

APPENDIX 6

Sector Guidance Note IPPC S5.06 - Supplementary PPC for Clinical Wastes

Contents

Executive Summary	2
A6-1 Introduction	3
A6-1.1 Definition of clinical waste	3
A6-1.2 Definition of Alternative Treatment	4
A6-1.3 Definition of Rendering Safe	4
A6-1.4 Wastes suitable for alternative treatment (disinfection)	5
A6-2 Techniques for pollution control	7
A6-2.1 In-process controls	7
A6-2.2 Emission control	13
A6-2.3 Management	14
A6-2.4 Raw materials	14
A6-2.5 Waste handling	15
A6-2.6 Waste (materials) recovery	15
A6-2.7 Energy	15
A6-2.8 Accidents	15
A6-2.9 Noise	15
A6-2.10 Monitoring	15
A6-3 Emission benchmarks	28
A6-3.1 Emissions inventory	28
A6-3.2 Emission benchmarks	28
A6-4 Impact	29
References	30

Executive Summary

This additional guidance has been produced by the Environment Agency, after external consultation, to clarify the requirements of the Sector Guidance Note IPPC S5.06 to the treatment of infectious clinical waste. The need for this clarity was identified during the permitting of hazardous waste treatment facilities.

This guidance does not replace the requirements of Sector Guidance Note IPPC S5.06 but provides focussed guidance on the application of PPC principles to alternative treatment processes (i.e. thermal and chemical) for rendering infectious healthcare waste (clinical waste) safe.

The guidance considers and identifies additional and alternative standards for:

- techniques for pollution control
- emissions benchmarks
- environmental Impact

as they are applied to alternative treatment plants.

A6-1 Introduction

This guidance supplements the current Sector Guidance Note IPPC S5.06 on the recovery and disposal of waste. It provides additional information on the principles to be applied to alternative treatment processes (i.e. thermal and chemical) for rendering safe infectious healthcare waste (clinical waste). It does not cover incineration. This guidance does not replace Sector Guidance Note IPPC S5.06.

The overarching principles in IPPC S5.06 should be applied to the alternative treatment processes that require a PPC permit, however this guidance identifies some additional and alternative standards to be applied to alternative treatment plants. These supplement or replace the standards in IPPC S5.06 as indicated.

A6-1.1 Definition of clinical waste

Clinical waste is defined in the Controlled Waste Regulations 1992 as:

“(a) 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

(b) 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”

Healthcare waste is a waste classified under Chapter 18 of the List of Wastes, which is waste from natal care, diagnosis, treatment or prevention of disease in humans/animals. Examples of healthcare waste include:

- infectious waste;
- laboratory cultures;
- anatomical waste and animal carcasses (infectious/non-infectious);
- sharps waste (radioactive, cytotoxic and cytostatic, medicinally contaminated, body fluid contaminated);
- medicinal waste (cytotoxic and cytostatic, other);
- chemicals (occur both as ‘laboratory smalls’, and diagnostic reagents/sample preservatives in healthcare waste streams);
- offensive waste (non-infectious);
- amalgam.

The relationship between the definitions of healthcare waste and clinical waste is as follows:

- (i) Healthcare waste includes wastes that are not hazardous, for example non-infectious hygiene wastes from patients. This waste would NOT be classed as clinical waste.
- (ii) Clinical waste can be produced from activities other than those included in Chapter 18 of the List of Wastes e.g. from body piercing, or arising as drug litter. This waste would NOT be classed as healthcare waste
- (iii) Healthcare wastes that present a hazard are also clinical wastes.

With the introduction of the Hazardous Waste Regulations, the List of Wastes Regulations, the reduction in incineration capacity, and the introduction of non-incineration technologies, it is therefore now necessary to consider clinical waste in terms of:

- hazardous and non-hazardous waste, and
- List of Wastes classification, and
- appropriate disposal option (incineration / alternative treatment)

rather than as the broad A-E groups indicated in the *Safe Disposal of Clinical Waste 1999*.

Adequate source segregation should reduce the amount of healthcare waste that is classified as clinical waste, and therefore the quantity of healthcare waste that requires rendering safe. *Technical Guidance WM2* provides the guidance on the definition and classification of hazardous waste.

A6-1.2 Definition of Alternative Treatment

Alternative treatment includes treatment by heat, chemicals and irradiation in order to render clinical waste safe. At present, this mostly relates to treating infectious clinical waste to render it safe by disinfecting it.

Thermal treatment uses heat to inactivate pathogenic micro-organisms. Heat treatment can be broadly divided into two groups.

- 1) 'Moist' heat processes that generate steam, including autoclaves, steam augers, and some microwaves
- 2) 'Dry' heat processes utilising electricity, hot-oil and some microwaves, which rely partially on moisture already within the waste.

Chemical treatment utilises disinfectants (e.g. sodium hypochlorite, chlorine dioxide, peracetic acid, glutaraldehyde, calcium oxide or quaternary ammonium compounds).

Treatment of clinical waste by gamma irradiation has also been used.

Emerging technologies, for example hot alkaline hydrolysis, may have scope to treat other hazardous components of clinical waste, beyond just disinfection. Potentially this provides for a broader range of waste types that could be treated.

A6-1.3 Definition of Rendering Safe

Rendering safe is defined in the Department of Health consultation document '*Safer management of healthcare waste*' as treatment that:

- a. for infectious waste – has 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;
- b. for anatomical waste – destroys any human tissue, organ or body part so that it is ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking such that it is no longer generally recognisable;
- c. for any clinical waste – renders any syringes, needles or any other equipment or item unusable and no longer in their original shape and form;
- d. for medicinal waste – destroys the component chemicals.

A6-1.4 Wastes suitable for alternative treatment (disinfection)

The purpose of alternative treatment (disinfection) is to render infectious waste safe. Therefore the wastes to be treated should have properties that require rendering safe and have properties capable of being rendered safe by alternative treatment. If other wastes are to be treated using alternative treatment the reasons for treating this waste should be fully justified.

The wastes listed in Table A6-1.1 below are identified in the European Waste Catalogue (EWC) as hazardous because they are infectious (hazardous property H9). Alternative treatment should be restricted to these wastes unless the operator can justify the treatment of other wastes. Guidance on how to determine if a waste falls within either of these codes is given in [Appendix C of WM2: C9 Assessment of Hazard H9: Infectious](#).

Table A6-1.1: Wastes suitable for alternative treatment (disinfection)

EWC Code	Description of Code Description
18 01	Waste from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03*	Waste whose collection and disposal is subject to special requirements in order to prevent infection.
18 02	Waste from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection.
20 01	Separately collected fractions (except 15 01)
20 01 99	Other fractions not otherwise specified (This may include separately collected fractions of <i>municipal</i> clinical waste whose collection and disposal is subject to special requirements in order to prevent infection, for example waste from tattoo parlours, body piercing and blood contaminated clothing.)

Wastes within these codes are infectious and require rendering safe. However, some wastes that may fall within these codes are not suitable for alternative treatment (disinfection) and some of these are listed in Table A6-1.2 below.

Table A6-1.2: Wastes not suitable for alternative treatment (disinfection)

Description	Reason
Pharmaceutical waste in any form or container (particularly sharps boxes).	Disinfection technologies have no recognised action against pharmaceutical molecules.
Cytotoxic and cytostatic contaminated waste.	See note below regarding treatment of sharps and pharmaceutical wastes
Anatomical waste and carcasses in any form	The Department of Health consultation document ' <i>Safer management of healthcare waste</i> ' states that 'the treatment of anatomical waste requires that the waste be rendered unrecognisable in suitable licensed facilities, which at this time means incineration.'
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).	See note below on standards for treatment of certain biohazardous wastes.
Any waste from containment level 3 laboratories	Guidance should be sought from the Health and Safety Executive before such wastes are moved (in untreated form) from the premises of production.
Any waste contaminated with UN transport Category A or ACDP hazard Group 4 pathogens	

Sharps may only be subject to alternative treatment where the following criteria have been met:

- No sharps or other material contaminated with cytotoxic and cytostatic medicines are present in the sharps box.
- No pharmaceutical waste is present in the box. The syringe body is considered to be a pharmaceutical waste when contaminated with, or containing residual quantities of medicines (some pharmaceutical waste, and manufactured pre-filled syringes are both sharps and pharmaceutical waste, and are therefore not suitable for alternative treatment). This means that **medicinally contaminated syringes** are not suitable for alternative treatment and must not be introduced into these processes.

Certain **biohazardous** waste represent either a heightened risk, require a higher level of treatment, are categorised as a Category A waste for transport, or are subject to guidance from the Health and Safety Executive with respect to treatment on the site of production. The following additional criteria apply to their acceptability at alternative treatment (disinfection) facilities

- No wastes containing ACDP 4 pathogens are suitable for treatment.
- No waste containing other listed unsuitable wastes are suitable for treatment.
- Processes employing physical treatment (maceration/shredding) of untreated wastes are unsuitable.
- A higher level of treatment (STAAT level IV criteria) is required for such wastes.

Such wastes should not routinely leave the premises of production in untreated form.

Treatment for **pharmaceutical wastes**, and materials contaminated with pharmaceuticals, require that all pharmaceutically active substances present in the waste, both hazardous and non-hazardous, should be destroyed during treatment. At present, high temperature incineration is the primary method of achieving this. It is possible that future alternative technologies, for example alkaline hydrolysis, may demonstrate treatment efficacy in this area. In general this would require laboratory trials to demonstrate that process parameters are theoretically able to treat a very broad range of representative pharmaceutical molecules before testing protocols for device based trials could be considered.

A6-2 Techniques for pollution control

A6-2.1 In-process controls

This section covers the key issues of pre-acceptance and acceptance procedures for clinical waste and clinical waste storage. It is essential that it be read in conjunction with the corresponding sections of IPPC S5.06.

A6-2.1.1 Waste pre-acceptance

Pre-acceptance procedures to assess waste are discussed in detail in section 2.1.1 of IPPC S5.06, however the examination of healthcare wastes is limited by health and safety concerns, placing an additional need for robust pre-acceptance procedures. Nevertheless the following principles should be applied. The operator must ensure that all wastes are pre-booked. The operator's pre-acceptance procedures should provide a level of confidence that enables the reduction in acceptance testing and auditing. Robust producer audit procedures and positive audit results are likely to inform the operator's approach to pre-acceptance.

The following box sets out indicative standards for clinical waste only. It replaces the equivalent requirements within IPPC S5.06. When considering other waste including laboratory smalls, the standards set out in IPPC S5.06 must be met.

Indicative requirements for pre-acceptance

1. From the waste disposal enquiry the operator should obtain information in writing relating to:
 - The details of the healthcare waste producer
 - The specific process from which the waste derives – veterinary, primary care, dental, acute, laboratory etc
 - The quantity of each waste type
 - Compositional audit analysis of the waste (individual constituents of each waste stream and their percentage compositions and chemical/pharmaceutical contaminants)
 - The form the waste takes and the types of containers used (colour, form and size of container and sub-containers)
 - Hazards associated with the waste and its components.
 - Date of production of the waste and waste storage and preservation techniques used since production (for example cold storage, or freezing, that may impede treatment).
2. Unless an audit analysis has already been completed and the operator has sufficient written information to support this, the operator should in every case obtain representative audit analysis of the waste from the premises of production / current holder and compare it with the written description to ensure that it is consistent. The audit data should be less than 18 months old.
3. The type of information that would demonstrate the reliability of the audit includes:
 - A diagram of the producer premises indicating the location, numbers, types and capacities of waste containers in use.
 - A list of the different wards, departments, or functional areas that exist within the premises.
 - A list of those areas that were included within the audit, and the containers within those areas that were examined.
 - A date and description of the audit and the procedures employed.
 - A confirmation of the number of containers of each type audited and a detailed list of the contents and labelling of each.

- Compositional audit analysis of the waste (individual constituents of each waste stream and their percentage composition and chemical/pharmaceutical contaminants).
 - The waste classification and disposal options for the constituents of each stream.
 - Where relevant, the audit should include examination of the segregation of waste containers placed in on site bulk containers (e.g. 770 litre carts).
 - A summary report indicating the findings for each area in the producer premises and each waste stream produced there.
4. 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.
 5. Following characterisation of the waste, a technical assessment should be made of its suitability for treatment, disposal or storage to ensure permit conditions are being met.
 6. Wastes should not be accepted at the installation without a clear method or defined treatment and disposal route being determined in advance.
 7. There must be a clear distinction between sales and technical staff roles and responsibilities. If non-technical sales staff are involved in waste disposal enquiries, then a final technical assessment prior to approval should be made. It is this final technical checking that should be used to avoid build-up of accumulations of wastes.
 8. All records relating to pre-acceptance should be maintained at the installation for cross-reference and verification at the waste acceptance stage. These records should be kept for a minimum of 3 years.

A6-2.1.2 Waste receipt and acceptance

It is not unusual for the operator to also act as the carrier and collect the waste from the producer's premises. In these instances, this can be the initiation of the acceptance stage. Waste acceptance must ensure that there are 2 levels of acceptance, the first being acceptance checking and the second, higher level being that of audit.

Clinical waste is usually bagged or sealed in UN approved packaging and then placed in larger carts for transportation. The contents of all carts should be visually inspected upon receipt to ensure that the carts do not contain obvious non-conforming wastes (for example waste containers of a type associated with an unsuitable waste, or waste types/containers not identified specifically on the documentation).

Where it is not possible to determine visually that non-conforming wastes are absent, procedures must be put in place to unload the cart, with due consideration for both emissions and health and safety. If it is not possible to unload the cart to achieve this, then the waste must be sent for incineration.

The following box includes indicative standards for clinical waste only. When considering other waste including laboratory smalls the standards set out in section 2.1.2 of IPPC S5.06 must be met.

Indicative requirements for acceptance procedures when waste arrives at the installation

1. On arrival loads should:
 - Be weighed unless alternative reliable volumetric systems are available
 - Not be accepted into site unless sufficient storage capacity exists and the site is adequately manned
 - Have all documents checked and approved, and any discrepancies resolved before the waste is accepted
2. Where possible confirmatory visual checks should be undertaken before offloading where safety is not compromised. Visual inspection of the waste within the 'carts' must in any event be carried out immediately upon offloading at the installation.
3. Every container should be checked to confirm quantities against accompanying paperwork. All containers should be clearly labelled and should be equipped with well fitting lids.
4. At this stage the waste tracking system should begin. A unique reference number should be applied to each container. Each container should also be labelled with the date of arrival on site.
5. The operator should ensure that waste delivered to the installation is 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.
6. Documentation provided by the driver, written results of acceptance analysis, details of offloading point or off-site transfer location should be added to the tracking system documentation.
7. A record of the inspection regime for each load and justification for the selection of this option should be maintained at the installation.
8. Should the inspection or analysis indicate that the wastes fail to meet the acceptance criteria then such loads should be stored in a dedicated quarantine area and dealt with appropriately. The maximum storage time for such loads should take account of the potential for odour generation and insect infestation. In all cases the maximum storage time for waste that has failed to meet the acceptance criteria should be five working days. Written procedures should be in place for dealing with wastes held in quarantine, together with a maximum storage volume.
9. The offloading, sampling point/reception and quarantine areas should have an impermeable surface with self-contained drainage, to prevent any spillage entering the storage systems or escaping off site. All surfaces should be of sufficient type and quality to allow effective disinfection.
10. The operator should have clear and unambiguous criteria for the rejection of wastes, together with a written procedure for tracking and reporting such non-conformance. This should include notification to the customer/waste producer and regulator. Written/computerised records should form part of the waste tracking system information. The operator should also have a clear and unambiguous policy for the subsequent storage and disposal of such rejected wastes. This policy should achieve the following:
 - Identifies the hazards posed by the rejected wastes
 - Labels rejected wastes with all information necessary to allow proper storage and segregation arrangements to be put in place
 - Segregates and stores rejected wastes safely pending removal
11. The waste tracking system should hold all the information generated during pre-acceptance, acceptance, storage, treatment and/or removal off-site. Records should be made and kept up to date on an ongoing basis to reflect deliveries, on-site treatment

and despatches. The tracking system should operate as a waste inventory/stock control system and include as a minimum:

- Date of arrival on-site
- Producers details
- 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 operators staff who have taken any decisions re acceptance or rejection of waste streams and decided upon recovery/disposal options

12. All records relating to pre-acceptance should be maintained and kept readily available at the installation for cross-reference and verification at the waste acceptance stage. Records should be held for a minimum of two years after the waste has been treated or removed off site.
13. The system adopted should be capable of reporting on all of the following
 - Total quantity of waste present on site at any one time
 - Breakdown of waste quantities being stored pending treatment
 - Indication of where the waste is located on site relative to a site plan
 - Comparison of quantity on site against total permitted
 - Comparison of time the waste has been on site against permitted limit
14. Back up copies of computer records should be maintained off-site.
15. Wastes should not be accepted at the installation without a clearly defined method of recovery or disposal being determined and sufficient capacity being available. These checks should be performed before the waste acceptance stage is reached.
16. There must be a clear distinction between sales and technical staff roles and responsibilities. If non-technical sales staff are involved in waste enquires then final technical assessment prior to approval should be made. It is this final technical checking that should be used to avoid build up of accumulations of wastes and to ensure that sufficient capacity exists.

A6-2.1.3 Waste storage

Waste storage is discussed in detail in section 2.1.3 of IPPC S5.06 and the relevant key issues identified in section 2.1.3 should be applied to the storage of clinical waste. In particular the operator should take account of the requirements specified in IPPC S5.06 concerning offloading/discharge of waste, record keeping, general storage requirements, and turnover. In addition the principles identified for the storage of chemical waste should be applied to waste pharmaceuticals. The following box includes additional indicative requirements for clinical waste storage.

Additional indicative requirements for clinical waste storage

1. Clinical waste should be stored in bins the lids of which shall be kept closed when the bin is not being loaded or unloaded.
2. There should be demarcated storage areas for different waste streams to ensure that the wastes streams are not mixed.
3. The surfaces of the storage areas should be of sufficient type and quality to allow effective disinfection.

4. Site surfaces and the surfaces of fixed storage containers should be cleaned and disinfected regularly. The frequency of cleaning and disinfection should be based upon a site specific risk assessment, which may include the results of the surface contamination monitoring.
5. Once emptied all re-usable mobile containers should be checked to ensure all waste has been removed. These containers should be cleaned and disinfected appropriately in order to prevent fugitive emissions.
6. The potential to generate odour should be considered when determining the length of time clinical waste is stored, this will be determined by the type of container used for storage and the temperature at which waste is stored.
7. Waste should be stored in a manner and for a time period that will prevent access by scavengers and pests.

A6-2.1.4 Treatment – general principles

The general principles for treating waste are specified in section 2.1.4 of IPPC S5.06. The key issues identified for the operator are also relevant to the treatment of clinical waste. The following sections highlight some more specific issues when considering clinical waste.

The surfaces of the treatment areas should be of sufficient type and quality to allow effective disinfection. Site surfaces should be cleaned and disinfected regularly, generally it is recommended that this should be done monthly.

In addition to the wastes identified in Table A6-1.2 as unsuitable for treatment in Alternative Treatment plants, items that could reduce the effectiveness of the treatment process or damage the plant must be prevented from entering the treatment plant. An example would be larger metallic objects such as titanium hip joints. The operator should use detection and warning systems where plant breakdown could occur as a result of these sorts of waste entering the plant.

A6-2.1.5 Treatment efficacy for alternative treatment (disinfection)

The fundamental principle of any alternative treatment (disinfection) is that it renders infectious clinical waste safe i.e. it changes it from hazardous to non-hazardous waste. The efficacy of a particular treatment process is a measure of its ability to render infectious clinical waste safe. Efficacy should be assessed as set out in the box below.

Indicative requirements for treatment efficacy

1. The test 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 is the Level III criteria recommended by the State and Territorial Association on Alternative Treatment Technologies (STAATT). Additional information on treatment levels defined by STAATT is given in section 7 of the Environment Agency's [Technical Guidance on Clinical Waste Management Facilities](#). The STAATT Level III criteria requires the inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 log₁₀ reduction or greater; and inactivation of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores at a 4 log₁₀ inactivation or greater. (Note: a higher level of treatment is indicated for certain biohazardous waste in A6-1.4).
2. The above standard must be demonstrated for the worst-case scenario challenge loads e.g. a rigid, 2 litre, gel-filled chest drains/suction canister. A worst-case challenge load must include waste articles that are likely to be

present in the waste treated at the installation that inhibit treatment. A challenge load would be expected to include items that provide thermal insulation or prevent chemical penetration e.g. rigid, 2 litre, gel filled chest drain/suction canisters. For chemical treatment the organic content of the waste may also inhibit treatment and should be considered when determining a worst-case scenario.

3. Where the waste is macerated or shredded prior to thermal/chemical treatment process, then the challenge load may be the size-reduced waste.
4. Where the waste is reduced in size as an integral process that occurs simultaneously with the thermal/chemical process then the use of size-reduced waste as the challenge load is **not** appropriate.
5. All clinical waste that is subjected to alternative treatment may contain items or disposable equipment that should be macerated. All such treatments should be capable of reducing the waste, by maceration or shredding, to a particle size of less than or equal to 50mm and no particle should exceed 80mm in any dimension.
6. Any plant that macerates/shreds clinical waste that has not already been rendered safe should also be designed and built specifically to ensure microbiological aerosol containment. This should include operation under negative pressure, with air drawn away from the hopper entrance and passed through HEPA filters. Hoppers should have doors on the opening to retain aerosols.
7. Treatment efficacy shall be validated and tested in accordance with the standards detailed in Section A6-2.10.
8. Data from the testing of one item of equipment cannot be used for an identical item of equipment in operation in the same or different premises. Generic testing of a technology, rather than individual items of equipment, is not acceptable.
9. Mobile plant should be fully validated on commissioning, be subject to routine monitoring, and undergo confirmatory parametric tests (e.g. thermal indicator strips) before commencing operations on another site. Full validation will be required if the device is to be resident for more than 6 months.

A6-2.1.6 Treatment technique

BAT is defined in the PPC Regulations as "the most effective and advanced stage in the development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing in principle the basis for emission limit values designed to prevent, and where that is not practicable, generally to reduce emissions and the impact on the environment as a whole".

The PPC Regulations describe several considerations to be taken into account in the determination of BAT, as described under Regulation 3 and listed in Schedule 2.

Schedule 2 to Regulation 3 of SI 1973 The PPC Regulations, 2000

- (1) the use of low waste technology
- (2) the use of less hazardous substances
- (3) the furthering of recovery and recycling of substances generated and used in the process and of waste, where appropriate
- (4) comparable processes, facilities or methods of operation which have been tried with success on an industrial scale
- (5) technological advances and changes in scientific knowledge and understanding
- (6) the nature, effects and volume of the emissions concerned
- (7) the commissioning dates for new or existing installations or mobile plant
- (8) the length of time needed to introduce the best available technique
- (9) the consumption and nature of raw materials (including water) used in the process and the energy efficiency of the process
- (10) the need to prevent or reduce to a minimum the overall impact of the emissions on the environment and the risks to it
- (11) the need to prevent accidents and to minimise the consequences for the environment
- (12) the information published by the Commission (e.g. BREF documents) or by international organisations

The following points from Schedule 2 are considered the most significant when assessing BAT for alternative treatment of clinical waste:

- the use of less hazardous substances
- the furthering of recovery and recycling of substances
- comparable processes
- the nature, effects and volume of the emissions concerned
- energy efficiency of the process
- the need to prevent accidents

Additionally one of the additional general principles of PPC is that the amount of waste generated is minimised and where it is generated, it is recovered. Where it is not able to be recovered it is to be disposed of in a manner that avoids or reduces its impact on the environment¹.

The selection of any new treatment technique, as well as justification for the continued use of existing treatment techniques, should be based upon a consideration of the requirements summarised in this section.

Examples include:

When determining when in the process to macerate/shred the clinical waste an assessment should be made of the cost versus benefit of the additional energy or chemical required to treat non-macerated waste compared with the energy required to macerate the waste.

A6-2.2 Emission control

Section 2.2 of IPPC S5.06 discusses emissions control and the general principles identified should be applied. The following sections identify additional requirements with respect to clinical waste.

A6-2.2.1 Point source emissions to air

Aerosol emissions from point sources such as steam pressure relief valves should be prevented by the appropriate use of high efficiency particulate air (HEPA) filters.

¹ See Regulation 11(3)

Indicative requirements for the control of point source emissions to air

1. HEPA filters should be effectively maintained to ensure a minimum particle removal efficiency of 99.97% for all particles of 0.3µm diameter.
2. Procedures should be in place to allow for the safe removal and disposal of HEPA filters.

A6-2.2.2 Point source emissions to surface water and sewer

The primary consideration should be to prevent releases of harmful substances to the aquatic environment, whether releases are direct or via a sewage treatment works. Consideration should be given to the discharge of disinfectants used in cleaning processes.

A6-2.2.3 Point source emissions to groundwater

There are no additional requirements identified for this section.

A6-2.2.4 Fugitive emissions to air

Plant that macerates/shreds clinical waste has the potential to generate fugitive emissions of pathogens.

Additional indicative requirements for the control of fugitive emissions to air

1. Plant that macerates/shreds clinical waste that has not been rendered safe should do so under negative pressure, with air drawn away from the hopper entrance and passed through HEPA filters. Hoppers should have doors on the opening to retain aerosols.

A6-2.2.5 Fugitive emissions to surface water, sewer, and groundwater

There are no additional requirements identified for this section.

A6-2.2.6 Odour

The potential to generate odour should be considered when determining the length of time clinical waste is stored, the type of container used for storage and the temperature at which waste is stored.

Additional indicative requirements for the control of odour

1. Clinical waste should be stored in bins the lids of which shall be kept closed when the bin is not being loaded or unloaded.

A6-2.3 Management

The general principles relating to management are specified in section 2.3 of IPPC S5.06. The issues identified are relevant to the treatment of clinical waste. In addition any accident plan should include the requirements of A6-2.8 below.

A6-2.4 Raw materials

The general principles relating to the selection of raw materials, use of water and techniques for minimising their use and impact are specified in section 2.4 of IPPC S5.06. The issues identified are relevant to the treatment of clinical waste. When choosing a disinfectant for dealing with spillages or cleaning, the contact time and level of dilution should be assessed. In general disinfectants containing 10,000 ppm available chlorine are recommended for spillages. Sodium dichloroisocyanurate (NaDCC) granules should be used in preference to prepared solutions that lose activity with time and require regular replacement.

A6-2.5 Waste handling

Waste handling issues are inherent to the alternative treatment of clinical waste and are therefore not discussed separately in this section.

A6-2.6 Waste (materials) recovery

The general principles for waste recovery are specified in section 2.6 of IPPC S5.06. Where relevant the issues identified should be considered. In addition the operator should consider the technical and economic possibility of recycling metal and plastic following treatment.

A6-2.7 Energy

Energy Efficiency is covered in section 2.7 of IPPC S5.06 and should be considered in full. However table A6-2.10 below shall be used instead of table 2.10 in IPPC S5.06.

Table A6-2.10: Example breakdown of delivered and primary energy consumption

Energy Source	Energy consumption		
	Delivered, MWh	Primary, MWh	% of total
Electricity (specify source)			
Gas			
Oil			
Other (operator to specify)			

A6-2.8 Accidents

The general principles relating to accidents and their consequences are specified in section 2.8 of IPPC S5.06. Where relevant the issues identified should be considered. In addition the operator should consider the appropriate use of disinfectants in any spill contingency procedure.

Additional indicative requirements for accidents and abnormal operation.

1. Disinfectant should be available on site for use as part of the spill contingency procedures.

A6-2.9 Noise

There are no additional requirements identified for this section.

A6-2.10 Monitoring

The general principles relating to monitoring are specified in section 2.10 of IPPC S5.06. Where relevant, issues identified should be considered. In addition the operator should also consider the following sections in A6-2.10, which specifically relate to monitoring requirements of alternative treatment plants that render clinical waste safe through disinfection:

- Validation of the plant
- Routine efficacy
- Emissions monitoring – includes point-source monitoring at vents to atmosphere, as well as fugitive emissions monitoring.

A6-2.10.1 Validation of the plant

This is required for newly installed equipment and in cases where existing plant is shut down because it failed to demonstrate routine efficacy. Validation must demonstrate that the plant can meet the requirements of STAATT level III using methodology consistent with this guidance, and that its procedures are applicable when a plant first begins to operate.

Indicative requirements for validation of alternative treatment plants

Validation report

1. A validation report should contain the following elements:
 - i) A microbial efficacy analysis, that demonstrates that the choice of test organism, the method of introduction to the plant, the choice of organism carrier, and the analytical method are adequate to demonstrate STAATT level III criteria for a worst case scenario challenge load.
 - ii) Evidence that effective parametric controls (e.g. recording of time, temperature, pressure, chemical concentration and chemical dosing date), and procedures for real-time monitoring and assessment of outputs, are in place with respect to any waste treated.
 - iii) Evidence that the parametric control data relates to microbial efficacy so that waste can therefore be considered to be treated satisfactorily on the basis of parametric controls alone.
 - iv) An environmental monitoring assessment of the site that addresses process emissions, including emissions from the macerator/shredder.
2. For newly installed treatment plants, operations must not commence until the operator has submitted the report to the regulator for assessment and has received from the regulator written confirmation that the validation report has been agreed.

Commissioning of the plant

3. The procedures and criteria that must be satisfied to demonstrate that treatment can achieve the microbial inactivation aspect of 'rendered safe' is specified in the following sections depending on the type of plant that is being commissioned:
 - **A6-2.10.1.1:** Procedure for microbial validation for pre-maceration technologies where spore strip integrity can be guaranteed (for examples augers).
 - **A6-2.10.1.2:** Procedure for microbial validation for pre-maceration or integral maceration technologies where spore strip integrity cannot be guaranteed (for example autoclave with integral macerator).
 - **A6-2.10.1.3:** Procedure for microbial validation for technologies that lack pre-maceration or integral maceration
4. Both the field and laboratory aspects of this procedure should be carried out by a suitably qualified microbiologist utilising a suitably accredited laboratory.

Test organism

5. For thermal and chemical processes the tests should be performed using either *Bacillus atrophaeus* (subtilis) OR *Geobacillus stearothermophilus*.
6. The operator should demonstrate that the choice of spore species, strain and certification is the most appropriate for the treatment method employed.
7. A single batch number of spore strips / spore suspension should be employed during commissioning.
8. Each batch of spores will have a certified D-value. The D-value is the time taken, in minutes, for a 1 log₁₀ reduction, in the number of spores exposed to specified conditions. Not all batches of spores will have the same D-value. This

D-value may vary by up to 100% for commercially available spores of the same type, and variance beyond this range is available on request. The choice of spore strip may therefore increase or reduce the number of spores recovered by a factor of 10. This can therefore alter the reported reduction by up to 2 log₁₀.

9. To maintain consistency of treatment standard, the STAATT level III criteria should be demonstrated using spores where the certified D-value is ≥ 2 minutes
 - at 121°C wet heat (*Geobacillus stearothermophilus*)
 - at 160°C dry heat (*Bacillus atrophaeus*)
10. Where the certified D-value of a batch of spores is < 2 minutes, or determined at parameters other than those identified above, they are not suitable for use. This applies to both routine monitoring and validation.

A6-2.10.1.1

Procedure for microbial validation for pre-maceration technologies where spore strip integrity can be guaranteed (e.g., augers).

1. This applies **only** to those technologies that have pre-maceration **and** where it is possible for the test materials to be inserted easily into the macerated waste prior to it entering the microbial treatment process

Spore strip containment

2. Spore strip challenges should be carried out on the technology using spore carriers where the integrity of the container can be guaranteed.
3. Spore carriers should be designed to mimic normal conditions in the waste being treated as much as possible, and the type chosen will be dependant on both the technology and the waste treated. Examples that may be suitable include net bags, tennis balls with holes in them, socks, plastic containers with holes in or alloy containers with holes in.
4. Where spore strips are placed in metal containers they must always be wrapped in a layer of cotton wool, or equivalent, to prevent direct conduction of heat from the metal.
5. Where technologies have integral mixing it is not appropriate to attach the spore carriers to the mixing arms because the waste is not fixed to the mixing arms i.e. the spore carriers should be loose in the waste. The operator may attach up to 50% of the spore carriers to fixed positions, however the results for these must be assessed separately, and both fixed and loose spore carriers must pass the criteria provided. If the operator can demonstrate statistically that there is no significant difference between the two data sets, then routine operational monitoring can use fixed carriers.
6. Similar criteria apply to the use of test ports into which spore strips can be placed. In general these are not representative of the treatment to which the waste is subjected and should not be used.

Outline test procedure

7. If the technology processes the waste in batches, the tests should be carried out over a minimum of 5 separate treatment cycles for each cycle format. For example where the device is operated at two different temperatures or times, each must be validated separately using 5 cycles.
8. For continuous technologies, the tests should be done in five distinct collections for each cycle format, with the tests for each previous collection being retrieved from the treated waste before the next set of tests is introduced to the treatment plant.
9. The minimum number of spore strips required is set out in table A6 2.10.1.

10. Strips should be spread out in the load as much as is practicable. For technologies with integral mixing this may be accomplished inside the machine. For static technologies the strips should be spread out throughout the length of the chamber, and should be placed as near the centre of the load as possible.
11. A minimum of 2 untreated control strips should be held outside the autoclave during each cycle/batch and processed along with the tests afterwards to provide an estimate of the numbers of spores retrievable from each strip.
12. The use of surrogate waste is not appropriate. Clinical waste of the type(s) to be treated by the technology under normal conditions should be used for all tests.
13. All waste 'treated' during testing should be either:
 - re-treated by another technology to ensure it is rendered safe, or
 - it should be quarantined until the validation report is agreed by the regulators (The storage requirements in this document and IPPC S5.06 shall be complied with).
14. For thermal processes, the microbial data should be supported by the parallel use of thermal indicator strips or multi-point thermal data loggers to record temperatures throughout the waste load. These strips should be chosen to support the parametric controls and measure both temperature achieved, and duration of exposure to that temperature.

Laboratory methods

15. These will be partly determined by the test organism, and the method specified by the spore supplier. Due consideration should also be given to the principles of the methodology in the [Environment Agency Technical Guidance on Clinical Waste Management Facilities](#).
16. 100% of each test sample must be analysed. This is not required for control samples. Analysis must be quantitative.

Validation Criteria

17. This requires quantitative enumeration of spore strips with a certified population of $>1 \times 10^6$ spores per strip. Qualitative analysis and/or the use of lower numbers are not appropriate for plant commissioning.
18. For the Control Run(s) the following are required:
 - The mean number (X_C) of spores recovered from the control strips should be calculated in cfu (colony forming unit).
 - The \log_{10} of (X_C) should be determined.
19. For the Test Runs the following require determining:
 - The mean (X_T) number of spores recovered
 - The standard deviation (σ) of spores recovered
 - The \log_{10} of (X_T)
 - The Upper 95% (Lu) confidence interval of (X_T) (this will be $X_T + 1.96\sigma$)
 - The \log_{10} of the Upper 95% confidence interval ($\log Lu$) of X_T
20. The following criteria represent the minimum standard that must be achieved:
 - $(\log(X_C) - 4) \geq \log Lu$
 - $\log(X_C)$ must be ≥ 5
 For thermal processes all thermal indicator strips should indicate that the required temperature time parameters have been achieved.
21. These criteria must include the proviso that **ALL** test strips, or spore samples, recovered from the plant must be considered valid. This includes those where contamination has occurred. Significant contamination will therefore require the exercise to be repeated.

22. Where these criteria are passed then it is $\geq 97.5\%$ probable that any clinical waste will be treated to the minimum required standard.

Table A6-2.10.1: Minimum number of spore strips required for microbial validation of Alternative Treatment Plants with Pre-maceration technologies where spore strip integrity can be guaranteed.

Single Load Capacity (Kg) Continuous throughput (Kg per Hour)	Minimum Number of spore strips per cycle or collection.	Minimum Number of spore strips (for each cycle format)	Minimum Number of control strips (for each cycle format)
0-10 kg	3	15	10
11-50 kg	6	30	10
51-250 kg	9	45	10
251-500kg	12	60	10
501-750kg	15	75	10
>750 kg.	18	90	10

A6-2.10.1.2

Procedure for microbial validation for pre-maceration or integral maceration technologies where spore strip integrity cannot be guaranteed (for example Autoclave with integral macerator).

1. This applies to those technologies with integral maceration, or pre-maceration that cannot easily be by-passed. It does not apply to those technologies with integral mixing or fragmentiser arms that do not meet the definition of maceration. (e.g. Hydroclaves and Rotaclaves.)
2. The 'fixing' of spore strips, in such a way as to bypass the integral maceration process, is not considered to be appropriate. This may overestimate the efficacy of the treatment process and is not representative of the processes to which the waste is subjected.
3. Where the integrity of the containers cannot be guaranteed, it is necessary to use spore suspensions.
4. The spore suspension is mixed with the waste before treatment, and a sufficient amount of the treated waste is collected after treatment to allow a numerical count of the number of surviving spores to be made. For each run the spore suspension should be placed in at least 6 discrete portions in representative challenge waste items, for example inside syringe bodies in sharps boxes, inside suction canisters or chest drains etc.
5. This procedure requires:
 - One control run, where waste is passed through the device with the thermal/chemical treatment inactivated. This provides an estimate of spore recovery from the waste.
 - Then three test runs should be performed for each treatment cycle format. These data are compared with the control run to provide an estimate of treatment efficacy.
6. The control run is required because of the 'natural' loss of spores with this procedure due to absorption or trapping of spores in the materials in the waste, the dilution factor, and the inadequacies of the retrieval and concentration process.
7. For chemical processes, it is essential that the device be thoroughly cleaned to remove residual traces of disinfectant prior to conducting control runs.

8. For health and safety reasons it may be appropriate to use for the control run either:

- A batch of treated clinical waste, or
- A prepared batch of clinical waste composed of uncontaminated items

Required testing parameters

9. For thermal processes the waste should be seeded with sufficient of a $> 1 \times 10^{10} \text{ml}^{-1}$ spore suspension to achieve at least 1×10^6 spores per gram throughout the load (this equates to at least 0.1 ml per kg of waste). *Geobacillus stearothermophilus* is strongly recommended in order to reduce the interference from other microbes.

10. Sub-samples of the treated waste should be collected from throughout the load and analysed separately

- 0-50 kg per cycle/hour – test using a minimum of 3 sub-samples per cycle/batch
- 50-500 kg per cycle/hour – test using a minimum of 4 sub-samples per cycle/batch
- >500 kg per cycle/hour – test using a minimum of 5 sub-samples per cycle/batch

11. Each sub-sample should 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 should equate to at least 1×10^7 spores.

12. Analysis is complex, the following being an indication of a typical procedure rather than an approved and accredited method. Expert advice should be sought before conducting such analysis.

- Samples should be placed in an appropriate transport medium and refrigerated 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)
- The liquid is decanted through a sterile coarse fabric filter to remove solid waste.
- The liquid is centrifuged at 3000g for 20 minutes to deposit the spores.
- 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.).
- Serial dilutions are made in BHI from 1:10 to 1: 1,000,000
- These should be analysed in triplicate in thick pour plates
- Plates are incubated in a moist chamber at 60°C for up to 7 days.

13. For thermal processes the microbial data should be supported by the parallel use of thermal indicator strips or multi-point thermal data loggers to record temperatures through out the waste load wherever possible.

Validation Criteria

14. This requires quantitative enumeration of the sub-samples relative to the control run. Qualitative analysis or the use of less than 1×10^6 spores per gram is not appropriate.

15. For the Control Run(s) the following are required:

- The mean number (X_C) of spores recovered from the control samples should be calculated in cfu.
- The \log_{10} of (X_C) should be determined.

16. For the Test Runs the following require determining:

- The mean (X_T) number of spores recovered
 - The standard deviation (σ) of spores recovered
 - The \log_{10} of (X_T)
 - The Upper 95% (Lu) confidence interval of (X_T) (this will be $X_T + 1.96\sigma$)
 - The \log_{10} of the Upper 95% confidence interval (logLu) of X_T
17. The following criteria represent the minimum standard that must be achieved:
- $(\log(X_C) - 4) \geq \log Lu$
 - $\log(X_C)$ must be ≥ 5
- For thermal processes all thermal indicator strips should indicate that the required temperature time parameters have been achieved.
18. These criteria must include the proviso that **ALL** test strips, or spore samples, recovered from the plant must be considered valid. This includes those where contamination has occurred. Significant contamination will therefore require the exercise to be repeated.
19. Where these criteria are passed then it is >97.5% probable that any clinical waste will be treated to the minimum standard.

A6-2.10.1.3

Procedure for microbial validation for technologies that lack pre-maceration or integral maceration

1. These technologies may have severe limitations and may lack the technical ability to treat a worst-case scenario challenge load of clinical waste.
2. Where there is no physical action to enable sealed waste containers, and sealed voids in the waste to be punctured, then the treatment is unlikely to penetrate the waste fully.
3. In general, specialist challenge load testing using methodology consistent with that developed by the Health Protection Agency would be required to confirm efficacy. This is beyond the scope of this document.
4. Static autoclaves, including those with vacuum cycles, are particularly affected by this issue and the waste will require either
 - Some form of physical pre-treatment (e.g. maceration), and/or
 - an extended cycle duration
 to enable effective treatment to take place.
5. As an indicator of methodology requirements, spore strips should be placed in each of the following:
 - Robust rigid 2 litre suction canister/chest drain containers made of thermostable plastic, of variable types containing 1-1.5 litres of fluid and thermally stable gel. The operator should demonstrate that the type(s) chosen represent the worst case challenge load.
 - Any other challenging items identified by audit where the penetration of the steam/chemical may be inhibited (for example lengths of tubing, inside syringe bodies in sealed sharps boxes etc).
6. Testing should cover 18 - 36 suction canisters and chest drains (in 3-6 test runs per plant), including approximately 6 of each type/brand, each containing two biological indicator strips and two thermal indicator strips.
7. These containers should be placed in rigid containers and/or yellow bags of the type to be taken by the plant, and to reflect normal operations, and mixed with a typical waste load.
8. The validation criteria from section A6-2.10.1.1 should be applied.

A6-2.10.2 Routine Efficacy Monitoring

All clinical waste treatment devices should be monitored routinely throughout their operational life to ensure that microbial inactivation is occurring and that performance is maintained.

The following is considered to be the minimum requirements for such monitoring.

For those plants for which the use of spore strips is appropriate

1. The minimum frequency of monitoring is specified in Table A6-2.10.2.
2. For thermal processes, thermal indicator strips or multipoint data loggers should always be used in parallel where possible.
3. Either qualitative or quantitative enumeration of spore strips with a certified population may be used.
4. Controls and certificates from the test batch should also accompany each set of samples.
5. The quantitative criteria for success are as follows
 - 95 % of the individual spores strips, with a population of $>1 \times 10^6$, in the first 6 months of operation, and each calendar year, should demonstrate $4 \log_{10}$ inactivation or higher
 - For thermal processes thermal indicator strips should accompany each spore strip and indicate that the minimum time and temperatures have been achieved for 99% of spore strips.
 - The number and type of spore/thermal indicator strips used, and the frequency of spore testing throughout the calendar year is uniform.
 - For each calendar year a summary report should be prepared that indicates the results obtained and any failures. The data should be referenced to the validation report to demonstrate that predicted treatment efficacy, rather than minimum standards, are being achieved. 90% of spore results should demonstrate a level of inactivation \geq the 95% confidence level of treatment determined during validation.
6. The qualitative criteria for success are as follows
 - 95 % of the individual spores strips, with a population of $>1 \times 10^4$, in the first 6 months of operation, and each calendar year, should demonstrate no growth.
 - For thermal processes thermal indicator strips should accompany each spore strip and indicate that the minimum time and temperatures have been achieved for 99% of spore strips.
 - The number and type of spore/thermal indicator strips used, and the frequency of spore testing throughout the calendar year is uniform.
 - For each calendar year a summary report should be prepared that indicates the results obtained and any failures.
 - Where $>5\%$ (or 1, whichever is greater) of spore strips exhibit growth in any calendar year quantitative testing should be used in future instead of qualitative testing.
7. These criteria must include the requirement for all test strips to be valid. The percentage allowance has been provided to allow for both potential contamination and the uncertainty of microbial data.
8. If at any time during the calendar year it becomes clear that these criteria cannot be met for that year, the regulator should be informed immediately, and the plant should cease operations until such time as the cause can be identified and remedied to the satisfaction of the regulators. In order to recommence

operations additional validation is required (see section A6-2.10.1.)

9. In any other circumstances, where the operator becomes aware that one or more batches of waste may not have been treated to the required standard, the operator is expected to regard that waste as untreated and take all necessary actions to ensure that it is re-treated or appropriately disposed of (e.g. by incineration).

Table A6-2.10.2: Routine Monitoring of Microbial Inactivation where the use of spore strips is appropriate

Continuous hourly throughput or batch cycle load.(kg)	Test frequency (first 6 months of operation)	Test frequency (operational, after the first 6 months)	Minimum number spore strips or sub-samples	Number of control strips
0-50kg	Monthly	quarterly	5	1
51-500 kg	Fortnightly	Bi-monthly	5	1
501-1000kg	Weekly	monthly	5	1

For those plants for which suspension testing is required.

1. The minimum frequency of monitoring is specified in Table A6-2.10.3
2. For thermal processes, thermal indicator strips or multipoint data loggers should be used in parallel where possible.
3. Quantitative enumeration of spore suspensions with a certified population is required.
4. A single control run is required.
5. The number of test runs and sub-samples per test run is indicated in Table A6-2.10.3.
6. In other respects:
 - the procedures in section A6- 2.10.1.2 should be followed.
 - the quantitative criteria for success from A6-2.10.1.2 should be used.

Table A6-2.10.3: Routine monitoring of microbial inactivation where suspension testing is required

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

A6 – 2.10.3 Emissions monitoring

It should be recognised that emissions from technically sound clinical waste treatment plants, operated under good practice with appropriate containment, and treating appropriate waste should be low.

Where waste acceptance or pre-acceptance procedures are poor, and/or containment is inadequate or unproven, this assumption cannot be made. The onus is therefore on the operator to demonstrate that emissions from the plant are controlled during both commissioning and more importantly during routine operation.

Potential emissions include

- Microbes, particularly in the form of bioaerosols

- Chemicals, particularly volatile organic carbons. Formaldehyde is of particular concern.
- Pharmaceuticals, as a source of complex chemical emissions.
- Microwaves, from containment failures of microwave technologies.

Examples of most of the above have previously been identified as significant issues on clinical waste treatment sites.

The purpose of this section is to ensure that monitoring is in place to identify failures in the design, integrity, containment or operation of the site or process.

Reference should be made to the Environment Agency's [Guidance M17 Monitoring of particulate matter in ambient air around waste facilities](#).

A6-2.10.4.1 Microbial emissions monitoring

Microbial monitoring is required, as there is the potential for aerosols 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 may also arise from other sources and therefore be unrelated to plant emissions. The following procedure uses tracer spore suspensions. However it should be noted that monitoring of other indicators may be undertaken as an alternative to tracer spore suspension where demonstrated by the operator to be appropriate. The procedures for such monitoring should be agreed with the regulator prior to implementation.

Procedure for microbial emissions monitoring using tracer spore suspension.

For technologies that shred or macerate the waste prior to treatment

1. A dry or liquid suspension of bacillus spores should be prepared and dispensed (in a laboratory environment) in a number of sealed, small volume plastic containers. These should be dispersed throughout the waste load and processed.

For other technologies

2. Dry or liquid suspensions of bacillus spores should be prepared and dispensed (in a laboratory environment) both loosely in waste inside containers (bags, boxes etc), and inside worst case challenge load containers (suction canisters/chest drains). These should be dispersed throughout the waste load and processed.
3. Spore strips should never be used for bioaerosol emissions monitoring.
4. The quantity of spores should equate to a minimum of 1×10^6 spores per gram of total waste load.
5. All devices should be tested, during commissioning validation, during the first six months of operation and periodically thereafter as indicated in Table A6-2.10.4
6. Process emission monitoring should continue throughout the operational life of the plant.

Frequency of testing

7. The minimum frequency of monitoring is specified in Table A6-2.10.4

Sampling methodology

8. The sampling should consist of 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 should be designed to take sufficient samples to enable the results to be quantitatively related to the input dose.
11. Samples should be taken:
 - prior to the processing of the seeded waste (controls),
 - at intervals during the processing of the seeded waste (the intervals should relate to process stages and timing of potential emissions), and
 - 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. Air monitoring should be conducted 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 buildings 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 should always be treated (e.g. filtered through a HEPA filter). Monitoring is required to demonstrate that the treatment of the gases has been effective and should 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 should

- 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 should 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.
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 should contain information indicating the recovery efficiency of the method used.
16. Monitoring should be conducted 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 contaminants and total microbial load.
19. The use of a regular exposure time, a series of plates at each sampling point, and a grid placement should enable an estimation/calculation of the total number of organisms that have settled 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 should also be monitored at intervals during the testing. For chemical processes, the potential need for neutralisation of disinfectant should be considered.
21. The purpose of this additional monitoring is to ensure that both the
- Treatment process is operating effectively; and
 - The wastewater arises post treatment
22. Wastewater should be sampled prior to entering the drainage system, and as near to the point of origin as possible.

Table A6-2.10.4: Process bioaerosol emissions monitoring

When a suspension of Bacillus Spores has been used				
	First 6 months	Subsequently (if proven and agreed)	Minimum number of sampling points	Minimum number of samples per sampling point
For devices which shred/macerate untreated waste	Quarterly	Annually	See text	See text
For other devices	6-monthly	Bi-annually	See text	See text

A6-2.10.4.2 Chemical emissions monitoring

Waste acceptance and pre-acceptance procedures are intended to prevent waste containing chemicals entering the treatment process. There are two primary consequences where these procedures are insufficient :-

- volatile chemicals are released to atmosphere/water . This is a particular concern with thermal processes.
- Incompatible reactions occur. This is a potential concern with chemical treatment processes.

During validation, a written assessment of the Volatile Organic Compounds (VOCs) emitted from the process shall be submitted to the regulator. The written assessment shall include:

- a scale drawing showing location of the emission points monitored;
- sampling of the emission and comparison against the benchmark values listed in Section 3.11 of IPPC S5.06, to assess their significance;
- proposal of any necessary modelling of the emission;
- details of how any emissions are to be prevented during the operation of the facility.
- particular attention should be paid to VOC's that are associated with the healthcare waste stream (for example Formaldehyde)

VOC monitoring should take place during commissioning, after the first 6 months of operation, and annually thereafter.

Thermal processes (e.g. autoclaves) that employ water condensers should monitor liquid discharges for VOC's.

A6-2.10.4.3 Pharmaceuticals emissions monitoring

Waste acceptance and pre-acceptance procedures are intended to prevent waste containing chemicals entering the treatment process. Monitoring of emissions from such substances would not normally be required where the operator can demonstrate that waste acceptance and pre-acceptance procedures are sufficient to exclude such waste.

A6-2.10.4.4 Microwaves emissions monitoring

Operators of microwave facilities should be aware that failures in containment might result in leakage of non-ionising radiation.

A6-2.10.4.5 Criteria for success

The operator should 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.

A6-2.11 Closure

There are no additional requirements identified for this section.

A6-2.12 Installation issues

There are no additional requirements identified for this section.

A6-3 Emission benchmarks

A6-3.1 Emissions inventory

There are no additional requirements identified for this section.

A6-3.2 Emission benchmarks

Emission benchmarks are discussed in detail in section 3 of IPPC S5.06 and the relevant key issues identified should be applied to the treatment of Clinical Waste.

Table A6-3.1 details emission benchmarks for point source emissions from the installation. These BAT-based benchmarks are not mandatory release limits and reference should be made to Section 1 of IPPC S5.06.

Table A6-3.1 Emission benchmarks

Emission	Measure	Cfu	Unit
Air – sample points <10m from the treatment plant.	Bacillus spores	1000	Per cubic metre ¹
Water	Bacillus spores	(300) ²	Per litre ¹
<p>Note 1 : These Units relate to the overall monitoring period so the cfu benchmark applies to</p> <ul style="list-style-type: none"> • Each individual sample of air taken, with a calculation made to report the result per cubic metre. • 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). • Each individual sample of water taken, with a calculation made to report the result per litre. <p>Note 2: These benchmarks are indicative only, and will be reviewed periodically.</p>			

Table A6-3.2 provides additional guidance with respect to fugitive emissions from the installation. These can be used to support the emission benchmarks in Table A6-3.1.

Table A6-3.2 Emission of spiked organisms

Emission	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
<p>Note 1 : These Units relate to the overall monitoring period so the cfu benchmark applies to</p> <ul style="list-style-type: none"> • Each individual sample of air taken, with a calculation made to report the result per cubic metre. • 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). • Each individual sample of water taken, with a calculation made to report the result per litre. <p>Note 2: These benchmarks are indicative only, and will be reviewed periodically.</p>			

A6-4 Impact

There are no additional requirements identified for this section.

References

[Waste Management Licensing Technical Guidance on Clinical Waste Management Facilities, July 2003, Environment Agency.](#)

Safe Disposal of Clinical Waste, 1999, Health Services Advisory Committee, ISBN 07176 2492 7.

[Safe Management of Healthcare Waste: A Public Consultation, Gateway No 5471, Department of Health.](#) www.dh.gov.uk.

[Technical Guidance WM2. Hazardous Waste. Interpretation of the Definition and Classification of Hazardous Waste, Environment Agency, ISBN 1 84432 4540.](#)

Clinical Waste Disposal/Treatment Technologies (alternatives to incineration), Health Technical Memorandum HTM 2075, NHS Estates, The Stationery Office, ISBN 0-11-322159-2.

CONTROL OF AEROSOL (BIOLOGICAL AND NONBIOLOGICAL) AND CHEMICAL EXPOSURES AND SAFETY HAZARDS IN MEDICAL WASTE TREATMENT FACILITIES FINAL REPORT Contract No. 200-95-2960 RTI Project No. 93U-6449 Prepared For National Institute for Occupational Safety and Health, November 1997

[M17 Monitoring of Particulate matter in ambient air around waste facilities](#), March 2003, Environment Agency