface water system.

Keep spill kits at locations close to areas where a spillage could occur and make sure relevant staff know how to use them. Make sure kits are replenished after use.

Stop spillages from entering drains, channels, gullies, watercourses and unmade ground. Make available proprietary sorbent materials, sand or drain mats for use when required.

Make sure the spillage response plan includes information about how to recover, handle and correctly dispose of waste produced from a spillage.

Equipment for washing waste containers must be purpose-built, designed to collect and contain all wash waters, including any spray and located in a designated area of the facility provided with self-contained drainage. Trained staff must operate, inspect and maintain it regularly.

## Emissions limits & monitoring

For permitted facilities, we may set emission limits and monitoring requirements in the authorisation, based on the emissions inventory and environmental risk assessment.

### Chemical emissions to air

Chemical emission limits and monitoring may not be required if both of these conditions apply:

* Waste pre-acceptance and acceptance checks by following the guidance on waste pre-acceptance, acceptance and tracking.
* The facility does not treat waste containing or contaminated with chemicals or medicines.

If the treatment plant treats pharmaceutically or chemically contaminated wastes, for example, medicinally contaminated sharps, agree with SEPA emission limits and monitoring requirements for relevant substances. This will be based on an assessment of the range of pharmaceuticals and chemicals in use and their:

* Occurrence and concentration within the waste.
* Properties and behaviour when subjected to the treatment process.
* Predicted environmental impact.

### Channelled emissions to air

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Standard** | **Frequency** | **Limit** |
| Dust  | EN 13284-1  | every 6 months  | 5 mg/m³ (where it is inappropriate to fit a fabric filter due to the potential effects of deflagration on the filter, the limit is 10 mg/m³)  |
| TVOC  | EN 12619  | every 6 months  | 30 mg/m3 |

Report results as the average value of three consecutive measurements of at least 30 minutes each.

### Microbial emissions to air

Monitor and assess microbial emissions using tracer spore suspensions. Alternative indicators can be used if demonstrated that microbial emissions only come from the waste on site (not from other environmental sources) and are present in enough numbers to provide the same level of test sensitivity.

Microbial emissions monitoring frequency

For process bioaerosol emissions monitoring using a suspension of *Bacillus* spores, test as follows:

* Devices which shred or macerate untreated waste – test them during site commissioning and then annually if proven and agreed.
* Other devices – test them during site commissioning and then every four years.

Microbial emissions monitoring methodology

Do not use spore strips for bioaerosol emissions monitoring.

The quantity of spores must be a minimum of 1 x 106 spores per gram of total waste load.

Waste loads processed by the plant during the emissions monitoring tests must be representative of the waste types and waste streams that will be accepted for treatment.

Follow an appropriate assessment methodology, which will depend on whether the waste is shredded or macerated before treatment.

For technologies that shred or macerate the waste prior to treatment prepare and dispense (in a laboratory environment) a dry or liquid suspension of *Bacillus* spores in a number of sealed, small volume plastic containers. Disperse the spores throughout the waste load and process.

For other technologies prepare and dispense (in a laboratory environment) dry or liquid suspensions of *Bacillus* spores, both:

* Loosely on dressings in waste inside containers, such as bags and boxes.
* Inside worst-case challenge load containers like suction canisters and chest drains.

Disperse the spores throughout the waste load processed.

The monitoring must consist of both air monitoring and surface monitoring.

Design the monitoring programme to take enough samples to quantitatively relate the results to the input dose. The number of samples and location of sampling points will depend on the nature of the process and size of the device.

Take samples:

* Before processing the seeded waste (controls).
* At intervals during processing the seeded waste - the intervals must relate to the process stages and the timing of potential emissions.
* Then periodically for at least 2 hours after the cycle is complete.

Through the monitoring programme, aim to produce a quantitative ‘estimate’ of the total number of tracer organisms emitted from the device, relative to the input dose by each route.

Monitoring microbial emissions to air

Carry out air monitoring from all these points, at:

* Identified emission points from the process.
* The site boundaries.
* Any other relevant locations within the site – for example, near open vehicle access doors to the building housing the plant.

Use active (centrifugal or vacuum) impaction onto agar using Anderson or slit samplers (or equivalent) to sample for bioaerosols. Data submissions should contain information indicating the recovery efficiency of the method used.

Conduct air monitoring throughout the emissions monitoring exercise. Individual sample times must coincide with the steps in the treatment process where emissions may occur, for example, during the passage of seeded waste through a shredder, or unloading of treated material.

Monitoring must consider all the main sources of emissions that are present at a site, including point source emissions and fugitive emissions. The main point source emission to air is from venting exhaust gases. Always treat exhaust gases, for example, by filtering through a HEPA filter. Monitoring is needed to demonstrate that treating the gases has been effective. Monitor at each emission point.

Common sources of fugitive emissions include the following:

* Shredding or macerating untreated clinical waste - this is potentially the most significant source of pathogenic bioaerosols. Monitoring must demonstrate that the containment measures in place are effective.
* Shredding or macerating treated clinical waste - this may also generate bioaerosols as treatment reduces the number of microorganisms but does not eliminate them. Monitoring must demonstrate if additional containment measures are needed.
* Maintenance or access ports - carry out monitoring to make sure that these do not compromise the integrity of the plant and are effectively sealed during operation, so emissions are not released. Failed seals and joints may also result in emissions.
* Bin washing - cleaning mobile containers may generate pathogenic bioaerosols. Chemical agents used for disinfection may also become aerosolised. Monitoring must demonstrate if additional containment measures are needed by contaminating these containers with a liquid ‘spill’ of not less than 100ml and equivalent to 1 x 106 spores per gram of waste typically present in the waste container.

Monitoring fugitive microbial emissions to surfaces

To support the air monitoring, use enough settle plates to form a grid-like pattern around the device or site.

The exposure time for each plate, and replacement frequency during testing, should consider contaminants and total microbial load.

Use a regular exposure time and a series of plates at each sampling point. Use a grid placement to calculate the total number of organisms that have settled per hour during the monitoring period for:

* Each grid square.
* The whole site.

Compare this to the input dose to provide a quantitative release estimate for the process.

Microbial emission limits

Compare and assess the results of microbial emissions monitoring against the emission limits that follow. This is to demonstrate that the containment and treatment of microbial emissions is effective.

Below are the microbial emission limits for emissions to air and surfaces:

Point source emissions to air

For emissions of *Bacillus* spores to air, the limits are 1,000 cfu per cubic metre.

The limit is based on a seeding dose of 1 x 106 spores per gram of waste load. Adjust it accordingly if using a higher or lower seed dose.

The units of the limit (per cubic metre) relate to the overall monitoring period, so the limit applies to each individual sample of air, with a calculation made to report the result per cubic metre.

Fugitive emissions to air

For fugitive emissions to air, where sample points are more than 10m from the treatment plant, the emissions limit for *Bacillus* spores is 300 cfu per cubic metre.

Fugitive emissions to surfaces

For fugitive emissions of *Bacillus* spores to surfaces, where sample points are less than 10m from the treatment plant, the emissions limit for *Bacillus* spores is 20,000 cfu per square metre per hour.

For fugitive emissions to surfaces, where sample points are more than 10m from the treatment plant, the emissions limit for *Bacillus* spores is 5,000 cfu per square metre per hour.

In both cases, the limit is based on a seeding dose of 1 x 106 spores per gram of waste load. Adjust it accordingly if using a higher or lower seeding dose.

The units relate to the overall monitoring period so the cfu limit applies to each individual:

* Sample of air – a calculation is made to report the result per cubic metre.
* Settle plate (this is not an average) - a calculation is made to adjust for surface area of a settle plate and exposure time (for example, if using settle plates for only 15 minutes of every hour then multiply the result by four).

## Emissions to the water environment or sewer

The emissions inventory must include information about the relevant characteristics of point source emissions to the water environment or sewer.

For relevant emissions to the water environment or sewer identified by the emissions inventory, carry out monitoring of key process parameters (for example, wastewater flow, pH, temperature, conductivity, or BOD) at key locations.

For example, these could either be at the:

* Inlet or outlet (or both) of the pre-treatment.
* Inlet to the final treatment.
* Point where the emission leaves the facility boundary.

Chemical emissions to the water environment or sewer

Chemical or pharmaceutical emissions monitoring may not be required if both of these apply:

* Waste pre-acceptance and acceptance checks by following the guidance on waste pre-acceptance, acceptance and tracking.
* The facility does not treat waste containing or contaminated with chemicals or medicines.

If the treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged), propose and agree with SEPA emission limits and monitoring requirements for relevant substances. Assess the range of chemicals and pharmaceuticals in use and their:

* Occurrence and concentration within the waste.
* Properties and behaviour when subjected to the treatment process.
* Predicted environmental impact.

Microbial emissions to the water environment or sewer

Where the treatment process produces a wastewater monitor this at intervals during the microbial emissions tests. Follow the method and frequency of the test set out in the section on microbial emissions to air.

Representatively sample wastewater for microbial emissions before it enters the drainage system and as near to the point of origin (the treatment plant) as possible.

Compare and assess the results of microbial emissions monitoring against the following emission limit to demonstrate that the treatment of microbial emissions is effective.

Here are the microbial emission limits for emissions to the water environment:

The emission limit for *Bacillus* spores to the water environment or sewer is 300 cfu per litre.

This limit is based on a seeding dose of 1 x 106 spores per gram of waste load. Adjust it accordingly if using a higher or lower seed dose.

These units relate to the overall monitoring period so the cfu limit applies to each individual

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# Annex 1 – Example waste audit and summary report

**Background**

A hypothetical hospital consists of six departments:

* Accident emergency.
* Pharmacy.
* Oncology ward.
* Surgical ward.
* Day care unit.
* Laboratory (clinical chemistry, microbiology, cytopathology etc.).

The hospital also has an exterior clinical waste storage yard.

Once a year the hospital waste manager audits each of the six departments and the clinical waste storage yard.

**Objective:**

The key objective of the audit is to identify the composition of each different clinical waste stream produced by the hospital (for example, yellow lidded sharps boxes) by assessing the departments that use them. This enables waste descriptions and classifications to be derived.

In particular, the manager is seeking to establish if any waste stream contains:

* Infectious waste - for example bagged ‘orange’ stream.
* Sharps - and if they are infectious and/or chemically contaminated.
* Anatomical waste or other human/animal tissues - and if this is chemically preserved.
* Cytotoxic and cytostatic medicines and material - for example sharps contaminated with them (the first step being that the hospital has implemented a system that allows staff to easily identify these).
* Other medicines and material contaminated with them - for example sharps or medicated IV bags.
* Dental amalgam
* Chemicals - for example laboratory reagents and auto-analyser cartridges, hand-gels, and diagnostic kits.
* Municipal wastes – for example flowers, magazines, food packaging, hand towels.
* Municipal offensive hygiene wastes - for example feminine hygiene waste from lavatories.
* Offensive hygiene wastes from healthcare - for example, non-infectious/hazardous wastes such as sanitary towels and tampons, incontinence products and nappies, catheter and stoma bags etc. (the first step being confirming that the hospital has implemented segregation of these wastes in the department of question).
* Gypsum wastes other than the small proportion that are genuinely infectious - for example plaster-casts from A&E and fracture clinics, dental moulds and podiatry moulds.

**Methodology**

 When the Auditor audits the surgical ward, they will:

* Look at the types of waste containers present, note in detail their contents, take a photograph of each for reference, and check the labels.
* Examine the on-ward pharmacy to check for cytotoxic and cytostatic drugs.
* Observes practice during the audit.
* Question staff about their understanding of cytotoxic and cytostatic medicines, about the disposal of medicated and non-medicated IV bags, the disposal of dropped tablets, medicine bottles and ampoules used with injections, alcohol hand-gel containers, and their tearoom/office wastes.
* Examine the ward waste storage area, and determine how and when the waste is collected, by whom, and where it is taken.
* Examine the contents of cupboards, stores and so on, to confirm all relevant items of healthcare waste, and chemicals have been identified and their disposal accounted for.

**Summary findings for surgical ward (*full results not presented here*):**

The following waste types were identified on the ward:

* Pharmaceutical waste (pharmacy area) - one purple lidded sharps box. Labelling indicates ‘For Cytotoxic or Cytostatic Waste from Chemotherapy Services’ and one blue lidded sharps box. Labelling indicates ‘Medicinal Products Waste but not Cytotoxic or Cytostatic Waste from Chemotherapy Services’
	+ Observations and staff feedback- The separate audit of the main hospital pharmacy confirmed that they had implemented the definition of ‘cytotoxic and cytostatic’ and that injectable medicines of this type are sometimes prescribed to patients on the ward. However, they are not sufficiently labelled to enable staff on the ward to easily identify them. Ward staff were unaware of this and have no procedures to identify or segregate such cytotoxic/cytostatic waste, meaning that it is contaminating other waste streams if not segregated.
* Infectious waste - Four orange bagsare present (one located in the treatment area of each bay, and one in the on-ward pharmacy). Packaging indicates ‘clinical waste for alternative treatment or incineration’.
* Observations and staff feedback- Three of the bags contained clinical waste. One of these bags was observed to be too close to a hand-wash sink and public/patient areas and contains a few handtowels, some food wrappers and a newspaper. Questioning of the staff also reveals that ‘empty’ alcohol hand-gel, medicated IV bags and non-medicated IV bags are disposed of in the orange bag stream.
* Infectious waste - Four orange lidded sharps boxes are present (one located on a treatment trolley for each bay, and one in the pharmacy area). Labelling indicates ’For Generic Orange Stream Waste’.
* Observations and feedback- The sharps boxes are observed to contain used syringes and the odd swab.
* Municipal waste - Four black bags (one in the nursing office and three in the patient areas). There is no labelling or description on the bags.
* Observations and feedback- All four bags contain only non-hazardous municipal waste items.
* Offensive waste - Tiger stripe bag in the ward toilet. There is no labelling or description on the bag.
* Observations and feedback-This is being used for municipal hygiene products. No other municipal or clinical wastes were evident. No offensive waste segregation is in place in treatment areas and is being disposed of in clinical orange bags.

 General observations and feedback for surgical ward:

* Ward management or staff had little knowledge, involvement in or ownership of waste management.
* The waste types are kept separate in the locked storage room, and each type is collected separately on a daily basis by support staff, who take it directly to the main waste storage yard.
* In the waste storage yard there are designated areas, and colour coded wheeled carts, for each waste stream. Each container type is kept completely separate.

**Classification and coding**

The hospital manager has now determined that the waste from the surgical ward can best be described as:

* Pharmaceutical waste – due to the lack of staff awareness and segregation procedures all medicinal waste should be managed via the purple stream and classified/coded as 18 01 08\* - cytotoxic and cytostatic medicines. Hazardous waste - to be treated via incineration.
* Infectious waste – Bagged waste, if not contaminated with pharmaceuticals or chemicals, to be manged via the orange stream and be classified/coded as 18 01 03\* - infectious clinical waste. Hazardous waste. To be treated via alternative treatment (preferred)or incineration.
* Bagged waste, if contaminated with pharmaceuticals or chemicals, to be manged via the yellow stream and be classified/coded as 18 01 03\* - infectious clinical waste contaminated with pharmaceuticals/chemicals. Hazardous waste. To be treated via incineration.
* Sharps boxes, if not contaminated with pharmaceuticals or chemicals, managed via orange stream, to be classified/coded as 18 01 03\* - infectious clinical waste. Hazardous waste. To be treated via alternative treatment (preferred) or incineration.
* Sharps boxes, if contaminated with pharmaceuticals or chemicals, managed via the yellow stream, to be classified/coded as 18 01 03\* - infectious clinical waste contaminated with pharmaceuticals/chemicals. Hazardous waste. To be treated via incineration.
* Municipal – Bagged waste to be managed via the domestic waste stream, classified/coded as 20 03 01 mixed municipal waste. Non-hazardous waste. Not suitable for alternative treatment.
* Offensive waste – Bagged (tiger stripe) waste to be managed via the offensive waste stream, classified/coded as 18 01 04 Offensive Waste. Non-hazardous waste. Not suitable for alternative treatment.

 **Actions**

 As a result of the audit the manager will take appropriate steps to ensure that:

* Cytotoxic and cytostatic drugs are clearly labelled when issued by the main hospital pharmacy, purple lidded containers are made available to the surgical ward, and staff are trained in appropriate procedures.
* Alcohol hand gel containers are either rinsed out and recycled as plastics or disposed of as hazardous chemicals.
* The orange bag bins are repositioned, so patients and visitors do not have access to them, and away from hand washing sinks, to prevent municipal waste entering the waste stream.
* Offensive hygiene bags are introduced alongside the orange bags to capture the healthcare offensive waste stream and remove it from the clinical waste stream.
* Procedures for IV bags are altered so medicated IV bags are disposed of as pharmaceutical waste in a designated and labelled rigid container. Non-medicated IV bags (where not infectious) are emptied down the sluice and the packaging disposed of in the offensive waste stream.
* In addition, one of the experienced ward staff is trained in internal waste management procedures, is assigned to conduct monthly audits of the ward, supports and trains ward staff, and communicates with the waste manager on waste issues.

**Return visit**

After one month the new procedures are audited and appear to be working so the manager is able to supply this additional audit information and confirm to the waste contractor that the waste from the surgical ward is now:

* Yellow lidded sharps boxes: 18 01 03\*, clinical waste, medicinally; contaminated sharps and pharmaceutical waste, (not including cytotoxic and cytostatic medicines), for incineration only.
* Orange bag: 18 01 03\*, clinical waste, infectious, suitable for alternative treatment. Suitable for carriage in bulk.
* Offensive Waste Bags: 18 01 04 offensive healthcare waste from human healthcare,
* 20 01 99 municipal offensive waste.
* Black bag: 20 03 01 mixed municipal waste.
* Cytotoxic and cytostatic bin: 18 01 08\* \* cytotoxic and cytostatic waste, including sharps, for incineration only.

 **Final audit report**

The final audit report from the hospital includes similar information from the other departments, an audit of the waste storage yard, and additional elements that are not addressed here. Although the initial audit identified several common problems, the waste contractor has considerable confidence over the waste because:

* The audit has obviously been very thorough.
* Problems were identified and were included in the final report.
* Remedial measures were clearly carried out.
* A follow up audit contained results that confirmed their success.

## Annex 2 – Minimum criteria for pre-acceptance audit

| **Required heading** | **Minimum information required** | **Supplementary guidance** |
| --- | --- | --- |
| 1 | Waste producer information | Name |  |
|  |  | Address |  |
|  |  | Type of premises  |  |
|  |  | Contact details   |  |
|  |  |  |  |
| 2 | Duration of audit | Audit start date |  |
|  |  | Audit end date |  |
|  |  | Review of audit and/or date of next audit |  |
|  |  |  |  |
| 3 | Description of the audit | Audit procedures used |  |
|  |  | Auditor’s names  |  |
|  |  | Auditor’s affiliation |  |
|  |  | Auditor’s competency   |  |
|  |  |  |  |
| 4 | Details of where waste is produced | Details of the different departments, wards or functional areas that exist with the premises and details of the specific processes that produce relevant wastes.  | This information can be provided in list form or as a diagram.  |
|  |  |  |  |
| 5 | Details of the wastes produced | Details of which waste types are produced by each department, ward or functional area. | The waste types the audit must identify include: * cytotoxic and cytostatic contaminated material -
* other pharmaceuticals or pharmaceutically contaminated material – such as medicinally contaminated syringes, intravenous (IV) therapy bags, tubing, bottles, vials, ampoules
* waste chemicals – such as laboratory agents, auto-analyser bottles, diagnostic kits, disinfectants
* human or animal tissue and associated chemical preservatives
* sharps, and whether they are contaminated with medicines (even if fully discharged)
* other infectious wastes
* dental amalgam
* non-hazardous offensive wastes - an offensive waste stream must be in place for offensive hygiene healthcare waste
* other non-hazardous wastes, including municipal waste and autoclaved wastes
* gypsum wastes other than the limited quantities correctly described as infectious
 |
|  |  |  |  |
| 6 | Description of individual waste types (as identified in 5) | Written description of the identified wastes | Must include type and classification and appropriate list of Waste (LoW) codes from the EWC.  |
|  |  | Physical form and composition |  |
|  |  | Hazardous properties |  |
|  |  | Type and colour-coding of the container or packaging the waste is placed in |  |
|  |  | How the packaging is labelled |  |
|  |  | Information to record whether the correct waste type was present in the container or packaging when it was checked during the audit |  |
|  |  | A comparison of the waste found during the audit to its proposed waste classification or description |  |
|  |  |  |  |
| 7 | Use of storage and bulk containers | Details of the segregation practices for wastes placed in storage areas and bulk containers or bins   |  |
|  |  | Specific storage requirements for wastes |  |
|  |  | The contents of a representative number of each type of bulk container that were checked visually |  |
|  |  | Details of any discussions held with staff that establish the validity of the segregation and storage standards, and the observation and recording of actual practice |  |
|  |  | Detail the findings made for each waste stream, and where applicable, the changes made as a result of this or previous audits |  |
|  |  |  |  |
| 8 | Producer policies and procedures | Provide information on the waste producer’s policies, staff training, internal audit regimes, and environmental management systems. |  |
|  |  |  |  |
| 9 | Quantity of waste | Provide an estimated quantity of each waste expected to be delivered to the site from the waste producer per year and in a typical load. |  |
|  |  |  |  |
| 10 | Presence of radioactive waste  | Confirmation that waste does not contain a radioactive source or, when there is a risk of radioactive contamination, confirmation that the waste is not radioactive, unless the authorisation allows acceptance of these materials. |  |
|  |  |  |  |
| 11 | Chemicals – safety data sheets (SDS/MSDS)  | Include any safety data sheets for single stream product chemicals, laboratory chemicals or pharmaceuticals (if available). |  |
|  |  |  |  |