How to comply with your environmental permit
Additional guidance for:

Clinical waste (EPR 5.07)

(Version 1.1 January 2011)

We are the Environment Agency. It's our job to look after your environment and make it a better place – for you, and for future generations.

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The Environment Agency. Out there, making your environment a better place.

Published by:
Environment Agency
Rio House
Waterside Drive,
Aztec West Almondsbury,
Bristol BS32 4UD
Tel: 0870 8506506
Email: enquiries@environment-agency.gov.uk
www.environment-agency.gov.uk

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Introduction

Our Guidance

This Sector Guidance Note is one of a series of additional guidance Notes for Part A(1) activities and waste operations listed in Schedule 1 to the Environmental Permitting Regulations (the Regulations). It sets out the standards and measures for the management of clinical wastes. In most cases these are required to meet both the requirements of the Waste Framework Directive and represent indicative Best Available Techniques (BAT). Where a standard and measure relates solely to BAT this will be indicated.

You should use this guidance in addition to the standards and measures described in ***"How to comply with your environmental permit"*** to demonstrate how you will comply with the objectives of your permit to prevent, or where that is not practicable, to minimise emissions to the environment. You may also need to consult the "horizontal" guidance that gives in depth information on particular topics such as odour or noise. These are listed in Part 3 of "*How to comply with your environmental permit".*

Link to permit conditions

EPR permit conditions describe the objectives (or outcomes) that we want you to achieve. They do not normally tell you how to achieve them. They give you a degree of flexibility. Where a condition requires you to take "appropriate measures" to secure a particular objective, we will expect you to use at the very least those measures you described as "appropriate" in your application or in a relevant management plan. But you will need to use further measures if the objectives of the permit condition are not being met.

You should use the techniques described in this note either individually or in combination to meet the objectives in your permit. The measures set out in this note may not all be appropriate for a particular circumstance and you may implement equivalent measures that achieve the same objective. This note states any cases where the measures are mandatory.

Derivation

Unless otherwise specified, the measures and indicative standards described in this note are based on the objectives of the Waste Framework Directive, and the latest revisions of EU BAT Reference (BREF) Notes for Waste Treatment Industries and Waste Incineration adopted by the EU Information Exchange Forum (IEF) in August 2006.

They will be reviewed again in the light of future BREF note revisions. These BREF standards are not binding, but we must have regard to them in determining BAT in individual permits.

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Waste Framework Directive

The Waste Framework Directive requires that you recover or dispose of waste without endangering human health and without using processes or methods which could harm the environment, and in particular without ;

- risk to water, air, soil, plants or animals;
- causing nuisance through noise or odours;
- adversely affecting the countryside or places of special interest.

In addition, your environmental permits for disposal operations must cover the types and quantities of waste, technical requirements, security precautions, disposal site, and treatment method.

This note provides appropriate measures that meet the objectives of the WFD.

Best Available Techniques

The IPPC Directive requires you to take all appropriate measures to **prevent** or, where this is not practicable, to minimise emissions to the environment, in particular (but not solely) through the application of Best Available Techniques (BAT).

If emissions can be reduced further, or prevented altogether, on an economically and technically viable basis, then this should be done irrespective of whether any environmental quality standards or even indicative emissions levels set out in guidance are already being met. The environment should not be considered as a recipient of pollutants and waste, which can be filled up to a given level, but you should do all that is practicable to minimise the impact of industrial activities.

The standards provided by this note for the WFD are considered to be standards for waste operations and waste installations. . Any additional standards that apply only to waste installations are provided separately. The indicative standards for waste installations include techniques as well as emission levels. New installations will normally be expected as a minimum to comply with BAT indicative standards, although if a particular installation is capable of better performance, then that will be BAT and the appropriate emission limit values (ELV) will be set in the permit. We also expect most existing installations to comply, although where significant improvements are needed we will allow an appropriate length of time to up-grade in order to achieve this. Where it has been established that a particular technique is BAT within a sector, then we will normally impose conditions that correspond to the use of that technique in all permits for that sector, unless the balance of costs and benefits is different at the installation level.

Deviation from Indicative Standards

You must justify any proposed departure from indicative standards for WFD or BAT

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on the basis that local considerations (i.e. technical characteristics, geographical location or local environmental conditions) mean that the costs of achieving indicative standards materially outweigh the environmental benefits. In certain situations you may need to achieve better performance than the indicative standard, such as where there are local sensitive receptors, or there is a risk that an Environmental Quality Standard may be exceeded. You may also be subject to other Directives' requirements, such as those in the Waste Incineration Directive, which may set stricter limits than those based on BAT.

Indicative BAT standards are based on an assessment throughout the European Union of the typical costs and environmental benefits of techniques and their viability within the sector as a whole. The aim is to ensure that those operators who comply with the relevant standards are not subject to unfair competition from operators who do not.

Examples of local considerations that may be taken into account are given below:

Technical requirements and characteristics:

It may be that the plant is already close to meeting the indicative standard so that the benefits of improvements, for example installing an indicative BAT, are marginal compared with the cost of the technique.

Or there could be a site-specific cross-media conflict which is unusual for typical operations or installations within the sector, such that meeting the indicative standard for a particular pollutant would result in other significant environmental disadvantages.

If your existing operation or installation is scheduled for closure and its effects are not excessive, it might be appropriate for us to set permit conditions accordingly. However, it is important that the operation or installation does close down as scheduled. Therefore, if you wish to continue running it after the scheduled date, or if you later reopen it, we will treat it as a new installation (i.e. expect it to comply with indicative standards before we allow it to continue or recommence).

Geographical location

It may be appropriate to set tighter standards if the operation or installation is located near a particularly sensitive receptor or could affect densely populated areas. On the other hand, the short term or long term impacts of emissions on the local receiving media might be shown to be far less than those assumed (for example in the BREF). As an example, the benefit of treating biodegradable effluent (i.e. that has no long term impact and no persistent pollutants) released into the sea is likely to be insignificant because there is rapid dispersion which mitigates short term impacts, compared with its release to a river.

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Local environmental conditions:

It might be appropriate to set tighter standards if there was a risk that an environmental quality standard for air or water, or similar impact threshold, would be exceeded locally even if the contribution from the operation or installation is relatively small. Or, if a technique selected to meet WFD objectives or as BAT in normal circumstances were to require significant water abstraction, then it might not be right to apply it to an operation or installation in a location where water resources are under stress.

Justifying deviation from indicative standards and BAT

You will need to explain how you will meet the objectives of the WFD and, for installations, what you consider to be BAT, as well as the key issues identified in "*How to comply with your environmental permit*", when you make an application for a permit or variation to a permit. You will also need to review whether your existing operation or installation continues to reflect WFD objectives or BAT, taking indicative standards and any other developments in into account, when we conduct a periodic review of your permit.

Where your proposals do not meet indicative standards, or an indicative BAT is not included, or where you propose to use an alternative measure, or where there is a choice of options, you should explain your choice on the basis of costs and benefits.

The Horizontal Guidance Note H1 Environmental Risk Assessment (see "*How to comply with your environmental permit*" Part 3) gives a formal method of assessing options which you should use where major decisions are to be made.

If you cannot comply with the indicative standards, you must explain why your proposals can be considered to meet the requirements of the WFD or BAT for the time being, and explain how and when you will upgrade your plant to comply with indicative standards.

We will keep a record of all cases where we have permitted conditions that are less strict than the indicative BAT standards.

Installations and Operations covered

This guidance applies to **all** waste management facilities that are permitted to accept **clinical waste.** For incinerators which burn clinical waste, there is additional guidance in the Sector Guidance note on Waste Incineration, EPR 5.01

Key issues

The key issues are:

Operations, maintenance and contingency

Incinerator or treatment plant shutdown can cause a build up of waste on producer

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premises or on other waste sites. Appropriate maintenance and contingency planning is essential to minimise the impact on the waste chain.

Permitted wastes

Different types of clinical/healthcare waste have different properties and disposal requirements.

This document provides advice on permitted waste, and tables to support applications for the sites permitted to store, treat and incinerate clinical wastes.

Waste acceptance

This guidance provides appropriate standards and measures for waste acceptance based on producer audit prior to delivery of the waste.

Treatment efficacy

This guidance specifies appropriate standards and measures for assessing the performance of treatment plants to ensure that the waste is rendered safe. The performance of incineration plants is covered in S5.01.

Waste storage, handling and dispatch

Appropriate measures and standards are provided for waste unloading, storage, segregation handling and dispatch.

Emissions

Standards and measures are provided for emission of bio-aerosols and chemicals from treatment processes. Standards and measures are provided for emissions from incineration plants in EPR 5.01.

Classification of output waste from clinical waste treatment

The classification of the output waste from clinical waste treatment is affected by the:

- types of wastes processed
- effectiveness of the treatment

This can affect subsequent disposal options.

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Introduction

Table 1 : How this document applies to your site.				
Key: ✓ : Applies to this facility type **X** : Does not apply to this facility type **IPPC** : Applies only to IPPC sites of this type **P** : For use during the permit application process 5.01 : Refer to Sector Guidance Note EPR 5.01	**Facility Type**			
Document Section	Pet Crematoria	Transfer station	Treatment	Incinerator
1: Managing your activities				
1.1. General management	✓	✓	✓	**5.01**
1.3 Energy efficiency	**IPPC**	**IPPC**	**IPPC**	**5.01**
1.4 Efficient use of raw materials and water	**IPPC**	**IPPC**	**IPPC**	**5.01**
1.5 Avoidance, recovery and disposal of wastes	**IPPC**	**IPPC**	**IPPC**	**5.01**
2: Operations				
2.1 Permitted wastes	**P**	**P**	**P**	**P**
2.2 Waste pre acceptance and waste acceptance	**IPPC**	**IPPC**	✓	✓
2.3 Validation of treatment	**X**	**X**	✓	**X**
3: Emissions and monitoring				
3.1 Introduction	✓	✓	✓	✓
3.2 Waste storage, handling and dispatch	✓	✓	✓	✓
3.3 Emissions monitoring	**X**	**X**	✓	**5.01**
4: Annexes				
Annex 1: Site commissioning validation	**X**	**X**	✓	**X**
Annex 2: Routine efficacy monitoring	**X**	**X**	✓	**X**
Annex 3: Emissions monitoring and benchmarks	**X**	**X**	✓	**X**
Annex 4: The classification and coding of waste from clinical waste treatment	**X**	**X**	✓	**X**
Annex 5: Section 2.1, Table 2.1 (permitted wastes)	**P**	**P**	**P**	**P**
Annex 6: An example of a waste audit	✓	✓	✓	✓

1

Managing your activities

1.1 General management
1.3 Energy efficiency
1.4 Efficient use of raw material and water
1.5 Avoidance, recovery and disposal of wastes

General management

1. Managing your activities

1.1 General management

Maintenance, Incidents and non-conformances

Incinerator or treatment plant malfunction or maintenance shutdown can cause problems at the disposal facility and disruption at transfer stations or producer premises. This can lead to permit conditions being breached.

Appropriate measures (General)

1. You must have and implement, a contingency plan that:
   - ensures compliance is maintained with all your permit conditions and operating procedures during maintenance/shutdown at your site or elsewhere;
   - ensures that permitted storage limits are not exceeded and appropriate measures for waste storage and handling continue to be applied; and
   - includes ceasing the acceptance of waste unless a clearly defined method of recovery or disposal has been determined **and** sufficient permitted storage capacity is available.
2. You must have procedures in place to ensure that you are aware in advance of planned shutdowns at disposal facilities where you send waste.
3. You should make your customers aware of your contingency plan, and of the circumstances in which you would cease accepting waste from them.
4. Consider whether the other sites or companies you rely on in your contingency plan are able to take the waste at short notice, and are authorised to do so in the quantities and types likely to be required, in addition to any existing activities they may currently be undertaking. We do not expect you to contract for 'contingency capacity'.
5. Do not discount disposal options on the basis of additional cost or geographical distance, if this may result in permitted storage limits being exceeded or storage procedures being compromised.
6. Do not include unauthorised capacity in your contingency plan. If your contingency plan includes the use of temporary storage of additional waste on your site, then you must ensure that your site is authorised for this storage and the appropriate infrastructure is in place.

General management

Appropriate measures (Treatment and Incineration 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 required to deal with them;
   - include a record of spare parts held, or setting out where they can be obtained from, with an assessment of how long they would take to obtain;
   - have a defined procedure for identifying, reviewing and prioritising items of plant for which a preventative regime is appropriate;
   - include all equipment or plant whose failure could directly or indirectly lead to an impact on the environment or human health and 'non productive' items such as tanks, pipework, retaining walls, bunds, reusable waste containers (for example wheeled carts), ducts, filters and security systems;
   - ensure the necessary spare parts, tools, and competent staff are available prior to commencing maintenance;
   - implement appropriate disinfection procedures for maintenance of equipment (or parts of equipment) contaminated with untreated clinical waste. The use of personal protective equipment (PPE), although essential to protect workers from exposure, should not form the primary control.

   Your management system must include an auditing of performance against the above and reporting of the audit results to the site manager.

Energy efficiency
Efficient use of raw materials and water

Requirements for IPPC Directive Activities

Note that the following sections (1.3, 1.4 and 1.5) are a legal requirement for activities covered by the IPPC Directive. However taking these actions would be an indicator of good practice.

For incineration installations the same principles must be applied in conjunction with *'How to comply with your environmental permit Additional guidance for: The Incineration of Waste (EPR 5.01)'*

1.3 Energy efficiency

Appropriate measures

1. For thermal disinfection (D9) treatment processes:
   - when processing waste that is not infectious (that is, does not possess the hazardous property H9 infectious) the energy required to disinfect will be considered during permit determination (see also section 2.1 of this document);
   - your application for the treatment of such waste must be supported by a detailed justification that demonstrated that this criteria is met.
2. For chemical disinfection (D9) treatment processes the same principles apply, however the overall energy usage may be less.

1.4 Efficient use of raw materials and water

When you are selecting a treatment technology evaluate the available options for efficient use of raw materials.

Avoidance, recovery and disposal of waste

Appropriate measures

1. For chemical disinfection (D9) treatment, consider:
   - disinfectants that might have a lower environmental impact (for example hazardous properties, bioaccumulation, degradability, emissions, etc.).
   - 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.
   - that processing of waste that is not infectious (that is, it does not possess the hazardous property H9 infectious) may be inconsistent with this condition. Your application for the treatment of such waste needs to be supported by a detailed justification that demonstrated that this criteria is met.
2. For thermal disinfection (D9) treatment processes, ensure that the overall raw material usage is minimised, for example by exploring re-use of water over several autoclave cycles.

1.5 Avoidance, recovery and disposal of wastes

When you are selecting a treatment technology evaluate the available options for the recovery of the treated waste.

Appropriate measures

1. In your permit application or permit reviews, include either:
   - detailed proposals, and an implementation schedule, for the recovery of treated clinical waste from D9 operations; or
   - an explanation of why recovery is technically and economically impossible.
2. Where you provide or advise producers on clinical waste packaging, in your new application or review consider:
   - reducing the quantity of packaging accompanying the waste, for example making sure that containers are being used efficiently;
   - selecting packaging that is either reusable or suitable for recycling.

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Operations

2.1 Permitted wastes
2.2 Waste acceptance
2.3 Validation of treatment

Permitted wastes

2. Operations

2.1 Permitted wastes

Introduction

This section considers the permitted wastes for clinical waste management activities.

Clinical waste segregation separates wastes that require incineration, from those that can be treated and those that can be landfilled. Your permitted wastes, although based on the List of Waste codes, must (in addition) include specific descriptive limitations to clarify which individual subtypes of clinical waste are included or excluded**.**

This information is presented here both as explanatory text and in Table 2.1 (sub tables 2.1a to 2.1c). This table is referred to in the permit application form and is explained in this section.

Permitted wastes for treatment:

Wastes suitable for alternative treatment (disinfection)

The purpose of alternative treatment (disinfection) is to disinfect infectious waste and render it safe.

If the waste is not infectious, or if it possesses other chemical, pharmaceutical or anatomical characteristics alternative treatment may not be suitable. The reasons for treating such waste need to be fully justified.

Table 2.1 (sub-table 2.1a) is an example of a permitted wastes table for an alternative treatment process. It includes the codes for wastes that are clinical waste due to their infectious properties, and therefore require disinfection.

A qualifying footnote excludes types and sub-types of clinical waste that have characteristics requiring additional justification. These are not normally considered suitable for alternative treatment (disinfection)

New environmental permits will normally include this information within Schedule 3 of the permit.

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Permitted wastes

Table 2.1a Waste types permitted for treatment (permitted activity D9)	
Waste Code	**Description**
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03*[1]	wastes whose collection and disposal is subject to special requirements in order to prevent infection.
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*[1]	wastes whose collection and disposal is subject to special requirements in order to prevent infection.
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 99[1]	other fractions not otherwise specified **(comprising only of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e., not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).**

[1] In addition, the following wastes are specifically excluded from waste treatment activities:

(i) : **Any waste** containing waste medicines and chemicals, waste contaminated with cytotoxic and cytostatic medicines, anatomical waste (identifiable human or animal tissue arising from healthcare), or dental amalgam;

(ii) : **Sharps boxes** containing any of the excluded wastes from (i) and (iii) or sharps that are contaminated with pharmaceuticals in any quantity (including syringes that are fully discharged, partially discharged or undischarged).

(iii) : **Biohazard waste :** Any waste known or likely to contain ACDP Hazard Group 4 biological agents; any waste from a containment level 3 laboratory: and all microbiological cultures from any source, and, any potentially infected waste from pathology departments and other clinical or research laboratories (Unless autoclaved before leaving the site of production).

Note: the 20 01 99 code is provided in Table 2.1a above for separately collected fractions of clinical waste that do not arise from healthcare activities. Examples include:

- cosmetic body piercing and body art;
- non-medical procedures in the hair and beauty sector;
- substance abuse;
- non-healthcare related incident clean up (for example crime scenes).

Permitted wastes

Wastes arising from healthcare in the community, for example from self-administering diabetics are classified in Chapter 18 of the list of wastes.

Wastes unsuitable for alternative treatment

Footnote 1 of Table 2.1a identifies those wastes that are normally excluded from alternative treatments for the following reasons. The waste:

- is not infectious, rendering disinfection questionable as a treatment process;
- contains chemicals, pharmaceuticals, dental amalgam or anatomical waste that the process may not be able to treat;
- contains human tissue or microbial cultures that require additional measures or create conflict with legislation, advice or guidance provided by other public bodies.

Treatment may also be potentially inconsistent with the requirements of the IPPC Directive.

Where the treatment process dilutes, rather than treats a component of the waste, this may adversely affect the classification of the treated waste.

We recognise that treatment technologies may exist or be developed that are technically capable of treating one or more of these wastes. If you believe that your process can, or you wish to treat these wastes, we will ask you for additional information (a justification) to demonstrate that your process is suitable.

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Waste containing or contaminated with pharmaceuticals or other chemicals

The Safe Management of Healthcare Waste indicates that to render clinical waste safe *'all pharmaceutically active substances present in the waste, both hazardous and non-hazardous, should be destroyed during disposal at a suitably authorised facility'.*

A justification is required for the treatment of waste contaminated with or containing any residual pharmaceuticals or hazardous chemicals. This must demonstrate that the process is able to effectively treat the range of chemicals or pharmaceuticals that may be present, rather than dilute them with other waste.

Typical examples of such wastes are:

- cytotoxic and cytostatic contaminated sharps;
- other pharmaceutically contaminated sharps (even if fully discharged);

Permitted wastes

- IV bags and other medicines;
- clinical waste packages containing chemically contaminated bottles (hand gel containers, auto-analyser cartridges, photochemical containers, diagnostic kits and reagents, and so on); and
- chemically preserved anatomical specimens.

Explanatory notes

Medicines: Medicines can be divided into four broad groups:

- Cytotoxic and cytostatic medicines (medicines that possess one or more of the hazardous properties Toxic, Carcinogenic, Mutagenic or Toxic for Reproduction);
- Medicines that possess other hazardous properties (for example flammable, irritant, harmful and ecotoxic);
- Medicines that possess no hazardous properties but are pharmaceutically active and may interact with biological systems at low doses.
- Medicines that have no hazardous properties and contain no pharmaceutically active agents (for example sterile water, saline, glucose, and so on).

Fully Discharged Syringes: We no longer regulate or permit on the basis of 'fully discharged syringes'. We do not distinguish these from other medicinally contaminated sharps for the following reasons:

- Our producer audits have identified that producers rarely produce and segregate this waste in practice.
- Such permit conditions may encourage producers to engage in secondary handling of syringes potentially leading to a discharge of pharmaceuticals to foul sewer or an increased risk of needlestick injuries.
- The permit conditions reliant on 'fully discharged' were very difficult to enforce.
- The presence of even small quantities of a dangerous substance can affect the classification of the treated waste if they are diluted rather than genuinely treated.
- The number of syringes is as relevant as the amount of residue in an individual syringe. One syringe containing 10 ml is the same as ten syringes containing 1ml.

The Classification of Medicinally Contaminated Syringes

Medicinally contaminated syringes consist of both a needle and a syringe body.

- The syringe body is a pharmaceutical waste (for example 18 01 09), and

Permitted wastes

- The needle is a sharp (for example 18 01 03*)

(Note: many medicines are manufactured as pre-filled syringes that are themselves, part of the medicinal product.)

Used medicinally contaminated syringes must therefore be dual coded.

Biohazardous Waste

Certain biohazardous wastes represent a greater risk, require a higher level of treatment, or are subject to additional transport or health and safety controls.

Wastes containing Class 3 and 4 GMM (genetically modified microorganism) cultures or contaminated material, and wastes containing most HG3 (hazard group) and HG4 pathogen cultures or positive specimens are classified as category A for transport. They must be inactivated on the site of production to meet the requirements of health and safety legislation. Wastes consisting of Class 2 GMMs or many HG2 pathogen cultures or positive specimens (category B for transport) are recommended for inactivation on the site of production.

Such wastes should not routinely leave the premises of production in untreated form. They must only arrive at an alternative treatment facility as a 'one off' where treatment at the site of production has temporarily broken down.

Appropriate measures (treatment of biohazardous waste)

1. Your process must not shred/macerate untreated wastes prior to the disinfection step.
2. The process must demonstrate a higher level of treatment (STAATT level IV criteria).
3. You must have waste acceptance and pre-acceptance procedures in place to ensure that this waste is only accepted in exceptional circumstances, for example as a 'one off', where on site treatment has malfunctioned.
4. You must submit a justification to demonstrate that you have addressed these issues and have the appropriate procedures in place.

Anatomical waste (Human and Animal)

The disposal options for anatomical waste are currently restricted to incineration for ethical reasons. It is not considered appropriate or acceptable to shred and treat anatomical waste.

Permitted wastes

Novel technologies like alkaline hydrolysis that dissolve, and therefore utterly destroy, the tissue leaving a 'bone shadow' equivalent to crematoria or incinerator ash may be applicable for such wastes.

Anatomical waste is often preserved in hazardous chemicals (for example formaldehyde or industrial methylated spirits). The Human Tissue Act and guidance from the Human Tissue Authority must also be considered.

Non-infectious waste

If the waste does not possess the hazardous property H9 Infectious, why would you wish to subject it to a disinfection process designed to reduce infectivity? Processing of such waste may also compromise the treatment of infectious waste or present other risks. Permits should not be issued for treatment of such wastes unless you can provide justification. The justification shall consider:

- non-infectious wastes may have a higher moisture content or organic content that can present an additional challenge for the thermal and chemical treatment processes; Validation protocols shall address this.
- the mixing of hazardous waste with non-hazardous waste is contrary to the principles of the Hazardous Waste Directive. The mixing of clinical (infectious) waste with non-infectious waste during the treatment process may not be appropriate;
- is the waste being incorrectly described as non-infectious (for example clinical waste classified as 18 01 04)?
- disinfection of non-infectious waste is not necessary to meet the pretreatment requirements for non-hazardous hygiene/offensive waste destined for landfill;
- for IPPC Directive activities, the justification must also address energy efficiency, the efficient use of raw materials and the avoidance, recovery, pre-treatment requirements for landfill and disposal of wastes produced. This is also good practice for non-IPPC Directive activities.

As an example, we may permit facilities where non-infectious waste is treated separately from infectious waste, and the disinfection step is essential to recycle or recover the non-infectious waste to divert it from landfill. We would also consider whether the waste can be recovered either more efficiently by other means, or without disinfection.

Permitted wastes

Permits and justifications for permitted wastes

For wastes 'unsuitable' for alternative treatments a justification is required to satisfy us that in the particular case, this is an acceptable treatment process for the wastes in question.

Typically this will be required by a pre-operational condition linked to an additional permitted wastes table.

Examples are provided below.

The key issues to consider may include:

- is the treatment effective?
- is the treatment of any other waste affected?
- are process emissions affected?
- Does it meet the IPPC requirements in section 1.3 to 1.5?

2.5 Pre-operational condition

2.5.2 the operations specified in schedule 1 table S1.4B shall not commence until the measures specified in that table have been completed.

Table S1.4B Pre-operational measures for future development		
Ref.	Operation	Pre-operational measures
1	**Physico-Chemical Treatment (D9)**	A written justification for the treatment of wastes listed in table S3.2.4 of this permit shall be submitted to the Environment Agency for approval. As a minimum, the justification shall take into account the principles specified in sections 2.1 and 2.3 of the sector guidance note for Clinical Waste EPR 5.07. Address whether the treatment of each of the wastes listed table S3.2.4: - is effective, including validation of the process using worst case scenario conditions; - is an efficient use of energy and raw materials; - impedes waste recovery or recycling; - compromises the treatment of any hazardous waste; - has an effect on emissions from the activity. No wastes specified in Table S3.2.4 shall be accepted for treatment unless we have given prior written approval under this condition.

Permitted wastes

Table S3.2.4 Permitted waste types for steam treatment in autoclaves and subsequent maceration subject to prior compliance with condition 2.5.2, and Table S1.4B Ref. 1	
Waste Code	**Description**
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03* (with or without 18 01 09)	medicinally contaminated infectious sharps/syringes[1]
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)[2]
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02* (with or without 18 02 08)	medicinally contaminated infectious sharps/syringes[1]
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection[2]
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 99	other fractions not otherwise specified (comprising only of non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research (i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection)[2]

Note: For the purpose of Table S3.2.4;

[1] These entries are limited to medicinally contaminated sharps/syringes (including those that are fully, partially, or un-discharged) and do not include other pharmaceutical or pharmaceutically contaminated wastes.

[2] These entries are limited to those wastes that are not classified, described, packaged, labelled or transported as infectious or clinical wastes.

Permitted wastes

Permitted wastes for storage (R13 and D15)

This section is provided as information to support permit applications, permit modifications and working plans.

Table 2.1b (in Annex 5) indicates the permitted wastes for storage (R13 and D15). These apply to any site managing clinical waste in this manner, including for example:

- transfer stations
- pet crematoria acting as transfer stations
- treatment plants
- clinical waste incinerators.

New environmental permits will normally include the information presented in Table 3.1c within Schedule 3 of the permit.

The relevant chapter 09 codes from the List of waste are included for X-ray photochemicals.

New environmental permits will normally include the information presented within Schedule 3 of the permit.

Permitted wastes for incineration (D10 and R01)

Table 2.1c (in Annex 5) lists those clinical and healthcare wastes **potentially** suitable for clinical waste incineration. Specific concerns are likely to include:

- the requirements for higher incineration temperatures for cytotoxic and cytostatic contaminated wastes;
- technical considerations surrounding the incineration of liquids.

Dental amalgam is not included due to its mercury content.

New environmental permits will normally include this information within Schedule 3 of the permit.

Note: Guidance document *'How to comply with your environmental permit Additional guidance for: The Incineration of Waste (EPR 5.01)'* provides standards and measures for incineration of waste (including clinical wastes) that must also be applied.

Waste pre acceptance and waste acceptance

2.2 Waste pre acceptance and waste acceptance

Scope

These standards and measures are **mandatory** for all permitted activities at facilities that treat, or incinerate clinical waste. They include small or mobile units located on the waste producer's premises.

Waste acceptance is made up of two separate stages referred to by this document as

- **Waste pre-acceptance**, and
- **waste acceptance**

Permit conditions

Typical permit conditions or rules
General 2.3.2 Waste shall only be accepted if: (a) it is of a type and quantity listed in schedule 3 table(s) S3.2, S3.2a, S3.2b, and S3.2c; (b) it conforms to the description in the documentation supplied by the producer and holder.
Clinical waste incineration 2.1.4 The operator shall incinerate only those hazardous wastes where the throughputs, calorific values and pollutant composition are within the ranges specified in the application. 2.1.5 The operator shall ensure that, prior to accepting waste subject to condition 2.1.4 at the permitted installation, it has obtained sufficient information about the hazardous wastes to be burned to demonstrate compliance with the characteristics described in condition 2.1.4. 2.1.6 The operator shall take representative samples of all hazardous waste deliveries to the permitted installation unless otherwise agreed in writing with the Agency and test a representative selection of these samples to verify conformity with the information obtained as required by condition 2.1.5. These samples shall be retained for inspection by the Agency for a period of XXXX after the material is incinerated.

Waste pre-acceptance and waste acceptance

Standard Rule

2.2.1 Waste shall only be accepted if:

(a) it is of a type and quantity listed in tables 2.2, 2.2a, 2.2b and 2.2c below;

(b) it conforms to the description in the documentation supplied by the producer and holder; and

(c) waste acceptance procedures are in place to determine (a) and (b).

Inclusions and Exclusions

These procedures apply to all clinical and offensive wastes arising from healthcare activities with the exception of those collected from domestic premises and care homes that do not provide nursing care.

In addition, they do not apply to clinical wastes or offensive wastes from non-healthcare activities (correctly classified under chapter 20 of the List of Wastes).

Purpose

The primary purpose of these procedures is to identify the presence of the following in clinical waste streams from healthcare activities:

- anatomical waste, other animal or human tissues, and blood products;
- medicines and medicinally contaminated waste);
- chemicals and chemically contaminated waste;
- microbiological cultures and related laboratory wastes to which additional controls may apply;
- infectious waste;
- mercury and amalgam;
- non-hazardous wastes, for example municipal waste or offensive waste;
- non-hazardous gypsum wastes (for example plastercasts) with specific landfill requirements.

The absence of an offensive-hygiene healthcare waste stream in treatment areas of a medical practice, is a key indicator of this waste being inappropriately mixed with clinical waste.

In addition, offensive hygiene waste streams from healthcare activities must be checked to ensure no clinical wastes are present.

Waste pre-acceptance and waste acceptance

Procedures

Waste acceptance is divided into two key stages in this document:

- stage 1 procedures undertaken prior to delivery of the waste to the disposal site (**waste pre-acceptance**) to determine the composition of the waste by audit of the original waste producer (that is the medical practice)
- stage 2 procedures undertaken on delivery of the waste to the disposal site (**waste acceptance**).

Appropriate measures

Waste Acceptance Stage 1: waste pre-acceptance procedures

1. Ensure that advice you give to waste producers on segregation and packaging is in accordance with the Safe Management of Healthcare Waste (HTM 07 01). Consider subsequent changes in legislation and guidance. Additional, non-conflicting, colour codes may be used where HTM 07 01 specifies no colour.
2. Obtain the following information in writing when you receive the waste disposal enquiry:
   - the details of the waste producer (e.g. medical practice) , including address and contact details;
   - the specific process from which the waste derives – veterinary, primary care, dental, acute, laboratory, and so on;
   - an indication of the waste streams produced, their quantity, physical form, composition, properties, classification and description (more detailed checks will be conducted as part of the site audit).
3. Obtain a representative audit analysis of the waste undertaken at the medical practice that produced the waste. This guidance places no restrictions on who may undertake this audit, however it assumes that in most cases this will be the waste producer.
4. The audit data must be obtained and assessed before delivery of the first batch of waste from each medical practice and then at the following minimum frequencies:
   - every 12 months for each medical practice that produces five tonnes or more of clinical waste in any calendar year (see point 9 below);
   - every two years for each veterinary practice, dental practice, and laboratory that produces less than five tonnes of clinical waste in any calendar year,
   - every five years for other healthcare producers of clinical waste,

Waste pre-acceptance and waste acceptance

The information is no longer valid for pre-acceptance once the time intervals above have passed since the date the producer audit was completed. In addition, repeat the audits if the producer makes significant changes to their waste segregation.

5. The type of information that would demonstrate the reliability of the site audit of the producer premises includes as a minimum:
   - a list (or diagram) of the different wards, departments, or functional areas that exist within the premises, identifying those that were included in the audit (see paragraphs 7 and 8);
   - the date commencement and completion of the audit, and description of the audit, the procedures employed, the auditors and their affiliation;
   - for each unit or area audited, identification of the waste items produced, the type (including colour), size and labelling of containers in-use, the segregation practices, contents of a representative number of each type of container, and therefore waste composition identified using the techniques in paragraph 9;
   - the hazardous properties associated with the waste and its components (medicines, chemicals etc.);
   - where relevant, the audit must include examination of the segregation of waste containers placed in departmental and main storage areas, and bulk containers (for example 770 litre carts). This would normally be by visual observation of contents and questioning of staff to establish practice.
   - a summary report indicating the findings for each area in the producer premises, each waste stream produced there, highlighting any issues identified, including proposed waste descriptions and classifications derived from the audit findings for each waste stream.

   In addition it may include;
   - any preservation techniques used (for example cold storage, or freezing);
   - any changes implemented as a result of issues identified with confirmatory evidence to demonstrate that this has occurred;
   - information on waste policies, staff training, internal audit regimes, and environmental management systems.
6. The compositional audit must as a minimum identify which of the following are produced by the unit/department, what container type they are placed in, whether they were present in each container examined, and a comparison to the proposed waste classification and description:

Waste pre-acceptance and waste acceptance

- cytotoxic and cytostatic contaminated material;
- other pharmaceuticals or pharmaceutically contaminated material (for example medicinally contaminated syringes, I.V. bags, tubing, bottles vials and ampoules, and so on)
- waste chemicals (for example laboratory reagents, autoanalyser bottles, diagnostic kits, disinfectant handgels, and so on.);
- 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 wastes including municipal wastes (paper, magazines, food wrappers, hand towels etc), offensive wastes, and autoclaved laboratory wastes;
- gypsum wastes (plastercasts, dental and podiatry moulds) other than the small proportion that can correctly be described as infectious.

Two key issues deserve specific consideration when you are assessing this:

- Has the medical practice implemented a definition of cytotoxic and cytostatic from technical guidance WM2/HTM 07 01, does the unit produce any of this waste, and if so is that definition in use for segregation in that unit?
- Has the medical practice implemented an offensive hygiene waste stream for healthcare waste (rather than municipal wastes from lavatories) in that unit

7. For medical practices that produce less than five tonnes of clinical waste per year, encompass the entire practice in the audit.
8. For medical practices that produce five tonnes or more of clinical waste, include the entire practice in the first audit. If this is satisfactory, and identifies consistent practice, each subsequent year can be reduced to include at least one third of the units, wards and departments. Over a three year audit cycle all units, wards and departments must be included.
9. Each element of the audit shall include each of the following techniques for each unit, are or department:
   - observation and recording of practice including examination of raw materials, equipment and stores to help identify what waste items may be produced;
   - observation of in use waste receptacle contents;
   - questioning of staff (for example nursing staff) who produce the waste, that considers the waste items and types produced (with a focus on those identified in paragraph 6),

Waste pre-acceptance and waste acceptance

the container types these are placed in, and elements of practice. This questioning can be undertaken verbally with the auditor recording the answers.

10. For pure product chemicals, laboratory smalls, or pharmaceutical waste containers, the audit can include reference to product data sheets or an extrapolation of information on product data sheets.
11. Ensure the waste is appropriately packaged and labelled.
12. Following characterisation of the waste, a technical assessment must be made of its suitability for treatment or storage to ensure compliance with permit conditions.
13. Suitably trained and competent staff must assess the producer waste audit report. These staff must have a clear understanding of clinical waste, its composition, classification, packaging and transport, the wastes associated with specific healthcare activities, any conditions within the permit that relate to these, and the requirements for the completion of waste consignment and transfer notes. Keep a record of this assessment, its conclusions, and any actions taken (for example advising the producer that they must implement an offensive hygiene waste stream) with the audit.
14. Where the audit report is partially incomplete or inadequate, in that it does not fully meet the requirements set out in the preceding paragraphs, request and obtain the required information (or an another audit report) prior to accepting the waste.
15. You must either keep all records relating to pre-acceptance at the site, or have direct access to those records held in electronic form, for cross-reference and verification at the waste acceptance stage. Keep these records for a minimum of two years, or three years where required by the Hazardous Waste Regulations.
16. Note: Although the required audit information may be collated by a number of means (for example on-line tools or by phone) it can only be generated by a physical audit of the practice and its waste by an auditor. A series of questions asked of a producer representative over the phone does **not** meet these requirements.
17. You are responsible for ensuring that pre-acceptance checks and subsequent assessments are conducted on each producer (e.g. medical practice) whose waste is received at your site. You may elect to employ another party to undertake these checks and assessments, in one or more of bullets 1 to 16, on your behalf. Where you elect to do so you must as a minimum:
    - ensure that you have the details of the content of any audit tools or methodologies and assessment criteria used by that party, and that they meet the standards set our here with regard to your site prior to accepting any waste.

Waste pre-acceptance and waste acceptance

- Periodically audit a random and representative cross-section of the other party's pre-acceptance checks to ensure both the quality of pre-acceptance checks, subsequent assessments, waste classification and descriptions, and that (in the case of carriers or transfer stations) it encompasses all relevant producers from whom they collect waste including new customers. As a minimum this should be annual, and follow shortly after a relevant pre-acceptance cycle date for the risk group audited.
- Keep a record of the above and a summary report from the third party that enables you to demonstrate that pre-acceptance and assessment has been conducted on waste from a relevant producer with regard to your specific site and its permit.
- Be able to obtain without unreasonable delay a copy of the pre-acceptance report and assessment for any individual producer where operationally necessary or requested to do so by our inspector.

The summary report should;

- confirm the producer types, waste types, containers etc .
- certify that the previous paragraphs 1 to 16 as appropriate have been completed for all producers, and what has been done where this is not the case for a particular producer,
- confirm a composite waste classification/description/composition/properties for each waste stream and container type destined for that site/activity, derived from each of the pre-acceptance audits and with reference to paragraph 6, and the permitted wastes for that site,
- confirm any issues that have been identified and what action has been taken with regard to the producers and wastes affected.
- be updated if any of the above changes.

Waste pre-acceptance and waste acceptance

Waste acceptance: It is not unusual for the permit holder to act as the carrier and collect the waste from the producer's premises. In these instances, the waste acceptance stage can start when the waste is collected, otherwise commence the procedure when the waste arrives at the site.

The following table specifies appropriate measures for Stage 2 site acceptance procedures.

Appropriate measures :

Waste Acceptance Stage 2: On-site Acceptance Procedures

1. On arrival:
   - weigh each consignment of clinical waste unless alternative reliable volumetric systems are available;
   - do not accept waste unless there is sufficient authorised storage capacity and adequate manning;
   - check and if appropriate approve all documents, resolving discrepancies before accepting the waste.
2. Poorly packaged or transported waste may present an increased risk of spillage or emissions on the waste site. Check delivery vehicles and their loads to ensure that the waste has been packaged and transported in accordance with the carriage of dangerous goods.
3. You may accept poorly packaged or transported waste where the site has appropriate procedures to mitigate the risk. Record the carrier identity, producer identity, vehicle details, the deficiency identified and the measures you have taken to prevent a repeat occurrence. Notify us of these details within seven days of the waste's acceptance or rejection.
4. Where possible undertake confirmatory checks before offloading. Visual or electronic inspection of the waste within the 'carts' must in any event be carried out prior to disposal or recovery. Where waste is delivered in wheeled carts, or other bulk containers, it is likely that the waste at the bottom of the carts is not wholly visible and additional procedures are needed to check that waste.

Waste pre-acceptance and waste acceptance

5. You must have procedures that ensure that any container of a type indicative of non-conforming waste present in any cart or similar bulk container arriving at your site is both identified and then managed in accordance with your permit. A non-conforming waste includes any waste that:
   - the disposal facility is not authorised to accept for an activity that the contents of the cart are destined for,
   - is not recorded on waste documentation, or
   - would not be expected, for any other reason, to be present in that cart.

   Your procedures should as a minimum;
   - identify the presence of any unknown or non-conforming waste arriving at the site,
   - prevent a waste being recovered or disposed of in breach of the permit,
   - enable you to identify and contact the producer of the waste to prevent recurrence, and
   - ensure that any waste accepted is correctly recorded on waste documentation, site records and returns.

   You should not open clinical waste bags, sharps boxes or similar packaging. Their contents are determined by pre-acceptance checks. The objective here is to identify non-conforming, unknown, undocumented or unexpected container types, for example a cytotoxic or cytostatic sharps box or rigid yellow bin of unknown content, buried in a wheeled cart under clinical waste bags.

   You must seek to minimise manual handling, for example by exploring mechanical means of unloading or screening technologies that avoid to need to unload carts unnecessarily.

   The impact of processing a non-conforming waste on the classification of treated waste from an AT process is set out in Annex 4. Additional consideration needs to be given to the Human Tissue Act in the case of anatomical waste.
6. Where no non-conforming wastes are identified in the wheeled carts from an individual producer, or transfer station if that is where waste is loaded into the carts, for either a period of three months or six collections then the visual inspection frequencies for that producer can be reduced to spot checks of one cart in ten. If a spot check identifies a non-conforming waste, preventative measures must be taken to prevent a recurrence, and all loads from that source must be checked for the period of time set out above.

Waste pre-acceptance and waste acceptance

7. You must check every container to confirm quantities against accompanying paperwork. All containers must be clearly labelled and also be equipped with well fitting lids.
8. At this stage the waste tracking system can begin, if it has not begun earlier. Your tracking system must be capable of meeting the requirements of the hazardous waste regulations, identifying the source producer, and date of arrival of each container on site. Apply a unique tracking reference number or label to each container.
9. Waste delivered to the site must:
    - be accompanied by a written description of the waste describing its composition, hazard characteristics and handling precautions, compatibility issues, and information specifying the original waste producer and process where required;
    - where non-hazardous waste is received under an annual waste transfer note you must ensure that the waste composition and source have not changed from that provided in the Stage 1 procedures applied at pre-acceptance.
10. Documentation provided by the driver, written results of acceptance analysis, and details of offloading point or off-site transfer location must be added to the tracking system documentation.
11. You must maintain a record of the inspection regime for each load and justification for the selection of this option at the site.
12. If the inspection or analysis indicate that the wastes fail to meet the acceptance criteria then store such loads in a dedicated quarantine area and deal with them appropriately. The maximum storage time for such loads must take account of the potential for odour generation and insect infestation. In all cases five working days is the maximum storage time for hazardous waste that has failed to meet the acceptance criteria. . You must have written procedures for dealing with wastes held in quarantine, together with a maximum storage volume.
13. The offloading, sampling point/reception and quarantine areas must have an impermeable surface with self-contained drainage, to prevent any spillage entering the storage systems or escaping off site. All surfaces are to be of sufficient type and quality to allow effective disinfection.

Waste pre-acceptance and waste acceptance

14. You must have clear and unambiguous criteria for the rejection of wastes, together with a written procedure for tracking and reporting such non-conformance. This includes notification to the customer/waste producer and regulator. Written/computerised records will form part of your waste tracking system information. You must also have a clear and unambiguous policy for the subsequent storage and disposal of such rejected wastes. This policy will achieve the following:
    - identify the hazards posed by the rejected wastes;
    - label rejected wastes with all information necessary to allow proper storage and segregation arrangements to be put in place;
    - segregate and store rejected wastes safely pending removal.
15. Your waste tracking system must hold all the information generated during pre-acceptance, acceptance, storage, treatment, incineration and/or removal off-site. Make and keep records up to date on an ongoing basis to reflect deliveries, on-site treatment and despatches. Your tracking system will operate as a waste inventory/stock control system and include as a minimum:
    - date of arrival on-site
    - original producers details (or unique identifier)
    - all previous holders
    - a unique reference number
    - pre-acceptance and acceptance analysis results
    - package type and size
    - intended treatment/disposal route
    - accurate records of the nature and quantity of wastes held on site, including all hazards and identification of primary hazards
    - where the waste is physically located in relation to a site plan
    - where the waste is in the designated disposal route
    - identification of staff that have taken any decisions re acceptance or rejection of waste streams and decided upon recovery/disposal options.
    - link each clinical waste container accepted to its consignment or transfer note..

Waste pre-acceptance and waste acceptance

16. All waste containers must be labelled with a unique identifier that enables the original producer of the waste to be identified. Where the waste is collected from the producer in a wheeled cart containing a single waste stream, and as long as the waste remains in the cart and is not combined with waste from other producers, it may be sufficient to label the cart. Where individual waste packages (for example sharps boxes or clinical waste bags) of different waste types or from more than one producer are unloaded from the cart, or are placed together in any storage container or area, these packages must be individually labelled with the unique identifier.
17. You must have access to all records relating to pre-acceptance at the site for cross-reference and verification at the waste acceptance stage. Records are to be held for a minimum of two years after the waste has been treated or removed off site.
18. The system adopted will be capable of reporting on all of the following:
    - total quantity of waste present on site at any one time;
    - breakdown by type of waste quantities being stored pending treatment, incineration or transfer;
    - indication of where a batch or consignment of waste is located on site relative to a site plan;
    - comparison of quantity on site against total permitted;
    - the time the waste has been on site.
19. Keep back up copies of computer records off-site.
20. Do not accept wastes at the site without a clearly defined method of recovery or disposal being determined and sufficient capacity being available. Perform these checks before the waste acceptance stage is reached.
21. You must maintain a clear distinction between sales and technical staff roles and responsibilities. If non-technical sales staff are involved in waste enquiries then make a final technical assessment prior to approval. It is this final technical checking that must be used to avoid build up of accumulations of wastes and to ensure that sufficient capacity exists.

Validation of treatment

2.3: Validation of treatment

Scope

The following additional standards and measures are **mandatory** for clinical waste treatment activities (D9).

This includes small plant, mobile plant, and devices located on producer premises.

Typical permit condition

Table S1.4a Pre-operational measures	
Reference	**Pre-operational measures**
	The operator shall submit a written site commissioning validation report to the Environment Agency for approval, that demonstrates: (i) the treatment efficacy of the waste facility, in accordance with the appropriate measures in Sections 2.1, 2.3 and Annex 1 of the sector guidance note EPR S5.07 on clinical wastes; (ii) the proposals for routine monitoring of treatment efficacy comply with the appropriate measures in section 3.2 and Annex 2 of the sector guidance note EPR S5.07 on clinical wastes; (iii) the installation's emissions, in accordance with the appropriate measures in Section 3.3 and Annex 3 of the sector guidance note EPR S5.07 on clinical wastes; (iv) the proposals for routine monitoring of emissions comply with the appropriate measures in section 3.3 and Annex 3 of the sector guidance note EPR S5.07 on clinical wastes. The treatment process (D9) shall not be made operational until the Environment Agency has given prior written approval under this condition.

Quality assurance of treatment efficacy

You must demonstrate that your treatment process is able to render clinical waste safe. Efficacy testing measures the ability of your process to achieve this.

There are three stages in the Quality Assurance of treatment efficacy.

- process efficacy
- site commissioning validation
- routine monitoring.

Validation of treatment

Appropriate measures

1. **Process Efficacy:** When you apply for your permit include information to demonstrate that the proposed technology is likely to be effective in treating **each** of the waste streams that you are applying to treat. We can then issue a permit for each of those waste streams for which information has been provided.
2. **Site Commissioning Validation:** Once you have received your permit, and have installed your clinical waste treatment device(s), you must validate the performance of each individual unit on the site.
   Submit the results to us in the form of a validation report and do not commence treatment operations until you have received written confirmation from us that we have approved the report. The device must not process waste:
   - using process parameters other than those validated;
   - of a type other than that tested during validation;
   - in a batch quantity or throughput rate greater than that assessed during validation;
   - or where the composition of the waste types in the load differs significantly from that tested during validation.
3. For mobile plant, the site commissioning tests for each unit must be undertaken prior to their commencing operation on the first deployment
4. Repeat the site commissioning validation:
   - periodically, at intervals no greater than 48 months during the operational life of the individual unit, or
   - if any process parameters (for example time, temperature, pressure, mass or type of waste and so on) are altered from those assessed during site commissioning, or
   - if mechanical or engineering changes are made to the treatment process, or
   - before recommencing treatment operations after a routine monitoring failure, or
   - if the clinical waste stream changes such that the worst case scenario challenge load considered during the original site commissioning validation is no longer the worst case scenario.
5. **Routine Performance Monitoring:** Monitor the efficacy of each of your clinical waste treatment devices throughout its operational life to ensure that its performance is maintained. Annex 2 provides the appropriate standards and measures for routine performance monitoring.

Validation of treatment

Criteria for quality assurance

Appropriate measures

1. You must demonstrate the following criteria during site commissioning:
   i. **for infectious waste** – the treatment must demonstrated the ability to reduce the number of organisms present in the waste to a level that no additional precautions are needed to protect workers or the public against infection by the waste;
   ii. **for anatomical waste** – destroys any human or animal issue, organ or body so that it is no longer generally recognisable;
   iii. **for any clinical waste** – renders any syringes, needles or any other equipment or item unusable and no longer in their original shape and form (un-recognisable);
   iv. **for wastes containing pharmaceuticals** or chemicals (for example medicinally contaminated syringes) – destroys the component pharmaceuticals and chemicals.

Note that more than one of the above may apply to each clinical waste stream, for example (i), (iii) and (iv) would apply to medicinally contaminated sharps. This affects the coding of the treated waste.

For infectious waste

In the USA, the State and Territorial Association on Alternate Treatment Technologies (STAATT) has provided four levels to define the microbial inactivation required for clinical waste treatment. We have adopted and adapted these principles to provide procedures to establish if the numbers or activity of pathogens has been reduced so that no additional precautions are needed to protect workers or the public against infection by the waste

Appropriate measures

1. You must meet
   - the level III criteria if your device treats infectious waste, and
   - the level IV criteria if your device treats certain bio-hazardous waste.

Appropriate standards and measures are provided in Annex 1.

Validation of treatment

STAATT	Description
Level III	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater; and inactivation of *B. stearothermophilus* or *B. atrophaeus* spores at a 4 $\log_{10}$ reduction or greater.
Level IV	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria and *B. stearothermophilus* spores at a 6 $\log_{10}$ reduction or greater.

Anatomical waste

Alternative treatments are not normally considered appropriate for the treatment of anatomical waste. (See section 2.1 of this document). This waste may also be subject to additional controls on animal by products or human tissue. Indicative standards and measures are provided in Annex 1.

For any clinical waste

Appropriate measures

1. Your treatment process must render any disposable items, equipment and sharps both unrecognisable and beyond use, and destroy any patient information within the waste
2. Maceration is the normal means of achieving this, however other equivalent means of achieving the same objective may be considered.
3. If your plant that macerates clinical waste that has not already been disinfected it must be designed and built specifically to ensure microbiological aerosol containment.

Waste containing or contaminated with pharmaceuticals

Appropriate measures

1. If your process is applying or permitted to treat waste containing or contaminated with pharmaceuticals (for example medicinally contaminated syringes) you must demonstrate that the pharmaceutically active substances present are destroyed during treatment. See section 2.1 and Annex 1 of this document.

3

Emissions and monitoring

Introduction
Waste storage, handling and dispatch

3 Emissions and monitoring

3.1 Introduction

This section is divided into two parts.

Section 3.2 focuses on preventing emissions by providing appropriate measures for waste storage, handling and despatch. This applies to all facilities that manage clinical waste and is intended to reduce the potential for

- spillage, resulting in the release of fluids, solids, aerosols and litter
- odour
- infestation by pests
- interference by trespassers.

This applies in addition to the requirements of "HOW TO COMPLY WITH YOUR ENVIRONMENTAL PERMIT".

Section 3.3 focuses on the emissions from treatment processes, and applies only to facilities that treat clinical waste.

In addition, for incinerator operators refer to guidance document *'How to comply with your environmental permit Additional guidance for: The Incineration of Waste (EPR 5.01)'*.

3.2. Waste storage, handling and dispatch

Handling of waste

Appropriate measures

1 On arrival, waste must either be in, or be unloaded from the delivery vehicle directly into, lockable rigid leak proof containers for storage and transport around the site.
2. Minimise the manual handling of clinical waste, for example to that required for waste acceptance, and ensure that appropriate Personal Protective Equipment is worn.
3. Loading, unloading and handling must only occur in areas with impermeable surfaces with sealed drainage.
4. Protect the integrity of waste packaging at all times to prevent emissions. Clinical waste must **never** be thrown, walked upon, or handled in any other manner that may result in a failure of packaging integrity.

6 Offensive/hygiene waste must be handled in accordance with the guidance on '*Managing offensive/hygiene waste'* issued by the Health and Safety Executive.

Waste storage, handling and dispatch

Storage of waste

Appropriate measures

1. Have separate storage areas or containers for each of the following wastes types, such that they are not in physical contact and a leak from one cannot contaminate another waste or its packaging:

   clinical wastes bags (requiring incineration), *clinical waste bags (alternative treatment),*
   offensive-hygiene wastes, *anatomical wastes (human or animal),*
   animal carcasses, *cytotoxic and cytostatic wastes,*
   other waste medicines, *other medicinally contaminated sharps,*
   non-medicinally contaminated sharps, *dental amalgam,*
   x-ray photographic fixer, *x-ray photographic developer*.

2. Have a separate, secure and clearly labelled 'Quarantine Area' for waste you are not authorised to accept or that does not meet the waste acceptance criteria.
3. Keep all clinical waste in totally enclosed, clearly labelled and secure areas sited on an impermeable pavement with a sealed or foul drainage system.
4. Store anatomical waste and animal carcasses securely in designated refrigerated unit within a secure building or suitable for long term use outside a building.
5. Store pharmaceutical waste within a designated area of a secure building.
6. Store clinical waste containing chemicals in a manner appropriate for its chemical properties and the potential for incompatible reactions.
7. Store other wastes in leak proof rigid containers the lids of which shall be kept closed when the container is not being loaded or unloaded:
8. The depth of waste in any container shall not result in failure of packaging at the base. Containers must be designed to retain litter and fluids when lids or doors are open. They must not be overloaded, and the closure of lids must not result in compression or puncture of packaged waste within.
9. Store waste in rigid packaging, for example sharps boxes, in an upright, stable and controlled manner to prevent and minimise the potential for spillages to occur. (The use of wheeled bins to contain spillages is not an equivalent measure).
10. Store offensive/hygiene waste in accordance with the guidance on '*Managing offensive/hygiene waste'* issued by the Health and Safety Executive.

Waste storage, handling and dispatch

Cleaning of storage areas and containers

Appropriate measures

1. The surfaces of the storage areas shall be of suitable type and quality to allow effective disinfection with a broad spectrum agent. Clean and disinfect surfaces regularly.
2. Once emptied, all re-usable mobile rigid containers must be checked to ensure all waste has been removed and then cleaned and disinfected both inside and out.
3. Inspect containers used to transport waste prior to each reuse to ensure that they have been cleaned and disinfected, are physically sound, the locking mechanism works, and that they meet the requirements for the Carriage of Dangerous Goods. This is to prevent fugitive emissions re-entering the healthcare environment.
4. You must be able to demonstrate that the mechanism of cleaning and disinfection of surfaces and containers physically removes contamination, is capable of achieving disinfection across the broad spectrum of micro-organisms with the parameters used (time, concentration, temperature, quantity etc.) and either does not produce emissions of pathogenic bioaerosols or chemical agents OR that such emissions are contained.
5. You must contain wash waters within an impermeable area and either discharge them to foul sewer or dispose of them appropriately offsite. Prevent run-off into external areas or to surface water drains.

Compaction of clinical and offensive hygiene waste

Poor handling or compaction of waste can result in the release of body fluids that may contain pathogens. These may infect through the eye, nose and mouth tissues, through cuts, and by inhalation or ingestion.

Appropriate measures

1 You must not compact or compress clinical waste by mechanical or manual means.

2 If you compact or compress offensive/hygiene wastes you must have detailed procedures to contain and minimise the release of body fluids, micro-organisms, and liquid discharges.

3 Conduct monitoring to demonstrate that your procedures are effective, to highlight releases and their causes, and to identify potential improvements. This could, for example include, monitoring of worker face visor protection and body clothing to determine visible and non visible releases via blood splashes.

Waste storage, handling and dispatch

Duration and monitoring of storage

Clinical waste has the potential to produce odour, create litter and to attract vermin or pests if the waste is not processed directly upon arrival at the facilities. This depends on a number of factors including the type of waste, when it was produced, ambient conditions, integrity of the packaging, and how it was stored and handled previously.

Where good practice has been employed by others in the waste chain, and waste is processed promptly, it is not necessary to stipulate storage times either in the permit or site procedures.

Permit conditions shall be used to control any potential problems that arise, for example odour and vermin.

Appropriate measures

1. Your site operating procedures shall
   - manage the waste in a manner that ensures that the problems with odour, litter and vermin/pests do not occur;
   - facilitate the transfer, treatment, and incineration of waste in rotation based on identification of its type, age on arrival, date of arrival and duration of storage on site;
   - enable the identification and prioritisation of wastes with a higher risk of causing odour, litter or pest problems during waste acceptance;
   - include additional measures to deal with these wastes to reduce and contain these problems;
   - address any problem wastes with the original producer, carrier and other previous holders as relevant to prevent a recurrence.
2. Monitor your storage regularly to check for pests and vermin, litter, odour, breached containers and spillages.
3. Your storage must be designed and operated to make this monitoring possible.
4. Keep records of the time, place, nature, cause and remedial action taken with regard to any problem identified.
5. Your site must have suitable procedures, equipment and broad spectrum disinfectants for dealing with the chemical and biological spillages that may arise from waste types accepted at your facility. All staff shall be aware of their location and trained in their use.

Waste storage handling and dispatch

Waste dispatch

The loading of waste onto vehicles for onward transport has the potential to result in breaches of packaging, spillages and contamination of vehicles creating a risk of releases during transport or at the destination site.

Appropriate measures

1. You must ensure that waste dispatched from the site is packaged in accordance with, and loaded onto vehicles that meet, the appropriate requirements for the carriage of dangerous goods.
2. Do not mix hazardous waste with other categories of hazardous waste, or with other wastes or materials. Load vehicles in a manner that prevents leakage or contamination from one type of waste contaminating another type or its packaging.
3. You must have documentary procedures to check outgoing vehicles and loads to confirm that these requirements have been met.
4. Your site inventory must be able to track and link the specific incoming consignments of waste to specific outgoing waste loads and documentation.
5. Where waste is transferred, you must able to demonstrate that the outgoing waste description and classification is the same as that for the incoming waste, unless the incoming waste description and classification is incorrect or incomplete.
6. if you believe the incoming waste classification and description is incorrect or incomplete then this shall be addressed, and documented, with the original waste producer during waste acceptance.

Emissions monitoring

3.3 Emissions monitoring

Scope

Section 3.3 applies to all clinical waste management facilities, including small plant, mobile plant and devices located on producer premises.

Potential emissions from clinical waste sites include:

- pathogenic micro-organisms
- chemicals and pharmaceuticals
- body fluids (faeces, urine, blood)

This guidance includes additional measures for monitoring these emissions

Note that *'How to comply with your environmental permit Additional guidance for: The Incineration of Waste (SGN 5.01)'* contains additional standards and measures for emissions from incineration processes.

Pathogenic- micro organisms (treatment only)

Clinical waste may contain pathogens. Microbial emissions must therefore be minimised and monitored. Examples of may include:

Emissions to air from

- breached packaging during manual handling procedures,
- the treatment process, particularly during shredding of untreated waste,
- cleaning and .disinfection of mobile rigid containers.

transmission beyond the site boundary by

- infection or contamination of staff or visitors, for example footwear and clothing being taken home by staff.
- infection or contamination of, or the removal of infected material by, pests or vermin,
- the return of contaminated waste containers to healthcare premises,
- by poor loading or packaging causing leakage from or contamination of vehicles.

Appropriate Measures

1. You must have operating procedures to identify, prevent and control potential emissions of pathogens. Note, the use of Personal Protective Equipment reduces the risk from but does not control or prevent the emission.
2. You must monitor emissions of bio-aerosols from your treatment process using spore tracers and the procedures provided in Annex 3.
3. Prevent bioaerosol emissions from point sources where practicable, by the appropriate use of high efficiency particulate air (HEPA) filters.
4. Effectively maintain HEPA filters to ensure a minimum particle removal efficiency of 99.97% for all particles of 0.3μm diameter.

Emissions monitoring

5. Put procedures in place to allow for the safe removal and disposal of HEPA filters.
6. Any plant that macerates/shreds clinical waste that has not already been rendered safe shall also be designed and built specifically to ensure microbiological aerosol containment. For example, include operation under negative pressure, with air drawn away from the hopper entrance and passed through HEPA filters. Hoppers must have doors on the opening to retain aerosols. The doors must be closed whilst the shredder is operating.
7. Releases to foul sewer are less likely to present a risk, however monitor such releases during spore tracer tests to identify failures in process integrity.

Chemicals and pharmaceuticals (treatment)

A wide range of pharmaceuticals and chemicals are used in healthcare. These may have a range of chemical risk phrases, and will occur in some clinical waste streams. If processed these can result in emissions of volatile chemicals to air or, via condensers, to foul sewer.

Permitted wastes and waste acceptance procedures shall prevent waste containing chemicals or pharmaceuticals entering the treatment process. Abatement can then be used to contain any residual emissions.

Appropriate measures

1. You must implement the waste acceptance procedures from section 2.2 of this document.
2. Install suitable abatement devices to remove residual emissions.
3. Where a treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged) **OR** where the waste acceptance procedures from section 2.2 of this document have not been implemented in full;
   - Conduct regular monitoring for chemical and pharmaceutical emissions.
   - You must propose benchmarks based on an assessment of the range of chemicals and pharmaceuticals in use, their occurrence and concentration within the waste, their properties and behaviour when subjected to the process. Agree these benchmarks with ourselves.
   - Carry out chemical and pharmaceutical emissions monitoring annually, as a minimum, or more frequently if emissions are > 10% of benchmark levels.

Emissions monitoring

Discharges to foul sewer

Appropriate measures

1. Discharges to foul sewer must be in accordance with a trade effluent consent issued by your sewerage undertaker. These might include
   - waste compactor runoff
   - vehicle washing
   - vehicle oil and fuel leaks
   - washing of reusable sharps bins
   - washing of clinical or offensive waste carts
   - spills and leaks in waste storage areas
2. Waste compactor run-off must be direct to foul sewer. Discharges to surface water or storm drains are not acceptable.
3. Vehicle washing and cleaning must be done in accordance with our Pollution Prevention Guidelines on vehicle washing and cleaning (PPG13). The washwaters must be directed to foul sewer and not, for example where a vehicle is washed on a road, to surface or storm drains.
4. Manage oil and fuel leaks from vehicles in accordance with Pollution Prevention Guidelines on Use and Design of Oil Separators in Surface Water Drainage Systems (PPG3)
5. Do not discharge sharps or pharmaceuticals from the washing of reusable sharps bin to foul, surface water or storm drainage.
6. Only discharge to foul sewer wash waters from the cleaning of clinical or offensive waste carts. This must meet any limits on effluent constituents in the consent, and may require pre-treatment.
7. The contents of clinical waste containers must not enter foul, surface or storm drainage systems. Spilt or leaked material (including fluids) must, rather than being disposed of to sewer, be cleaned up and disposed of at a suitably authorised waste management facility.

Microwave emissions monitoring

Appropriate measures

1. If you operate a microwave facility, you must be aware that failures in containment might result in leakage of non-ionising radiation and have operational procedures to check for such leakage at regular intervals.

4

Annexes

Annex 1-Site commissioning validation for clinical waste treatment

4. Annexes

Annex 1- Site commissioning validation for clinical waste treatment

1.1 Introduction

Read this annex in conjunction with section 2.3 of this document.

This annex contains the standards and appropriate measures for demonstration of disinfection efficacy for clinical waste treatment devices.

These take precedence over procedures provided by manufacturers or suppliers.

We recommend you employ a qualified, independent microbiologist and an accredited laboratory for this work.

Additional measures are also provided for the treatment of:

- anatomical wastes
- medicinally contaminated wastes (including sharps)
- chemically contaminated wastes.

1.2 The validation report

Appropriate measures

1. Your validation report shall, as a minimum, contain the following information:
   - a description of the treatment process and the parameters tested during validation
   - the waste types and quantities included in each test
   - who participated in the testing, their roles, and when the testing was done
   - the site validation methodology and outline laboratory analytical methods
   - parametric records from the treatment device
   - test organism documentation/certification
   - biological emissions monitoring methods (see Annex 3)
   - test results, including raw data, calculations used, and any conclusions drawn
2. Ensure that your report demonstrates that
   - the STAATT level III criteria are achieved for the worst case scenario challenge load
   - parametric controls, and procedures for real-time monitoring and assessment of treatment outputs, are in place and can be related to microbial efficacy
   - process emissions, including emissions from the macerator/shredder (see Annex 3), are contained.
   - routine monitoring procedures, where they differ, are effective and have been proven comparable to validation procedures during site commissioning.

Annex 1- Site commissioning validation for clinical waste treatment

1.3 Selection of test organism

Appropriate measures

1. The spore species, strain and certification must be appropriate for the treatment process.
2. For thermal processes the Level III tests must be performed using either *Bacillus atrophaeus* OR *Geobacillus stearothermophilus* (as appropriate). Perform level IV tests performed using *Geobacillus stearothermophilus.*
3. Use *Bacillus atrophaeus for chemical processes.*
4. Employ a single batch number of spore strips/ pore suspension during commissioning.
5. Where spore strips are used, each must contain ≥ 1 x 10^6 spores.
6. For thermal processes the spores must have a certified thermal D-value ≥ 1.8 minutes
   - at 121°C wet heat (Geobacillus stearothermophilus)
   - at 160°C dry heat (Bacillus atrophaeus)

   Spores with Lower D-values must not be used.
7. For chemical processes, where the D-value for the chemical disinfectant is not available, you must determine it and show that it is comparable to values reported in the literature.
8. For thermal processes, the spores shall always be supported by the parallel use of thermal indicator strips (time **and** temperature) or multi-point thermal data loggers co-located in the waste load. The time/temperature combination used must be indicative of the required microbial inactivation being achieved (that is93°C for 10 minutes is insufficient).

1.4 Challenge load

Appropriate Measures

1. You must measure the efficacy of disinfection using a **worst case challenge load** that is inserted into a **typical waste load**. This may vary depending on the nature of the process.
2. The **typical waste load** must be the maximum waste quantity (Kg) that you intend to process (batch quantity or throughput rate) and include all the waste streams that the process is authorised to treat. The use of surrogate waste is not normally appropriate.
3. The 'treated' clinical waste from the validation shall be considered untreated until the validation report is approved by us. You may dispose of it as untreated waste elsewhere in the interim.
4. **Worst case challenge load** is discussed in the following text.

Annex 1- Site commissioning validation for clinical waste treatment

The three main options for worst case challenge load are set out below for:

- pre-maceration thermal technologies where spore strip integrity can be guaranteed;
- other thermal technologies where spore strip integrity can be guaranteed, and
- chemical disinfection technologies.

(No procedure is provided for thermal technologies where spore strip integrity cannot be guaranteed. The method for this would be based on the use of spore suspensions.)

Appropriate measures for microbial validation for pre-maceration thermal technologies where spore strip integrity can be guaranteed

This applies **only** to thermal technologies that **both** macerate prior to disinfection **and** where the test materials can be inserted easily into the macerated waste prior to it entering the disinfection process. An example of this type of process would be a hot oil augur.

Spore Strip Containment

1. Spore strips are placed in spore carriers designed to mimic normal conditions in the waste being treated. The type of carrier may depend on the technology and the type of waste treated. Examples may include net bags, tennis balls with holes in them, socks, plastic containers with holes in or alloy containers with holes in.
2. Where spore strips are placed in metal containers they must be wrapped in a thick layer of cotton wool, or equivalent, to prevent direct conduction of heat from the metal.
3. Spore carriers shall be loose in the bulk of the waste, and must not be fixed in position or placed in test ports. This would not be representative of treatment to which the waste is subjected. If this is a concern use spore suspensions instead.
4. Undertake separate testing if you intend to use fixed carriers for routine monitoring to demonstrate that there is no significant difference between the two methods.

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Appropriate measures for microbial validation for other thermal technologies where spore strip integrity can be guaranteed.

This applies **only** to thermal technologies that do not macerate prior to disinfection, (for example autoclaves).

Spore Strip Containment

Clinical waste commonly contains a range of items of varying size, composition and robustness. Where there is no pre-maceration then the treatment may experience some difficulties in penetrating waste items, containers and voids in the load. The worst case challenge load is designed to test this using the toughest items commonly found in clinical waste. Prepare challenge loads as follows :

1. Fix spore strips in the centre of filled, sealed suction canisters and chest drains.
2. You may use a number of types of suction canisters and chest drains; however you must demonstrate that the type(s) chosen include the most resistant type(s).
3. At least one third must be robust rigid ≥2 litre suction canister/chest drain containers made of thermostable plastic, containing at least 1.5 litres of fluid and thermally stable gel.[1]
4. Other challenging items identified, where heat penetration may be inhibited (for example lengths of tubing, inside syringe bodies in sealed sharps boxes etc) may also be included.
5. Place challenge items inside worst case packaging. For example, sealed rigid yellow bins and sealed clinical waste bags.
6. Where challenge items are likely to occur together in numbers, the test package shall reflect this. For example the chest drain containing spore strips might be placed in a yellow rigid bin with a number of other chest drains.
7. Distribute the test packages throughout the waste load, ensuring that during the validation the position is varied to assess different cart positions, different locations within an a cart, and so on, to identify areas where thermal treatment may be challenged.

Appropriate measures for microbial validation for chemical disinfection technologies

This applies to all chemical technologies, and assumes that the technology either macerates the waste prior to or during exposure to the disinfectant.

Spore Suspensions

1. You must use spore suspensions for testing all chemical disinfection technologies. Spore strips must not be used because the envelope may affect the interaction between the

Annex 1- Site commissioning validation for clinical waste treatment

spores and inhibitory substances, disinfectants or neutralising agents.

2. You must add sufficient spore suspension to each test run to produce ≥ 1 x 10^6 spores per gram in the mass of the whole waste load.
3. Add the same total quantity of spore suspension to each control/test run even if the mass of waste differs slightly between them.

Interfering Substances

You disinfectant may be inhibited by organic matter, chemicals or other substances present in the waste.

4. Validate your process with a typical clinical waste load to which has been **added** a minimum of 5% strong organic load (for example blood) by weight. This can be achieved, for example, by adding an **additional** box of theatre suction canisters containing 15L of blood to a 300kg waste load.
5. Identify what other substances may interfere with or inhibit your disinfectant, and whether they may be present in the waste.
6. Interfering substances, including blood, must be included with the test packages at the maximum concentration they can occur at in any individual waste container.
7. Where the waste load is less than 250 kg the potential for random variation, and greater extremes, of organic concentration is greater. Where a process is authorised to process blood products, for example transfusion bags, the organic concentration may be much higher. In those circumstances 5% may be insufficient and higher concentrations considered.

Containment

The containment below is indicative and maybe affected by process specific factors.

8. Prepare sufficient small sealed vials or bottles (≥ 6) of spore suspensions to enable their distribution in a number of test packages.
8. Attach these securely to the outside of suction canisters containing blood and place each of these in their normal packaging (for example one in a group of six in a cardboard box).

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1.5 Test format

Appropriate measures for the microbial validation of thermal technologies where spore strip integrity can be guaranteed.

Test Runs

The efficacy of the plant is assessed as follows:

1. Test a minimum of three separate treatment cycles if your plant processes the waste in batches/cycles.
2. For continuous technologies do the tests in three separate groups. The test packages for one collection being inserted and retrieved before the next set of tests is introduced to the treatment plant.
3. Repeat the tests for each cycle format you wish to operate.
4. The minimum number of 'spore strips recovered' is set out in table A1.5. If less than this number is recovered conduct more tests until this number is reached. If you expect to lose some spore strips we recommend that you use more to ensure that this minimum number is recovered. Otherwise use spore suspensions instead.

Control Data

5. Hold a minimum of six untreated spore strips outside the device and analyse them as controls.

Laboratory Methods

6. These will be partly determined by the test organism, the method specified by the spore supplier, and reference to other guidance on microbiological methods.
7. 100% of each test sample must be analysed. This is not required for control samples, where serial dilution will be required.
8. Analysis must be quantitative and report number of spores per spore strip.

Appropriate measures for the microbial validation of chemical technologies

This procedure requires both:

- a control run
- a number of test runs

Note: Add the same total quantity of spore suspension to each control and test run even if the mass of waste differs slightly between them.

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Control Run

1. Perform a control run where waste is passed through the device with the thermal/chemical treatment inactivated. This provides an estimate of spore recovery.
2. The control run is required because of the 'natural' loss of spores during the process and subsequent analysis.
3. Clean the device thoroughly cleaned to remove residual traces of disinfectant prior to conducting the control run.
4. For health and safety reasons you may use thermally treated clinical waste, or a surrogate waste that closely resembles the test run clinical waste, for the control run

Test Runs

The efficacy of the plant is assessed as follows:

5. If your plant processes the waste in batches/cycles test a minimum of 3 separate treatment cycles.
6. For continuous technologies carry out the tests in three separate groups. The tests packages for one collection being inserted and samples retrieved before the next set of tests is introduced to the treatment plant.
7. Repeat the tests for each cycle/batch format you operate.
8. The minimum number of samples recovered is set out in table A1.5.
9. Collect sub-samples of the treated waste from throughout the load and analysed separately. For a continuous process this might include samples taken from the initial, middle and final part of the process discharge.
10. Each sub-sample must equate to at least 0.1% of the waste load, with the minimum sub-sample size set at 50g for smaller units. The sub-sample size must therefore equate to a minimum of 5×10^7 spores.
11. You may test a larger number of smaller sub-samples as an alternative, as long as the total quantity tested is consistent with points 8 and 9.

Laboratory Methods

Analysis is complex, the following being an indication of a typical procedure. Seek expert advice before conducting such analysis.

12. Analyse the control and test runs using the same procedures.
13. Preserve samples appropriately until received by the laboratory and subjected to testing. The testing must commence within an appropriate time scale. The entire sub-sample is mixed with excess sterile physiological saline for at least 15 minutes on an orbital shaker. (Note that neutralising buffer may be required for chemical treatments).

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14. The liquid is decanted through a sterile coarse fabric filter to remove solid waste.
15. The liquid is centrifuged at 3000g for 20 minutes to deposit the spores.
16. The deposit is resuspended in 10 ml of brain heart infusion broth (BHI). (additional washing of the deposit in saline/buffer may be necessary prior to this step).
17. Serial dilutions are made in BHI from 1:10 to 1: 1,000,000.
18. The entire test of each sample must be analysed, typically on pour plates. This is not necessary for the control samples.
19. Plates are incubated in a moist chamber at the conditions appropriate for the test organism

Table A1.5: Minimum number of spore strips or samples recovered, required for microbial validation of Alternative Treatment Plants.

	Minimum number of samples (spore strips)			Minimum number of samples (spore suspensions)		
Single Load Capacity (Kg) Continuous throughput (Kg per Hour)	recovered per cycle or collection.	recovered for each cycle format	retained as controls	recovered Per Test Run	recovered for each cycle format	recovered per Control Run
0-10 kg	3	9	6	3	9	3
11-50 kg	4	12	6	3	9	3
51-250 kg	6	18	6	4	12	4
251-500kg	8	24	6	4	12	4
501-750kg	10	30	6	5	15	5
>750 kg.	12	36	6	5	15	5

Annex 1- Site commissioning validation for clinical waste treatment

1.6 Data analysis and validation criteria

Appropriate measures for Microbial Disinfection Efficacy – Spore Strips

Control Data

For the control data, calculate and record the following:

1. the number of spores (cfu) recovered from each individual control spore strip;
2. the mean number (X_C) of spores recovered from the control strips;
3. the $\log_{10}$ of (X_C);
4. subtract 4 from the $\log_{10}$ of (X_C) to generate the **pass criteria**.

The subtraction of 4 is the 4 $\log_{10}$ reduction for STAATT Level III criteria. (Note: for the treatment of certain biohazard wastes a 6 $\log_{10}$ reduction is required so your pass criteria is ($\log_{10}$ (X_C)-6)).**Test Data**

For the <u>combined</u> test runs calculate the following:

5. the number of spores recovered from each individual test strip;
6. the mean (X_T) number of spores recovered;
7. the standard deviation (σ) of spores recovered;
8. the Upper 95% (Lu) confidence interval of (X_T) (this will be approximated by $X_T + 1.96\sigma$);
9. the $\log_{10}$ of the Upper 95% (Lu) confidence interval of X_T. ($\log_{10}$Lu).
   (note if Lu = 0, then use '0' for $\log_{10}$Lu)

This must include **<u>all</u>** the recovered test strips. If contamination is suspected either retest the sample or, if that is not possible, include the results in the data analysis.

Interpretation

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

10. the $\log_{10}$Lu for each run must be less than or equal to the pass criteria
11. $\log_{10}(X_C)$ must be ≥ 5.
12. 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 >97.5% probable that the worst case items present in any clinical waste will be treated to the minimum standard.

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A1.6.2: Worked Example

Control Data

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 10^6 cfu respectively (X)
2. The mean (X_C) of spores recovered from each control strip = 1.0 x 10^6
3. The $\log_{10}$ of (X_C) = 6
4. The **Pass criteria** = $\log_{10}$ of (X_C) – 4 = 2 (Level III criteria)

Test Data

Three test runs were undertaken, each with 3 test strips. All were recovered and analysed.

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
6. The mean (X_T) of colonies recovered from each spore strip = 8.33 cfu
7. The standard deviation (σ) of the results = 13.63 cfu
8. The upper 95% (Lu) = 8.33 + (1.96*13.63) = 35.04 cfu
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)
- $\log_{10}$ (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 STAATT Level III criteria have therefore been successfully demonstrated.

Annex 1- Site commissioning validation for clinical waste treatment

Appropriate measures for Microbial Disinfection Efficacy – Spore Suspensions

If you have used spore suspensions you may need to correct the data to allow for differences in the total mass of waste used in each control and test run.

Control Data

1. Determine the results from the controls samples using the procedures given for spore strips.
2. Instead of determining how many spores are present in each control spore strip determine how many are present per kg of control sample.
3. Record the Mass (M_C) of waste used in control run in Kg.

Test Data

4. Determine the results from the test samples using the procedures given for spore strips with the following exception.
5. Record the mass of waste used to load each of test runs in Kg (M_{T1},M_{T2},M_{T3}).
6. Determine the individual results (cfu) from step 5 of the procedure for spore strips per kg of test sample and then multiplied by

$$\frac{M_{T(1,2,\text{or 3 as appropriate})}}{M_C}$$

before proceeding to step 6 of the spore strip procedures. This corrects for differences in mass between test or control runs.

1.7 Worst case scenario considerations for specific circumstances

There are specific circumstances where the worst case scenario needs to be considered further in the context of the specifics of plant operation.

Appropriate measures -

Treatment plants located on a producer premises, operated by that producer, and only treating waste from that producer premises.

1. We recommend you use the 'general' worst case challenge load, particularly for mobile plant. However you may use the worst case challenge load for that producer or department.
2. You must ensure your waste acceptance checks (see 2.2) include identification of waste case challenge load from each source department or unit.
3. Note: implementing segregation (in addition to that in HTM 07 01) to remove the worst case scenario waste items, which a device is unable to treat, is **not**, acceptable as an equivalent measure.
4. It is not necessary to include worst case challenge items that are too big to be placed in the

Annex 1- Site commissioning validation for clinical waste treatment

treatment chamber.

1.8 Anatomical, pharmaceutical and chemically contaminated wastes

See text in Section 2.1 of this document on permitted wastes.

Appropriate measures

Anatomical wastes

1. Demonstrate that your process achieves a tissue destruction equivalent to that achieved by incineration.

Medicinally contaminated wastes (including sharps)

2. Conduct a review of the available scientific literature, to determine if your process parameters are technically capable of destroying waste containing the range of pharmaceutical contamination that is likely to occur. Submit this as part of a justification to support your application to treat such waste.
3. If you operate an installation subject to IPPC or BAT requirements, supply a detailed justification to demonstrate that the treatment of medicinally contaminated waste in your process is consistent with these requirements.
4. Assess the efficacy of your plant in treating pharmaceutically contaminated waste during site commissioning.
5. We recommend that you use the available literature and small scale laboratory trials to assist in your selection of worst case challenge load pharmaceuticals. Also consider what detection methods are available and appropriate.
6. Site commissioning, like microbiological tests, shall include:
   - a control run
   - a minimum of three test runs
   - at least 3 worst case pharmaceuticals.
7. The seeded dose of each pharmaceutical must be sufficient to raise the levels in the treated waste significantly above both the limit of detection (from waste material of this type) for the analytical method used, and the background level of any potentially interfering pharmaceuticals in the waste.
8. Chemical tracer dyes, that are stable in the process, shall be introduced with the pharmaceuticals (normally mixed with them before introduction), to demonstrate the degree of homogeneity in the treated waste, and to inform/assess the design of sampling

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protocols. Results showing relatively high levels of tracer dye and low levels of pharmaceutical may be indicative of loss of the pharmaceutical.

9. Consider analysing for the breakdown products from the destruction as a means of secondary confirmation of destruction. This will allow for background levels and other sources of interference.
10. Provide an assessment of the measured and possible effect on process emissions of treating this material. The primary objective is to prevent or reduce emissions, before considering abatement of those that remain
11. If you are proposing to use a chemical treatment, include an assessment of the potential for reactions between pharmaceutical chemicals and the treatment agent.
12. 'Dilution' of medicines with large quantities of other waste or processing only 'small quantities' does not equate to efficacy of treatment, is unlikely to be consistent with BAT, and may affect the classification and coding of the treated waste (see Annex 4).

Chemically Contaminated Wastes

Clinical wastes, particularly from laboratory areas, may contain chemicals with hazardous properties. A full discussion of this issue is beyond the scope of this document. However:

13. 'dilution' of chemicals with large quantities of other waste or processing only 'small quantities' does not equate to efficacy of treatment, is unlikely to be consistent with BAT, and may affect the classification and coding of the treated waste (see Annex 4).

Annex 2- Routine efficacy monitoring (microbial)

Annex 2- Routine efficacy monitoring (microbial)

Monitor routinely all clinical waste treatment devices throughout their operational life to ensure that microbial inactivation performance is maintained.

Appropriate measures where monitoring using spore strips is appropriate

1. The minimum frequency of monitoring is specified in Table B1. Monitoring must be scheduled and evenly spaced throughout the calendar year.
2. The methods used for routine monitoring shall be the same as that used for site commissioning validation, unless an alternative method was demonstrated by parallel testing during commissioning to produce the same results.
3. For thermal processes, thermal indicator strips or multipoint data loggers must always be used in parallel where possible.
4. Spore strips can be quantitatively (population of >1 x 10^6) or qualitatively population of (>1 x 10^4) tested. Controls and certificates from the test batch shall also accompany each set of samples.
5. The criteria for success are as follows:
   - investigate each individual 'fail' result as soon as possible;
   - 95 % of the individual spores strips, in the first six months of operation, and each subsequent calendar year, must demonstrate 4 $\log_{10}$ inactivation or higher (quantitative) or no growth (qualitative);
   - thermal indicator strips must accompany each spore strip and indicate that the minimum time and temperatures have been achieved for 99% of spore strips;
   - prepare, for each calendar year. a summary report that indicates the results obtained and any failures. Reference the data to the validation report to demonstrate that commissioning treatment efficacy, rather than minimum standards, are being achieved;
   - where >5% (or 1, whichever is greater) of qualitative spore strips exhibit growth in any calendar year quantitative testing must be used for the next calendar year.
6. These criteria must include all scheduled monitoring results. The percentage allowance has been provided to allow for both potential contamination and the uncertainty of microbial data. Do not include additional investigative results.
7. Cease plant operations if at any point during the calendar year the number of failure exceeds the annual 5%, until such time as the cause can be identified and the plant recommissioned (see Annex 1.)
8. In any circumstances, where you become aware that one or more batches of waste may not have been treated to the required standard, you are expected to take appropriate action and manage the waste as untreated.

Annex 2- Routine efficacy monitoring (microbial)

Table B1 - Routine Monitoring of Microbial Inactivation where the use of spore strips is appropriate				
Continuous hourly throughput or batch cycle load.(kg)	**Test frequency (first six months of operation)**	**Test frequency (operational, after the first six months)**	**Minimum number of spore strips or sub-samples**	**Number of control strips**
0-50kg	monthly	quarterly	3	1
51-500 kg	fortnightly	every two months	3	1
501-1000kg	weekly	monthly	3	1

Appropriate measures where spore suspension testing is required

1. The minimum frequency of monitoring is specified in Table B2.
2. The methods used for routine monitoring must be the same as that used for site commissioning validation, unless an alternative method was demonstrated by parallel testing during commissioning to produce the same results
3. For thermal processes, thermal indicator strips or multipoint data loggers must be used in parallel where possible.
4. Quantitative enumeration of spore suspensions with a certified population is required.
5. A single control run is required.
6. The number of test runs and sub-samples per test run is indicated in Table B2.
7. In other respects: the procedures in section and the quantitative criteria for success from the section on spore strips apply.

Annex 2- Routine efficacy monitoring (microbial)

Table B2 - Routine Monitoring of Microbial Inactivation Where Suspension testing is required				
Continuous hourly throughput or batch cycle load.(kg)	**Test frequency (first six months of operation)**	**Test frequency (operational, after the first six months)**	**Number of sub-samples per test run**	**Number of test runs**
0-250kg	six-monthly	annually	3	1
251-750 kg	six-monthly	annually	3	2
751+kg	quarterly	six-monthly	3	3

Annex 3- Emissions monitoring and benchmarks

Annex 3- Emissions monitoring and benchmarks

Microbial emissions from technically sound clinical waste treatment plants, operated under good practice with robust waste acceptance, appropriate containment, and treating suitable wastes should be low.

Demonstrate that emissions from the plant are controlled during both site commissioning and more importantly during routine operation.

This annex provides standards and measures for microbial emissions only.

Also consider our guidance on monitoring of particulate matter in ambient air around waste facilities (M17).

Chemical and pharmaceutical emissions monitoring is not required where pre-acceptance checks are performed in accordance with section 2.2 of this document **and** such wastes are not processed.

3.1 Microbial emissions monitoring

Microbial monitoring is required, as there is the potential for aerosols/body fluid splashes containing pathogenic organisms to be released during the operation of alternative waste treatment plants. Potential sources include:

- during maceration of untreated clinical waste
- the release of exhaust gases
- during maceration of treated clinical waste
- failures in plant integrity.

One of the problems associated with such monitoring is the variation of types and number of microbes within the load. Determining which ones to monitor for, and the quantitative relevance of any detected, is difficult to ascertain. Several types of microbes may arise from other sources and therefore be unrelated to plant emissions.

The following procedure using tracer spore suspensions is recommended. These spores are very unlikely to arise from any other environmental source, although it is possible that some may be present within clinical waste received on the site. The large number of spores used in this method makes the procedure very sensitive.

Monitoring using other indicators may be undertaken. This is as an alternative to tracer spore suspension, where you can demonstrate that these indicators arise solely from the waste present on site (and not from environmental sources), and in numbers sufficient to give equivalent sensitivity.

Annex 3- Emissions monitoring and benchmarks

The procedures for such monitoring must be agreed with us prior to implementation.

Appropriate measures:

Microbial emissions monitoring using tracer spore suspension.

For technologies that shred or macerate the waste prior to treatment

1. Prepare and dispense (in a laboratory environment), a dry or liquid suspension of bacillus spores in a number of sealed, small volume plastic containers. Dispersed these throughout the waste load and processed.

For other technologies

2. Prepare and dispense (in a laboratory environment), dry or liquid suspensions of bacillus spores **both** loosely on dressings in waste inside containers (bags, boxes and so on), and inside worst case challenge load containers (suction canisters/chest drains). These shall be dispersed throughout the waste load and processed.
3. Never use spore strips for bioaerosol emissions monitoring.
4. The quantity of spores must equate to a minimum of 1×10^6 spores per gram of total waste load.
5. Test all devices, during commissioning validation, during the first six months of operation and periodically thereafter as indicated in Table C1.
6. Continue process emission monitoring throughout the operational life of the plant.

Frequency of Testing

7. The minimum frequency of monitoring is specified in Table C1.

Sampling Methodology

8. The sampling must consist of **both** air monitoring **and** surface monitoring.
9. The number of samples and location of sampling points will depend on the nature of the process and size of the device. Recommended sample locations are specified under the respective headings of Air Monitoring, Surface Monitoring and Wastewater Discharge Monitoring.
10. The sampling programme must be designed to take sufficient samples to enable the results to be quantitatively related to the input dose.
11. Take samples:
    - prior to the processing of the seeded waste (controls);

Annex 3- Emissions monitoring and benchmarks

- at intervals during the processing of the seeded waste (the intervals shall relate to process stages and timing of potential emissions);
- periodically thereafter for at least 2 hours after the cycle is complete;

12. The aim of the monitoring programme is to produce a quantitative 'estimate' of the total number of tracer organisms emitted from the device relative to the input dose by each route.

Air Monitoring

13. Conduct air monitoring around identified point source emissions from the process, as well as at the site boundaries, and at any other relevant locations within the site – for example open vehicle access doors to building within which the plant is located.

14. Key examples of emission sources:-

Point Source Emissions

The main point source emission to air is from the venting of exhaust gases. Exhaust gases must always be treated (for example filtered through a HEPA filter). Monitoring is required to demonstrate that the treatment of the gases has been effective and shall take place at each emission point.

Sources of fugitive Emissions include:

i) Maceration of untreated clinical waste. This is potentially the most significant source of pathogenic bioaerosols. Monitoring must demonstrate that containment measures in place are effective.

ii) Maceration of treated clinical waste may also result in the generation of bioaerosols as treatment is required to reduce the number of micro-organisms rather than eliminate them. This monitoring must demonstrate if additional containment measures are required.

iii) Maintenance or access ports. Monitoring is necessary to ensure that these do not compromise the integrity of the plant, that they are effectively sealed during operation, and that emissions are not released. Failed seals and joints may also result in emissions.

iv) Bin washing. Physical cleaning of mobile containers may result in the generation of pathogenic bioaerosols. Chemical agents used for disinfection may also become aerosolised. This monitoring must demonstrate if additional containment measures are required by contaminating these containers with a liquid 'spill' of not less than 100ml and equivalent to 1 x 10^6 spores per gram of waste typically present in the cart.

15. It is recommended that active (centrifugal/vacuum) impaction onto agar using Anderson or slit samplers, or equivalent, is used to sample for bioaerosols. Data submissions must

Annex 3- Emissions monitoring and benchmarks

contain information indicating the recovery efficiency of the method used.

16. Conduct monitoring throughout the emissions monitoring exercise, and with individual sample times to coincide with steps in the process where emissions may occur (for example the passage of seeded waste through a shredder).

Surface Monitoring

17. To support the air monitoring outlined above, it is recommended that settle plates are employed in large numbers to form a grid-like pattern around the device/site.
18. The exposure time for each plate, and replacement frequency during testing, may need to consider both contaminants and total microbial load.
19. Use a regular exposure time, a series of plates at each sampling point, and a grid placement to calculate the total number of organisms that have settled per hour during the monitoring period for:
    - each grid square, and
    - for the whole site.

This can be compared to the input dose to provide a quantitative release estimate for the process.

Wastewater Discharge Monitoring

20. Where the process produces a wastewater this must also be monitored at intervals during the testing. For chemical processes, consider the potential need for neutralisation of disinfectant.
21. The purpose of this additional monitoring is to ensure that both the:
    - treatment process is operating effectively
    - wastewater arises post treatment.

Sample wastewater prior to entering the drainage system as near to the point of origin as possible.

Annex 3- Emissions monitoring and benchmarks

Table C1 - Process Bioaerosol Emissions Monitoring when a suspension of Bacillus Spores has been used				
	First six months	**Subsequently (if proven and agreed)**	**Minimum no. of sampling points**	**Minimum no. of samples per sampling point**
For devices which shred/macerate untreated waste	During site commissioning	annually	see text	see text
For other devices	During site commissioning	every four years	see text	see text

3.2 Criteria for success

Monitor and react to changes, trends and patterns in emissions. For example a gradually increasing trend around the site may require improvements in site procedures generally, whilst a sudden increase of emissions around the shredder may indicate a failure of a specific containment feature.

3.3 Emission benchmarks

Table C3 details emission benchmarks for point source emissions from the clinical waste site.

These best practice benchmarks are not mandatory release limits.

Table C3 : Emission Benchmarks			
Emission	**Measure**	**Cfu**	**Unit**
Air – sample points <10m from the treatment plant.	Bacillus spores	1000[2]	Per cubic metre[1]
Water	Bacillus spores	(300)[2]	Per litre[1]
Note 1: These units relate to the overall monitoring period so the cfu benchmark applies to each individual sample of air or water taken, with a calculation made to report the result per cubic metre or litre. These are based on a seeding dose of 1 x 10^6 spores per gram of waste load, and would need to be adjusted if the seed dose were higher or lower. Note 2: These benchmarks are indicative only, and will be reviewed periodically.			

Annex 3- Emissions monitoring and benchmarks

Table C4 provides additional guidance with respect to fugitive emissions from the site; these can be used to support the emission benchmarks in Table C2.

Table C4 : Emission of spiked organisms			
mission	**Measure**	**Cfu**	**Unit**
Air – sample points>10m from the treatment plant.	Bacillus spores	300	Per cubic metre[1]
Surface – sample point < 10m from the treatment plant.	Bacillus spores	$(20000)^2$	Per square metre per hour [1]
Surface – sample points > 10 m from the treatment plant.	Bacillus spores	$(5000)^2$	Per square metre per hour [1]

Note 1: These Units relate to the overall monitoring period so the cfu benchmark applies to:

- Each individual sample of air or water taken, with a calculation made to report the result per cubic metre or litre.
- For each individual settle plate (this is not an average) a calculation made to adjust for surface area of a settle plate and exposure time (for example if settle plates are deployed for only 15 minutes of every hour then the result must be multiplied by 4),
- These are based on a seeding dose of 1×10^6 spores per gram of waste load, and would need to be adjusted according if the seed dose were higher or lower.

Note 2: These benchmarks are indicative only and will be reviewed periodically.

Annex 4- The classification and coding of waste from clinical waste treatment

Annex 4- The classification and coding of waste from clinical waste treatment

This section provides guidance on the coding classification of waste from the treatment of clinical waste.

Table A4: The Classification and coding of waste from clinical waste treatment

Appropriate codes	Inappropriate codes
Scenario 1: The plant treats only the infectious waste listed in Table 2.1a	
The waste may be coded either as • 19 02 06 (sludges) • 19 02 10 (combustible wastes only) • 19 02 99 (where these classifications are not appropriate)	19 02 03 – do not use. This would require that all the wastes entering the process were non-hazardous 20 03 01- do not use. Waste from a physico-chemical treatment plant is classified under chapter 19 02.
Scenario 2: The plant treats waste containing chemicals or pharmaceuticals	
If the hazardous waste contains chemical(s) or pharmaceutical(s) that possesses one or more hazardous properties • 19 02 04*	19 02 03 and 20 03 01, see above 19 02 06 and 19 02 99 only consider if it has been demonstrated during validation that the process treats (rather than dilutes) the pharmaceuticals and chemicals.
Scenario 3: Process failures	
Wastes that have been mixed and incompletely treated are coded as19 02 04* Wastes that have not been treated at all retain their original code.	19 02 03, 19 02 06, 19 02 99 and 20 03 01
Scenario 4: Laboratory Autoclave (Infectious waste that is not shredded)	
Infectious healthcare waste (for example 18 01 03*) that is sterilised but not shredded in a laboratory autoclave becomes the non-infectious equivalent (for example 18 01 04)	

Annex 5- Section 2.1, Table 2.1 (permitted wastes)

Annex 5- Section 2.1, Table 2.1 (permitted wastes)

Section 2.1: Permitted Wastes (continued)

This section contains table 2.1 (including sub-tables 2.1a to 2.1c) and forms part of section 2.1 of this document.

Table 2.1a Waste types permitted for treatment (permitted activity D9)

Waste Code	Description
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03*[1]	wastes whose collection and disposal is subject to special requirements in order to prevent infection.
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*[1]	wastes whose collection and disposal is subject to special requirements in order to prevent infection.
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 99[1]	other fractions not otherwise specified (comprising only of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).

[1] In addition, the following wastes are specifically excluded from waste treatment activities:

(i) : **Any waste** containing waste medicines and chemicals, waste contaminated with cytotoxic and cytostatic medicines, anatomical waste (identifiable human or animal tissue arising from healthcare), or Dental amalgam;

(ii) : **Sharps boxes** containing any of the excluded wastes from (i) and (iii) or Sharps that are contaminated with pharmaceuticals in any quantity (including syringes that are fully discharged, partially discharged or undischarged).

(iii) : **Biohazard waste :** Any waste known or likely to contain ACDP Hazard Group 4 biological agents; Any waste from a containment level 3 laboratory: and All Microbiological cultures from any source, and, any potentially infected waste from pathology departments and other clinical or research laboratories (Unless autoclaved before leaving the site of production).

Annex 5- Section 2.1, Table 2.1 (permitted wastes)

Table 2.1b Waste types permitted for storage (permitted activities D15 and R13)	
Waste Code	**Description**
09	WASTES FROM THE PHOTOGRAPHIC INDUSTRY
09 01	wastes from the photographic industry
09 01 01*	water-based developer and activator solutions[2]
09 01 02*	water-based offset plate developer solutions[2]
09 01 03*	solvent based developer solutions[2]
09 01 04*	fixer solutions[2]
09 01 05*	bleach and bleach fixer solutions[2]
09 01 07	photographic film and paper containing silver or silver compounds[2]
09 01 08	photographic film and paper free of silver or silver compounds[2]
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	sharps (except 18 01 03) [3]
18 01 02	body parts and organs including blood bags and blood preserves (except 18 01 03) [3]
18 01 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) [3]
18 01 06*	chemicals consisting of or containing dangerous substances **(excluding X-ray photochemicals)**
18 01 07	chemicals other than those mentioned in 18 01 06 **(excluding X-ray photochemicals)**
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	medicines other than those mentioned in 18 01 08
18 01 10*	amalgam waste from dental care
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	sharps (except 18 02 02)[3]
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection. [3]
18 02 05*	chemicals consisting of or containing dangerous substances **(excluding X-ray photochemicals)**
18 02 06	chemicals other than those mentioned in 18 02 05 **(excluding X-ray photochemicals)**
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	medicines other than those mentioned in 18 02 07

Annex 5- Section 2.1, Table 2.1 (permitted wastes)

Table 2.1b (continued)	
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 31*	cytotoxic and cytostatic medicines
20 01 32	medicines other than those mentioned in 20 01 31
20 01 99	other fractions not otherwise specified **(comprising of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).**
	other fractions not otherwise specified **(comprising only of non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection)**[3]
[2] These entries are limited to photographic wastes arising from healthcare and/or related research. [3] These entries are limited to those wastes that are not described, packaged, labelled or transported as infectious or clinical wastes.	

Annex 5- Section 2.1, Table 2.1 (permitted wastes)

Table 2.1c Waste types permitted for incineration (permitted activities D10 and R01)	
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	sharps (except 18 01 03) [3]
18 01 02	body parts and organs including blood bags and blood preserves (except 18 01 03) [3]
18 01 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) [3]
18 01 06*	chemicals consisting of or containing dangerous substances **(excluding X-ray photochemicals)**
18 01 07	chemicals other than those mentioned in 18 01 06 **(excluding X-ray photochemicals)**
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	medicines other than those mentioned in 18 01 08
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	sharps (except 18 02 02)[3]
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection. [3]
18 02 05*	chemicals consisting of or containing dangerous substances **(excluding X-ray photochemicals)**
18 02 06	chemicals other than those mentioned in 18 02 05 **(excluding X-ray photochemicals)**
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	medicines other than those mentioned in 18 02 07
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 31*	cytotoxic and cytostatic medicines
20 01 32	medicines other than those mentioned in 20 01 31
20 01 99	other fractions not otherwise specified **(comprising of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).**
	other fractions not otherwise specified **(comprising only of non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection)[3]**
[3] These entries are limited to those wastes that are not described, packaged, labelled or transported as infectious or clinical wastes.	

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Annex 6-An example of a waste audit

Annex 6- An example of a waste audit

An Example of An Audit of A Ward

A hypothetical hospital consists of six departments

- accident emergency
- pharmacy
- oncology ward
- surgical ward
- day care unit
- laboratory (clinical chemistry, microbiology, cytopathology etc)

The hospital also has an exterior clinical waste storage yard.

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

The key objective of the audit is to identify the composition of each different clinical waste stream produced by the hospital (for example yellow lidded sharps boxes) by assessing the departments that use them. This enables waste descriptions and classifications to be derived. In particular the manager is seeking to establish if any waste stream from each unit contains:

- anatomical waste or other human/animal tissues, and if this is chemically preserved.
- Cytotoxic and cytostatic medicines and material, for example sharps, contaminated with them (the first step being that the hospital has implemented a system that allows staff to easily identify these).
- other medicines and material contaminated with them, for example sharps or medicated IV bags.
- dental amalgam
- chemicals, for example laboratory reagents and autoanalyser cartridges, handgels, and diagnostic kits.
- municipal wastes (flowers, magazines, food packaging, hand towels etc)
- municipal offensive hygiene wastes, for example feminine hygiene waste from lavatories.
- offensive hygiene wastes from healthcare (the first step being confirming that the hospital has implemented segregation of these wastes in the department of question)
- gypsum wastes other than the small proportion that are genuinely infectious (for example plastercasts from A&E and fracture clinics, dental moulds and podiatry moulds.

Annex 6- An example of a waste audit

When the manager audits the surgical ward they will:

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

The summary findings are as follows (full results not presented here):

- ward management or staff had little knowledge, involvement in or ownership of waste management;
- no anatomical waste or human tissue is produced in this department;
- four yellow lidded sharps boxes are present (one located on a treatment trolley for each bay, and one in the pharmacy area), these are observed to contain used syringes, associated medicine vials/bottles, and the odd swab;
- the labels on the boxes indicates '*18 01 03* and 18 01 09 clinical waste, mixed sharps and pharmaceutical waste for incineration*;'
- questioning of the staff also reveals that these boxes are used for dropped tablets and leftover controlled drugs;
- the separate audit of the main hospital pharmacy confirmed that they had implemented the definition of 'cytotoxic and cytostatic' and that injectable medicines of this type are sometimes prescribed to patients on the ward. However they are not labelled to enable staff on the ward to easily identify them. Ward staff were unaware of this and have no procedures to identify or segregate such waste, meaning that it is contaminating other waste streams.
- four orange bags are present (one located in the treatment area of each bay, and one in the on ward pharmacy), three are observed to contain clinical waste, one is observed to be too close to a hand-wash sink and public/patient areas. This one contains a few handtowels, some food wrappers and a newspaper.

Annex 6- An example of a waste audit

- questioning of the staff also reveals that ‘empty’ alcohol handgel, medicated IV bags and non-medicated IV bags are disposed of in the orange bag stream;
- the labels on the orange bags used indicated that they are suitable for carriage in bulk;
- the nursing office contains only a black bag, which contains only non-hazardous municipal waste items;
- the three black bags in patient areas contain only non-hazardous municipal waste items
- there is only one offensive waste bag in the ward toilet. This is being used for municipal hygiene products. No other municipal or clinical wastes were evident. No offensive waste segregation is in place in treatment areas, and such waste is being disposed of in the clinical orange bags;
- no pharmaceutical waste bin is in use. Unopened/reusable medicines are returned to the main hospital pharmacy, and opened medicines/loose tablets are disposed of in the sharps boxes;
- the waste types are kept separate in the locked storage room, and each type is collected separately on a daily basis by support staff, who take it directly to the main waste storage yard;
- In the waste storage yard there are designated areas, and colour coded wheeled carts, for each waste stream. Each container type is kept completely separate.
- medicines with hazardous properties have been identified by the main hospital pharmacy, those in use in this ward were noted for use on waste documentation.

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

- yellow lidded sharps boxes : 18 01 03*, 18 01 08* and 18 01 09: clinical waste, mixed sharps and pharmaceutical waste, including cytotoxic and cytostatic medicines, for incineration only;
- orange bags: 18 01 03*, 18 01 04, 18 01 06*, 18 01 09, and 20 03 01 Mixed infectious clinical waste, flammable chemicals, pharmaceutical waste, offensive waste and municipal waste;
- offensive waste bag : 20 01 99 Offensive waste;
- black bags: 20 03 01 Mixed municipal waste.

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

- cytotoxic and cytostatic drugs are clearly labelled when issued by the main hospital pharmacy, purple lidded containers are made available to the surgical ward, and staff are trained in appropriate procedures;
- alcohol handgel containers are either rinsed out and recycled as plastics or disposed of as hazardous chemicals;

Annex 6- An example of a waste audit

- the orange bag bins are repositioned so patients and visitors do not have access to them, and away from hand washing sinks, to prevent municipal waste entering the waste stream;
- offensive hygiene bags are introduced alongside the orange bags to capture the healthcare offensive waste stream, and remove it from the clinical waste stream;
- procedures for IV bags are altered so medicated IV bags are disposed of as pharmaceutical waste in a designated and labelled rigid container. Non-medicated IV bags (where not infectious) are emptied down the sluice and the packaging disposed of in the offensive waste stream.
- in addition one of the experienced ward staff is trained in internal waste management procedures, is assigned to conduct monthly audits of the ward, supports and trains ward staff, and communicates with the waste manager on waste issues.

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

- yellow lidded sharps boxes : 18 01 03*, and 18 01 09: clinical waste, medicinally; contaminated sharps and pharmaceutical waste, (not including cytotoxic and cytostatic medicines), for incineration only;
- orange bag: 18 01 03*, clinical waste, infectious, suitable for alternative treatment. Suitable for carriage in bulk;
- offensive Waste Bags : 18 01 04 Offensive healthcare waste from human healthcare, 20 01 99 municipal offensive waste;
- black bag : 20 03 01 Mixed municipal waste;
- rigid Yellow Bin : 18 01 09 pharmaceutical waste for incineration only (medicated IV bags);
- cytotoxic and cytostatic bin: 18 01 08* and 18 01 03* cytotoxic and cytostatic waste, including sharps, for incineration only.

The final audit report from the hospital includes similar information from the other departments, an audit of the waste storage yard, and the additional elements from section 2.2 of this documents that are not addressed here.

Although the initial audit identified a number of common problems, the waste contractor has considerable confidence over the waste because;

- the audit has obviously been very thorough;
- problems were identified and were included in the final report;
- remedial measures were clearly carried out;
- a follow up audit contained results that confirmed their success.

Annex 7-Other relevant guidance and glossary

Annex 7- Other relevant guidance and definitions

7.1 Other relevant guidance

For a full list of available Technical Guidance and other relevant guidance see Annex A of "*How to comply with your environmental permit*" (http://publications.environment-agency.gov.uk/pdf/GEHO1110BTFP-E-E.pdf). In addition to the guidance in "How to comply with your environmental permit" the following guidance documents are also relevant to this sector:

1) Health Technical Memorandum 07-01: Safe management of healthcare waste, Department of Health 2006. Health Technical Memorandum 07-01: Safe Management of Healthcare Waste : Department of Health - Publications
2) Technical Guidance WM2, Hazardous Waste, Interpretation of the Definition and Classification of Hazardous Waste, Environment Agency, ISBN 1 84432 4540.
3) How to comply with your environmental permit Additional guidance for: The Incineration of Waste (EPR 5.01).http://publications.environment-agency.gov.uk/pdf/GEHO0209BPIO-e-e.pdf
4) Safe management of Wastes from Healthcare Activities. World health Organisation, 1999, http://www.healthcarewaste.org/en/documents.html?id=1

7.2 Definitions

"Clinical waste" has the meaning given in the Controlled Waste Regulations 1992 as:

i) any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, or syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and

ii) any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it.

Annex 7-Other relevant guidance and glossary

Guidance on the application of this definition is provided by the Safe Management of Healthcare Waste (HTM 07 01)

"Cytotoxic and cytostatic medicines" are medicinal products that possess one or more of the hazardous properties toxic, carcinogenic, mutagenic or toxic for reproduction. Cytotoxic and cytostatic waste is the fraction of waste medicines, as described below for ***'medicines'***, that contains or is contaminated with cytotoxic and cytostatic medicines.

"*Healthcare waste"* means a waste classified under Chapter 18 of the List of Wastes, that is both

- produced by human and animal healthcare and/or related activities; and
- is of a type specifically associated with such activities

"Medicines" are 'medicinal products' as defined in Regulation 130 of Part VIII of the Medicines Act 1968. Waste medicines (or pharmaceutical waste) include

- expired, unused, spilt and contaminated medical products that are no longer required and need to be disposed of appropriately;
- discarded items contaminated with medicines such as bottles or boxes with residues, gloves, masks, connecting tubing, syringe bodies and drug vials.

"Sharps" means items that could cause cuts or puncture wounds. They include needles, hypodermic needles, scalpels and other blades, knives, infusion sets, saws, broken glass, and nails.

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