

Guidance for the storage and treatment of healthcare waste

Storage and treatment of healthcare waste: Appropriate measures and supporting guidance 1.0

February 2022

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1 Introduction

This guidance sets out the standards (appropriate measures) that are relevant to facilities or sites with an environmental authorisation to store or treat healthcare waste.

In Scotland, the storage or treatment of healthcare waste is regulated by the Scottish Environment Protection Agency (SEPA) under different regimes. These regimes are the Pollution Prevention and Control (Scotland) Regulations 2012 and the Environmental Protection Act 1990.

For the purposes of this guidance the term "<u>environmental authorisation</u>" means a permit granted by SEPA in accordance with the Pollution Prevention and Control (Scotland) Regulations 2012 or a waste management licence granted by SEPA under the Environmental Protection Act 1990.

SEPA will have regard to this guidance when determining whether an <u>operator</u> can comply with, or is compliant with, the conditions of an environmental authorisation for the storage, and or treatment of healthcare waste.

This guidance should be used by operators who store or treat healthcare waste, to demonstrate compliance with the objectives of your environmental authorisation, to prevent, or where that is not practicable, to minimise emissions to the environment.

If you operate an activity which is exempt from the requirement to be authorised by a waste management licence, under paragraph 28 or 39 of the Waste Management Licensing (Scotland) Regulations 2011 (<u>exemptions</u> or exempt activities), you should follow parts of this guidance as detailed in section 1.4 Table 2.

Producers and transporters of healthcare waste are expected to follow sections on classification and segregation and waste pre-acceptance.

Adoption of 'Storage and Treatment of Healthcare Waste: Appropriate Measures and Supporting Guidance 1.0 - (Healthcare Waste: AMSG 1.0)'

In Scotland, the large-scale treatment/storage of Healthcare Waste has been regulated under the Pollution Prevention Control (PPC) and Waste Management Licencing (WML) regimes. Historically, when developing its regulatory approach to the Healthcare Waste sector, SEPA has incorporated guidance from various sources for example, the WHO 'blue book', EU prepared documents such as BAT references or joint UK agency (SEPA, NRW, NIEA and EA) prepared documents such as PPG Notes and Sector Technical Guidance Notes.

Since its introduction in 2010, EPR 5.07 (Clinical waste guidance published by the Environment Agency) has been the primary source of guidance for the Healthcare Waste sector in England and Wales. Differences in regulatory regimes and approach, prevented SEPA from being able to simply adopt EPR 5.07. SEPA did however incorporate parts of EPR 5.07 into the existing Scottish regulatory framework, where appropriate to do so.

To support SEPA's regulatory delivery and to align our approach with other parts of the UK, SEPA has prepared consolidated guidance, which will benefit operators who work across the UK.

The introduction of Scottish guidance, aimed at the Healthcare Wase sector, will enable SEPA to regulate consistently and proportionately. Furthermore, the guidance will support those involved in the production, handling, transport, storage and treatment of Healthcare Waste to comply with their regulatory obligations and enable them to manage their waste in a manner that minimises pollution of the environment or harm to human health.

Question 4. Do you agree with the introduction of a guidance document which will supersede, and where relevant replace, existing guidance documents and regulatory position statements, and, in general align regulation of the healthcare waste sector in Scotland to the rest of the UK?

1.1 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 are those wastes listed in Chapter 18 of the European Waste Catalogue (EWC) and arise from human and animal healthcare, i.e. from hospitals, GP surgeries, dental surgeries, veterinary surgeries etc. Healthcare wastes from municipal sources are listed in Chapter 20 of the EWC.

For the purpose of this guidance '<u>clinical waste</u>' is healthcare waste produced from human or animal healthcare and similar activities that may pose a risk of infection, for example, swabs, bandages, dressings etc., or which may prove hazardous, for example medicines, unless <u>rendered safe</u>. The most commonly used definition can be found in the Controlled Waste Regulations 1992.

For clinical waste to be considered rendered safe, it must be treated to:

- 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 from the waste;
- destroy any anatomical waste (human or animal tissue) so that it is no longer recognisable;
- make it (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.

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

- may cause offence due to the presence of recognisable healthcare waste items or body fluids;
- does not meet the definition of an infectious waste;
- does not possess any hazardous properties;
- is not identified by the producer, or holder, as needing disinfection, or any other treatment, to reduce the number of microorganisms present
- falls within waste codes 18 01 04, 18 02 03 or 20 01 99;
- is not clinical waste.

In general, offensive waste will include:

- sanitary towels and tampons;
- panty liners;
- feminine wipes;
- incontinence products and nappies;
- catheter and stoma bags;
- animal faeces and animal bedding etc.

Please note that offensive waste is also commonly referred to as 'hygiene' waste and both terms are interchangeable for the purposes of this guidance.

Wastes produced by healthcare in the community, and similar types of waste produced by non-healthcare activities are also healthcare waste, for example wastes from:

- cosmetic body piercing and body art;
- non-medicinal procedures in the hair and beauty sector;
- substance abuse crime scene clean-up.

1.2 What are appropriate measures

<u>Appropriate measures</u> is a collective term used by SEPA in this guidance to describe:

- best available technique (BAT) requirements for permitted installations authorised under the Pollution Prevention and Control (Scotland) Regulations 2012 (PPC installations);
- standards for waste management facilities authorised under the Environmental Protection Act 1990 (WML facilities);
- industry best practice techniques.

Appropriate measures are the standards that SEPA expects operators (as a minimum) to consider, to help them comply with their environmental authorisation. In some cases, you may be legally required to apply appropriate measures.

1.3 When appropriate measures apply

The appropriate measures set out in the guidance apply to all healthcare waste received at facilities or sites with an environmental authorisation to store or treat healthcare waste.

This guidance sets out what you should consider (as a minimum) when you assess the appropriate measures for your facility or site. It is not exhaustive, and it does not replace your obligation to ensure you assess appropriate measures comprehensively.

Some measures may not be suitable or relevant for your operation. Appropriate measures for your operation will depend on:

- which regime your operation is regulated under (regime specific considerations are highlighted in relevant sections of this document);
- the requirements set out in your environmental authorisation;
- the activities being carried out;
- the size and nature of the activities;
- the location of the site.

Where an appropriate measure is not suitable for your operation, you must use alternative measures that achieve the same level of environmental protection or be able to demonstrate the measure is not necessary for environmental protection purposes. The use of alternative measures should be discussed with SEPA. Where a measure is not relevant you should be able to provide an explanation of why this is the case.

In certain situations, you may need to provide a higher standard of environmental protection, for example:

- where there are local sensitive receptors;
- if there is a risk that an Environmental Quality Standard may be exceeded.

1.4 The appropriate measures that apply to different types of facilities

Table 1 indicates which sections of this guidance you should consider if you operate a PPC installation, or a WML facility to store or treat healthcare waste.

Table 1. Which appropriate measures apply to different types of facilities

Key		Facility Type		
✓ X 5.01 Sectio	Applies to this type of facility Does not apply to this type of facility Refer to <u>Incineration Sector</u> <u>Guidance Note EPR 5.01</u>	Transfer station (storage facility)	Alternative treatment	Incineration
1.5 M - clas	anaging healthcare wastes sification and segregation	~	~	~
2. Ge	neral management	\checkmark	~	5.01
3. Waste pre-acceptance, acceptance and tracking		√	~	~
4. Waste storage, segregation and handling		\checkmark	~	~
5. Wa	aste treatment	Х	✓	5.01
6. En	nissions control	\checkmark	✓	5.01
7. Emissions monitoring and limits		\checkmark	~	5.01
 8. Process efficiency * (measures for using energy, raw materials and water apply to PPC installations only 		√*	~	5.01

Table 2 indicates which sections of this guidance you should follow if you operate under an exemption.

Table 2. Which appropriate measures apply to exemptions

	Key		Exemption Paragraph	
	✓ X	Applies to this type of facility Does not apply to this type of facility	Paragraph 28 – the use of autoclaves to treat waste at the	Paragraph 39 – the storage of healthcare wastes
Section		n	place it is produced	at specific premises
1.5 Managing healthcare wastes - classification and segregation		anaging healthcare wastes sification and segregation	~	~
2. General management		neral management	X	Х
3. Waste pre-acceptance, acceptance and tracking		iste pre-acceptance, stance and tracking	х	\checkmark

4.Waste storage, segregation and handling	\checkmark	\checkmark
5.Waste treatment	~	Х
6.Emissions control	~	~
7.Emissions monitoring and limits	~	Х
8.Process efficiency	Х	Х

Other generic technical guidance may also apply to healthcare waste facilities, such as <u>guidance on emissions</u>, <u>odour and noise</u>.

Additional specific technical guidance is also available for sites that store or treat other <u>chemical hazardous wastes</u>.

Combustion plant with a rated thermal input less than 50 megawatts must comply with the relevant <u>requirements</u> of the Medium Combustion Plant Directive and specified generator regulations.

Healthcare waste may include radioactive materials. This guidance does not cover managing these waste materials. You must comply with <u>Radioactive substances</u> regulation guidance when managing radioactive materials.

We consider the accident and fire prevention measures specified in this guidance are appropriate measures for managing the fire risks of healthcare waste. Fire prevention measures should be included in your accident management plan or working plan. If you have an authorisation to carry out an activity involving the storage of other non-hazardous combustible wastes, you may need to consider additional measure applicable to those waste types.

Further guidance on reducing fire risk at waste management sites is provided by the Waste Industry Safety and Health (WISH) forum guidance (Waste 28, Reducing fire risk at waste management sites). Both the WISH forum guidance (Waste 28, Reducing fire risk at waste management sites) and this guidance, supplement, but do not replace any statutory requirements under Fire (Scotland) Act 2005, The Fire Safety (Scotland) Regulations 2006 or other applicable legislation.

<u>The Scottish Government</u> provides information and guidance on how to meet obligations under the Fire (Scotland) Act 2005 and The Fire Safety (Scotland) Regulations 2006.

Incorporation of Appropriate Measures for sites utilising paragraph 28 and paragraph 39 exemptions

Schedule 1 to The Waste Management Licensing (Scotland) Regulations 2011 details a number of 'activities' exempt from the full requirements of waste management licensing, two such activities, the use of autoclaves to sterilise waste (paragraph 28) and the secure storage of medical, nursing or veterinary wastes (paragraph 39), specifically include healthcare waste.

Both these activities are classed as simple exemptions, and as such they need to be registered with SEPA however they do not attract a fee.

In recognition of the various waste streams caught under the category of 'Healthcare Waste' and their associated risks and in an attempt to introduce a fairer consistent approach to the management of all healthcare waste across different regulatory regimes, SEPA intends to apply some of the 'appropriate measures' identified in this document to these exempt activities.

Questions 5. Do you agree with SEPA's intention to apply appropriate measures, to activities carried out under a Paragraph 28 exemption, where relevant (as detailed in sections 1.4 (classification and segregation), 4. (waste storage, segregation and handling), 5. (waste treatment), 6. (emission control) and 7. (emission monitoring and limits) of Healthcare Waste: AMSG 1.0)?

Question 6. Do you agree with SEPA's intention to apply appropriate measures, to activities carried out under a Paragraph 39 exemption, where relevant (as detailed in sections 1.4 (classification and segregation), 3. (Waste pre-acceptance and tracking), 4. (waste storage, segregation and handling) and 6. (emission control) of Healthcare Waste: AMSG 1.0)?

1.5 Implementing appropriate measures at new and existing facilities

The appropriate measures in this guidance apply to both new and existing facilities.

For new PPC installations or WML facilities the appropriate measures must be in place before operations start.

For existing PPC installations or WML facilities, if the cost of implementing appropriate measures is disproportionate to the environmental benefit, immediate implementation may not be reasonable. SEPA intends, in conjunction with operators, to undertake a programme of authorisation reviews to assess current operating techniques against relevant appropriate measures. Where appropriate measures are not being used, operators should provide proposed improvement plans and implementation timetables to SEPA. We will review proposals and set formal timescales for making the improvements needed. We will do this by varying the environmental authorisation to include improvement conditions where necessary. Improvements at existing PPC installations or WML facilities are likely to fall into one of the following two categories.

Standard good practice requirements

For example:

- updated management systems;
- waste, water and energy efficiency measures;
- measures to prevent fugitive or accidental emissions;
- waste handling techniques;
- appropriate monitoring equipment.

Where these improvements are relatively low cost, they should be implemented as soon as practicable and within 12 months of the improvement need being identified.

Larger, capital investment improvements

For example:

- installing significant abatement equipment;
- the significant redesign of facility layout, including the design and installation of new buildings or treatment plant.

Where improvements require larger capital investment we would expect them to be completed as soon as practicable and within three years.

Local environmental impacts (for example, having sensitive receptors or an air quality management area close by) may mean an operator has to take action more quickly than the timescales provided here.

By August 2022, unless we approve a <u>derogation</u>, existing PPC installations must comply with relevant BAT Associated Emission Levels (AELs). These are set out in the published <u>Waste Treatment BAT Conclusions document</u>.

New PPC installations (including new or replacement plant at existing facilities) will be expected to comply with any relevant BAT AELs from when operations begin, unless a derogation is approved.

Exempt activities must not be carried out in a manner which is likely to cause pollution of the environment or harm to human health. To help ensure exempt activities do not cause pollution of the environment or harm to human health, SEPA recommends that operators carrying on an exempt activity follow this guidance as set out in section 1.4 Table 2.

Implementation and permit/WML

The 'appropriate measures' being proposed in 'Healthcare Waste: AMSG 1.0' and their application to both the PPC and WML regimes, is a new concept and a new addition to SEPA's regulatory toolkit. It is SEPA's intention to use them to shape existing and future environmental authorisations for PPC installations and waste management licence (WML) facilities. To provide consistency across the sector, existing environmental authorisations will need to be reviewed and amended where appropriate.

Post-publication of **Healthcare Waste: AMSG 1.0** SEPA intends to carry out reviews of existing environmental authorisations for PPC installations and WML facilities that store, treat or transfer healthcare waste. We will do this in conjunction with site operators, to assess current operating techniques against relevant appropriate measures contained in AMSG 1.0. It is our intention for all existing environmental authorisations for PPC installations and WML facilities to reflect relevant appropriate measures by the summer of 2025.

Furthermore, it is our intention to increase regulatory focus on the sector as a whole, with a view to carrying out increased site visits/audits to all those involved in the production, handling, transport, storage and treatment of Healthcare Waste to support implementation of the guidance and progress towards a level playing field across the sector.

Question 7. Do you agree with SEPA's intention to review existing permits and licences, and where appropriate, amend to reflect the regulatory approach of this guidance document?

Question 8. Do you agree with SEPA's intention to have a more visible regulatory presence on your premises?

Questions 9. SEPA wants to create a level playing field for all involved in the production and management of healthcare waste. In addition to our guidance, is there anything that would help improve the production, handling, transport, storage and treatment of healthcare waste?

1.6 Classification and segregation of healthcare wastes

The correct classification and segregation of healthcare waste at source makes sure that the right waste goes to the right place for appropriate storage and treatment. Segregating healthcare waste at source based upon type and properties means that it can be treated effectively and efficiently. It also helps divert certain healthcare wastes (for example, offensive wastes) away from more costly and energy intensive treatment processes. This means that more healthcare waste can be sent to alternative recycling and recovery operations. The most important step in this process is that healthcare premises, producing healthcare waste, make sure they rigorously segregate their wastes at source. Healthcare waste producers must check and confirm through an audit that they are doing this on an ongoing basis. Section 3.1 provides further information on pre-acceptance procedures, waste audits carried out at producer premises and their assessment.

In the United Kingdom there is no legal requirement on those producing and managing healthcare wastes to segregate and package their waste by anything other than its characterisation, compatibility, classification and disposal route.

In the absence of other legal requirements on segregation and packaging, SEPA recommends that the system in Table 3, which is based on current industry best practice, is implemented as an appropriate measure for the management of healthcare wastes.

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

Colour of packaging	Waste types	List of waste (LoW) codes from EWC	Appropriate activities
	human healthcare (may contain sharps)	18 01 03*	
	animal healthcare (may contain sharps)	18 02 02*	
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
	commercial, separately collected fractions of absorbents, wiping cloths and protective clothing contaminated by infectious substances	15 02 02*	Incineration
Yellow: Infectious waste, contaminated with	human healthcare (may contain sharps)	18 01 03*	Storage
chemicals or medicines (not cytotoxic or cytostatic)	animal healthcare (may contain sharps)	18 02 02*	Incineration
Red: Infectious anatomical.	Human Healthcare	18 01 03*	
chemically preserved	Animal Healthcare	18 02 02*	
Infectious anatomical, not	Human Healthcare	18 01 03*	Storage
chemically preserved	Animal healthcare	18 02 02*	Incineration
Non-	Human Healthcare	18 01 02	
infectious anatomical	Animal Healthcare	18 02 03	
Purple:	Human Healthcare	18 01 08* 20 01 31*	Storage
medicines	Animal Healthcare	18 02 07* 20 01 31*	Incineration

Table 3. Types of healthcare waste by packaging colour,	list of waste code and
activity	

Blue: Pharmaceuticals,	Human Healthcare	18 01 09 20 01 32	Storage
medicines and controlled drugs	Animal Healthcare	18 02 08 20 01 3	Incineration
	Human Healthcare	18 01 04	Storage
Offensive	Animal Healthcare	18 02 03	Landfill
	Not from healthcare or research-related sources	20 01 99	Incineration
Colour not specified	Amalgam waste from dental care	18 01 10*	
	Infectious gypsum wastes (for example, plaster casts and moulds)	18 02 02* 18 01 03*	Storage

Not all healthcare waste is clinical waste. However, it is common for operators to collect and/or store non-clinical healthcare wastes for bulking-up/storage prior to onward transport to a suitable facility for treatment/disposal. Table 4 details the most common non-clinical wastes produced as a result of healthcare and similar activities. Please note that unlike the wastes in Table 3 there is no recommended colour coded packaging for non-clinical wastes.

Where bulking up/storage prior to onward transport occurs, it is recommended that operators ensure that the wastes covered in Table 4 are segregated and stored separately from those in Table 3. This will ensure that any wastes not suitable for treatment by alternative treatment will not be processed alongside those that are suitable.

Table 4. Common non-clinical wastes	s produced during	y healthcare activities
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Waste type	List of waste (LoW) codes from EWC	Appropriate activities
Non-infectious sharps, not contaminated with chemicals or medicines	18 01 01 or 18 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

Table 3 & 4 accompanying notes

An asterisk (*) at the end of a LoW code means the waste is hazardous.

In Scotland, waste with hazardous properties is called special waste. The Special Waste Regulations 1996 (as amended) are the principal piece of legislation covering special waste arising in Scotland. They set out the procedures to be followed when disposing of, carrying and receiving special waste.

Joint agency <u>Guidance on the classification and assessment of waste (WM3)</u> identifies 15 hazardous properties and provides comprehensive guidance on the assessment and classification of waste in each of the hazard groups.

In Scotland, waste must be classified using a single LoW code that reflects the processes that produced the waste. A fuller description of each waste present must be included on Special Waste Consignment Notes and the most appropriate disposal route followed. Further guidance on consigning special waste can be found in SEPA's <u>Consigning Special Waste Guidance</u>.

'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, broken glass, and nails.

20 10 99 includes healthcare waste from care homes that do not provide nursing or medical care.

In accordance with Appendix A, <u>WM3</u>, waste medicinal products from the manufacture and supply of pharmaceuticals must be classified under the medicine codes in chapter 18 of the LoW.

Where possible, gypsum waste should be segregated and sent for recovery and recycling under an appropriate environmental authorisation. If being sent to

landfill, it must be deposited in a separate cell in which no biodegradable waste is accepted. If infectious, then gypsum waste must be rendered safe.

Where the colour of packaging for a particular type of waste is not specified, the most appropriate colour that takes into account the nature of the waste and the waste disposal or recovery route should be used. 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.

1.7 Treatment and disposal of healthcare waste - general

For carefully segregated infectious healthcare wastes you can use chemical or heatbased disinfection as an alternative treatment to incineration. These wastes are put into orange bags, or orange-lidded rigid yellow containers. The waste must not contain or be contaminated with:

- anatomical waste;
- chemicals;
- medicines.

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 1,100°C).

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.

The alternative treatment of wastes not identified in Table 3 must only be undertaken if the facility has been specifically permitted and validated for the treatment of such wastes. Section 5.1.10 provides further information.

Treatment of orange lidded sharps

Healthcare waste is a complex waste stream consisting of many different subgenres, some of which require different standards of treatment, namely, where those sub-genres are deemed clinical waste, they must be 'rendered safe' for example cytotoxic/cytostatic medicines and anatomical wastes must be incinerated and are not suitable or alternative treatment (AT).

The introduction of pre-acceptance audits and continued application of colour coded segregation of healthcare waste will help producers and operators ensure their waste is 'rendered safe' however there is still scope for mis-segregation and for waste to be treated incorrectly. The guidance considers orange stream waste to be 'infectious waste, not contaminated with chemicals or medicines' however there is a greater risk with this stream for chemical/medicinal contamination which could lead to the waste not being 'rendered safe' prior to final disposal if it is sent to AT for treatment.

As is commonplace elsewhere in the UK, this guidance is proposing that where orange stream waste is treated via AT that operators provide assurances that the waste treatment technology being permitted can treat chemical/medicinal waste, and, where this cannot be achieved any post-treatment waste, floc and wastewater, should be classified appropriately and sent for the appropriate standard of treatment.

Question 10. Do you agree with this proposal to align the regulation of the treatment of orange lidded sharps with the rest of the UK?

2 General management appropriate measures

These are the appropriate measures for the general management of a healthcare waste facility operating under an environmental authorisation (PPC installation or WML facility) for storing or treating healthcare waste.

2.1 Management system (PPC installations only)

The level of detail and nature of your management system will generally reflect the nature, scale and complexity of the facility. The potential range of environmental impacts it may have and the type and amount of waste processed.

You must have and follow an up to-date, written management system that incorporates the following features:

- management commitment, including from senior managers;
- an environmental policy that is approved by senior managers and includes the continuous improvement of the facility's environmental performance;
- your plan to establish the resources, procedures, objectives and targets needed for environmental performance alongside your financial planning and investment.

How you will implement your environmental performance procedures, paying particular attention to:

- staff structure and relevant responsibilities;
- staff recruitment, training, awareness and competence;
- communication (for example, of performance measures and targets);
- employee involvement;
- documentation;
- effective process control;
- maintenance programmes;
- the management of change ;
- emergency preparedness and response;
- making sure you comply with environmental legislation;

How you will check environmental performance and take corrective or preventative action, paying particular attention to:

- monitoring and measurement;
- learning from incidents, near misses and mistakes, including those of other organisations;
- records maintenance;

• independent (where practicable) internal or external auditing of the management system to confirm it has been properly implemented and maintained.

How you will review the management system to check it is still suitable, adequate and effective.

How you will review the development of cleaner technologies and their applicability to site operations.

How, when designing new plant, you will make sure you assess the environmental impacts from the plant's operating life and eventual decommissioning.

How you will compare your site's performance against relevant sector guidance and standards on a regular basis, known as sectoral benchmarking.

As part of your management plan, you must have and maintain the following documentation:

- inventory of emissions to air and water;
- residues management plan;
- accident management plan;
- <u>site infrastructure plan;</u>
- <u>site report;</u>
- odour management plan, if required;
- noise and vibration management plan, if required;
- dust management plan, if required;
- pest management plan, if required;
- fire prevention plan, if required.

2.2 Accident management plan

- 1. As part of your written management system you must have an accident management plan for dealing with any incidents or accidents that could result in pollution of the environment or harm to human health.
- 2. The accident management plan must identify and assess the risks the facility poses to human health and the environment.
- 3. Particular areas to consider include:
 - waste types;
 - vessels overfilling;
 - failure of plant and equipment (for example over-pressure of vessels and pipework, blocked drains);

- failure of containment (for example, bund failure, or drainage sumps overfilling);
- failure to contain firefighting water;
- making the wrong connections in drains or other systems;
- preventing incompatible substances coming into contact with each other;
- unwanted reactions and runaway reactions;
- checking the composition of an effluent before emission;
- vandalism and arson;
- extreme weather conditions for example flooding or very high winds.
- 4. You must assess the risk of accidents and their possible consequences. Risk is the combination of the likelihood that a hazard will occur and the severity of the impact resulting from that hazard. Having identified the hazards, you can assess the risks by addressing six questions:
 - How likely is it that the accident will happen?
 - What may be emitted and how much?
 - Where will the emission go what are the pathways and receptors?
 - What are the consequences?
 - What is the overall significance of the risk?
 - What can you do to prevent or reduce the risk?
- 5. In particular, you must identify any fire risks that may be caused, for example by:
 - arson or vandalism;
 - self-combustion, for example due to chemical oxidation;
 - plant or equipment failure and electrical faults;
 - naked lights and discarded smoking materials;
 - hot works (for example welding or cutting), industrial heaters and hot exhausts;
 - reactions between incompatible materials;
 - neighbouring site activities;
 - sparks from loading buckets;
 - hot loads deposited at the site.
- 6. The depth and type of accident risk assessment you carry out will depend on the characteristics of the facility and its location. The main factors to take into account are the:
 - scale and nature of the accident hazard presented by the facility and its activities;

- risks to areas of population and the environment (the receptors);
- nature of the facility and complexity of the activities and how difficult it is to decide and justify adequate risk control techniques.
- 7. Through your accident management plan, you must also identify the roles and responsibilities of the staff involved in managing accidents. You must provide them with clear guidance on how to manage each accident scenario.
- 8. You must appoint one facility employee as an emergency co-ordinator who will take lead responsibility for implementing the plan. You must train your employees so they can perform their duties effectively and safely and know how to respond to an emergency.
- 9. You must also:
 - establish how you will communicate with relevant authorities, emergency services and neighbours (as appropriate) both before, during and after an accident;
 - have appropriate emergency procedures, including for safe plant shutdown and site evacuation;
 - have post-accident procedures that include making an assessment of the harm that may have been caused by an accident and the remediation actions you will take;
 - test the plan by carrying out emergency drills and exercises.

2.3 Accident prevention measures

1. You must take the following measures, where appropriate, to prevent events that may lead to an accident.

Segregating waste

- 2. You must keep apart incompatible or segregated wastes and substances by their hazardous properties.
- 3. You must segregate incompatible waste types into bays or store them in dedicated buildings. The minimum requirement is to use a kerbed perimeter and separate drainage collection. You must also have measures in place to prevent containers falling over into other storage areas.

Preventing accidental emissions

- 4. You must make sure you contain the following (where appropriate) and route to the effluent system (where necessary):
 - process waters;

- site drainage waters;
- emergency firefighting water;
- chemically contaminated waters;
- spillages of chemicals.
- 5. You must be able to contain surges and storm water flows. You must provide enough buffer storage capacity to make sure you can achieve this. You can define this capacity using a risk-based approach, for example, by taking into account the:
 - nature of the pollutants;
 - effects of downstream waste water treatment;
 - sensitivity of the receiving environment.
- 6. You can only discharge waste water from this buffer storage after you have taken appropriate measures, for example, to control, treat or reuse the water.
- 7. You must have spill contingency procedures to minimise the risk of an accidental emission of raw materials, products and waste materials, and to prevent their entry into water.
- 8. Your emergency firefighting water collection system must take account of additional firefighting water flows or firefighting foams. You may need emergency storage lagoons to prevent contaminated firefighting water reaching a receiving water body.
- 9. You must consider and, if appropriate, plan for the possibility that you need to contain or abate accidental emissions from:
 - overflows;
 - vents;
 - safety relief valves;
 - bursting discs.

If this is not advisable on safety grounds, you should focus on reducing the probability of the emission.

Security measures

- 10. You must have security measures in place (including staff) to prevent:
 - entry by vandals and intruders;
 - damage to equipment;
 - theft;
 - fly-tipping;

- arson.
- 11. Facilities should use an appropriate combination of the following measures:
 - security guards;
 - total enclosure (usually with fences);
 - controlled entry points;
 - adequate lighting;
 - warning signs;
 - 24-hour surveillance, such as CCTV.

Fire prevention

- 12. You must:
 - minimise the likelihood of a fire happening;
 - aim for a fire to be extinguished within four hours;
 - minimise the spread of fire within the site and to neighbouring sites.
- 13. You must have appropriate systems for fire prevention, detection and suppression or extinction.
- 14. You must have suitable procedures and provisions to store certain types of hazardous waste, for example, fire resistant stores, automatic alarms and possibly sprinklers.
- 15. Your facility must have enough water supplies to extinguish fires where appropriate. You must have an alternative type of fire protection system if you store or treat any water-reactive waste, for example dry powder extinguishers.
- 16. You must isolate drainage systems from flammable waste storage areas to prevent fire spreading along the drainage system by solvents or other flammable hydrocarbons.
- 17. You must regularly inspect and clean your site to prevent the build-up of loose combustible material (including waste and dust), particularly around treatment plant, equipment and other potential sources of ignition.

Other accident prevention measures

- 18. You must maintain plant control in an emergency using one (or a combination) of the following measures:
 - alarms;
 - process trips and interlocks;

- automatic systems based on microprocessor control and valve control;
- tank level readings such as ultrasonic gauges, high level warnings, process interlocks and process parameters.

19. You must:

- make sure all the measurement and control devices you would need in an emergency are easy to access and operate in an emergency situation;
- maintain the plant so it is in a good state through a preventive maintenance programme and a control and testing programme;
- use techniques such as suitable barriers to prevent moving vehicles damaging equipment;
- have procedures in place to avoid incidents due to poor communication between operating staff during shift changes and following maintenance or other engineering work;
- where relevant, use equipment and protective systems designed for use in potentially explosive atmospheres.

Record keeping and procedures

20. You must:

- keep an up-to-date record of all accidents, incidents, near misses, changes to procedures, abnormal events, and the findings of maintenance inspections;
- carry out investigations into accidents, incidents, near misses and abnormal events and record the steps taken to prevent their reoccurrence;
- maintain an inventory of substances, which are present (or likely to be) and which could have environmental consequences if they escape – many apparently innocuous substances can damage the environment if they escape;
- have procedures for checking raw materials and wastes to make sure they are compatible with other substances they may accidentally come into contact with.

2.4 Contingency plan and procedures

- 1. You must have and implement a contingency plan, which makes sure that you:
 - comply with all your authorisation conditions and operating procedures during maintenance or shutdown at your site or elsewhere;
 - do not exceed the storage limits in your environmental authorisation and you continue to apply appropriate measures for storing and handling waste;
 - stop accepting waste unless you have a clearly defined method of recovery or disposal and enough permitted storage capacity.

- 2. You must have contingency procedures to make sure that, as far as possible, you know in advance about any planned shutdowns at waste management facilities where you send waste.
- 3. You must make your customers aware of your contingency plan, and of the circumstances in which you would stop accepting waste from them.
- 4. You must consider whether the sites or companies you rely on in your contingency plan:
 - can take the waste at short notice;
 - are authorised to do so in the quantities and types likely to be needed in addition to carrying out their existing activities.
- 5. You must not discount alternative disposal or recovery options on the basis of extra cost or geographical distance if doing so means you could exceed your authorised storage limits or compromise your storage procedures.
- 6. You must not include unauthorised capacity in your contingency plan. If your contingency plan includes using temporary storage for additional waste on your site, then you must make sure your site is authorised for this storage and you have the appropriate infrastructure in place.

Treatment sites only

- 7. Your management procedures and contingency plan must:
 - identify known or predictable malfunctions associated with your technology and the procedures, spare parts, tools and expertise needed to deal with them;
 - include a record of spare parts held, especially critical spares or state where you can get them from and how long it would take;
 - have a defined procedure to identify, review and prioritise items of plant which need an appropriate maintenance programme;
 - include all equipment or plant whose failure could directly or indirectly lead to an impact on the environment or human health;
 - identify 'non-productive' or redundant items such as tanks, pipework, retaining walls, bunds, reusable waste containers (for example wheeled bins), ducts, filters and security systems;
 - make sure you have the spare parts, tools, and competent staff needed before you start maintenance.
- 8. You must carry out appropriate disinfection procedures when maintaining equipment (or parts of equipment) contaminated with untreated clinical waste. Using personal protective equipment (PPE), although essential to protect workers from exposure, must not be your primary control measure.

- 9. If you produce an end of-waste material at your facility, your contingency planning must consider issues with storage capacity for end of-waste products and materials that fail the end-of-waste specification.
- 10. Your management system must include procedures for auditing your performance against all of these contingency measures and for reporting the audit results to the site manager.

2.5 Plant decommissioning

- 1. You must consider the decommissioning of the plant at the design stage and make suitable plans to minimise risks during later decommissioning.
- 2. For existing plants where potential risks are identified, you must have a programme of design improvements. These design improvements need to make sure you:
 - avoid using underground tanks and pipework if it is not economically possible to replace them, you must protect them by secondary containment or a suitable monitoring programme;
 - drain and clean out vessels and pipework before dismantling;
 - use insulation which you can dismantle easily without dust or hazard;
 - use recyclable materials, taking into account operational or other environmental objectives.
- 3. You must have and maintain a decommissioning plan to demonstrate that:
 - plant will be decommissioned without causing pollution;
 - the site will be returned to a satisfactory condition.
- 4. Your decommissioning plan should include details on:
 - whether you will remove or flush out pipelines and vessels (where appropriate) and how you will empty them of any potentially harmful contents;
 - site plans showing the location of all underground pipes and vessels;
 - the method and resources needed to clear any on-site lagoons;
 - the method for closing any on-site landfills;
 - how asbestos or other potentially harmful materials will be removed, unless we have agreed it is reasonable to leave such liabilities to future owners;
 - methods for dismantling buildings and other structures, and for protecting surface water and groundwater at construction and demolition sites;
 - any soil testing needed to check for any pollution caused by the site activities, and information on any remediation needed to return the site to a satisfactory state, as defined by the initial site report;

- the measures proposed, once activities have definitively stopped, to avoid any
 pollution risk and to return the site of operation to a satisfactory state (including,
 where appropriate, measures relating to the design and construction of the
 plant);
- the clearing of deposited residues, waste and any contamination resulting from the waste treatment activities.
- 5. You should make sure that equipment taken out of use is decontaminated and removed from the site.

2.6 Working Plan (WML facilities only)

1. WML facilities regulated under the Environmental Protection Act 1990, are not currently required to prepare a management system as outlined in section 2 above.

However, SEPA considers the preparation of a management system incorporating relevant features, to be best practise for healthcare WML facilities with an environmental authorisation.

2. All healthcare WML facilities must have a working plan, setting out how a facility is to be designed, engineered, operated, monitored and restored.

For new facilities, a working plan must be submitted with an application for a waste management licence. Guidance on the preparation of a working plan is contained in <u>SEPA's A guide to waste management licensing and Working Plan</u> Guidance for Waste Transfer/Treatment Facilities.

3. There is overlap between management systems and working plans. Where relevant, appropriate measures outlined in sections 2.1, 2.2, 2.3, 2,4 & 2.5 above may be helpful in the preparation of a working plan.

2.7 Staff competence

- 1. Your site must be operated at all times by an adequate number of staff with appropriate qualifications and competence.
- 2. The design and maintenance of infrastructure, plant and equipment must be carried out by competent people.
- 3. You must have appropriately qualified managers for your waste activity.

See <u>A practical guide for Part A activities for PPC installations</u> or <u>Provision &</u> <u>assessment of technically competent management at licensed waste management</u> <u>facilities.</u>

3 Waste pre-acceptance, acceptance and tracking appropriate measures

These are the appropriate measures for waste pre-acceptance, acceptance and tracking at sites operating under an environmental authorisation (PPC installation, WML facility) for storing and treating healthcare waste.

If you operate under a paragraph 39 exemption, you should follow appropriate measures where relevant. Section 3.1.8 details certain waste types which do not need to be covered by a waste pre-acceptance audit report.

3.1 Waste pre-acceptance

- 1. Your environmental authorisation will require you to implement waste preacceptance procedures. These must ensure you know enough about any waste to assess whether it is technically and legally suitable for acceptance, before it arrives at your site, and before you transfer it onto others. Procedures must follow a risk-based approach and must identify and consider:
 - the source and nature of the waste;
 - its hazardous properties;
 - potential risks to process safety, human health and the environment including odour and other emissions;
 - information about the previous waste holder(s) including name, address, type of premises and contact details;
 - information provided by previous waste holders including waste producer preacceptance audit reports.
- 2. The advice you give to waste producers about segregating and packaging waste must follow section 1.6 (classification and segregation) of this guidance.
- 3. If you receive waste from producers outside of Scotland, you must still comply with all waste pre-acceptance requirements and obtain waste producer audit reports for the waste.
- 4. If you receive waste from a country that does not use the same waste segregation process or colour-coded packaging as set out in section 1.6 of this guidance, you must confirm the segregation practices and colour-coding used by the waste producer so you can understand the waste stream and appropriate treatment.
- 5. You must get the following information in writing when you receive a customer query:
 - waste producer information including name, address, type of premises and contact details;

- details of the specific source of the waste;
- details of the waste streams and types produced, including quantity, physical form, composition, properties, classification and description (more detailed checks must be undertaken as part of your audit of the waste pre-acceptance report).
- 6. Before waste arrives at your facility you must get a representative waste preacceptance audit report, from the waste producer. The waste producer is responsible for making sure that a waste pre-acceptance audit is carried out for their premises to ensure they are classifying and segregating waste correctly. Pre-acceptance audits must be undertaken through physical presence at the premises, by an appropriately trained and experienced member of site staff or an external auditor.
- 7. You must obtain and assess representative waste pre-acceptance audit reports on an ongoing basis following the minimum frequencies and scope detailed in Table 5.

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 practices, 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.

Table 5. Frequency and scope of pre-acceptance audit reports

- 8. You do not need an audit report for:
 - waste produced at domestic premises;
 - waste produced at care homes that do not provide nursing care as classified under chapter 20 of the LoW;

- healthcare wastes from non-healthcare activities as classified under chapter 20 of the LoW.
- 9. You must ensure that the waste pre-acceptance audit reports you receive from waste producers contain the information detailed in sections 9 to 13 inclusive below.

A waste pre-acceptance audit report must include:

- waste producer information including name, address, type of premises and contact details;
- audit start and end dates;
- a description of the audit including the procedures employed, the auditors, their affiliation, and their competence;
- a list or diagram of the different, departments, wards or functional areas that exist within the waste producer premises highlighting the specific processes that produce relevant wastes.
- 10. The audit report must also include information to list or show 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 where cytotoxic and cytostatic waste is produced you must consider if the producer has implemented a definition of cytotoxic and cytostatic waste from WM3 and if that definition is in use for segregation;
 - 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.

- 11. For each waste type identified in accordance with 10 above the audit report must detail:
 - the waste's written description, type and classification, including List of Waste (LoW) codes from the EWC;
 - 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;
 - information to record whether the correct waste type was present in the container or packaging when it was checked during the audit;
 - a comparison the waste found during the audit to its proposed waste classification or description.
- 12. The pre-acceptance audit report must also include information about:
 - the segregation practices for wastes placed in storage areas and <u>bulk</u> <u>containers</u> or bins;
 - specific storage requirements for 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.
- 13. The pre-acceptance audit report must also include:
 - the findings made for each waste stream, and where applicable, the changes made as a result of this or previous audits;
 - information on the waste producer's policies, staff training, internal audit regimes, and environmental 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 for your site allows you to accept these materials;
 - safety data sheets for single stream product chemicals, laboratory chemicals or pharmaceuticals (if available).
- 14. The audit report will no longer be valid for pre-acceptance purposes, and you must obtain a new report if:

- the time intervals (minimum frequency of audits) detailed in Table 5 above are exceeded;
- the waste producer makes significant changes to its on-site practices;
- the waste changes;
- you find that the waste received contains significant non-conformances to the pre-acceptance information.
- 15. You must ensure that staff carrying out the assessment of the waste preacceptance audit reports have the professional skills, training and experience needed to undertake the assessment. They must have a clear understanding of healthcare waste and its:
 - composition;
 - classification;
 - packaging and transport.
- 16. You must ensure staff also understand:
 - the wastes associated with specific healthcare activities;
 - any conditions within the authorisation that relate to these wastes;
 - the requirement to complete waste consignment and transfer notes.
- 17. If a pre-acceptance audit report is partially incomplete or inadequate, because it does not meet all the requirements set out in appropriate measures 9 to 13, you must request the missing information (or another audit report). You must assess this before you accept the waste.
- 18. If the audit report is acceptable (it meets all the requirements set out in appropriate measures 9 to 13) you must technically assess the suitability of the wastes for on-site treatment (or transfer) to make sure you can meet your authorisation conditions. You must not accept wastes which are not suitable.
- 19. You must keep records that relate to pre-acceptance for a minimum of six years in a computerised process control system. This includes:
 - audit reports;
 - assessment of the reports;
 - additional information received;
 - your assessment that the waste is acceptable.
- 20. If an enquiry from a waste producer does not lead to you receiving waste, you do not need to keep records.

- 21. You must keep separate the roles and responsibilities of sales staff and technical staff. If sales staff are involved in waste enquiries, then technical staff must do a final technical assessment before approval. You must use this final technical check, independent of commercial considerations, to make sure that you:
 - only accept wastes that are suitable for the site;
 - avoid accumulating waste;
 - have enough storage and treatment capacity.
- 22. You must carry out appropriate pre-acceptance checks and subsequent assessments on the waste received from each producer. You can employ a third party to carry out these checks and assessments for you. You must meet the following measures as a minimum if you employ a third party:
 - The third party must provide you with details of any audit tools or methodologies and assessment criteria used these must meet the standards in this guidance.
 - You must periodically review their pre-acceptance checks and assessments (at least annually) to make sure pre-acceptance checks, subsequent assessments, waste classification and descriptions meet the standards in this guidance.
 - If you employ others to carry out the pre-acceptance checks and assessments for you, these must cover all relevant producers from whom you collect waste, including new customers.
 - You must keep records of the third party's pre-acceptance checks and assessments and a summary report that demonstrates they have carried out the correct checks on wastes from relevant producers.
- 23. The summary report must:
 - list the producer types, for example dental practice;
 - detail the waste types and waste streams produced and destined for the authorised facility, including details of their composition, classification and any hazardous properties;
 - describe the containers or packaging used for each waste stream (including colours);
 - confirm that the relevant appropriate measures for waste pre-acceptance have been completed for all relevant producers – where this is not the case for a particular producer, the report must state what has been done.
- 24. The summary report must also:
 - confirm any issues the third party has identified and what action they have taken with the producers about the wastes affected;
 - be updated if any details about the producers or the wastes change.

- 25. You must ensure that the information in the summary report is relevant to the waste types that your facility is authorised to accept. It must be taken from the pre-acceptance audits carried out on the relevant producer premises, which must meet the waste pre-acceptance requirements of this guidance.
- 26. You must be able to get (without unreasonable delay) a copy of the preacceptance audit report and assessment about any individual producer. This may be needed for operational reasons or because an officer from SEPA asks to see it.

Introduction of pre-acceptance audits

The correct classification and segregation of healthcare waste at source makes sure that the right waste goes to the right place for appropriate storage and treatment. It also means healthcare waste can be treated effectively and efficiently.

The most important step in this process is that healthcare waste producers, rigorously segregate their wastes at source. This rigorous segregation should be checked and confirmed through an audit (pre-acceptance audit) on an ongoing basis.

Pre-acceptance audits (see section 3.1 of the guidance) will provide producers with a greater understanding of their waste and will enable them to adapt or amend their in-house waste management practice to ensure that their healthcare waste is being managed in appropriate manner. Similarly, having a greater insight into the wastes they are potentially managing and accepting onto their premises, will help operators to comply with their environmental authorisation and ensure waste is being handled effectively and efficiently

Additionally, a small percentage of healthcare waste produced in Scotland cannot be treated domestically and cross-border movement, to England and Wales (where pre-acceptance audits are standard) is commonplace. Currently in Scotland, the need for healthcare waste producers to carry out pre-acceptance audits, is applied inconsistently, because not all environmental authorisations contain pre-acceptance requirements. Raising potential compliance issues for cross-border movements of healthcare waste. However, the appropriate measures detailed in section 3, if followed and applied consistently, should facilitate compliance for cross border movements.

Question 11. How best can SEPA support the introduction of pre-acceptance audits?

- staggered introduction of guidance
- inclusion of example 'pre-acceptance audit' in guidance
- Supplemental 'pre-acceptance audit' guidance
- Training
- Other

3.2 Waste acceptance

Healthcare wastes are potentially infectious, therefore it is difficult to open each container or bag to check that they contain only the correct waste. If you can demonstrate that you are following this guidance on pre-acceptance, SEPA will not expect you to check the contents of individual containers or bags received at your site. In these instances, you can check and confirm that the healthcare waste is appropriate for storage and treatment based on its colour-coded packaging. If it is, you can accept it.

- 1. You must implement waste acceptance procedures to check that the characteristics of the waste received matches the information you obtained during waste pre-acceptance. This is to confirm that the waste is as expected and you can accept it. If it is not, you must confirm that you can accept it as a non-conforming waste, or you must reject it.
- 2. Your procedures must follow a risk-based approach, considering:
 - the source, nature and age of the waste;
 - the waste's hazardous properties;
 - potential risks to process safety, human health and the environment (for example, from odour and other emissions);
 - knowledge about the previous waste holder(s).
- 3. Other than in an emergency (for example, taking waste resulting from an emergency incident clean-up), you must only receive pre-booked wastes onto site that have undergone adequate pre-acceptance assessment and that are consistent with the pre-acceptance information.
- 4. All relevant storage areas (quarantine, reception and general) and treatment processes in your facility must have the physical capacity needed for the waste you receive. You must not receive wastes if this capacity is not available. The amount of waste you receive must also comply with storage limits in your authorisation.
- 5. You must visually check waste containers and packages and verify them against pre-acceptance information and transfer documentation (waste transfer notes/special waste consignment notes) before you accept them on site.
- 6. You must weigh each consignment of waste on arrival to confirm the quantities against the accompanying paperwork, unless alternative reliable systems are available (for example, based on volume). You must record the weight in the computerised waste tracking system.
- 7. You must check and validate all transfer documentation and resolve discrepancies before you accept the waste. If you believe the incoming waste classification and description is wrong or incomplete, then you must address this
with the original waste producer during waste acceptance. You must record any non-conformance. If you have assessed the waste as acceptable for on-site storage or treatment, you must document this.

- 8. After you have completed the initial visual inspection and confirmatory checks, you should offload waste containers into a dedicated reception or storage area. You must not unload wastes if you do not have enough space.
- 9. Once offloaded, and as soon as practicable to do so, you should assess the waste and verify it for acceptance.
- 10. You must carry out a thorough visual check of all loads of waste you receive (for example, in bulk containers, or on pallets) to identify any non-conforming items. Initially, you must inspect the contents of each 770 litre wheeled bin or similar bulk container and check to see 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) you can 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.
- 11. If you later identify a non-conforming waste during a spot check, you must take measures to prevent a recurrence (including contacting the customer). You should reinstate thorough visual checks on all loads from that customer until there are no non-conformances for the period stated in appropriate measure 3.2.10 in the paragraph above.
- 12. The person carrying out waste acceptance checks (the visual inspection of the waste) must be trained to identify and manage any non-conformances in the loads received, complying with this guidance and the conditions of your authorisation.
- 13. You do not need to open healthcare waste bags, sharps boxes, rigid bins or similar packages during the thorough visual check for non-conforming items. The waste pre-acceptance checks determine their contents, and you can verify this by referring to the appropriate colour coded waste packaging. The objective of the thorough visual check is to identify 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.

- 14. 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 you use 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.
- 15. You should minimise the manual handling of waste. You should 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.
- 16. 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. You should securely close the lid of the bin or other bulk container when you are not loading waste into or out of it.
- 17. 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, you should 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.
- 18. Waste packages should be in sound condition. All containers (boxes and bins) should have well-fitting lids or other secure closing mechanisms. You must deal immediately with any non-conforming packages or put them in a bulk container. You must put non-conforming packages into quarantine to be dealt with appropriately. You must record all non-conformances.
- 19. You must have clear and unambiguous criteria that you use to reject nonconforming wastes. You must also have a written procedure for recording, reporting and tracking non-conforming wastes, including notifying the relevant customer or waste producer to prevent reoccurrence.
- 20. All waste packages received must be labelled or marked with a unique identifier. The unique identifier must allow you to track the waste (see appropriate measures for waste tracking) and easily identify the producer of the waste, its type and hazardous properties, and its receipt date.
- 21. If you receive or store waste packages 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, you can mark or label the unique identifier on the bulk container for as long as the waste remains in there. Similarly, if you receive waste packages on a pallet, provided they are from the same producer, all received at the same date and time, and contain a single waste stream, you can mark or label the same producer all received at the same date and time, and contain a single waste stream, you can mark or label the pallet with the unique identifier for as long as the waste remains on it. If you split a bulk or palletised load, you must

mark or label each container with the unique identifier so that you can track them.

- 22. You must hold all records about waste received on a computerised waste tracking system. This must be able to cross-reference all the available waste stream information for a receipt using the unique identifier. You must update the tracking system whenever you move or treat a waste on site or send it off site. You must follow your written procedures when you move wastes between different locations on site (or off site).
- 23. 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), you must check the waste to determine that it does not include radioactive material, unless you are authorised to accept these materials.
- 24. Your facility must have a dedicated waste quarantine area located within a building.
- 25. Quarantine storage must be for a maximum of five working days. You must have written procedures for dealing with wastes you hold in quarantine, and a maximum storage volume. For some limited and specific cases (for example, the detection of radioactivity), you can extend quarantine storage time if SEPA agrees. The maximum storage time must take account of the potential for odour generation, insect infestation and storage conditions, such as refrigeration (for example, for anatomical waste). Quarantine storage must be separate from all other storage and clearly marked as a quarantine area.
- 26. 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.

3.3 Waste tracking

- 1. You must 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 of your facility. You must use a pre-booking system to make sure that you have enough waste storage and process capacity for the incoming acceptable waste.
- 2. Your waste tracking system should hold all the information generated during:
 - pre-acceptance;
 - acceptance;
 - storage;

- repackaging;
- treatment;
- removal off site.

This information should be readily accessible.

- 3. You should create records and update them to reflect deliveries, on-site treatment and despatches. Your tracking system will also operate as a waste inventory and stock control system. It must include this information as a minimum:
 - 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.
- 4. 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 you are storing 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 your authorisation;
 - the length of time the waste has been on site;
 - the quantity of end-of-waste product materials on site at any one time, where applicable.

- 5. If you receive 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) your systems and procedures must allow you to:
 - track the waste back to the original load received at the facility;
 - see associated waste acceptance information and records.
- 6. If you add individual packages of waste (for example, bags or boxes) to a bulk container or pallet at your facility, your waste 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.
- 7. You must store back-up copies of computer records off site. Records must be readily accessible in an emergency.
- 8. You must hold acceptance records for a minimum of six years after you have treated the waste or removed it off site.

4 Waste storage, segregation, handling and compaction appropriate measures

These are the appropriate measures for waste storage, segregation and handling at sites operating under an environmental authorisation (PPC installation, WML facility) for storing or treating healthcare waste.

If you operate under an exemption, you should follow appropriate measure where relevant.

4.1 Waste storage, segregation and handling

- 1. You should not store individual bags and containers (for example, bins and boxes) of waste loose.
- 2. You should store and handle bagged waste on site in fully enclosed, lockable, rigid, leak-proof and weather-proof bulk containers (for example, bins).
- 3. Rigid waste containers (bins and boxes) should be sealed and in good condition. You should 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. They should be stored either:
 - in enclosed bulk containers (for example, 770 litre wheeled bins);
 - on pallets, stacked no more 2.2m high (including the height of the pallet).
- 4. Where you use pallets, containers should be stable, 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 you can identify waste types, damaged containers, leaks or spillages and incorrectly stacked containers. If you know waste contains free liquid (for example, chemical wastes such as fixer and developer solutions) you should store the pallets in a dedicated area of the facility that has self-contained drainage.
- 5. Bulk containers should have a lid and you should securely close the lid whenever they contain any waste, except when waste is being loaded into or unloaded from them.
- 6. The maximum storage capacity of the site and designated storage areas must be clearly established. You should define capacity in terms of numbers of bulk containers, bins, or pallets, as well as by tonnage. You must regularly monitor the quantity of stored waste on the site. You must not exceed the established maximum capacity in your environmental authorisation or exemption.
- 7. Where possible, you should locate storage areas away from watercourses and sensitive perimeters, for example, those close to public rights of way, housing or

schools. You must store all waste within the security protected area of your facility to prevent unauthorised access and vandalism.

- 8. Where wastes are known to be sensitive to heat, light, air or water you should make sure that they are protected from these ambient conditions, for example, by storing the wastes in a building or under cover. These storage provisions apply to any container held in any storage area, or waste which is being emptied, sorted, repackaged or otherwise managed.
- 9. You should store and handle all pharmaceutical, chemical, anatomical and palletised wastes within designated areas of a secure building. A building is a covered structure enclosed on all vertical sides that provides sheltered cover and contains emissions of, for example, noise, particulate matter, odour and litter.
- 10. You must store anatomical waste and animal carcasses in designated refrigerated units (operating below 8°C) or designated freezer units (operating below -18°C).
- 11. You should store and handle infectious wastes that are not pharmaceutical, chemical, anatomical or palletised wastes in a secure building. You may however store these infectious wastes outside at facilities that were operating before we published this guidance, but only if you meet all of these conditions:
 - 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;
 - you carry out 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 locked at all times, except when waste is being loaded or unloaded from them;
 - you hold the bulk containers in a secure area of the site that has impermeable surfacing and sealed drainage.
- 12. You should store and handle offensive wastes in a secure building or in secure, fully enclosed, rigid, waterproof and leak-proof bulk containers. If you store waste externally in bulk containers, the containers should remain closed at all times, except when waste is being loaded or unloaded from them.
- 13. You must not store or hold wastes on site in vehicles or vehicle trailers, unless specifically authorised to do so in your environmental authorisation.
- 14. You should store floc produced by alternative treatment plant in fully enclosed, waterproof and leak-proof containers. Wastes produced by incineration plant must be stored in-line with technical guidance for the <u>waste incineration sector</u>.

- 15. You must maintain the integrity of waste packaging at all times. You should design and operate your facility in a way that minimises waste handling. You should never offload, throw, walk on or handle healthcare wastes in a way that might damage the packaging.
- 16. You must store waste in a way that protects its integrity and prevents or, where that is not possible, minimises the risk of packaging failing. You should pay particular attention to items at or near the bottom of bulk containers and avoid, for example, overloading, compressing or puncturing waste.
- 17. You should 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, which you should store in accordance with the relevant measures set out in <u>HSG 71 Chemical warehousing</u>: <u>The storage of packaged</u> <u>dangerous substances</u>;
 - anatomical waste and animal carcases;
 - non-infectious gypsum wastes (for example, plaster casts and moulds) ;
 - infectious gypsum wastes.
- 18. You should store all bulk waste containers in a way that allows safe and easy access for inspection at all times and minimises the need to remove others that may be blocking access. You should maintain safe access (inspection aisles) to at least one side of palletised wastes. You should handle and store containers so that labels and markings are easy to see and continue to be legible.
- 19. You should 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.

20. The maximum storage times of wastes held on site must be clearly established. Wastes should be treated on, or removed from, the site as soon as possible. You must not store relevant wastes on-site for longer than the established maximum storage times in your environmental authorisation. Table 6 provides an overview of standard storage times.

Table 6. Standard storage times for	or different types of healthcare waste
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Healthcare waste	are waste Colour of		Maximum storage times		
раскадіпд		Transfer station	Alternative treatment		
		(storage facility)	Outside	Total on site	
Infectious clinical waste	Orange & Yellow	5 days if awaiting direct transfer	5 days	14 days	
Treated waste from AT plant (e.g. autoclave floc)	Not specified		5 days	14 days	
Offensive waste (Non-infectious)	Yellow/Black	5 days			
Anatomical waste (All) and animal carcasses	Red	3 days if 8oC 28 days if -18oC			
Cytostatic and cytotoxic medicinal waste	Purple	6 months			
Other medicinal waste	Blue	6 months			
Hazardous chemical waste	Not specified	6 months			
Non-hazardous chemical waste	Not specified	(6 months		
Amalgam waste from dental care	Not specified		6 months		
Photographic processing wastes	Not specified	(6 months		

- 21. You should prioritise the treatment or off-site transfer of waste based on:
 - its type;
 - age on arrival (if known);
 - date of arrival;
 - duration of storage on site.

You should follow the first-in, first-out principle and also identify and prioritise wastes with a higher risk of causing odour, litter or pest problems.

- 22. You should 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 you receive waste in damaged packaging, you must record this as a non-conformance. You must transfer the contents to a new, clearly labelled container or package of the appropriate type and condition.
- 23. If you repackage waste received in containers designed for reuse, you must be specifically authorised to do the repackaging in your environmental authorisation. You must repackage waste inside a building and make sure you protect the safety of staff and prevent potential emissions. For example, you could use an automated process in a contained environment with air extraction and abatement. You should carefully record the transfer of waste from individual packages or containers to bulk containers and should update the waste inventory accordingly.
- 24. Unless specifically authorised by your environmental authorisation, you must not mix hazardous waste with other categories of hazardous waste, or with other wastes or materials.
- 25. The type and quality of storage area surfaces must be suitable for effective disinfection with a broad spectrum agent. Your procedures must make sure that surfaces are regularly cleaned and disinfected.
- 26. Once emptied, you should check all bulk containers to make sure you have removed all of the waste and then clean them inside and out. You must disinfect containers that have held infectious waste.
- 27. You should 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 <u>Carriage of Dangerous Goods and</u> <u>Use of Transportable Pressure Equipment Regulations.</u>

- 28. The methods you use for cleaning and disinfecting surfaces and containers should:
 - physically remove contamination;
 - be capable of achieving disinfection across the broad spectrum of microorganisms 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.

29. You 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).
- 30. The way you store and handle waste should prevent pests and vermin. You must have specific measures and procedures in place to identify and manage any wastes that are causing pests or vermin at your site.
- 31. You should inspect storage areas, containers and infrastructure daily. You must deal with any issues immediately. You must keep written records of the inspections. You must rectify and log any spillages of waste.
- 32. Your site must have suitable procedures, equipment and broad spectrum disinfectants to deal with the chemical and biological spillages that may arise from waste types accepted at your facility. All staff must be aware of their location and trained in their use.
- 33. You must have and follow suitable procedures for moving waste between different locations (or loading for removal off site). You should amend your waste tracking system to record these changes.
- 34. When you load vehicles you must prevent leakage or contamination of one waste type (or its packaging) by another waste type. You should have written procedures to check outgoing vehicles and loads and a mechanism to log such checks have taken place to confirm you have met these requirements.
- 35. Your site inventory must be able to track and link all incoming consignments of waste to specific outgoing waste loads and their documentation.
- 36. If you transfer waste, you must be able to demonstrate that the description and classification for the outgoing waste is the same as that for the incoming waste unless the incoming waste description and classification was incorrect or incomplete.

Storage times

The waste storage, segregation and handling section of the guidance sets out standard storage times for different types of healthcare waste, and some associated wastes, for transfer stations and AT facilities (summarised in Tables 5(a) and 5(b) below).

The storage times have been included in the guidance to set clear standards promoting best practice and consistency across the sector, to ensure effective, efficient management of the waste inventory and to prevent waste accumulation and associated impacts such as waste degradation, generation of odour and pests/vermin.

Question 12. Do you think the standard storage times proposed for Transfer Stations, in Section 4 of the guidance, summarised in Table 5(a) below, are appropriate and achievable during normal operating?

Propose alternative maximum storage times (with justification) that you think would represent best practice and achieve an equivalent level of environmental protection. If your comment(s) relate to a specific waste type then please make it clear which waste type the comment relates to.

Transfer Station	Maximum Storage Time	
Waste Type		
Infectious clinical waste	5 days if awaiting direct transfer	
Offensive waste (Non-infectious)	5 days	
Anotomical wasta (All) and animal apressos	3 days if 8⁰C	
Anatomical waste (Air) and animal carcasses	28 days if -18⁰C	
Cytostatic and cytotoxic medicinal waste	6 months	
Other medicinal waste		
Hazardous chemical waste	C as a with a	
Non-hazardous chemical waste	o months	
Amalgam waste from dental care		
Photographic processing wastes		

Table 5(a): Standard Storage times for transfer stations

Question 13. Standard Storage times for Alternative Treatment Facilities

Do you think the standard storage times proposed for Alternative Treatment Facilities, in Section 4 of the guidance, summarised in Table 5(b) below, are appropriate and achievable during normal operating?

Propose alternative maximum storage times (with justification) that you think would represent best practice and achieve an equivalent level of environmental protection. If you're comment(s) relate to a specific waste type then please make it clear which waste type the comment relates to.

AT Facility	Maximum Storage Time	
Waste Type	Outside	Total on site
Infectious clinical waste	5 days 14 days	
Treated Waste from AT (e.g. Floc)	5 days 14 days	
Offensive waste (Non-infectious)	5 days	
Anatomical waste (All) and animal carcasses	3 days if 8⁰C 28 days if -18⁰C	
Cytostatic and cytotoxic medicinal waste	6 months	
Other medicinal waste		
Hazardous chemical waste	6 months	
Non-hazardous chemical waste		
Amalgam waste from dental care		
Photographic processing wastes		

Table 5(b): Maximum Storage times for Alternative Treatment Facility

4.2 Compaction of healthcare waste

- 1. You must not compact or compress infectious clinical waste by mechanical or manual means.
- 2. You can compact offensive waste if you are specifically authorised to do this under your environmental authorisation, but you must do 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. You should carry out monitoring to demonstrate that your procedures and associated measures are effective;
 - use 'light compaction' where there is a risk of bags splitting.

5 Waste treatment appropriate measures

These are the appropriate measures for waste treatment at sites operating under an environmental authorisation (PPC installation, WML facility) for treating healthcare waste.

If you operate under a paragraph 28 exemption, you should follow appropriate measures where relevant. In situations where the criteria provided by the <u>International Society of Analytical Assessment of Treatment Technologies</u> (IStAATT) is not applicable, treatment should meet an equivalent standard. Operators should document and be able to show how treatment standards have been validated and measured.

Validation and efficacy

To be considered fully treated, Clinical Waste must be 'rendered safe'.

Rendering safe can be seen as a pre-treatment phase prior to final disposal. Treatment options for clinical waste can be broadly split up into two areas, burn technologies (i.e. incineration) and non-burn or alternative treatment (autoclave, microwave, chemical disinfection).

Operators who treat waste via incineration should refer to 'Sector Guidance Note EPR 5.01' for guidance on appropriate measures for treatment.

Operators treating clinical waste using alternative technology should refer to Section 5 which provides guidance on the appropriate measures required for the treatment of clinical waste by non-burn technologies.

Waste treatment must have a clear and defined benefit and operators should understand, monitor and optimise the waste treatment process ensuring effective and efficient treatment. For clinical waste, the chosen treatment technology has to successfully complete a commissioning (and re-commissioning) phase and continually validate the treatment process both of which incorporate a set of criteria, Level III and Level IV depending on the wate types, provided by the International Society on Analytical Assessment of Treatment Technologies (IStAATT).

The validation and efficacy requirements, for clinical waste treatment, have been rigid for a number of years, and although there is no desire to move away from the outcome of the iStAATT requirements, i.e. $4 \log_{10}$ and $6 \log_{10}$ level inactivation will still be required, SEPA is looking to gather opinion as to whether the appropriate measures found in section 5 should be reviewed to reflect improvements in technology and changes in practice by both operator and producer.

Question 14. We plan to continue the application of iStAATT criteria, do you think this is appropriate and achievable?

5.1 General waste treatment

- Waste treatment must have a clear and defined benefit. You should fully understand, monitor and optimise the waste treatment process to make sure that you treat waste effectively and efficiently. The treated output material should meet your expectations and be suitable for its intended disposal or recovery route. You must identify and characterise emissions from the process and take appropriate measures to control them at source.
- 2. You must have up-to-date written details of your treatment activities, and the abatement and control equipment you are using. This should include information about the characteristics of the waste you will treat and the waste treatment processes, including:
 - simplified process flowsheets that show the origin of any emissions;
 - details of emission control and abatement techniques for emissions to air and the water environment, including details of their performance;
 - diagrams of the main plant items where they have environmental relevance for example, storage, tanks, treatment and abatement plant design;
 - details of physical treatment processes, for example shredding, separation, compaction, filtration, heating, cooling or washing;
 - details of any chemical treatment processes;
 - details of any biological treatment processes;
 - details of any effluent treatment, including a description of any flocculants or coagulants used;
 - an equipment inventory, detailing plant type and design parameters for example, time, temperature, pressure;
 - waste types to be subjected to the process;
 - the control system philosophy and how the control system incorporates environmental monitoring information;
 - process flow diagrams (schematics);
 - venting and emergency relief provisions;
 - a summary of operating and maintenance procedures;
 - process instrumentation diagrams.
- 3. You should have up to date written details of the measures you will take during abnormal operating conditions to make sure you continue to comply with authorisation conditions. Abnormal operating conditions include:
 - unexpected releases;
 - start-up;

- momentary stoppages;
- shut-down.
- 4. You must demonstrate that your treatment process will make sure that clinical waste is '<u>rendered safe</u>'.

For clinical waste to be considered rendered safe, your 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 by the waste;
- 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.
- 5. You must have tested and validated each treatment device you use as part of a site commissioning validation programme. This must meet the requirements in section **Plant commissioning and validating treatment efficacy**.
- 6. You must carry out appropriate efficacy testing to measure and demonstrate that your process can effectively treat clinical waste on an ongoing basis. This testing must meet the requirements in section **Routine plant efficacy testing**.
- 7. Your treatment process must, as a minimum, meet the level 3 criteria provided by the International Society on Analytical Assessment of Treatment Technologies (IStAATT) if you treat infectious waste. It must meet the level 4 criteria if you treat certain bio-hazardous waste (for example, some laboratory waste).

Here are descriptions of the IStAATT level 3 and 4 treatment criteria.

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 log_{10} reduction or greater:

- Geobacillus stearothermophilus spores;
- Bacillus atrophaeus spores;

Level 4

Inactivation of the following organisms at a $6 \log_{10}$ reduction or greater:

- vegetative bacteria;
- fungi;
- lipophilic or hydrophilic viruses;
- parasites;
- mycobacteria;
- Geobacillus stearothermophilus spores;
- Bacillus atrophaeus spores.
- 8. Your treatment process 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.

- 9. You must have appropriate containment measures to prevent microbial emissions from pre-shredded or pre-macerated waste before its disinfection. You must assess and demonstrate the effectiveness of these measures through your microbial emissions monitoring.
- 10. You must exclude the following wastes from alternative treatment activities unless you have provided us with written justification for their treatment and we have specifically authorised and approved your plant for the treatment of these wastes:
 - 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 <u>challenge load</u> 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.

Where you provide justification for the alternative treatment of any waste containing or contaminated with medicines or chemicals or anatomical waste, your justification 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.

You must also make sure that the approved testing and validation of your treatment plant (based upon worst-case challenge load) remains valid, taking into account the type(s) and composition of waste you will accept for treatment.

11. You must exclude biohazard waste from alternative treatment activities, unless we have specifically authorised and approved your plant 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).

12. 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 you can receive these wastes for treatment at an authorised waste facility. For

example, when the treatment process at the site of production has broken down. If you receive any of this waste at your authorised facility under these circumstances, then you must meet the following appropriate measures:

- you must not shred or macerate untreated wastes before the disinfection step;
- the treatment process must demonstrate a higher level of treatment (IStAATT level 4 criteria);
- you must have waste pre-acceptance and acceptance procedures that make sure you only accept this waste in exceptional circumstances, for example as a 'one off' because on-site treatment has malfunctioned;
- you must submit a written justification in advance to SEPA to demonstrate that you have addressed all of these requirements and have the appropriate procedures in place.
- 13. You must 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 you are 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 you are 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*.

You can 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 you are 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 waste code 19 02 10.

5.2 Plant commissioning and validating the efficacy of treatment

- 1. As part of the plant commissioning process, you must carry out performance validation tests to demonstrate that the treatment plant will render safe each of the waste types that your facility is authorised to treat. You must submit written proposals detailing the plant commissioning process and validation tests that you will carry out to SEPA for prior approval.
- 2. 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.
- 3. To comply with the pre-operational conditions in your facility's environmental authorisation, you must submit the results of plant validation tests in a written report to SEPA for approval. We must approve this before you can start the waste treatment operation of the treatment plant at your facility.
- 4. The validation report must detail the operating conditions and parameters of the plant at which you carried out the validation tests. You must 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.
- 5. For mobile plant, you must carry out site commissioning and validation tests before you start operations on the first deployment.
- 6. As part of the plant commissioning process, you must carry out performance validation tests to demonstrate that the treatment plant will render safe each of the waste types that your facility is authorised to treat. You must submit written proposals detailing the plant commissioning process and validation tests that you will carry out to SEPA for prior approval.

- 7. 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.
- 8. To comply with the pre-operational conditions in your facility's environmental authorisation, you must submit the results of plant validation tests in a written report to SEPA for approval. We must approve this before you can start the waste treatment operation of the treatment plant at your facility.
- 9. The validation report must detail the operating conditions and parameters of the plant at which you carried out the validation tests. You must 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.
- 10. For mobile plant, you must carry out site commissioning and validation tests before you start operations on the first deployment.
- 11. 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.
- 12. You must 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. You must also do this 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;
 - you make any changes 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 worstcase scenario;
 - the plant fails routine treatment efficacy testing.
- 13. 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) then you must stop plant operations until you can identify the cause and recommission the plant. Before restarting operation, plant validation must be approved in writing by SEPA.
- 14. You must repeat plant validation and send a written validation report to SEPA periodically throughout the operational life of the plant and at intervals of four years or less. You must also do this 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;
- you make any changes 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 worstcase scenario;
- the plant fails routine treatment efficacy testing.
- 15. 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) then you must stop plant operations until you can identify the cause and recommission the plant. Before restarting operation, plant validation must be approved in writing by SEPA.

5.3 Validation tests for treating infectious wastes

- 1. You should use an appropriate certified test organism for the tests.
- 2. You can use spore strips to validate thermal treatment plant if you can guarantee their integrity. That is, if you can insert them into the waste after the pre-shredding or maceration process and before the disinfection step. Or, if there is no pre-shredding or maceration, you can insert them into the waste before the disinfection step. You should use spore suspensions to validate chemical treatment plant or thermal treatment plant if you cannot guarantee the integrity of spore strips.
- 3. You must use Bacillus atrophaeus (BA) or Geobacillus stearothermophilus (GS) for IStAATT tests. You should use BA to test chemical treatment processes and those involving dry heat technologies, and GS for wet heat (steam) treatment.
- 4. When using spore strips or suspensions:
 - you must use spore strips or suspensions from the same batch number in the tests;
 - if you use spore strips, they must be certified as containing $\ge 1 \times 10^6$ spores;
 - if you use spore suspensions, you must add sufficient suspension to each load to make sure that ≥1 x 10⁶ spores are present per gram mass of the total load.
- 5. For thermal treatment plant, the spores used must have a minimum certified D-value ≥1.8 minutes at either:
 - 121°C wet heat for GS;
 - 160°C dry heat for BA.

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, you should determine the D-value and demonstrate it is comparable to the values reported in available literature.

- 6. 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.
- 7. The time and temperature combination of the indicator strips must be indicative of the plant operating parameters needed to achieve microbial inactivation.
- 8. You must 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.
- 9. 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.
- 10. You must detail and justify the worst-case challenge load used in the validation report.

Here are example challenge loads for three 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. You can only use fixed carriers or test reports for routine monitoring if you have 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. You should also 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 six 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

11. You must use an appropriate validation test format, which will depend on whether you are using spore strips or suspensions, as follows.

Spore strips

12. You must test each plant over 3 separate treatment cycles, retrieving the treated test packages before starting the next cycle. In total, you must hold a minimum of six untreated spore strips outside of the device to use as controls that you will compare with the treated strips.

The minimum number of spores strips recovered is set out in Table 7 below.

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

Table 7. Minimum number of spore strips

251 to 500kg	8	24	6
501 to 750kg	10	30	6
Over 750kg	12	36	6

- 13. You must analyse the entire test sample except for the control samples which will require serial dilution. You must preserve samples appropriately and send to an accredited laboratory for analysis in a timely manner.
- 14. Analysis must be quantitative and based upon the number of spores per spore strip. You must 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

15. You must test each plant over three 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. You should 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 8 below.

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

Table 8. Minimum number of samples

If the mass of the waste differs between each control and test run, you will need to correct the test data for each run (spores present per kg of sample) to account for this difference. 16. Each sample should be at least 0.1% of the waste load, with a minimum sample of 50g for smaller units. You must 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. You should 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

17. You must follow an appropriate assessment methodology, which will depend on whether you are using spore strips or suspensions, as follows.

Microbial disinfection efficacy – spore strips

For the control data, you must calculate and record the following:

- number of spores (colony-forming units (cfu)) recovered from each individual control spore strip;
- mean number (X_C) of spores recovered from the control strips;
- log₁₀ of X_{C.}

You must then subtract 4 from the log_{10} of X_C to generate the pass criteria.

Subtracting 4 provides the 4 log_{10} reduction for IStAATT Level 3 criteria. For the treatment of certain biohazard wastes a 6 log_{10} reduction is needed, in which case 6 must be subtracted from the log_{10} of X_C to generate the pass criteria.

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

- number of spores recovered from each individual test strip;
- mean (X_T) number of spores recovered;
- standard deviation (σ) of spores recovered;
- upper 95% (Lu) confidence interval of X_T (this will be approximated by X_T + 1.96 σ);
- \log_{10} of the upper 95% (Lu) confidence interval of X_T (\log_{10} Lu).

Note, if Lu = 0, then use '0' for $log_{10} Lu$.

The test data used must include all the recovered test strips. If you suspect contamination, you should 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 X_C 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 worstcase items present in any clinical waste will be treated to the minimum standard.

Here is a worked example:

Control data

Step 1.

6 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.

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The mean (X<sub>C</sub>) of spores recovered from each control strip = 1.0 \times 10^6
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Step 3.

The log_{10} of $X_C = 6$

Step 4.

The pass criteria = \log^{10} of X_C – 4 = 2 (Level III criteria)

Test data

Three test runs were done, each with 3 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 (X_T) 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 \log_{10} of Lu (\log_{10} Lu) = 1.54

Interpretation

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

We have determined in step 9 that the log_{10} of the upper 95% confidence interval (log_{10} 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 (X_C) 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 you have used spore suspensions you must correct the data to allow for any differences in the total mass of waste used in each control and test run.

You must 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 you determine how many are present per kg of control sample.

You must record the mass of waste used in the control run (MC) in kg.

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

You must 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).

You must 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).

You must then 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. You must 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).

5.4 Validation tests treating wastes contaminated with or containing medicines

1. Validation tests must demonstrate that the plant is capable of destroying the range of pharmaceuticals and active ingredients that may be present in the waste stream.

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

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

- 2. Validation tests must assess and demonstrate the efficacy of each plant. These must involve:
 - a control run;
 - a minimum of 3 test runs;
 - considering at least 3 worst case substances.

The three worst-case substances are those that literature reviews and trials have identified as being the most thermally resistant. You must 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.

- 3. You should introduce chemical tracer dyes resistant to the treatment process with the pharmaceuticals to demonstrate the treated waste is homogenous and material sampling is appropriate.
- 4. You must consider and assess any effect on plant emissions that may result from the treatment of the pharmaceuticals.

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

- 1. 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. You should clearly define the objectives of the treatment process, along with any reaction chemistry.
- 2. You must 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.
- 3. Validation tests must assess and demonstrate the efficacy of each plant. These must involve a control run and a minimum of 3 test runs. You must take representative samples from the treated material resulting from each test run.

4. You must consider and assess any effect on plant emissions that may result from the treatment of the chemical contaminants.

5.6 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.
- 2. 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. See **Validation tests for chemically contaminated wastes**.

5.7 Routine plant efficacy testing

- 1. You must 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. You should follow an appropriate testing methodology, which for infectious wastes will depend on whether you use spore strips or suspensions.
- 2. The methods you use for routine efficacy tests must be the same as those used for site commissioning validation. You can only use alternative methods if parallel tests carried out during commissioning validation demonstrated that an alternative method met both of these criteria:
 - It was appropriate (accurate, reliable and repeatable).
 - It produced the same results as those produced following the methods described in this guidance.
- 3. For thermal processes, you must always use thermal indicator strips or multipoint data loggers in parallel where possible.

Spore strip tests

4. The minimum frequency of efficacy tests and number of control strips used is specified in Table 9 below. You must schedule the efficacy tests and evenly space them throughout the calendar year.

Table 9. 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 50kg	Monthly	Quarterly	3	1
51 to 500 kg	Fortnightly	Every 2 months	3	1
501 to 1,000kg	Weekly	Monthly	3	1

- 5. You can test spore strips quantitatively (population of >1 x 10^6) or qualitatively (population of >1 x 10^4). Controls and certificates from the test batch must also accompany each set of samples.
- 6. The criteria for success are as follows:
 - you must 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 that you achieved the minimum time and temperatures for 99% of spore strips;
 - for each calendar year you must prepare a summary report that indicates the results obtained and any failures;
 - the data in your summary report must be referenced to the validation report to demonstrate that you are meeting the treatment efficacy achieved during plant commissioning, rather than minimum standards;
 - if more than 5% (or 1, whichever is greater) of qualitative spore strips exhibit growth in any calendar year, you must use quantitative testing for the next calendar year.

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

7. If at any point during the calendar year the number of failures exceeds the annual 5%, you must stop operations at the plant until you can identify the cause and recommission the plant. In any circumstances, if you become aware that one or more batches of waste may not have been treated to the required standard, you should take appropriate action and manage the waste as untreated.

Spore suspension tests

8. The minimum frequency of monitoring, number of test runs and sub-samples per test run is specified in Table 10 below.

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 250kg	6 monthly	Annually	3	1
251 to 750 kg	6 monthly	Annually	3	2
Over 751kg	Quarterly	6 monthly	3	3

Table 10. Routine monitoring of microbial inactivation using spore suspension

- 9. You must carry out quantitative enumeration of spore suspensions with a certified population.
- 10. You must carry out a single control run.
- 11. In other respects, the procedures and quantitative criteria for success in the section on spore strips will apply, including the actions you must take if a plant fails the test requirements, or waste is not treated to the required standard.

6 Emissions control appropriate measures

These are the appropriate measures for emissions control at sites operating under an environmental authorisation (PPC installation or WML facility) to store or treat waste.

If you operate under an exemption, you should follow appropriate measure where relevant.

You must identify, characterise and control emissions from your activities that may cause pollution.

6.1 Point source emissions to air

- 1. You must contain waste treatment plant (including shredders) to make sure you collect, extract and direct all process emissions to an appropriate abatement system for treatment before release.
- 2. You must identify the main chemical constituents of the site's point source emissions as part of the site's inventory of emissions to air. You should include the speciation of volatile organic compounds (VOCs) if you have identified them in the emissions inventory and it is practicable to do so.
- 3. You should make an assessment of the fate and impact of the substances emitted to air.
- 4. A wide range of pharmaceuticals and chemicals are used in healthcare. If processed these can result in emissions of volatile chemicals to air or, via condensers, to foul sewer. Your waste pre-acceptance and acceptance procedures should prevent healthcare waste containing (or contaminated with) chemicals or pharmaceuticals entering the treatment process unless your plant is authorised and validated to treat this type of waste. You should then provide abatement to treat and remove any residual emissions.
- 5. To reduce point source emissions to air from the treatment of waste (for example, dust, volatile organic compounds and odour), you must use an appropriate combination of abatement techniques, including one or more of the following systems:
 - adsorption (for example, activated carbon);
 - biofiltration;
 - wet scrubbing;
 - fabric filters;
 - high efficiency particulate filtration (HEPA);
 - condensation;
 - cyclonic separation;

- electrostatic precipitation.
- 6. You must assess and design vent and stack locations and heights to make sure dispersion capability is adequate. Where monitoring is required, including for odour, you should install a suitable monitoring point.
- 7. Your procedures must make sure you correctly install, operate, monitor and maintain abatement equipment. For example, this includes monitoring and maintaining:
 - appropriate flow and chemical concentration of wet scrubber liquor;
 - the handling and disposal or regeneration of spent scrubber or filter medium.
- 8. You should have operating procedures to identify, prevent and control potential emissions of pathogens.
- 9. You must use HEPA filters to prevent bioaerosol emissions from relevant point sources.
- 10. Your procedures must make sure that HEPA filters 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.
- 11. You should design and operate abatement systems to minimise water vapour plumes.

6.2 Fugitive emissions to air (including odour)

- 1. You must use appropriate measures to prevent emissions of dust, mud, litter and odour.
- 2. You must 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, you must 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.

- 3. To make sure fugitive emissions are collected and directed to appropriate abatement, your treatment plant should use high integrity components (for example, seals or gaskets). Your treatment plant should be fully enclosed, with air extraction systems located close to emission sources where possible.
- 4. You must use your waste pre-acceptance, waste acceptance and site inspection checks and procedures to identify and manage wastes that could cause, or are causing, fugitive emissions to air. When you identify any of these wastes you must:
 - take appropriate, risk assessed measures to prevent and control emissions;
 - prioritise their treatment or transfer.
- 5. Where necessary, to prevent fugitive emissions to air from the storage and handling of such wastes, you should use 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.
- 6. You should set up 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).
- 7. You must regularly inspect and clean all waste storage and treatment areas, equipment (including conveyor belts) and containers or bins.
- 8. Your maintenance and cleaning schedules must make sure that tanks and plant are regularly cleaned to avoid large-scale decontamination activities.
- 9. You must take measures to 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.
- 10. You must 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.
- 11. If you carry out container washing activities, you should 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.
- 12. You should fully enclose and contain pre- and post-treatment shredder plant to prevent emissions. You should 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.
- 13. You must have procedures to minimise the amount of time odorous wastes spend in your storage and handling systems (for example, pipes, conveyors, hoppers, tanks). In particular, you should have provisions to manage waste during periods of peak volume.
- 14. You must 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.
- 15. You must 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.
- 16. Contaminated waters have potential for odours and you should store them in covered or enclosed tanks or containers.
- 17. Where there is a risk of offensive odour at sensitive receptors you should periodically monitor odour emissions using European (EN) standards, for example either:
 - dynamic olfactometry according to EN 13725 to determine the odour concentration;
 - EN 16841-1 or -2 to determine the odour exposure.

If you are using alternative methods for which no EN standards are available (for example, estimating odour impact), you should use ISO, national or other international standards to make sure you use data of an equivalent scientific quality. You must set out the monitoring frequency in the odour management plan (see point 18 below).

18. Where there is a risk of offensive odour at sensitive receptors you must also set up, implement and regularly review an odour management plan. It should be part of your management system and include all of the following elements:

- actions and timelines to address any issues identified;
- a procedure for conducting odour monitoring;
- a procedure for responding to identified odour incidents, for example, complaints;
- an odour prevention and reduction programme designed to identify the source(s), to characterise the contributions of the sources and to implement prevention and reduction measures.
- 19. Where an odour management plan is required, you should develop and implement it following our <u>guidance</u>.
- 20. If you operate a microwave facility, you must be aware that failures in containment might result in non-ionising radiation leaks. Your operational procedures must include checking for these leaks at regular intervals.

6.3 Emissions of noise and vibration

- You should design the layout of the facility to locate potential sources of noise (including building exits and entrances) away from sensitive receptors and boundaries. You should locate buildings, walls, and embankments so they act as noise screens.
- 2. You must employ appropriate measures to control noise, for example, including:
 - adequately maintaining plant or equipment parts which may become noisier as they deteriorate - for example, bearings, air handling plant, building fabric, and specific noise attenuation kit associated with plant or machinery;
 - closing doors and windows of enclosed areas and buildings;
 - avoiding noisy activities at night or early in the morning;
 - minimising drop heights and the movement of waste and containers;
 - using white noise reversing alarms and enforcing the on-site speed limit;
 - using low-noise equipment, for example, drive motors, fans, compressors and pumps;
 - adequately training and supervising staff;
 - where possible, providing additional noise and vibration control equipment for specific noise sources - for example, noise reducers or attenuators, insulation, or sound-proof enclosures.
- 3. Where there is a risk of noise or vibration at sensitive receptors you should create, use and regularly review a noise and vibration management plan. This should be part of the environmental management system, and should include:
 - actions and timelines to address any issues identified;

- a procedure for conducting noise and vibration monitoring;
- a procedure for responding to identified noise and vibration events, for example, complaints.

The noise and vibration management plan should also include a noise and vibration reduction programme designed to:

- identify the source(s) of noise and vibration;
- measure or estimate noise and vibration exposure;
- characterise the contributions of the sources;
- implement prevention and reduction measures.
- 4. Where a noise management plan is required, you should develop and implement it following our <u>guidance</u>.

6.4 Point source emissions to the water environment and sewer

- 1. You must 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.
- 2. You must assess the fate and impact of the substances emitted to the water environment and sewer.
- 3. Discharges to the water environment or sewer must comply with the conditions of an environmental authorisation or trade effluent consent. Relevant sources of waste water 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.
- 4. To reduce emissions to the water environment and sewer, if you need to treat waste water before discharge or disposal, you must use an appropriate combination of treatment techniques, including one or more of the following:
 - preliminary or primary treatment for example, equalisation, neutralisation or physical separation;

- physico-chemical treatment for example, adsorption, distillation or rectification, precipitation, chemical oxidation or reduction, evaporation, ion exchange, or stripping;
- biological treatment for example, activated sludge process or membrane bioreactor;
- nitrogen removal for example, nitrification and denitrification;
- solids removal for example, coagulation and flocculation, sedimentation, filtration or flotation.
- 5. You must 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.
- 6. You must not discharge sharps or medicines (for example, resulting from the washing of reusable sharps bins) to surface water, storm drainage or foul sewer.
- 7. You must direct wash waters from cleaning healthcare waste containers to foul sewer or a sealed drainage system for off-site disposal. You may need to pre-treat the waters to meet any limits on the effluent discharge consent.
- 8. The contents of healthcare waste containers (bags, bins and boxes) must not enter foul, surface or storm drainage systems. You should 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.
- 9. For chemical treatment processes, you must consider whether you need to neutralise effluent (disinfectant) before discharging to the water environment or sewer.

6.5 Fugitive emissions to land and the water environment

- 1. You must use appropriate measures to control potential fugitive emissions and make sure that they do not cause pollution.
- 2. You must have the following in operational areas of the facility (where appropriate):
 - an impermeable surface;
 - spill containment kerbs;
 - sealed construction joints;
 - a sealed drainage system.
- 3. You must 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.
- 4. You must 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. You should make sure that you segregate uncontaminated water streams from those that require treatment.
- 5. You must use suitable drainage infrastructure to collect surface drainage from areas of the facility where you store, handle and treat waste. You should also collect washing water and occasional spillages. Depending on the pollutant content, you should either recirculate what you have collected or send it for further treatment.
- 6. You must 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.
- 7. You should provide appropriate buffer storage capacity at your 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 waste water treatment plant and receiving environment.
- 8. You must have appropriate measures in place to monitor, treat and reuse the water held in the buffer storage before discharging.
- 9. You must take measures to prevent emissions from washing and cleaning activities, including:
 - directing liquid effluent and wash-waters to foul sewer or collecting them in a sealed system for off-site disposal – you must not discharge them to surface or storm drains;
 - where possible, using biodegradable and non-corrosive washing and cleaning products;
 - storing 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;
 - preparing cleaning or disinfection solutions in contained areas of the site and never in areas that drain to the surface water system.
- 10. Where relevant, you must have measures to prevent pollution from the on-site storage, handling and use of <u>oils and fuels</u>.

- 11. You must produce and implement a spillage response plan and train staff to follow it and test it.
- 12. Your procedures and associated training should make sure you deal with spillages immediately. These should follow the manufacturer's health and safety advice for any products or substances involved.
- 13. You should 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.
- 14. You should stop spillages from entering drains, channels, gullies, watercourses and unmade ground. You must make available proprietary sorbent materials, sand or drain mats for use when required.
- 15. You must make sure your spillage response plan includes information about how to recover, handle and correctly dispose of waste produced from a spillage.
- 16. 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.
- 17. For sub-surface structures, you must:
 - establish and record the routing of all site drains and sub-surface pipework;
 - identify all sub-surface sumps and storage vessels;
 - engineer systems to minimise leakages from pipes and make sure they are detected quickly if they do occur, particularly where <u>hazardous substances</u> are involved;
 - provide secondary containment or leakage detection for sub-surface pipework, sumps and storage vessels;
 - establish an inspection and maintenance programme for all sub-surface structures, for example, pressure tests, leak tests, material thickness checks or CCTV.
- 18. For surfacing, you must design appropriate surfacing and containment or drainage facilities for all operational areas, taking into account:
 - collection capacities;
 - surface thicknesses;
 - strength and reinforcement;
 - falls;
 - materials of construction;
 - permeability;

- resistance to chemical attack;
- inspection and maintenance procedures.
- 19. You must have an inspection and maintenance programme for impermeable surfaces and containment facilities.
- 20. You must bund all above-ground tanks containing liquids whose spillage could be harmful to the environment. Bunds must:
 - be impermeable and resistant to the stored materials;
 - have no outlet (that is, no drains or taps) and drain to a blind collection point;
 - have pipework routed within bunded areas with no penetration of contained surfaces;
 - be designed to catch leaks from tanks or fittings;
 - have a capacity greater than 110 % of the largest tank or 25 % of the total tankage, whichever is the larger;
 - have regular visual inspections any contents must be pumped out or otherwise removed under manual control after checking for contamination;
 - be fitted with a high-level probe and an alarm (as appropriate) if not frequently inspected;
 - have tanker connection points within the bund (where possible), otherwise provide adequate containment;
 - have programmed engineering inspections normally visual, but extending to water testing if structural integrity is in doubt;
 - be emptied of rainwater regularly to maintain their containment capacity.

7 Emissions limits and appropriate measures for monitoring

These are the emissions limits and appropriate measures for monitoring emissions to air and water at sites storing and treating healthcare waste which operate under a PPC or WML environmental authorisation.

For PPC installations and WML facilities, we may set emission limits and monitoring requirements in your environmental authorisation, based on your emissions inventory and environmental risk assessment. Where relevant, you should set emission limits at the values provided in this guidance unless you justify and agree alternative values with us.

- Where you are required to monitor emissions to comply with the requirements of your environmental authorisation you should follow our <u>monitoring guidance</u> when carrying this out.
- 2. You should create and maintain an inventory (emissions inventory) of point source emissions to air and the water environment (including emissions to sewer) for your facility.

If you operate under a paragraph 28 exemption, you should follow appropriate measures where relevant.

7.1 Emissions to air

- 1. Your facility's emissions inventory must include information about the relevant characteristics of point source emissions to air, such as the:
 - average values and variability of flow and temperature;
 - average concentration and load values of relevant substances and their variability;
 - flammability, lower and higher explosive limits and reactivity;
 - presence of other substances that may affect the waste gas treatment system or plant safety for example, oxygen, nitrogen, water vapour, dust.

Chemical emissions to air

- 2. You may not need to carry out chemical emissions monitoring if both of these conditions apply:
 - you have carried out waste pre-acceptance and acceptance checks by following the guidance on waste pre-acceptance, acceptance and tracking appropriate measures;
 - you are not treating wastes containing or contaminated with chemicals or medicines.

You will need to confirm this through your site-specific emissions inventory and environmental risk assessment.

- 3. If your treatment plant treats pharmaceutically or chemically contaminated wastes, for example, medicinally contaminated sharps (even if fully discharged), you must propose and 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.

Chemical emission limits and monitoring requirements

4. You should apply the following emission limits and monitoring requirements for point source emissions to air where they are relevant, based on your facility's emissions inventory and environmental risk assessment. You must comply with any other emission limits or monitoring requirements in your environmental authorisation.

Here are the emission limits for **dust**. When using:

- fabric filters an emission limit (including unit) of 5 mg/m^{3;}
- other abatement techniques a higher emission limit of 10 mg/m³ may be appropriate.

For dust, the monitoring:

- frequency is once every six months;
- standard or method is BS EN 13284-1;

You should report results as the average value of three consecutive measurements of at least 30 minutes each.

For **total volatile organic compounds** (TVOCs) the emission limit is 30 mg/m³, and the monitoring:

- frequency is once every six months;
- standard or method is BS EN 12619.

You should report results as the average value of three consecutive measurements of at least 30 minutes each.

Microbial emissions to air

5. You must demonstrate that emissions from the plant are controlled during both site commissioning and routine operation.

- 6. You must monitor and assess microbial emissions using tracer spore suspensions. You can use alternative indicators if you can demonstrate 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.
- 7. You must comply with the following guidance when monitoring microbial emissions from alternative treatment plant.

Microbial emissions monitoring frequency

8. You must test all devices during commissioning validation and then periodically.

For process bioaerosol emissions monitoring, when you have used a suspension of bacillus spores, you must 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

- 9. You must not use spore strips for bioaerosol emissions monitoring.
- 10. The quantity of spores must be a minimum of 1 x 10⁶ spores per gram of total waste load.
- 11. 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.
- 12. You must 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 you must 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 you must 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.

You must disperse the spores throughout the waste load processed.

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

- 14. You should design your monitoring programme, so you 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.
- 15. You must 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, you should 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

16. You must carry out air monitoring from all of 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.
- 17. You must use active (centrifugal or vacuum) impaction onto agar using Anderson or slit samplers (or equivalent) to sample for bioaerosols. Your data submissions should contain information indicating the recovery efficiency of the method used.
- 18. You must 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;
 - unloading of treated material.
- 19. 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. You must always treat exhaust gases, for example, by filtering through a HEPA filter. Monitoring is needed to demonstrate that treating the gases has been effective. You must 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. Your 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. Your monitoring must demonstrate if additional containment measures are needed.
- **Maintenance or access ports:** You must 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. Your 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

- 20. To support the air monitoring, you must use enough settle plates to form a gridlike pattern around the device or site.
- 21. The exposure time for each plate, and replacement frequency during testing, should consider contaminants and total microbial load.
- 22. You must use a regular exposure time and a series of plates at each sampling point. You must also 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.

You should compare this to the input dose to provide a quantitative release estimate for the process.

Microbial emission limits

23. You must 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 1×10^6 spores per gram of waste load. You should adjust it accordingly if you use 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. You should adjust it accordingly if you use 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 you use settle plates for only 15 minutes of every hour then you must multiply the result by 4).

7.2 Emissions to the water environment or sewer

- 1. Your facility's emissions inventory must include information about the relevant characteristics of point source emissions to the water environment or sewer, such as:
 - average values and variability of flow, pH, temperature, and conductivity;
 - average concentration and load values of relevant substances and their variability – for example, COD (chemical oxygen demand) and TOC (total organic carbon), nitrogen species, phosphorus, metals, priority substances or micropollutants;
 - data on bio-eliminability for example, BOD (biological oxygen demand), BOD to COD ratio, Zahn-Wellens test, biological inhibition potential, for example, inhibition of activated sludge.
- 2. For relevant emissions to the water environment or sewer identified by the emissions inventory, you must carry out monitoring of key process parameters

(for example, waste water 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

- 3. You may not need to carry out chemical or pharmaceutical emissions monitoring if both of these apply:
 - you have carried out waste pre-acceptance and acceptance checks following the guidance in section Waste pre-acceptance, acceptance and tracking appropriate measures;
 - you are not treating the wastes containing or contaminated with chemicals or medicines.

You will need to confirm this through your site-specific emissions inventory.

- 4. If your treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged), you must propose and agree with SEPA emission limits and monitoring requirements for relevant substances. You will need to 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

- 5. Where the treatment process produces a waste water you must also monitor this at intervals during the microbial emissions tests. You must follow the method and frequency of the test set out in the section on microbial emissions to air.
- 6. You must representatively sample waste water for microbial emissions before it enters the drainage system and as near to the point of origin (the treatment plant) as possible.
- 7. You must 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 1×10^6 spores per gram of waste load. You should adjust it accordingly if you use a higher or lower seed dose.

These units relate to the overall monitoring period so the cfu limit applies to each individual sample of water taken, with a calculation made to report the result per litre.

8 **Process efficiency appropriate measures**

These are the appropriate measures for process efficiency at PPC and WML sites operating under an environmental authorisation for storing or treating healthcare waste.

- 1. For your facility, you must monitor and review the annual quantity of:
 - water, energy and raw materials used;
 - residues and waste water produced.

You must do this at least once every year.

8.1 Energy efficiency (PPC installations only)

- 1. You must create and implement an energy efficiency plan at your facility. This must:
 - define and calculate the specific energy consumption of the activity (or activities) you carry out and waste stream(s) you treat;
 - set annual key performance indicators for example, specific energy consumption (expressed in kWh/tonne of waste processed);
 - plan periodic improvement targets and related actions.
- 2. You must regularly review and update your energy efficiency plan as part of your facility's management system.
- 3. You must have and maintain an energy balance record for your facility. This must provide a breakdown of your energy consumption and generation (including any energy or heat exported) by the type of source (electricity, gas, conventional liquid fuels, conventional solid fuels, and waste). You should provide Sankey diagrams or energy balances to show how energy is used in your waste treatment processes.
- 4. You must regularly review and update your energy balance record as part of your facility's management system, alongside the energy efficiency plan.
- 5. You must have operating, maintenance and housekeeping measures in place in relevant areas, for example, for:
 - air conditioning, process refrigeration and cooling systems (leaks, seals, temperature control, evaporator or condenser maintenance);
 - the operation of motors and drives;
 - compressed gas systems (leaks, procedures for use);
 - steam distribution systems (leaks, traps, insulation);
 - space heating and hot water systems;

- lubrication to avoid high friction losses;
- boiler operation and maintenance, for example, optimising excess air;
- other maintenance relevant to the activities within the facility.
- 6. You must have measures in place to avoid gross energy inefficiencies. These should include, for example:
 - Insulation;
 - containment methods (such as seals and self-closing doors);
 - avoiding unnecessary discharge of heated water or air (for example, by fitting simple control systems such as timers and sensors).
- 7. For alternative treatment plant that thermally disinfect waste, we do not consider treating non-infectious waste appropriate unless you provide detailed justification. This should take into account the purpose and benefit of the treatment process and its energy consumption.
- 8. You should implement additional energy efficiency measures at the facility as appropriate, following our<u>guidance.</u>

8.2 Raw materials (PPC installations only)

- 1. You must maintain a list of the raw materials used at your facility and their properties. This includes auxiliary materials and other substances that could have an environmental impact.
- 2. You must regularly review the availability of alternative raw materials and use any suitable ones that are less hazardous or polluting. This should include, where possible, substituting raw materials with waste or waste-derived products.
- 3. You must justify the continued use of any substance for which there is a less hazardous alternative.
- 4. You must have quality assurance procedures in place to control the content of raw materials.
- 5. For facilities that treat waste using chemical disinfection, you must consider the following when you select and use raw materials:
 - using the optimum amount of disinfectant that maintains effective treatment;
 - disinfectants that might have a lower environmental impact (for example hazardous properties, bioaccumulation, degradability, emissions);
 - minimising or reducing the quantity of, or neutralising, the residual active disinfectant in the outputs from the treatment process;

- the potential for components of the waste, for example organic matter, to inhibit or react with the chemical disinfectant.
- 6. Processing waste that is not infectious with disinfectant is not consistent with minimising the use of raw materials. If you want to disinfect non-infectious waste you need to support your application to treat such waste. You must provide a detailed justification demonstrating that you meet the requirement to minimise raw material use.

8.3 Water use (PPC installations only)

- 1. You must take measures to make sure you optimise water consumption to:
 - reduce the volume of waste water generated;
 - prevent or, where that is not practicable, reduce emissions to soil and water.
- 2. Measures you must take include:
 - implementing a water saving plan (involving establishing water efficiency objectives, flow diagrams and water mass balances);
 - optimising the use of washing water (for example, dry cleaning instead of hosing down, using trigger control on all washing equipment);
 - recirculating and reusing water streams within the plant or facility, if necessary after treatment;
 - reducing the use of water for vacuum generation (for example, using liquid ring pumps with high boiling point liquids), where relevant.
- 3. You must carry out a regular review of water use (a water efficiency audit) at least every four years.
- 4. You must also:
 - produce flow diagrams and water mass balances for your activities;
 - establish water efficiency objectives and identify constraints on reducing water use beyond a certain level (usually this will be site specific);
 - identify the opportunities for maximising reuse and minimising use of water;
 - have a timetabled improvement plan for implementing additional water reduction measures.
- 5. To reduce water use and associated emissions to water, you should apply these general principles in sequence:
 - use water efficient techniques at source where possible;

- reuse water within the process, by treating it first if necessary if not practicable, use it in another part of the process or facility that has a lower water quality requirement;
- if you cannot use uncontaminated roof and surface water in the process, you should keep it separate from other discharge streams at least until after you have treated the contaminated streams in an effluent treatment system and have carried out final monitoring.
- 6. You should establish the water quality requirements associated with each activity and identify whether you can substitute water from recycled sources. Where you can, include it in your improvement plan.
- 7. Where there is scope for reuse (possibly after some form of treatment) you should keep less contaminated water streams, such as cooling waters, separate from more contaminated streams.
- 8. You must minimise the volume of water you use for cleaning and washing down by:
 - vacuuming, scraping or mopping in preference to hosing down;
 - reusing wash-water (or recycled water) where practicable;
 - using trigger controls on all hoses, hand lances and washing equipment.
- 9. You must directly measure freshwater consumption and record it regularly at every significant usage point, ideally on a daily basis.

8.4 Waste minimisation, recovery and disposal (PPC installations and WML facilities)

- 1. You should create and implement a residues management plan that:
 - minimises the generation of residues arising from waste treatment;
 - optimises the reuse, regeneration, recycling or energy recovery of residues, including packaging;
 - ensures the proper disposal of residues where recovery is technically or economically impractical.
- 2. Where you must dispose of waste, you should carry out a detailed assessment identifying the best environmental options for waste disposal.
- 3. You should review options for recovering and disposing of waste produced at the facility on a regular basis. You should do this as part of the management system to make sure you are still using the best environmental options and promoting the recovery of waste where technically and economically viable.
- 4. If you provide or advise producers on healthcare waste packaging, consider:

- reducing the quantity of packaging accompanying the waste, for example making sure that containers are being used efficiently;
- using packaging that is either reusable or suitable for recycling.

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Strathallan House, Castle Business Park, Stirling, FK9 4TZ