Appropriate measures for permitted facilities that take healthcare waste

Consultation Draft

May 2019

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We help people and wildlife adapt to climate change and reduce its impacts, including flooding, drought, sea level rise and coastal erosion.

We improve the quality of our water, land and air by tackling pollution. We work with businesses to help them comply with environmental regulations. A healthy and diverse environment enhances people's lives and contributes to economic growth.

We can't do this alone. We work as part of the Defra group (Department for Environment, Food & Rural Affairs), with the rest of government, local councils, businesses, civil society groups and local communities to create a better place for people and wildlife.

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Introduction

We have produced this guidance to help you understand what standards (appropriate measures) are relevant to regulated facilities permitted for the treatment or transfer of healthcare waste.

When appropriate measures apply

Because there is considerable overlap between best available techniques (BAT) for waste installations facilities and necessary measures for waste operation facilities, we use the term 'appropriate measures' to cover both sets of requirements.

For installations there are additional standards that cover using energy and raw materials (including water) efficiently.

Appropriate measures are the minimum standards that operators must meet to comply with their environmental permit requirements.

Some appropriate measures may not be suitable in particular site-specific circumstances. Where this is the case, an operator can propose alternative measures if they can justify that they achieve the same level of environmental protection. In certain situations, a higher standard of environmental protection may be needed, for example:

- where there are local sensitive receptors
- if there is a risk that an operator may exceed an Environmental Quality Standard.

How the standards in this technical guidance apply to different types of facilities that treat or transfer healthcare waste is summarised in Table 1.

Table 1 – How the standards apply to different facility types

Document section	Transfer station	Alternative treatment	Incineration
Management and contingency	✓	✓	Incineration sector guidance
Waste stream management	✓	✓	✓
Waste storage and segregation	✓	✓	✓
Waste treatment	×	✓	Incineration sector guidance
Emissions control	×	✓	
Emissions limits and monitoring	×	✓	
Use of energy and raw materials	IED Installations only	IED Installations only	

Other technical guidance may also apply to healthcare waste facilities, including guidance on emissions, odour and noise.

Specific technical guidance may also be appropriate. For example, sites that incinerate healthcare waste and facilities that store or treat non-healthcare waste should refer to additional technical guidance.

Combustion plant with a rated thermal input equal to or greater than 1 megawatt (but less than 50 megawatts) must have a permit and comply with the relevant requirements of the Medium Combustion Plant Directive (2015/2193).

Implementing appropriate measures at new and existing facilities

The appropriate measures in this guidance apply to both new and existing facilities that treat or transfer healthcare waste.

For new facilities the appropriate measures must be in place before operations start.

For existing facilities, if the cost of complying with the appropriate measures is disproportionate to the environmental benefit, immediate compliance may not be reasonable. Through permit reviews, the Environment Agency will assess the current operating techniques of existing facilities against the relevant appropriate measures. Where appropriate measures are not being used, we will expect these operators to provide improvement plans and timetables for implementing the relevant appropriate measures. We will review these proposals and set formal timescales for making the improvements needed. This will be done through improvement conditions in the varied environmental permits.

Improvements at existing facilities are likely to fall into one of the following two categories.

Standard 'good-practice' requirements
For example, these could be:

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

Where these improvements are relatively low cost, operators should implement them as soon as possible and within 12 months.

Larger, more capital-intensive improvements
For example, these could be:

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

These improvements should be completed as soon as practicable. All facilities must be compliant with the relevant appropriate measures by August 2022.

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

Definition of healthcare waste

Healthcare waste is waste produced during human or animal healthcare, or related research activities, and covers both clinical and offensive waste.

It includes wastes produced by healthcare in the community, and similar types of waste produced by non-healthcare activities, for example:

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

Table 2 lists the different types of healthcare waste.

'Clinical waste' and 'offensive waste' are defined in the Controlled Waste (England and Wales) Regulations 2012.

'Clinical waste' is healthcare waste that:

- contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms
- contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent
- is a sharp, or a body fluid or other biological material (including human and animal tissue) containing or contaminated with a hazardous substance
- is waste of a similar nature from a non-healthcare activity

‘Offensive waste’ is waste that:

- is not clinical waste
- contains body fluids, secretions or excretions
- falls within waste code 18 01 04, 18 02 03 or 20 01 99

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

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

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

Healthcare waste may include radioactive materials. This guidance does not cover managing these waste materials. You must comply with Radioactive Substances Regulation (RSR) guidance when managing radioactive materials.

Managing healthcare wastes

Healthcare practices must follow the guidance Healthcare Technical Memorandum (HTM) 07-01: safe management of healthcare waste, which explains how to segregate healthcare wastes. They should also use colour-coded packaging (bags and rigid containers) into which they only put the waste types specified.

Correctly classifying and segregating healthcare waste at source makes sure that the right waste goes to the right place for appropriate storage and treatment. Segregating waste based upon type and properties means that it can be treated effectively and efficiently. It also helps divert certain wastes (for example, offensive wastes) away from more costly and energy intensive treatment processes. This means that more waste can be sent to alternative recycling and recovery operations.

The most important step in this process is that healthcare practices producing the waste make sure that they rigorously segregate their wastes at source and that they check and confirm (audit) this is being done on an ongoing basis.

As part of their waste pre-acceptance procedures, operators of permitted healthcare waste facilities must obtain and assess the results of waste audits carried out at producer premises. They must do this before they first accept waste from a producer and then at regular intervals, as set out in this guidance.

When you receive waste at your permitted healthcare waste facility, you must inspect the contents of each cart or similar bulk container and check to see that the contents match those expected.

In this document, the term ‘bulk container’ means a large, rigid, enclosed secondary container, This includes 770 litre carts used to store and transfer healthcare wastes packaged in bins, bags or boxes. This is a different definition to the one specified in UN 3291, and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), because it does not include vehicles or vehicle trailers.

Because healthcare wastes are potentially infectious, it is difficult to open each container or bag at waste sites to check that they contain only the correct waste. If you comply with the requirements of this guidance, the Environment Agency has agreed that you do not need to check the contents of individual containers or bags received at your site. In these instances, you can base your waste acceptance confirmatory checks on checking and confirming that waste is appropriate for storage and treatment based on its colour-coded packaging.

The waste types listed in Table 2 cover the range of wastes that are produced at human and animal healthcare provider sites. For each waste type, the table provides:

- the relevant List of Waste (LoW) code(s)
- appropriate waste management activity (storage includes transfer)
- colour-coding of the packaging

Some wastes are given two or more LoW codes. If you receive multi-coded wastes (for example, medicinally contaminated infectious sharps), your site must have a permit that allows you to receive all of the individually identified LoW codes. If you move waste specified in Table 2 from one site to another, you must include all of the LoW codes relevant to the waste on the consignment note or transfer note.

Energy from waste (municipal waste incineration) or landfill are acceptable disposal methods for carefully segregated offensive hygiene wastes. In England, these wastes are put into yellow bags with a black stripe, otherwise known as 'tiger' bags.

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

- anatomical waste
- chemicals
- medicines

You must provide a detailed justification for the alternative treatment of any anatomical waste, or waste containing or contaminated with medicines or chemicals. This must demonstrate that:

- all pharmaceutically active substances (hazardous or non-hazardous) will be destroyed
- chemicals will be fully treated and not diluted and released to the environment

You must send all other healthcare waste for incineration, for example:

- anatomical waste
- medicinal waste
- chemical waste
- medically or chemically contaminated infectious waste

You must use high temperature incineration (that is at temperatures greater than 1000°C) for wastes containing cytotoxic or cytostatic medicines.

The requirements (appropriate measures) set out in this guidance apply to all waste received at permitted facilities, including waste received from producers outside of England.

Operators of permitted facilities that receive waste from producers outside of England must make sure that they will comply with all the waste pre-acceptance requirements, for example, by obtaining waste producer audit reports. They must also make sure that the approved testing and validation of the treatment plant (based upon worst-case challenge load) remains valid, taking into account the type(s) and composition of waste that will be accepted for treatment.

Table 2 – Types of healthcare waste

Type of waste [Note 1]	**LoW Code(s)**	**Appropriate waste management activity**	**Colour coding of packaging**
Water-based developer and activator solutions	09 01 01*	Storage. Photographic wastes arising from healthcare and/or related research only	**NA**
Water-based offset plate developer solutions	09 01 02*		**NA**
Solvent based developer solutions	09 01 03*		**NA**
Fixer solutions	09 01 04*		**NA**
Bleach and bleach fixer solutions	09 01 05*		**NA**
Photographic film and paper containing silver or silver compounds	09 01 07*		**NA**

Table 2 – Types of healthcare waste			
Type of waste [Note 1]	**LoW Code(s)**	**Appropriate waste management activity**	**Colour coding of packaging**
Photographic film and paper free of silver or silver compounds	09 01 08		**NA**
Non-infectious sharps, not contaminated with chemicals or medicines - human healthcare	18 01 01	Storage and clinical waste incineration (CWI)	**YELLOW**
Non-infectious sharps, not contaminated with chemicals or medicines - animal healthcare	18 02 01		
Infectious clinical waste, contaminated with chemicals - human healthcare	18 01 03* and 18 01 06* and/or 18 01 07	Storage and CWI	**YELLOW**
Infectious clinical waste, contaminated with chemicals - animal healthcare	18 02 02* and 18 02 05* and/or 18 02 06		
Infectious clinical waste, medicinally contaminated (not cytotoxic or cytostatic) - human healthcare (may contain sharps)	18 01 03* and 18 01 09 Note 2		
Infectious clinical waste, medicinally contaminated (not cytotoxic or cytostatic) - animal healthcare (may contain sharps)	18 02 02* and 18 02 08 Note 2		
Infectious clinical waste, not contaminated with chemicals or medicines - human healthcare (may contain sharps)	18 01 03*	Storage, alternative treatment and CWI	**ORANGE**
Infectious clinical waste, not contaminated with chemicals or medicines - animal healthcare (may contain sharps)	18 02 02*		
Infectious clinical waste, not contaminated with chemicals or medicines - municipal, separately collected fractions, not from healthcare or research-related sources (may contain sharps)	20 01 99		
Infectious anatomical clinical waste, chemically preserved - human healthcare	18 01 06* and 18 01 03* and/or 18 01 02	Storage and CWI	**RED**
Infectious anatomical clinical waste, chemically preserved - animal healthcare	18 02 05* and 18 02 02* and/or 18 02 03		
Infectious anatomical clinical waste, not chemically preserved - human healthcare	18 01 03* and/or 18 01 02		
Infectious anatomical clinical waste, not chemically preserved - animal healthcare	18 02 02* and/or 18 02 03		
Non-infectious anatomical waste, chemically preserved - human healthcare	18 01 02 and 18 01 06*		
Non-infectious anatomical waste, chemically preserved - animal healthcare	18 02 03 and 18 02 05*		
Cytotoxic and cytostatic medicines - human healthcare	18 01 08* Note 3	Storage and CWI	**PURPLE**
Cytotoxic and cytostatic medicines - animal healthcare	18 02 07* Note 3		
Infectious clinical waste, contaminated with cytotoxic and cytostatic clinical waste - human healthcare (may contain sharps)	18 01 03* and 18 01 08* and/or 20 01 31*		

Table 2 – Types of healthcare waste			
Type of waste [Note 1]	**LoW Code(s)**	**Appropriate waste management activity**	**Colour coding of packaging**
Infectious clinical waste, contaminated with cytotoxic and cytostatic clinical waste - animal healthcare (may contain sharps)	18 02 02* and 18 02 07* and/or 20 01 31		
Other waste medicines, excluding cytotoxic and cytostatic medicines	18 01 09 or 18 02 08 and/or 20 01 32	Storage and CWI	**BLUE**
Non-infectious offensive waste - human healthcare	18 01 04 [Note 2]	Storage and municipal incineration or landfill. Compaction, where specifically authorised.	
Non-infectious offensive waste, animal healthcare	18 02 03 [Note 2]		**YELLOW AND BLACK STRIPES (TIGER BAGS)**
Non-infectious offensive waste - municipal, separately collected fractions not from healthcare or research-related sources	20 01 99 [Note 2]		
Amalgam waste from dental care	18 01 10*	Storage	**NA**
Lead foils from dental care	15 01 10*	Storage	**NA**

Note 1: As set out in HTM 07 01 and shown in the examples above, a waste stream may need to be dual coded and described to ensure that multiple components of the waste are adequately identified (for example, infectious sharp (18 01 03*) containing cytotoxic contamination (18 01 08*)). The presence of sharps in a waste stream should be identified through the written description given to the waste and appropriate packaging used (lidded, rigid containers).

Note 2: These wastes may be accepted for alternative treatment subject to written justification being received and approved by the Environment Agency. This must demonstrate that:

- the treatment is effective (including validation of worst case scenario conditions)
- it is an efficient use of energy and raw materials
- it enhances the recovery or recycling of the waste,
- it does not impede the treatment of any other wastes and assesses any impact upon emissions from the facility (to air and water)

Note 3: In accordance with Appendix A, Guidance on the classification and assessment of waste (WM3), waste medicinal products from the manufacture and supply of pharmaceuticals should be classified under the medicine codes in chapter 18 of the LoW.

General management appropriate measures

Environmental management system

1. You must have an up-to-date, written environmental management system (EMS).

2. To improve your overall environmental performance, you must put in place and follow an EMS that incorporates the following features.

   You have management commitment, including from senior managers.

   You have an environmental policy that is defined by senior managers and includes the continuous improvement of the facility's environmental performance.

   You plan and establish the procedures, objectives and targets needed for environmental performance alongside your financial planning and investment.

   You implement your environmental performance procedures, paying particular attention to:
   - staff structure and relevant responsibilities
   - staff recruitment, training, awareness and competence
   - communication (for example, of performance measures and targets)
   - employee involvement
   - documentation
   - effective process control
   - maintenance programmes
   - emergency preparedness and response
   - making sure you comply with environmental legislation

   You check environmental performance and take corrective action, paying particular attention to:
   - monitoring and measurement
   - corrective and preventive action
   - records maintenance
   - independent (where practicable) internal or external auditing of the EMS to conform it has been properly implemented and maintained

   Senior managers review the EMS to check it is still suitable, adequate and effective.

   You review the development of cleaner technologies and their applicability to site operations.

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

   You apply sectoral benchmarking on a regular basis by comparing site operations with:
   - the requirements of relevant sector guidance
   - those carried out by others in the sector

   You carry out appropriate waste stream management.

   You have:
   - an inventory of waste water and waste gas streams
   - a residues management plan
   - an accident management plan
   - an odour management plan, if required
   - a noise and vibration management plan, if required

Staff competence

1. Your site must be operated at all times by an adequate number of staff with appropriate qualifications and competence.

2. You must have appropriately qualified managers for your waste activity who are members of a government-approved technical competency scheme.

Accident management plan

1. As part of your up-to-date written management system you must have a plan for dealing with any incidents or accidents that could result in pollution.

2. The accident management plan must identify the hazards to the environment posed by the plant.

3. Particular areas to consider may include:
    - waste types
    - overfilling of vessels
    - failure of the plant and equipment (for example over-pressure of vessels and pipework, blocked drains)
    - failure of containment (for example failure of the bund, or overfilling of drainage sumps)
    - failure to contain firefighting water
    - making the wrong connections in drains or other systems
    - preventing incompatible substances coming into contact with each other
    - unwanted reactions and runaway reactions
    - adequately checking the composition of an effluent before emission
    - vandalism and arson
    - extreme weather conditions for example flooding or very high winds

4. You must assess the risk of accidents and their possible consequences (risk is the combination of the likelihood that a hazard will occur and the severity of the impact resulting from that hazard). Having identified the hazards, you can assess the risks by addressing six basic questions:
    - how likely is it that the accident will happen?
    - what may be emitted and how much?
    - where will the emission go - what are the pathways and receptors?
    - what are the consequences?
    - what is the overall significance of the risk?
    - what can you do to prevent or reduce the risk?

5. In particular, you must identify any fire risks that may be caused, for example by:
    - arson or vandalism
    - self-combustion (for example due to chemical oxidation)
    - plant or equipment failure and other electrical faults
    - naked lights and discarded smoking materials
    - hot works (for example welding or cutting), industrial heaters and hot exhausts
    - reactions between incompatible materials
    - neighbouring site activities
    - sparks from loading buckets
    - hot loads deposited at the site

6. The depth and type of accident risk assessment you carry out will depend on the characteristics of the plant and its location. The main factors to take into account are the:
    - scale and nature of the accident hazard presented by the plant and its activities
    - risks to areas of population and the environment (the receptors)
    - nature of the plant and complexity of the activities and how difficult it is to decide and justify adequate risk control techniques

7. Through your accident management plan, you must also identify the roles and responsibilities of the staff involved in managing accidents. You must provide them with clear guidance on how to manage each accident scenario, for example, whether to use containment or dispersion to extinguish fires, or let them burn.

8. You must appoint one facility employee as an emergency coordinator who will take lead responsibility for implementing the plan. It is important that you train your employees so they can perform their duties effectively and safely and know how to respond to an emergency

9. You must also:
    - establish how you will communicate with relevant authorities and emergency services both before, during and after an accident
    - put in place appropriate emergency procedures, including for safe plant shutdown and site evacuation
    - put in place post-accident procedures that include undertaking an assessment of the harm that may have been caused by an accident and the remediation actions you will take

Accident prevention measures

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

Records keeping and procedures

11. You must:
    - keep an up-to-date plant log or diary to record all accidents, incidents, near misses, changes to procedures, abnormal events, and the findings of maintenance inspections
    - record leaks, spills and accidents in the site diary – you can use the incident and response to estimate notifiable releases for the annual report
    - establish procedures to identify, respond to and learn from such incidents and accidents
    - maintain an inventory of substances, which are present (or likely to be) and which could have environmental consequences if they escape - many apparently innocuous substances can damage the environment if they escape
    - have procedures in place for checking raw materials and wastes to make sure they are compatible with other substances they may accidentally come into contact with

Segregating waste

12. You must keep apart incompatible or segregated wastes and substances according to their hazardous properties.

13. You must segregate incompatible waste types into bays or store them in dedicated buildings. The minimum requirement is to use a kerbed perimeter and separate drainage collection. You must also have measures in place to prevent containers falling over into other storage areas.

Preventing accidental emissions

14. You must make sure that you contain the following (where appropriate) and route to the effluent system (where necessary):
    - process waters
    - site drainage waters
    - emergency firefighting water
    - chemically contaminated waters
    - spillages of chemicals

15. You must have a provision to contain surges and storm water flows. You must provide enough buffer storage capacity to make sure that you can achieve this. You can define this capacity using a risk-based approach, for example, by taking into account the:
    - nature of the pollutants

- effects of downstream waste water treatment
- sensitivity of the receiving environment

16. You can only discharge waste water from this buffer storage after you have taken appropriate measures, for example, to control, treat or re-use the water.

17. You must put spill contingency procedures in place to minimise the risk of an accidental emission of raw materials, products and waste materials and to prevent their entry into water.

18. Your emergency firefighting water collection system must take account of additional firefighting water flows or firefighting foams. You may need emergency storage lagoons to prevent contaminated firefighting water reaching a receiving water body.

19. You must consider and, if appropriate, plan for the possibility that you may need to contain or abate accidental emissions from:
    - vents and
    - safety relief valves
    - bursting discs

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

Security measures

20. You must have enough security measures in place (including staff) to prevent:
    - entry by vandals and inadvertent intruders who could be exposed to harmful substances by contact with waste
    - damage to the equipment
    - theft
    - illicit dumping

21. Facilities must use a combination of the following measures:
    - security guards
    - total enclosure (usually with fences)
    - controlled entry points
    - adequate lighting
    - proper warning signs
    - 24-hour surveillance

    Typically, the guards also operate the gatehouse to where they prevent entry of unscheduled trucks and monitor the entry of visitors.

Fire prevention

22. If you have a permit to carry out an activity involving the storage of non-hazardous combustible waste you must have an approved fire prevention plan that meets the requirements of our guidance.

23. You must have appropriate systems in place for fire prevention, detection and suppression or extinction.

24. You must have suitable procedures and provisions to store certain types of hazardous waste, for example automatic alarms and possibly sprinklers.

25. Your facility must have enough water supplies to extinguish fires and the capability to collect and store firefighting water run-off.

26. You must have an alternative type of fire protection system if you store or treat any water-reactive waste.

27. You must isolate drainage systems from flammable waste storage areas to prevent fire being spread along the drainage system by solvents or other flammable hydrocarbons.

Other accident prevention measures

28. You must maintain plant control in an emergency using one or a combination of the following measures:
    - process design alarms
    - process trips and interlocks
    - automatic systems based on microprocessor control and valve control
    - tank level readings such as ultrasonic gauges, high level warnings, process interlocks and process parameters

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

Contingency plan and procedures

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

2. You must have contingency procedures in place to make sure that, as far as possible, you know in advance about any planned shutdowns at waste management facilities where you send waste.

3. You must make your customers aware of your contingency plan, and of the circumstances in which you would stop accepting waste from them.

4. You must consider whether the sites or companies you rely on in your contingency plan:
    - can take the waste at short notice
    - are authorised to do so in the quantities and types likely to be needed - in addition to carrying out their existing activities

5. You must not discount alternative disposal options on the basis of additional cost or geographical distance, if doing this may result in exceeding your permitted storage limits or compromising your storage procedures.

6. You must not include unauthorised capacity in your contingency plan. If your contingency plan includes using temporary storage for additional waste on your site, then you must make sure your site is authorised for this storage and the appropriate infrastructure is in place.

Treatment and Incineration sites only

7. Your management procedures and contingency plan must:
    - identify known or predictable malfunctions associated with your technology and the procedures, spare parts, tools and expertise needed to deal with them

- include a record of spare parts held - or state where you can get them from and how long it would take
- have a defined procedure to identify, review and prioritise items of plant which need a preventative regime
- include all equipment or plant whose failure could directly or indirectly lead to an impact on the environment or human health
- identify 'non-productive' or redundant items such as tanks, pipework, retaining walls, bunds, reusable waste containers (for example wheeled carts), ducts, filters and security systems
- make sure you have the spare parts, tools, and competent staff needed before you start maintenance

8. You must carry out appropriate disinfection procedures when maintaining equipment (or parts of equipment) contaminated with untreated clinical waste. Using personal protective equipment (PPE), although essential to protect workers from exposure, should not be your primary control measure.

9. Your management system must include procedures for auditing your performance against all the contingency measures detailed above and for reporting the audit results to the site manager.

Plant decommissioning

1. You must consider the decommissioning of the plant at the design stage and make suitable plans to minimise risks during later decommissioning.

2. For existing plants where potential problems are identified you must put in place a programme of design improvements. These designs improvements need to make sure that you:
    - avoid using underground tanks and pipework - if it is not economically possible to replace them, you must protect them by secondary containment or a suitable monitoring programme
    - drain and clean-out vessels and pipework before dismantling
    - use insulation which you can dismantle easily without dust or hazard
    - use recyclable materials – taking into account operational or other environmental objectives

Waste stream management appropriate measures

Waste pre-acceptance and characterisation

1. You must implement waste pre-acceptance procedures so that you know enough about a waste (including its composition) before it arrives at your facility. You need to do this to assess and confirm the waste is technically and legally suitable for your facility. Your procedures must follow a risk-based approach, considering:
    - the source and nature of the waste
    - its hazardous properties
    - potential risks to process safety, occupational safety and the environment

2. You must make sure that the advice you give to waste producers about segregating and packaging waste follows the Safe Management of Healthcare Waste (HTM 07 01). Where HTM 07 01 does not specify the colour of packaging for a particular type of waste, the waste producer should use the most appropriate waste colour. They should take into account the nature of the waste and the waste disposal or recovery route needed. For example, it should be:
    - yellow if the waste requires clinical waste incineration
    - orange if alternative treatment is appropriate
    - black or black and yellow if municipal incineration is appropriate
    - or (if possible) an additional non-conflicting colour code

3. If you receive waste from a country that does not use the same waste segregation process or colour-coded packaging as set out in HTM 07 01, you must get additional information from the producer. This must confirm the segregation practices and colour-coding they have used so that you can fully understand the waste stream and send it for appropriate treatment.

4. You must get the following information in writing when you receive a waste disposal enquiry:
    - details of the waste producer (for example, medical practice) including address and contact details
    - the specific source of the waste – for example, veterinary, primary care, dental, acute care, laboratory
    - details of the waste streams and types produced, including their quantity, physical form, composition, properties, classification and description (you must carry out more detailed checks as part of the site audit)

5. Before waste arrives at your facility you must get a representative audit analysis report from the producer or medical practice. You do not need an audit report for waste produced at:
    - domestic premises
    - care homes that do not provide nursing care
    - healthcare wastes from non-healthcare activities - as classified under Chapter 20 of the LoW

6. The audit report must, as a minimum, identify which of the following waste types are produced by each unit or department. It must also identify the container or packaging type they are placed in (including colour-coding) and whether the correct waste type was present in each container when examined. The report must also compare the waste to its proposed waste classification or description. These are the waste types the audit must identify:
    - cytotoxic and cytostatic contaminated material
    - other pharmaceuticals or pharmaceutically contaminated material - for example, medicinally contaminated syringes, I.V. bags, tubing, bottles, vials, ampoules
    - waste chemicals – for example, laboratory agents, auto-analyser bottles, diagnostic kits, disinfectants
    - human or animal tissue, and associated chemical preservatives
    - sharps, and whether they are contaminated with medicines (even if fully discharged)
    - other infectious wastes
    - dental amalgam
    - non-hazardous offensive wastes
    - other non-hazardous wastes, including municipal waste and autoclaved wastes
    - gypsum wastes other than the limited quantities correctly described as infectious

7. The audit report must include the following general information:
    - the name, address and contact details of the healthcare waste practice
    - the type of practice (for example, hospital, veterinary clinical, general practice)
    - dates for when the audit started and ended
    - a description of the audit, the procedures employed, the auditors, their affiliation and their competence

8. It must also include a list (or diagram) of the different wards, departments, or functional areas that exist within the premises. This should detail all the specific processes producing relevant wastes at the practice (for example, pharmacy, primary care, dental acute or laboratory).

9. The audit report must include a list of the wastes produced at each unit or area within the premises, including:
    - its type and the colour-coded packaging used
    - the type and labelling of containers used
    - EWC code(s)
    - physical form
    - packaging
    - composition
    - hazardous properties
    - classification and written description

10. The audit report must include information about:
    - the segregation practices for wastes placed in storage areas and bulk containers or carts
    - specific storage requirements (for example, cold storage or freezing)
    - the contents of a representative number of each type of bulk container that were checked visually
    - discussions held with staff that establish the validity of the segregation and storage standards, and the observation and recording of actual practice

11. The audit report must include a comparison of practice with the requirements of HTM 07-01 Safe Management of Healthcare Waste and of WM3. For example, the medical practice should have an:
    - acceptable and working definition of cytotoxic and cytostatic waste where applicable
    - offensive waste stream for healthcare waste (rather than municipal wastes from lavatories)

12. The report must also include:
    - the findings made for each waste stream, and where applicable the changes made as a result of this or previous audits
    - information on waste policies, staff training, internal audit regimes, and environmental management systems
    - the estimated quantity of each waste expected to be delivered to the operator from the medical practice per year and in a typical load
    - confirmation that any waste does not contain a radioactive source or, when there is a risk of radioactive contamination, confirmation that the waste is not radioactive
    - safety data sheets for single stream product chemicals, pharmaceuticals or laboratory chemicals

13. It is the responsibility of the waste producer to ensure that a waste pre-acceptance audit is carried out for their premises. The audit report must not be completed wholly over the phone or using online tools. Physical presence at the practice is needed. This may be provided by an appropriately trained and experienced member of site staff or an external auditor.

14. You must obtain and assess an audit analysis report before you take delivery of the first batch of waste from each medical practice. You must then do this at the following minimum frequencies, every:
    - 12 months for each medical practice that produces 5 tonnes or more of healthcare waste in any calendar year
    - 2 years for each veterinary practice, dental practice, and laboratory that produces less than 5 tonnes of clinical waste in any calendar year
    - 5 years for other healthcare producers of healthcare waste

15. The audit report will no longer be valid for pre-acceptance purposes:
    - once the time intervals have been exceeded
    - if the producer makes significant changes to on-site practices
    - if the waste changes
    - if you find that the waste received contains significant non-conformances to the pre-acceptance information (for example, it contains waste type that was not included in the pre-acceptance audit of the producer)

16. Where a medical practice produces 5 tonnes or more of healthcare waste per year, the first audit must cover the entire practice. If this is satisfactory, and identifies consistent practice, you can reduce the scope of each subsequent yearly audit to cover at least one third of the units, wards and departments. A three year audit cycle must include all units, wards and departments. If a medical practice produces less than 5 tonnes of healthcare waste per year each audit should include the entire practice. It should be clear in the audit report which units, wards and departments have been inspected.

17. The operator of the waste facility must assess the producer waste audit report. The staff doing the assessment must have the professional skills, training and experience needed. They must have a clear understanding of clinical waste, its:
    - composition
    - classification
    - packaging and transport

18. These staff must also understand:
    - the wastes associated with specific healthcare activities
    - any conditions within the permit that relate to these wastes
    - the requirement to complete waste consignment and transfer notes

19. If the audit report is partially incomplete or inadequate, because it does not meet all the requirements set out in the preceding paragraphs, you must request the missing information (or another audit report). You must assess this before you accept the waste.

20. If the audit report is acceptable (it meets all the requirements above) you must technically assess the suitability of the wastes for on-site treatment (or transfer) to make sure you can meet your permit conditions. You must not accept wastes which are not suitable.

21. You must keep records that relate to pre-acceptance for a minimum of 3 years in a computerised process control system. For example, this includes:
    - audit reports
    - assessment of the reports
    - additional information received
    - your assessment that the waste is acceptable

22. If an enquiry from a waste producer does not lead to the receipt of waste, you do not need to keep records.

23. You must keep separate the roles and responsibilities of sales staff and technical staff. If non-technical sales staff are involved in waste enquiries then you must carry out a final technical assessment before approval. You must use this final technical check to make sure that you:
    - only accept wastes that are suitable for the site
    - avoid accumulating waste
    - have enough storage and treatment capacity

24. The operator of the waste facility is responsible for making sure that they carry out appropriate pre-acceptance checks and subsequent assessments on the waste received from each producer (for example, a medical practice). You can employ a third party to carry out these checks and assessments for you, for example, if you receive the waste via a waste carrier or transfer station. Where this is the case you must meet the following measures as a minimum:

- the third party must provide you with details of any audit tools or methodologies and assessment criteria used and these must meet the standards in this guidance
- you must periodically review the other party's pre-acceptance checks and assessments (at least annually) to make sure pre-acceptance checks, subsequent assessments, waste classification and descriptions meet the standards in this guidance
- if you employ waste carriers or transfer stations to carry out the pre-acceptance checks and assessments for you these must cover all relevant producers from whom waste is collected, including new customers
- you must keep records of the third party's pre-acceptance checks and assessments and a summary report that demonstrates they have carried out the correct checks on wastes from relevant producers

25. The summary report must:
    - list the producer types
    - detail the waste types and waste streams produced and destined for the permitted facility, including details of their composition, classification and any hazardous properties
    - describe the containers or packaging used for each waste stream (including colours)
    - confirm that the relevant appropriate measures for waste pre-acceptance have been completed for all relevant producers - where this is not the case for a particular producer, the report must state what has been done

26. The summary report must also:
    - confirm any issues the third party has identified and what action they have taken with the producers about the wastes affected
    - be updated if any details about the producers or the wastes change

27. The information in the summary report must be relevant to the waste types that your facility is permitted to accept. It must be taken from the pre-acceptance audits carried out on the relevant producer premises, which must comply with the requirements of this guidance.

28. The operator must be able to get (without unreasonable delay) a copy of the pre-acceptance report and assessment about any individual producer. This may be needed for operational reasons or because an Environment Agency officer requests to see it.

Waste acceptance

1. You must carry out waste acceptance procedures to check the characteristics of the waste received matches the information you obtained during waste pre-acceptance. This is to confirm the waste is as expected and you can accept it, or that you must reject it.

2. Your procedures should follow a risk-based approach, considering:
    - the source and nature of the waste
    - its hazardous properties
    - potential risks to process safety, occupational safety and the environment

3. Acceptance checks may involve waste inspection, sampling and analysis. You must implement a waste tracking system that holds information about all the waste on site generated by:
    - pre-acceptance
    - acceptance or rejection
    - storage
    - treatment
    - transfer

4. Other than in an emergency (for example, taking waste resulting from an emergency incident clean-up), you must only receive pre-booked wastes onto site that have been adequately pre-accepted and that are consistent with the pre-acceptance information.

5. All relevant storage areas (quarantine, reception and general) and treatment processes in your facility must have the physical capacity needed for the waste you receive. You must not receive wastes if this capacity is not available. The amount of waste you receive must also comply with storage limits in your permit.

6. You must visually check wastes and verify them against pre-acceptance information and transfer documentation before you accept them on site.

7. If you receive packaged items collected from multiple premises loose and not in labelled bulk containers (for example, from smaller producers, such as GP surgeries, dental practices, tattoo parlours), you must check each individual package to make sure it is labelled with the relevant information to allow you to track the waste. As a minimum this must identify the original waste producer.

8. You must weigh each consignment of waste on arrival to confirm the quantities against the accompanying paperwork, unless alternative reliable systems are available (for example, based upon volume).

9. You must check and validate all transfer documentation and resolve discrepancies before you accept the waste. If you believe the incoming waste classification and description is incorrect or incomplete, then you must address this with the original waste producer during waste acceptance. You must record any non-conformances.

10. If you identify the classification or description of waste received as incorrect or incomplete, but you have assessed it as acceptable for on-site storage or treatment, you must document this. You must then address the discrepancies with the original waste producer as part of your waste acceptance procedures.

11. After you have carried out the initial visual inspection and confirmatory checks, you must offload waste containers into a dedicated reception or storage area. You must not unload wastes if you do not have enough space.

12. Once offloaded, and as soon possible and practicable to do so, you must assess the waste and verify it for acceptance.

13. You must carry out a thorough visual check of all loads of waste received (for example, in carts or similar bulk containers, or on pallets) to identify any non-conforming items. If a specific customer has no non-conformances for a period of either 3 months or 6 collections (whichever is the longer period) you can reduce the visual inspection of their waste to a spot check of one cart, bulk container or pallet in ten.

14. If you subsequently identify a non-conforming waste during a spot check, you must take measures to prevent a recurrence (including contacting the customer). You must reinstate thorough visual checks on all loads from that customer until there are no non-conformances for the period stated above.

15. The person carrying out waste acceptance checks (the visual inspection of the waste) must be trained to identify and manage any non-conformances in the loads received, complying with this guidance and the conditions of your permit.

Figure 1 Example of a non-conforming waste - yellow bag in cart of orange-lidded containers and containers not upright

16. You do not need to open healthcare waste bags, sharps boxes, rigid bins or similar packages during the thorough visual check for non-conforming items. The waste pre-acceptance checks determine their contents, and you can verify this by referring to the appropriate colour-coded waste packaging. The objective of the thorough visual check is to identify non-conforming items that may be:
    - unknown
    - undocumented
    - unexpected packaging types or colours
    - a waste type that the facility is not permitted for

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

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

18. You must minimise the manual handling of waste. You should use mechanical unloading or screening technologies where it is possible and practicable to do so.

19. On arrival, bagged waste must either be in carts or other rigid, leak-proof bulk containers or you must unload it from the delivery vehicle directly into carts or other rigid leak-proof bulk containers for storage and handling around the site. You must securely close the lid of the cart or other bulk container when you are not loading waste into or out of it.

20. On arrival, rigid containers (bins or boxes) must be either in, or unloaded onto, enclosed bulk containers (for example, carts) or pallets. You must keep rigid containers (bins or boxes) in an upright position as far as it is possible to do so during storage and handling.

21. Where pallets are used, containers must be stacked no more than 1.8m high (including the height of the pallet) and secured with clear or transparent shrink-wrap. The containers must not extend beyond (over-hang) the sides of the pallet. The shrink-wrap must be clear or transparent so that you can identify waste types, damaged containers, leaks or spillages and incorrectly stacked containers.

22. Waste packages must be in sound condition. All containers (boxes and bins) must have well-fitting lids. You must deal immediately with any non-conforming packages or place them into a bulk container. You must put non-conforming packages into quarantine to be dealt with appropriately. You must record all non-conformances.

23. You must have clear and unambiguous criteria that you use to reject non-conforming wastes. You must also have a written procedure for recording, reporting and tracking non-confirming wastes, including notifying the relevant customer or waste producer and the regulator.

24. You must mark or label all waste packages received with a unique identifier. The unique identifier must allow you to track the waste (see appropriate measures for waste tracking) and easily identify the producer of the waste, its type and hazardous properties and its receipt date.

25. If you receive or store waste packages in a bulk container (for example, a wheeled cart), provided they are from the same producer and contain a single waste stream, you can mark or label the unique identifier on the bulk container for as long as the waste remains in there. Similarly, if you receive waste packages on a pallet, provided they are from the same producer and contain a single waste stream, you can mark or label the pallet with the unique identifier for as long as the waste remains on it. If a bulk or palletised load is split, each container must be marked or labelled with the unique identifier so that it can be tracked.

26. If you add packages to a bulk container or pallet at your facility, you must mark the container or pallet with all the unique identifiers for the packages it holds, and the earliest receipt date of any package. You must do this even where you use bar coding systems.

27. You must hold all records relating to waste received on a computerised waste tracking system. This must be able to cross-reference all the available waste stream information for a receipt using the unique identifier. You must update the tracking system whenever you move or treat a waste on site, or send it off site. You should only move wastes between different locations (or off site) following your written procedures.

28. If you receive containers holding laboratory chemicals, or photo-chemicals for treatment or transfer, your waste acceptance procedures must comply with the appropriate measures in EPR 5.06 Guidance for the Recovery and Disposal of Hazardous and Non Hazardous Waste.

29. If there is an established risk of radioactive contamination, you must check the waste to determine that it does not include radioactive material, unless the permit for your site allows you to accept these materials.

30. Your facility must have a dedicated waste quarantine area located within a building.

31. Quarantine storage must be for a maximum of five working days. You must have written procedures in place for dealing with wastes held in quarantine, together with a maximum storage volume. For some limited and specific cases (for example detection of radioactivity), you can extend quarantine storage time if the Environment Agency agrees. The maximum storage time must take account of the potential for odour generation, insect infestation and storage conditions such as refrigeration (for example for anatomical waste). Quarantine storage must be separate from all other storage and clearly marked as a quarantine area.

32. The waste offloading, 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 must be of a type and quality that will allow effective disinfection.

Waste tracking

1. You must use a computerised tracking system to update information about the available capacity of the waste quarantine, reception, general and bulk storage areas of your facility. You must use a pre-booking system to make sure that you have enough waste storage and process capacity for the incoming acceptable waste.

2. Your waste tracking system must hold all the information generated during:
    - pre-acceptance
    - acceptance
    - storage
    - treatment
    - incineration
    - removal off-site

3. You must create records and update them regularly to reflect deliveries, on-site treatment and despatches. Your tracking system will operate as a waste inventory and stock control system. It must include this information as a minimum:
    - the date the waste arrived on-site
    - the original producer's details (or unique identifier)
    - all previous holders
    - a unique reference number
    - the pre-acceptance and acceptance analysis results
    - the package type and size
    - the intended treatment or disposal route
    - accurate records of the nature and quantity of wastes held on site, including all hazards - identifying the primary hazards
    - where the waste is physically located on site
    - where the waste is in the designated disposal route
    - identifying the staff who have taken any decisions about accepting or rejecting waste streams and who have decided on recovery or disposal options
    - linking each clinical waste container accepted to its consignment or transfer note
    - non-conformances

4. The tracking system must be able to report:
    - the total quantity of waste present on site at any one time
    - a breakdown by type of the waste quantities you are storing pending treatment, incineration or transfer
    - an indication of where a batch or consignment of waste is located based on a site plan
    - the quantity of waste on site on site compared with the limits authorised by your permit
    - the length of time the waste has been on site

5. You must store back-up copies of computer records off-site.

6. You must hold acceptance records for a minimum of 2 years after the waste has been treated or removed off site.

Waste storage, segregation and handling appropriate measures

1. You must not store individual bags and containers (for example, bins and boxes) of waste loose.

2. You must store and handle bagged waste on-site in lockable, rigid, leak-proof bulk containers (for example, carts).

3. Rigid waste containers (bins and boxes) must be sealed and in good condition. You should store and handle them in an upright position (as far as possible) to prevent and minimise the risk of spillages. They must be stored either:
    - in enclosed bulk containers or carts
    - on pallets, stacked no more 1.8m high (including the height of the pallet)

Figure 2 Example of a bulk container (waste cart)

4. You must secure containers stored or handled on pallets with shrink-wrap. The containers must not extend beyond (over-hang) the sides of the pallet. The shrink-wrap must be clear or transparent so you can identify waste types, damaged containers, leaks or spillages and incorrectly stacked containers. If you know waste contains free liquid (for example, chemical wastes such as fixer and developer solutions) you must store the pallets in a dedicated area of the facility that has self-contained drainage.

5. Bulk containers or carts must have a lid, and you must securely close the lid whenever they contain any waste, except when waste is being loaded into or unloaded from them.

6. You must clearly establish the maximum storage capacity of the site and designated storage areas and you must not exceed these maximum capacities. You must define capacity in terms of numbers of carts or pallets, as well as by tonnage. You must regularly monitor the quantity of stored waste on the site and designated areas to check against the allowed maximum capacity.

7. You must create and keep up to date a site plan which identifies all of the tanks, vessels, storage areas, bunds and drainage on site.

8. Where possible, you should locate storage areas away from watercourses and sensitive perimeters, for example, those close to public rights of way, housing or schools. You must store all waste within the security-protected area of your facility to prevent unauthorised access and vandalism.

9. Where wastes are known to be sensitive to heat, light, air or water you must ensure that they are protected from such ambient conditions. These storage provisions apply to any container held in any storage area, or which is being emptied, sorted, repackaged or otherwise managed.

10. You must store all non-healthcare wastes following EPR 5.06 Guidance for the Recovery and Disposal of Hazardous and Non Hazardous Waste.

11. You must handle and store all wastes in a building, except when you are preparing the waste for imminent transport off-site. A building is a covered structure enclosed on all vertical sides that has the objectives of providing sheltered cover and containing emissions of noise, particulate matter, odour and litter.

12. You must maintain the integrity of waste packaging at all times. You should design and operate your facility in a way that minimises waste handling. You must never throw, walk on or handle healthcare wastes in a way that might damage the integrity of the packaging.

13. You must store waste in a way that protects its integrity and prevents and minimises the risk of packaging failing Pay particular attention to items at or near the bottom of bulk containers – avoid, for example, overloading, compression or puncture.

14. You must store wastes according to waste type and destination. You must store the following wastes types in separate storage areas or containers:
    - clinical waste bags for incineration
    - clinical waste bags for alternative treatment
    - offensive hygiene waste
    - cytotoxic and cytostatic medicines
    - other waste medicines
    - other medicinally contaminated sharps
    - non-medicinally contaminated sharps
    - dental amalgam
    - x-ray photographic fixer
    - x-ray photographic developer
    - other photographic waste (for example, films)
    - anatomical waste and animal carcases
    - chemicals, which you must segregate from each other following HSG 71 Chemical warehousing: The storage of packaged dangerous substances

15. You must not place the different waste types in physical contact with one another. You must use sealed drainage systems to prevent leaks and spillages contaminating other wastes.

16. You must store all waste containers in a way that allows easy inspection. You must maintain safe access between rows of bulk containers or palletised wastes. You must be able to clearly see labels and date markings from access points.

17. You must not stack bulk containers, carts and pallets, unless they are held in purpose-built racking systems.

18. You must not store relevant wastes on-site for longer than the maximum durations specified below:

Waste type	**Maximum on-site storage duration prior to treatment or transfer**
Infectious clinical waste (contaminated with chemicals)	Up to 7 days
Infectious clinical waste (not contaminated with chemicals)	Up to 7 days
Offensive or non-infectious waste	Up to 7 days
Anatomical waste (refrigerated)	Up to 7 days
Anatomical waste (not refrigerated)	Up to 24 hours (72 hours if over a weekend)
Cytotoxic and cytostatic drugs	Up to 6 months
Other medicines or drugs	Up to 6 months
Dental amalgam	Up to 6 months
Other chemicals or other wastes	Up to 6 months

19. You must store anatomical waste and animal carcasses securely within a designated area of a secure building. You must store them in designated refrigerated units within the secure building unless you are storing them on-site for less than 24 hours (72 hours if over a weekend).

20. You must store pharmaceutical waste securely within a designated area of a secure building.

21. You must prioritise the treatment or off-site transfer of waste based on:
    - its type
    - age on arrival
    - date of arrival and
    - duration of storage on site

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

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

23. If you repackage waste received in containers designed for re-use, the repackaging must be specifically authorised by the environmental permit (for example, as a D14 or R12 waste operation). It must be carried out in a way that protects the safety of staff and prevents potential emissions. For example, you could do this using an automated process carried out in a contained environment with air extraction and abatement. You must carefully record the transfer of waste from individual packages or containers to bulk containers and must update the waste inventory accordingly.

24. You must not mix hazardous waste with other categories of hazardous waste, or with other wastes or materials.

25. The surfaces of the storage areas must be of a type and quality suitable for effective disinfection with a broad spectrum agent. You must put procedures in place and use them to make sure that surfaces are regularly cleaned and disinfected.

Figure 3 Examples of containers designed for re-use

26. Once emptied, you must check all bulk containers to make sure you have removed all the waste and then clean and disinfect them inside and out.

27. You must inspect containers used to transport waste before each reuse to make sure that:
    - they have been cleaned and disinfected
    - are physically sound
    - the locking mechanism works
    - they meet the requirements for the International Carriage of Dangerous Goods by Road

28. The measures you use for cleaning and disinfecting surfaces and containers must:
    - physically remove contamination
    - be capable of achieving disinfection across the broad spectrum of micro-organisms with the parameters used (time, concentration, temperature, quantity)
    - either not produce emissions of pathogenic bioaerosols or chemical agents or make sure that such emissions are contained and managed appropriately

29. You must:
    - contain wash waters within an impermeable area and either discharge them to foul sewer or dispose of them appropriately offsite
    - prevent run-off into external areas or to surface water drains
    - prevent healthcare waste items from being discharged to water (including to sewer)

30. You must manage waste in a way that makes sure that odour, litter and pest or vermin problems do not occur. You must have specific measures in place to deal with wastes that are identified as causing a problem. You

must address the issue of problem wastes with the original producer, carrier or previous holders to prevent reoccurrence.

31. You must inspect storage areas, containers and infrastructure daily. You must deal with any issues immediately. You must keep written records of the inspections. You must rectify and log any spillages of waste.

32. Your site must have suitable procedures, equipment and broad spectrum disinfectants to deal with the chemical and biological spillages that may arise from waste types accepted at your facility. All staff must be aware of their location and trained in their use.

33. There must be pedestrian and vehicular access (for example, forklift) at all times to the whole of the storage area so that you can retrieve bulk containers without removing others that may be blocking access - other than removing those in the same row.

34. You must only move wastes between different locations (or load for removal off-site) following written procedures. You must then amend your waste tracking system to record these changes.

35. You must make sure that when you dispatch waste from your site you package it and load it onto vehicles following the appropriate requirements for the International Carriage of Dangerous Goods by Road.

36. You must load vehicles in a way that prevents leakage or contamination of one waste type (or its packaging) by another waste type.

37. You must have written procedures to check outgoing vehicles and loads to confirm that you have met these requirements.

38. Your site inventory must be able to track and link all incoming consignments of waste to specific outgoing waste loads and their documentation.

39. If you transfer waste, you must be able to demonstrate that the description and classification for the outgoing waste is identical to that for the incoming waste - unless the incoming waste description and classification was incorrect or incomplete.

Compaction of healthcare waste

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

41. You can compact offensive waste if you are specifically authorised to do this under an environmental permit and have appropriate measures in place to prevent pollution, for example, through odorous emissions to air or the release of liquids to surface water.

42. To minimise the risk of pollution, compacting offensive waste should be limited to ‘light compaction’. This is limited to where:
    - the design and operation of the compaction process is unlikely to result in any bags splitting
    - it is only carried out to move bags along a bulk container - for example, by operating at low hydraulic pressure

43. If you compact or compress any offensive wastes you must use detailed procedures to contain and minimise the release of body fluids, micro-organisms and liquid discharges. You must carry out monitoring to demonstrate that your procedures, and associated measures, are effective.

44. Heavier compaction, which might result in bags splitting, is likely to lead to the release of odorous emissions and pathogens to air, or liquids to surface or groundwater. If you subject offensive waste to heavier compaction, you must have appropriate measures in place to make sure that you fully capture, contain and abate (if required) all such emissions.

45. Compacting offensive waste will fall under either a D9 or D14 waste operation if you carry it out prior to disposal or an R12 waste operation if you carry it out prior to recovery. You should follow the limitations set out below:

- D14 or R12 repackaging operation – this only authorises light compaction (as defined above)
- D9 physico-chemical treatment or an R12 operation - this activity must be included in your permit if heavier compaction is undertaken (as defined above).

Waste treatment appropriate measures

General waste treatment

1. You must fully understand, monitor and optimise the waste treatment process to make sure that you treat waste effectively and efficiently. The treated output material must meet your expectations and be suitable for its intended disposal or recovery route. You must identify and characterise emissions from the process, and take appropriate measures to control them at source.

2. You must provide adequate process descriptions of your treatment activities, and the abatement and control equipment you are using. This should include information about the characteristics of the waste to be treated and the waste treatment processes, including:
    - simplified process flowsheets that show the origin of the emissions
    - descriptions of process-integrated techniques and waste water or waste gas treatment at source - including their performances
    - diagrams of the main plant items where they have environmental relevance - for example, storage, tanks, treatment and abatement plant design
    - an equipment inventory, detailing plant type and design parameters - for example, time, temperature, pressure
    - waste types to be subjected to the process
    - the control system philosophy and how the control system incorporates environmental monitoring information
    - process flow diagrams (schematics)
    - venting and emergency relief provisions
    - a summary of operating and maintenance procedures
    - process instrumentation diagrams

3. You must also include a description of the protection provided during abnormal operating conditions to make sure you continue to comply with permit conditions. Abnormal operating conditions include:
    - unexpected releases
    - start-up
    - momentary stoppages
    - shut-down

4. You must demonstrate that your treatment process will make sure that clinical waste is ‘rendered safe’, as defined in Health Technical Memorandum 07-01 – Safe Management of Healthcare Waste.

5. In order for a relevant waste to be considered rendered safe, your treatment process must:
    - reduce the number of infectious organisms present in any infectious waste to a level that no additional precautions are needed to protect workers or the public against infection by the waste
    - destroy any anatomical waste (human or animal tissue) so that it is no longer recognisable
    - make any clinical waste (including any medical equipment and items) unusable and unrecognisable
    - destroy the component chemicals of any chemical, or medicinal and medicinally-contaminated waste
    - make any patient information within the waste unrecognisable

6. You must have tested and validated each treatment device you use as part of a site commissioning validation programme. This must meet the requirements in the section Plant commissioning and validating treatment efficacy.

7. You must carry out appropriate efficacy testing to measure and demonstrate that your process can effectively treat clinical waste on an ongoing basis. This testing must meet the requirements in the section Routine plant efficacy testing.

8. Your treatment process must, as a minimum, meet the Level 3 criteria provided by the International Society of Analytical Assessment of Treatment Technologies (iSTAATT) if you treat infectious waste. Or it must meet the level 4 criteria if you treat certain bio-hazardous waste (for example, laboratory waste). The iSTAATT levels of treatment are detailed further in the table below. You must only receive bio-hazardous waste under exceptional circumstances and must not pre-macerate or shred these wastes.

iSTAATT	Description
Level 3	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 4	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria and *B. stearothermophilus* or *B. atrophaeus* spores at a 6 $\log_{10}$ reduction or greater.

9. Your treatment process must not shred or macerate untreated infectious wastes before the disinfection step unless the plant used is specifically designed and built to provide full bioaerosol containment. This would be provided by operating the plant under negative pressure, with air drawn away from the feed hopper entrance and passed through High Efficiency Particulate Air (HEPA) filters. Feed hoppers must have doors on the opening to contain bioaerosols and other potential emissions. The doors must be closed whilst the shredder or macerator plant is operating with process interlocks or equivalent measures in place to prevent the plant operating when the doors are open. Shredded or macerated waste must remain within the bioaerosol containment system until it has been disinfected.

10. Human anatomical waste must be made unrecognisable and this means that it is generally treated by incineration. It is not appropriate or acceptable to shred and treat anatomical waste by alternative treatments involving chemical or heat-based disinfection. Novel technologies like alkaline hydrolysis that dissolve and utterly destroy the tissue may be applicable for such wastes.

11. You must exclude the following wastes from alternative treatment activities:
    - any waste containing waste medicines and chemicals
    - waste contaminated with cytotoxic and cytostatic medicines
    - anatomical waste (identifiable human or animal tissue arising from healthcare)
    - dental amalgam

12. You must exclude biohazard waste from alternative treatment activities. This is:
    - any waste known or likely to contain ACDP Hazard Group 4 biological agents
    - any waste from a containment level 3 laboratory
    - all microbiological cultures from any source
    - any potentially infected waste from pathology departments and other clinical or research laboratories (unless autoclaved before leaving the site of production)

13. You must also exclude sharps boxes containing any of the excluded wastes in the bullets points above or sharps that are contaminated with hazardous medicines in any quantity. This includes syringes that are fully discharged, partially discharged or undischarged.

14. You must not accept the following wastes for alternative treatment unless you have provided additional justification to the Environment Agency and received their approval:
    - offensive/non-infectious wastes – coded as 18 01 04, 18 02 03, 20 01 99 in the LoW
    - sharps or syringes contaminated with non-hazardous medicines - coded as 18 01 03* (with or without 18 01 09) and 18 02 02* (with or without 18 02 06 or 18 02 08 wastes) in the LoW

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

- is effective (including validation of worst case scenario conditions)
- is an efficient use of energy and raw materials
- enhances the recovery or recycling of the waste
- does not impede the treatment of any other wastes

15. The following wastes must be treated (inactivated) at the site of production:
    - class 3 and 4 genetically modified microorganism (GMM) cultures or contaminated material
    - hazard group (HG) 3 and HG 4 pathogen cultures or positive specimens
    - class 2 GMMs or HG 2 pathogen cultures or positive specimens

    However, there may be very exceptional (emergency) circumstances when you can receive these wastes at a permitted waste facility for treatment, for example, when the treatment process at the site of production has broken down. If you receive any of this waste at your permitted facility under such circumstances, then you must meet the following appropriate measures:
    - you must not shred or macerate untreated wastes before the disinfection step
    - the treatment process must demonstrate a higher level of treatment (STAATT level 4 criteria)
    - you must have waste pre-acceptance and acceptance procedures in place to make sure that you only accept this waste in exceptional circumstances, for example as a 'one off' because on site treatment has malfunctioned
    - you must submit a written justification in advance to the Environment Agency to demonstrate that you have addressed the requirements above and have the appropriate procedures in place

16. You must correctly describe, classify and code waste from alternative clinical waste treatment using the appropriate LoW codes to make sure that it reflects the residual characteristics and properties. Guidance on this is provided in the table below.

Treatment scenario	Coding guidance
Treatment (rendering safe) of waste hazardous by 'infectious' property only (orange stream waste – 18 01 03*, 18 02 02* & 20 01 99).	19 02 10 (if combustible), or 19 02 06 or 19 02 99 depending upon nature of output material.
Treatment of hazardous waste containing or contaminated with chemicals or medicines, which are not specifically treated (removed or destroyed) by the treatment process.	19 02 04* 19 02 06 or 19 02 99 can only be used if the treatment plant validation shows that the process treats all chemical and medicines (including pharmaceutically active substances).
Process failures, where waste has not been fully treated or rendered safe.	19 02 04* - if wastes have been mixed and not fully treated/rendered safe. Wastes must keep their original waste code and classification if they have not had any form of treatment.
Infectious healthcare waste (18 01 03*) sterilised on-site in a laboratory autoclave.	18 01 04 - waste must rendered unusable and unrecognisable unless it is subsequently incinerated.
Treatment of 18 01 04 to produce a waste derived fuel.	19 12 10 – if it has had mechanical treatment –such as shredding.

Plant commissioning and validating the efficacy of treatment

1. As part of the plant commissioning process, you must carry out performance validation tests to demonstrate that the treatment plant will render safe each of the waste types that your facility is permitted to treat.

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

be supervised by an appropriately qualified microbiologist and analysis undertaken at an accredited microbiological laboratory.

3. You must submit the results of the plant validation tests to the Environment Agency for approval. This must be a written validation report submitted and approved before commercial operations start at the facility, in accordance with the pre-operational conditions in your facility's permit.

4. The validation report must detail the operating conditions and parameters of the plant under which you carried out the validation tests. You must include the type and composition of waste stream(s) treated, batch quantity or throughput rate. Approval of the validation report will be based on these validated plant operating conditions and parameters. The subsequent operation of the plant will be limited to those operating conditions and parameters.

5. For mobile plant, you must carry out site commissioning and validation tests before you start operations on the first deployment.

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

7. You must repeat plant validation and send a validation report to the Environment Agency at these points:
    - periodically throughout the operational life of the plant and at intervals of 4 years or less
    - if any process parameters (for example, treatment duration, temperature, pressure, mass or type of waste) differ from those assessed during site commissioning
    - if you make any changes to the design or engineering of the treatment plant
    - before restarting treatment operations after a routine monitoring failure
    - if changes to the clinical waste stream mean that the worst case scenario challenge load considered during the original site commissioning validation is no longer the worst case scenario

Validation tests for infectious wastes

8. You must use an appropriate certified test organism in the tests.

9. You can use spore strips to validate thermal treatment plant if you can guarantee their integrity. That is, if you can insert them into the waste after the pre-shredding or maceration process and before the disinfection step or if there is no pre-shredding or maceration before the disinfection step. You should use spore suspensions to validate chemical treatment plant or thermal treatment plant if you cannot guarantee the integrity of spore strips.

10. You must use Bacillus atrophaeus (BA) or Geobacillus stearothermophilus (GS) for iSTAATT tests. You should use BA to test chemical treatment processes and those involving dry heat technologies.

11. When using spore strips or suspensions:
    - you must use spore strips or suspensions from the same batch number in the tests
    - if you use spore strips, they must be certified as containing ≥1 x 106 spores
    - if you use spore suspensions, you must add sufficient suspension to each load to make sure that ≥1 x 106 spores are present per gram mass of the total load

12. For thermal treatment plant, the spores used must have a minimum certified D-value ≥1.8 minutes at either:
    - 121°C wet heat for GS
    - 160°C dry heat for BA

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

13. For thermal processes, the spores must be supported by the parallel use of either:
    - thermal indicator strips which indicate time and temperature of exposure

- multi-point thermal data loggers co-located in the waste load

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

15. You must base the validation of plant performance for disinfection on:
    - the treatment of a worst case challenge load - in terms of spore strip containment or insulation and presence of interfering or inhibiting substances or items
    - the maximum quantity of waste that will be treated - that is the maximum batch size or throughput of the plant

16. The worst case challenge load used must reflect the type and design of the treatment plant, specifically:
    - whether the treatment process provides thermal or chemical disinfection
    - whether or not the waste is pre-shredded/macerated prior to disinfection

17. The worst case challenge load used must be detailed and justified in the validation report.

    Here are example challenge loads for three test scenarios.

    - *Spore strips - thermal treatment with pre-shredding or maceration*

      Spore strips are placed in carriers designed to mimic normal conditions in the waste being treated. Examples used include net bags, tennis balls, socks, punctured plastic or alloy containers. If metal containers are used, the spore strips must be insulated, for example using cotton wool or equivalent, to prevent direct heat conduction. The spore carriers must be inserted loose into the bulk of the waste. You can only use fixed carriers or test reports for routine monitoring if you have demonstrated through additional parallel testing that there is no significant difference between the results from these and loose carriers.

    - *Spore strips - (thermal treatment without pre-shredding/maceration*

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

    - *Spore suspensions - assuming pre-shredding or maceration before or during treatment*

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

Validation test format for infectious wastes

18. You must use an appropriate validation test format, which will depend upon whether you are using spore strips or suspensions, as set out below.

- *Spore strips*

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

  The minimum number of spores strips recovered is set out in Table 3. You must analyse the entire test sample except for the control samples which will require serial dilution. You must preserve samples appropriately and send to an accredited laboratory for analysis in a timely manner.

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

- *Spore suspensions*

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

  If the mass of the waste differs between them then you will need to correct the test data for each run (spores present per kg of sample) to account for this difference.

  The minimum number of samples taken from the treated material is set out in Table 3. Each sample should be at least 0.1% of the waste load, with a minimum sample of 50g for smaller units. You must preserve samples appropriately and send them to an accredited laboratory for analysis in a timely manner. The entire test sample must be analysed, except the control samples. You must achieve the required log reduction (the number of spores recovered from control samples compared with those recovered from the test samples) with 95% confidence. Samples must be preserved appropriately until received by the laboratory for testing.

Table 3 – Minimum number of spore strips or samples needed to validate alternative treatment plant

	Minimum number of spore strips			**Minimum number of samples**		
Plant load (kg) or throughput (kg/hr) capacity	Recovered per cycle or collection	Total recovered (assuming 3 runs)	Retained as controls	Recovered per test run	Total recovered (assuming 3 runs)	Recovered per control run
0-10kg	3	9	6	3	9	3
11-50kg	4	12	6	3	9	3
51-250kg	6	18	6	4	12	4
251-500kg	8	24	6	4	12	4
501-750kg	10	30	6	5	15	5
>750kg	12	36	6	5	15	5

Assessment methodology for infectious wastes

19. You must follow an appropriate assessment methodology, which will depend upon whether you are using spore strips or suspensions.

- *Microbial disinfection efficacy – spore strips*

  For the control data, you should calculate and record the following:
  - number of spores (colony-forming units (cfu)) recovered from each individual control spore strip
  - mean number (X_C) of spores recovered from the control strips

- $\log_{10}$ of (X_C)

You should then subtract 4 from the $\log_{10}$ of (X_C) to generate the pass criteria.

Subtracting 4 provides the 4 $\log_{10}$ reduction for iSTAATT Level 3 criteria. For the treatment of certain biohazard wastes a 6 $\log_{10}$ reduction is required so your pass criteria is ($\log_{10}(X_C)$-6).

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

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

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

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

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

- the $\log_{10}$Lu for each run must be less than or equal to the pass criteria
- $\log_{10}(X_C)$ must be ≥ 5
- for thermal processes all thermal indicator strips should indicate that the required temperature time parameters have been achieved

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

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 iSTAATT Level III criteria have therefore been successfully demonstrated.

- *Microbial disinfection efficacy – spore suspensions*

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

  You should determine the results from the controls samples using the procedures given for spore strips.

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

  You should record the Mass (M_C) of waste used in control run in kg.

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

  You should record the mass of waste used to load each of test runs in kg (M_{T1}, M_{T2}, M_{T3}).

  You should determine the individual results (cfu per kg) for each test sample taken (equivalent to step 5 of the worked example provided for spore strips) and then multiply them by: M_T ($_{1, 2}$ or $_3$ as appropriate) divided by M_C.

  This is in order to correct for differences in mass between test or control runs and should be done before proceeding to the next step of the calculation (equivalent to step 6 of the worked example provided for spore strips).

Validation tests for medicinally contaminated wastes (if applicable)

20. Validation tests must demonstrate that the plant is capable of destroying the range of pharmaceuticals and active ingredients that may be present in the waste stream. You must base your identification of potential substances (including potential break-down products) and assessment of their thermal stability and decomposition on an initial review of available literature. This must be supported by laboratory scale trials where appropriate, in order to define a worst case challenge load. Dilution of pharmaceuticals is not considered a valid form of treatment.

21. Validation tests must assess and demonstrate the efficacy of each plant. These must involve a control run, a minimum of 3 test runs and consideration of at least 3 worst case substances. These are substances that literature reviews and trials have identified as being the most thermally resistant. You must dose the waste with the substances so that the concentration is significantly higher than the limit of detection and the background level of any potentially interfering pharmaceuticals or other chemicals.

22. You must introduce chemical tracer dyers resistant to the treatment process with the pharmaceuticals or chemicals in order to demonstrate the waste is homogenous and material sampling is adequate. The minimum number of samples you must take from the treated material is set out in Table 4. The assessment must also identify and consider any effect on plant emissions that may result from the treatment of the pharmaceuticals.

Validation tests for chemically contaminated wastes (if applicable)

23. Validation tests must demonstrate that the plant is capable of effectively treating the range of chemical contaminants that may be present in the waste. You must clearly define the objectives of the treatment process, along with any reaction chemistry. You must provide an assessment of the efficacy of the treatment, demonstrating the fate of the substances in question. Simple physical dilution or absorption, without any concurrent chemical change, is not an acceptable treatment process in itself.

Validation tests for anatomical wastes (if applicable)

24. Validation tests must demonstrate that the treatment process achieves the equivalent level of tissue destruction as incineration.

Routine plant efficacy testing appropriate measures

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

Appropriate measures when spore strip testing is required

2. The minimum frequency of monitoring and number of control strips is specified in Table 4. You must schedule monitoring and evenly space it throughout the calendar year.

3. The methods you use for routine monitoring should be the same as those used for site commissioning validation, unless parallel testing during commissioning demonstrated an alternative method produced the same results.

4. For thermal processes, you must always use thermal indicator strips or multipoint data loggers in parallel where possible.

5. You can test spore strips quantitatively (population of $>1 \times 10^6$) or qualitatively (population of $>1 \times 10^4$). Controls and certificates from the test batch must also accompany each set of samples.

6. The criteria for success are as follows:
    - you must investigate each individual 'fail' result as soon as possible
    - 95% of the individual spores strips in the first 6 months of operation, and each subsequent calendar year, must demonstrate 4 log10 inactivation or higher (quantitative), or no growth (qualitative)
    - thermal indicator strips must accompany each spore strip and indicate that you achieved the minimum time and temperatures for 99% of spore strips
    - for each calendar year you must prepare a summary report that indicates the results obtained and any failures
    - the data in your summary report must be referenced to the validation report to demonstrate that you are achieving commissioning treatment efficacy, rather than minimum standards
    - If more than 5% (or 1, whichever is greater) of qualitative spore strips exhibit growth in any calendar year, you must use quantitative testing for the next calendar year

7. 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. You should not include additional investigative results.

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

Table 4 - 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 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

9. The minimum frequency of monitoring and number of test runs and sub-samples per test run is specified in Table 5.

Table 5 - 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)	Minimum number of sub-samples per test run	Number of test runs
0-250kg	6 monthly	Annually	3	1
251-750 kg	6 monthly	Annually	3	2
751+kg	Quarterly	6 monthly	3	3

10. The methods you use for routine monitoring should normally be the same as those for site commissioning validation, unless parallel testing has identified an alternative method produces the same results.

11. For thermal processes, you must use thermal indicator strips or multipoint data loggers in parallel where possible.

12. You must carry out quantitative enumeration of spore suspensions with a certified population.

13. You must carry out a single control run.

14. In other respects, the procedures and quantitative criteria for success in the section on spore strips will apply.

Emissions control appropriate measures

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

Point source emissions to air

1. You must contain and seal waste treatment plant (including shredders) to make sure that you collect, extract and direct all process emissions to an appropriate abatement system for treatment prior to release.

2. You must identify the main chemical constituents of the site's point source emissions as part of the site's inventory of waste gas streams, including VOC speciation if this has been identified in the emissions inventory and it is practicable.

3. You must make an assessment of the fate and impact of the substances emitted to air, following the Environment Agency's air emissions risk assessment methodology.

4. A wide range of pharmaceuticals and chemicals are used in healthcare. If processed these can result in emissions of volatile chemicals to air or, via condensers, to foul sewer. Your waste acceptance procedures should prevent waste containing chemicals or pharmaceuticals entering the treatment process. You should then provide abatement to treat and remove any residual emissions.

5. To reduce point source emissions to air (for example, dust and volatile organic compounds) from the physico-chemical treatment of waste, you must use one or a combination of the following abatement techniques:
    - adsorption
    - biofilter

- fabric filter
- wet scrubbing
- high efficiency particulate filter (HEPA)

6. You must assess and design vent and chimney locations and heights to ensure adequate dispersion capability.

7. You must have procedures in place to ensure that you correctly operate, monitor and maintain abatement equipment. This includes the handling and disposal or regeneration of spent scrubber or filter medium.

8. You must have operating procedures to identify, prevent and control potential emissions of pathogens.

9. You must use HEPA filters to prevent bioaerosol emissions from relevant point sources.

10. You must have procedures in place to make sure that HEPA filters are monitored (for example, by measuring the pressure drop across the filter) and maintained to achieve a minimum particle removal efficiency of 99.97% for particles ≥0.3µm diameter.

11. You must have procedures in place to make sure that HEPA filers are safely removed and disposed of.

12. You should design and operate abatement systems to minimise water vapour plumes. As well as causing possible local visibility amenity issues, in severe cases, plumes can cause loss of light, fogging or icing of roads. High moisture content can also adversely affect plume dispersion so, where practicable, you should reduce the water content of the exhaust stream. Using primary energy to reduce a plume simply because it is visible is not considered appropriate. However, it may be appropriate to use waste or recovered heat from the treatment process or an alternative heat source.

Fugitive emissions to air

1. You must use appropriate measures to prevent emissions of dust and particulates, mud and litter.

2. You must have a dust management plan in place for relevant activities.

3. You must design, operate and maintain treatment plant in a way that prevents and minimises fugitive emissions to air. This includes associated equipment such as:
   - shredders
   - conveyors
   - skips or containers

4. Your treatment plant must use high integrity components (for example seals or gaskets) and be fully contained and sealed with air extracted to appropriate abatement. Where possible, batch operated treatment plant should have localised air extraction systems. These should be located above the loading and unloading door(s) of the plant. This is so any residual emissions (for example of steam or vapour) released when the doors are opened following treatment can be collected and directed to appropriate abatement.

5. To prevent fugitive emissions, you must store, handle and treat odorous or dusty wastes (as identified through your waste pre-acceptance and acceptance procedures) in a building with access and egress points covered with fast-acting doors that default closed. These buildings should be maintained under adequate pressure and have a suitable air circulation or extraction system, and abatement system, as required. Where possible, you should locate air extraction points close to potential emission sources.

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

7. You must regularly inspect and clean all waste storage and treatment areas, equipment (including conveyor belts) and containers or carts.

8. Your maintenance and cleaning schedules must make sure tanks and plant are regularly cleaned to avoid large scale decontamination activities.

9. You must take measures to prevent the corrosion of plant and equipment (for example, conveyors or pipes). This includes selecting and using appropriate construction materials, lining or coating equipment with corrosion inhibitors and regularly inspecting and maintaining plant.

10. You must have an appropriate regular maintenance programme covering all plant and equipment. This must also include protective equipment such as curtains and fast-action doors used to prevent and contain fugitive releases.

11. If you carry out bin or cart washing activities, you must design and operate the bin washing process and associated equipment in a way that prevents emissions to air (for example, carrying out this activity in a contained or enclosed system).

12. You must fully enclose and contain pre and post-treatment shredder plant in order to prevent emissions. You must design and operate the shredder plant using appropriate process interlocks so that it cannot operate unless it is enclosed and contained (for example, only when the loading door on the hopper has been closed or sealed). Potential emissions from the shredder plant must be contained and extracted to an appropriate abatement system (for example, HEPA air filtration).

13. You should use contained or fully enclosed material transfer and storage systems and equipment (conveyors, hoppers and skips) where possible.

14. If you operate a microwave facility, you must be aware that failures in containment might result in non-ionising radiation leaks. You must have operational procedures in place to check for such leaks at regular intervals.

Point source emissions to land and water

1. You must identify the main chemical constituents of the site's point source emissions to water and sewer as part of the site's inventory of waste water streams.

2. You must assess the fate and impact of the substances emitted to water and sewer following the Environment Agency's risk assessment guidance.

3. Discharges to water or sewer must comply the conditions of an environmental permit or trade effluent consent. Relevant sources of waste water include:
    - process water or condensate collected from treatment process
    - 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
    - loading and unloading areas

4. In order to reduce emissions to water, if you need to treat waste water before discharge or disposal, you must use an appropriate combination of these techniques:
    - preliminary or primary treatment – for example, equalisation, neutralisation or physical separation
    - physico-chemical treatment – for example, adsorption, distillation or rectification, precipitation, chemical oxidation or reduction, evaporation, ion exchange, or stripping
    - biological treatment – for example, activated sludge process or membrane bioreactor
    - nitrogen removal – for example, nitrification and denitrification
    - solids removal – for example, coagulation and flocculation, sedimentation, filtration or flotation

5. You must direct waste compactor run-off to foul sewer or a sealed drainage system for on-site reuse or off-site disposal. Discharges to surface water or storm drains are not acceptable.

6. You must not discharge sharps, or medicines from washing reusable sharps bins, to surface water, storm drainage or foul sewer.
7. You must direct wash waters from cleaning clinical or offensive waste carts to foul sewer or a sealed drainage system for off-site disposal. You may need to pre-treat the waters in order to meet any limits on the effluent discharge consent.

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

9. For chemical treatment processes, you must consider whether you need to neutralise effluent (disinfectant) before discharging to water or sewer.

Fugitive emissions to land and water

1. You must use appropriate measures to control potential fugitive emissions and make sure that they do not cause pollution.

2. All areas of the facility where waste is stored, handled or treated (including waste reception, dispatch and quarantine areas) must have an impermeable surface and sealed drainage.

3. You must have measures in place to prevent overflows and failures from tanks and vessels, including where relevant:
    - overflow detectors and alarms
    - directing over-flow pipes to contained drainage system
    - locating tanks in suitable secondary containment (bunds)
    - providing isolation mechanisms (for example, closing valves) for tanks, vessels and secondary containment

4. You must collect and treat separately each water stream generated at the facility, for example, surface run-off water or process water. Separation must be based on pollutant content and treatment required. In particular you must make sure that you segregate uncontaminated water streams from those that require treatment.

5. You must use suitable drainage infrastructure to collect surface drainage from areas of the facility where you store, handle and treat waste. You must also collect washing water and occasional spillages. Depending on the pollutant content, you must either recirculate what you have collected or send it for further treatment.

6. You must have design and maintenance provisions in place to detect and repair leaks. These must include regularly monitoring, inspecting and repairing equipment and the minimising underground equipment and infrastructure. You must use secondary containment on components located underground that pose a risk of soil or water contamination due to potentially polluting substances.

7. You must provide appropriate buffer storage capacity at the facility to store waste waters. This must take into account:
    - potential abnormal operating scenarios and incidents
    - the nature of any polluting substances and their impact on the downstream waste water treatment plant and receiving environment

8. You must have appropriate measures in place to monitor, treat and re-use the water held in the buffer storage before discharging.

9. You must take measures to prevent emissions from washing and cleaning activities, including:
    - directing liquid effluent and wash-waters to foul sewer or collecting them in a sealed system for off-site disposal – you must not discharge them to surface or storm drains
    - where possible, using biodegradable and non-corrosive washing and cleaning products

- storing all detergents, emulsifiers and other cleaning agents in suitable bunded or containment facilities, within a locked storage area, or in a building away from any surface water drains
- preparing working strength cleaning or disinfection solutions in contained areas of the site and never in areas that drain to the surface water system

10. Where relevant, you must have measures to prevent pollution from the on-site storage, handling and use of oils and fuels.

11. You must produce and implement a spillage response plan and train staff to follow it and test it.

12. You must have procedures and associated training in place to make sure that you deal with spillages immediately. These must follow the manufacturer's health and safety advice for any products or substances involved.

13. You must keep suitable spill kits where cleaning chemicals are stored and used, and make sure everyone knows how to use them. Make sure kits are replenished after use.

14. You must stop spillages from entering drains, channels, gullies, watercourses and unmade ground. You must use proprietary sorbent materials, sand or drain mats.

15. You must make sure your spillage response plan includes information about how to recover, handle and correctly dispose of all waste produced from a spillage.

16. Bin washing equipment must be purpose-built, contained and located in a designated area of the facility provided with self-contained drainage. The bin wash must be designed to collect and contain all wash waters, including any spray. It must be operated by trained staff and inspected and maintained regularly.

17. For subsurface structures, you must:
    - establish and record the routing of all site drains and subsurface pipework
    - identify all sub-surface sumps and storage vessels
    - engineer systems to minimise leakages from pipes and make sure they can be detected quickly if they do occur, particularly where hazardous (that is Groundwater-listed) substances are involved
    - provide secondary containment or leakage detection for sub-surface pipework, sumps and storage vessels
    - establish an inspection and maintenance programme for all subsurface structures, for example, pressure tests, leak tests, material thickness checks or CCTV

18. For surfacing, you must design appropriate surfacing and containment or drainage facilities for all operational areas, taking into account:
    - collection capacities
    - surface thicknesses
    - strength/reinforcement
    - falls
    - materials of construction
    - permeability
    - resistance to chemical attack
    - inspection and maintenance procedures

19. You must have an inspection and maintenance programme for impervious surfaces and containment facilities.

20. Unless the risk is negligible, you must have improvement plans in place if operational areas do not have:
    - an impervious surface
    - spill containment kerbs
    - sealed construction joints
    - connection to a sealed drainage system

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

Emissions of odour

1. If you can contain odour, for example within buildings, you should maintain the containment and manage the operations in a way that prevents releasing odour at all times.

2. You must use pre-acceptance screening and waste acceptance checks to identify and manage the receipt of odorous wastes. If you receive odorous wastes, you prioritise their treatment and/or transfer.

3. You must put in place and use procedures to minimise the amount of time odorous wastes spend in your storage and handling systems (for example, pipes, conveyors, hoppers, tanks). In particular, you must have provisions in place to manage waste during periods of peak volume.

4. You must have measures in place to contain, collect and treat potential odorous emissions, including using contained building and plant or equipment with appropriate air extraction and abatement.

5. You must monitor abatement systems to ensure optimum performance, for example, by ensuring that scrubber liquors are maintained at the correct pH and replenished or replaced at an appropriate frequency.

6. Contaminated waters have potential for odours and you must store them in covered or enclosed tanks or containers.

7. Where an odour nuisance at sensitive receptors is expected, or has been substantiated, you must periodically monitor odour emissions using EN standards, for example either:
    - dynamic olfactometry according to EN 13725 in order to determine the odour concentration
    - EN 16841-1 or -2 in order to determine the odour exposure

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

9. Where an odour nuisance at sensitive receptors is expected, or has been substantiated, you must also set up, implement and regularly review an odour management plan, as part of your environmental management system. It must include all of the following elements:
    - a protocol containing actions and timelines
    - a protocol for conducting odour monitoring (as set out above)
    - a protocol for response to identified odour incidents, for example, complaints
    - an odour prevention and reduction programme designed to identify the source(s), to characterise the contributions of the sources and to implement prevention and/or reduction measures

10. Where an odour management plan is required, you must develop and implement it following our guidance.

Emissions of noise and vibration

1. You should design the layout of the facility to make sure that, where possible, you locate potential sources of noise (including building exits and entrances) away from sensitive receptors and boundaries. You should locate buildings, walls, and embankments so they act as noise screens.

2. You must employ basic good practice measures to control noise, including:
    - adequately maintaining plant or equipment parts which may become more noisy as they deteriorate (for example, bearings, air handling plant, the building fabric, and specific noise attenuation kit associated with plant or machinery)
    - closing doors and windows of enclosed areas and buildings
    - avoiding noisy activities at night or early in the morning
    - minimising drop heights and the movement of waste and containers
    - using white noise reversing alarms and enforcing the on-site speed limit
    - using low-noise equipment (for example, drive motors, fans, compressors, pumps)
    - adequately training and supervising staff
    - where possible, providing additional noise and vibration control equipment for specific noise sources (for example, noise reducers or attenuators, insulation, or sound-proof enclosures)

3. If you expect a noise or vibration nuisance at sensitive receptors, or if this has been substantiated, you must create, use and regularly review a noise and vibration management plan. This must be part of the environmental management system, and should include the following elements:
    - a protocol containing appropriate actions and timelines
    - a protocol for conducting noise and vibration monitoring
    - a protocol for responding to identified noise and vibration events, for example, complaints

    The noise and vibration management plan should also include a noise and vibration reduction programme designed to:
    - identify the source(s) of noise and vibration
    - measure or estimate noise and vibration exposure
    - characterise the contributions of the sources
    - implement prevention and reduction measures

4. If you need a noise management plan, you must follow our guidance when developing and using the plan.

Emissions monitoring and limits appropriate measures

1. Where you are required to monitor emissions to comply with the requirements of your environmental permit you must do so in accordance with our monitoring guidance.

2. You must create and maintain an inventory (emissions inventory) of waste water and waste gas streams for your facility.

We may set emission limits and monitoring requirements in your permit, based upon your inventory of waste water and waste gas streams and environmental risk assessment. Where relevant, emission limits should be set at the values provided in this guidance unless alternative values are justified and agreed with the Environment Agency.

Emissions to air

3. Your facility's emissions inventory must include information about the relevant characteristics of waste gas streams, such as the:
    - average values and variability of flow and temperature

- average concentration and load values of relevant substances and their variability
- flammability, lower and higher explosive limits and reactivity
- presence of other substances that may affect the waste gas treatment system or plant safety (for example, oxygen, nitrogen, water vapour, dust)

Chemical emissions to air

4. The emission limits and monitoring requirements in Table 6 should apply to point source emissions from alternative treatment plant where they are identified as being relevant, based upon the facility's waste gas stream emissions inventory.

Table 6 – Emission limits and monitoring requirements

Source	Parameter	Emission limit (including unit)	Reference Period	Monitoring frequency	Monitoring standard or method
For example, point source emission(s) from alternative treatment plant	Dust	5 mg/m^3 Note 1	Note 2	Once every 6 months	BS EN 13284-1
	Total Volatile Organic Compounds (TVOC)	30 mg/m^3	Note 2	Once every 6 months	BS EN 12619
	Ammonia	-	Note 2	Once every 6 months	BS EN 14791 (procedural requirements)

Note 1 This emission limit is applicable to fabric filters. A higher emission limit of 10 mg/m^3 may be appropriate when a fabric filter is not applicable and other abatement techniques are used.

Note 2 Results should be reported as the average value of three consecutive measurements of at least 30 minutes each.

5. It is unlikely that you will need to carry out chemical and pharmaceutical emissions monitoring if both of these apply, you:
   - have carried out waste pre-acceptance and acceptance checks in accordance with the section on Waste stream management
   - are not treating the wastes containing or contaminated with chemicals or medicines

   This will be subject to confirmation by the site specific emissions inventory.

6. If your treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged), you must propose and agree with the Environment Agency emission limits based on an assessment of the range of chemicals and pharmaceuticals in use and their:
   - occurrence and concentration within the waste
   - properties and behaviour when subjected to the treatment process

7. If your treatment plant is authorised to process medicinally or chemically contaminated waste, you must also carry out chemical and pharmaceutical emissions monitoring annually, as a minimum, or more frequently if emissions are > 10% of the agreed emission limits.

Microbial emissions to air

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

9. You must monitor and assess microbial emissions using tracer spore suspensions. You can use alternative indicators if you can demonstrate that microbial emissions only come from the waste on site (not from other environmental sources) and are present in enough numbers to provide the same level of test sensitivity.

10. You must comply with the following guidance when monitoring microbial emissions from alternative treatment plant.

General

11. You must not use spore strips for bioaerosol emissions monitoring.

12. The quantity of spores must be a minimum of 1×10^6 spores per gram of total waste load.

13. You must follow an appropriate assessment methodology, which will depend upon whether or not the waste is shredded or macerated before treatment.

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

    For other technologies
    You must prepare and dispense (in a laboratory environment) dry or liquid suspensions of bacillus spores both:
    - loosely on dressings in waste inside containers (bags, boxes and so on)
    - inside worst case challenge load containers (suction canisters and chest drains)

    You must disperse the spores throughout the waste load processed.

Monitoring frequency

14. You must test all devices during commissioning validation and then periodically, as indicated in Table 7.

Table 7 - Process bioaerosol emissions monitoring when a suspension of bacillus spores has been used

	First six 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	During site commissioning	annually	see text	see text
For other devices	During site commissioning	every four years	see text	see text

Monitoring methodology

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

16. You must design your monitoring programme so that you take enough samples to quantitatively relate the results to the input dose. The number of samples and location of sampling points will depend on the nature of the process and size of the device.

17. You must take samples:
    - before processing the seeded waste (controls)
    - at intervals during processing the seeded waste (the intervals must relate to the process stages and the timing of potential emissions)
    - then periodically for at least 2 hours after the cycle is complete

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

Air monitoring

18. You must carry out air monitoring from all of these points:
    - around identified point source emissions from the process
    - at the site boundaries
    - at any other relevant locations within the site – for example, near open vehicle access doors to the building housing the plant

19. You must use active (centrifugal or vacuum) impaction onto agar using Anderson or slit samplers (or equivalent) to sample for bioaerosols. Your data submissions must contain information indicating the recovery efficiency of the method used.

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

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

    Common sources of diffuse emissions include the following:

    The maceration of untreated clinical waste
    This is potentially the most significant source of pathogenic bioaerosols. Your monitoring must demonstrate that the containment measures in place are effective.

    The maceration of treated clinical waste
    This may also generate bioaerosols as treatment reduces the number of micro-organisms but does not eliminate them. Your monitoring must demonstrate if additional containment measures are needed.

    Maintenance or access ports
    You must carry out monitoring to make sure that these do not compromise the integrity of the plant and are effectively sealed during operation and emissions are not released. Failed seals and joints may also result in emissions.

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

Surface monitoring

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

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

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

- each grid square
- the whole site

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

Microbial Emission limits

25. You must compare and assess the results of microbial emissions monitoring against the emission limits provided in Tables 8 and 9 to demonstrate that the containment and treatment of microbial emissions is effective.

Table 8: Emission limits for point source emissions

Emission	Measure	Cfu	Unit
Air	Bacillus spores	1000 Note 1	Per cubic metre Note 2

Note 1: These limits are based on a seeding dose of 1 x 10^6 spores per gram of waste load, and should be adjusted accordingly if the seed dose used is higher or lower.

Note 2: These units relate to the overall monitoring period so the limit applies to each individual sample of air, with a calculation made to report the result per cubic metre.

Table 9 Emission limits for fugitive emissions

Emission	Measure	Cfu	Unit
Air – sample points >10m from the treatment plant.	Bacillus spores	300 Note 1	Per cubic metre Note 2
Surface – sample point < 10m from the treatment plant.	Bacillus spores	20000 Note 1	Per square metre per hour Note 2
Surface – sample points > 10 m from the treatment plant.	Bacillus spores	5000 Note 1	Per square metre per hour Note 2

Note 1: These limits are based on a seeding dose of 1 x 10^6 spores per gram of waste load, and should be adjusted accordingly if the seed dose used is higher or lower.

Note 2: These units relate to the overall monitoring period so the cfu limit applies to:

- Each individual sample of air, with a calculation made to report the result per cubic metre
- 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)

Emissions to water or sewer

1. Your facility's emissions inventory must include information about the relevant characteristics of the waste water streams, such as:
    - average values and variability of flow, pH, temperature, and conductivity
    - average concentration and load values of relevant substances and their variability - for example, COD and TOC, nitrogen species, phosphorus, metals, priority substances/micropollutants
    - data on bioeliminability - for example, BOD, BOD to COD ratio, Zahn-Wellens test, biological inhibition potential (for example, inhibition of activated sludge)

2. For relevant emissions to water identified by the inventory of waste water streams, you must carry out monitoring of key process parameters (for example, waste water flow, pH, temperature, conductivity, or BOD) at key locations. For example, these could either be at the:
    - inlet or outlet (or both) of the pre-treatment
    - inlet to the final treatment
    - point where the emission leaves the facility boundary

Chemical emissions to water or sewer

3. It is unlikely that you will need to carry out chemical and pharmaceutical emissions monitoring if both of these apply, you:
    - have carried out waste pre-acceptance and acceptance checks in accordance with the section on Waste stream management
    - are not treating the wastes containing or contaminated with chemicals or medicines

    This will be subject to confirmation by the site specific emissions inventory.
4. If your treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged) you must propose and agree with the Environment Agency emission limits based on an assessment of the range of chemicals and pharmaceuticals in use and their:
    - occurrence and concentration within the waste
    - properties and behaviour when subjected to the treatment process

5. If your treatment plant is authorised to process medicinally or chemically contaminated waste, you must also carry out chemical and pharmaceutical emissions monitoring annually, as a minimum, or more frequently if emissions are > 10% of agreed limits.

Microbial emissions to water or sewer

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

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

8. You must compare and assess the results of microbial emissions monitoring against the emission limit provided in Table 10 to demonstrate that the treatment of microbial emissions is effective.

Table 10 – Emission limits to sewer

Emission	Measure	Cfu	Unit
Water	Bacillus spores	300 Note 1	Per litre Note 2

Note 1: 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 units relate to the overall monitoring period so the cfu limit applies to each individual sample of water taken, with a calculation made to report the result per litre.

Process efficiency appropriate measures

1. The annual consumption of water, energy and raw materials as well as the annual generation of residues and waste water, must be monitored and reviewed for the facility with a frequency of at least once per year.

Energy efficiency (installations only)

2. You must create and implement an energy efficiency plan at your facility. This must:
    - define and calculate the specific energy consumption of the activity (or activities) you carry out and waste stream(s) you treat
    - set annual key performance indicators - for example, specific energy consumption (expressed in kWh/tonne of waste processed)
    - plan periodic improvement targets and related actions

3. You must regularly review and update your energy efficiency plan as part of your facility's EMS.

4. You must have an energy balance record in place. This must provide a breakdown of your energy consumption and generation (including any exportation of energy or heat) by the type of source (electricity, gas, conventional liquid fuels, conventional solid fuels, and waste).

5. The record must include:
    - information on energy consumption in terms of delivered energy
    - information on energy exported from the facility
    - energy flow information (for example, Sankey diagrams or energy balances) showing how the energy is used throughout the process

6. You must regularly review and update your energy balance record as part of your facility's EMS, alongside the energy efficiency plan.

7. You must have operating, maintenance and housekeeping measures in place in the following areas, where relevant:
    - air conditioning, process refrigeration and cooling systems (leaks, seals, temperature control, evaporator/condenser maintenance)
    - operation of motors and drives
    - compressed gas systems (leaks, procedures for use)
    - steam distribution systems (leaks, traps, insulation)
    - space heating and hot-water systems
    - lubrication to avoid high-friction losses
    - boiler operation and maintenance, for example, optimising excess air
    - other maintenance relevant to the activities within the facility

8. You must have basic low-cost physical techniques in place to avoid gross energy inefficiencies. These should include:
    - insulation
    - containment methods (such as seals and self-closing doors)
    - avoiding unnecessary discharge of heated water or air (for example, by fitting simple control systems such as timers and sensors)

9. For alternative treatment plant that thermally disinfect waste, treating non-infectious waste would not be considered appropriate or representative of BAT unless it is supported by a detailed justification. This should take into account the purpose and benefit of the treatment process and its energy consumption.

10. Additional energy efficiency measures should be implemented at the facility as appropriate, in accordance with our guidance.

Raw materials (installations only)

1. You must maintain a list of the raw materials used at your facility and their properties.

2. You must have procedures for regularly reviewing new developments in raw materials and using any suitable ones with an improved environmental profile. This should include, where possible, substituting raw materials with waste.

3. You must have quality-assurance procedures for controlling the impurity content of raw materials.

4. You must complete any longer-term studies needed into the less polluting options and should make any material substitutions identified.

5. For facilities that treat waste using chemical disinfection, you must consider the following when selecting and using raw materials:
    - disinfectants that might have a lower environmental impact (for example hazardous properties, bioaccumulation, degradability, emissions)
    - minimising or reducing the quantity of, or neutralising, the residual active disinfectant in the outputs from the treatment process
    - the potential for components of the waste, for example organic matter, to inhibit or react with the chemical disinfectant
    - that processing waste that is not infectious (it does not possess the hazardous property H9 infectious) may be inconsistent with this condition – you need to support your application to treat such waste by a detailed justification demonstrating that you meet this criteria

Water use (installations only)

1. You must take measures to make sure you optimise water consumption in order to:
    - reduce the volume of waste water generated
    - prevent or, where that is not practicable, reduce emissions to soil and water

2. Measures you must take include:
    - implementing a water saving plan (involving establishing water efficiency objectives, flow diagrams and water mass balances)
    - Optimising the use of washing water (for example, dry cleaning instead of hosing down, using trigger control on all washing equipment)
    - reducing the use of water for vacuum generation (for example, using liquid ring pumps with high boiling point liquids)
    - recirculating and reusing water streams within the plant or facility, if necessary after treatment

3. You must carry out a regular review of water use (a water efficiency audit) at least every 4 years.

4. You must also:
    - produce flow diagrams and water mass balances for your activities
    - establish water-efficiency objectives and identify constraints on reducing water use beyond a certain level (usually this will be site specific)
    - use water pinch techniques in more complex situations such as chemical plant, to identify the opportunities for maximising reuse and minimising use of water
    - have a time-tabled improvement plan for implementing additional water reduction measures

5. To reduce emissions to water, you should apply these general principles in sequence:
    - use water-efficient techniques at source where possible
    - re-use water within the process, by treating it first if necessary. If this is not practicable, use it in another part of the process or facility that has a lower water-quality requirement
    - if you cannot use uncontaminated roof and surface water in the process, you should keep it separate from other discharge streams - at least until after you have treated the contaminated streams in an effluent treatment system and have carried out final monitoring

6. You must have measures in place to minimise the risk of contaminating surface waters or groundwater with fugitive releases of liquids or solids.

7. You should establish the water-quality requirements associated with each activity and identify whether you can substitute water from recycled sources and, where you can, include it in your improvement plan.

8. Where there is scope for reuse (possibly after some form of treatment) you should keep less contaminated water streams, such as cooling waters, separate from more contaminated streams.

9. You must minimise the volume of water you use for cleaning and washing down by:
    - vacuuming, scraping or mopping in preference to hosing down
    - reusing wash water (or recycled water) where practicable
    - using trigger controls on all hoses, hand lances and washing equipment

10. You must directly measure fresh water consumption and record it regularly at every significant usage point - ideally on a daily basis.

Waste minimisation, recovery and disposal

1. You must have a residues or waste management plan in place to maximise the reuse or recycling of packaging that is in good condition and sufficiently clean. If necessary, you should send packaging for appropriate treatment before reusing (for example, reconditioning or cleaning).

2. You should avoid producing waste wherever possible. You should recover any waste you produce, unless it is technically or economically impractical to do so.

3. Where you must dispose of waste, you must carry out a detailed assessment identifying the best environmental options for waste disposal.

4. You must review on a regular basis options for recovering and disposing of waste produced at the facility. You must do this as part of the EMS to make sure that you are still using the best environmental options and promoting the recovery of waste where technically and economically viable.

5. If you provide or advise producers on clinical waste packaging, consider:
    - reducing the quantity of packaging accompanying the waste, for example making sure that containers are being used efficiently
    - using packaging that is either reusable or suitable for recycling

Example waste audit for a hospital ward

A hypothetical hospital consists of six departments:

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

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 the departments that produce them. This enables waste descriptions and classifications to be derived. In particular the manager should establish if any waste stream from a department contains:

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

What the waste manager does during an audit

When the manager audits the surgical ward they look at the types of waste containers present and:

- note in detail their contents,
- take a photograph of each for reference
- check the labels

They also

- examine the on-ward pharmacy to check for cytotoxic and cytostatic drugs
- observe practice during the hour the audit takes place
- 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.

They also question staff about their understanding of cytotoxic and cytostatic medicines and about the disposal of:

- medicated and non-medicated IV bags
- dropped tablets,
- medicine bottles and ampoules used with injections
- alcohol hand gel containers
- tearoom and office wastes

Summary findings from the audit

The summary findings made by the waste manager are as follows.

Ward management or staff had little knowledge, involvement in or ownership of waste management

No anatomical waste or human tissue is produced in the surgical department.

There are four yellow lidded sharps boxes. One on a treatment trolley in each bay, and one in the pharmacy area.

These contained used syringes, associated medicine vials and bottles, and the odd swab.

The labels on the boxes indicated '18 01 03 and 18 01 09 clinical waste, mixed sharps and pharmaceutical waste for incineration'.*

Interviews with staff also revealed that these boxes are used for dropped tablets and leftover controlled drugs.

The separate audit of the main hospital pharmacy confirmed that they are using an acceptable and working definition of cytotoxic and cytostatic and that injectable medicines of this type are sometimes prescribed to patients on the ward. However these medicines are not labelled in a way that allows staff on the ward to easily identify them. Ward staff have no procedures to identify or segregate medicinal waste, so it is contaminating other waste streams.

There are four orange bags. There is one in the treatment area of each bay and one in the on-ward pharmacy. Three contained clinical waste. One is too close to a hand-washing sink and public and patient areas. It contained a few handtowels, some food wrappers and a newspaper.

Interviews with staff also revealed that 'empty' alcohol hand gel, 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 only contained a black bag, which only contained non-hazardous municipal waste items.

The three black bags in patient areas only contained 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 found. Offensive waste segregation is not in place in treatment areas, and this waste is being disposed of in the clinical orange bags.

There was no pharmaceutical waste bin in use. Unopened or reusable medicines are returned to the main hospital pharmacy. Opened medicines and 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.

The main hospital pharmacy has identified medicines with hazardous properties. Those in use in this ward were noted on waste documentation.

The waste 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

Changes needed following the audit

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

Cytotoxic and cytostatic drugs will be clearly labelled when issued by the main hospital pharmacy. Purple lidded containers will be given to the surgical ward and staff will be trained in appropriate procedures

Alcohol hand gel containers will either be rinsed out and recycled as plastics or disposed of as hazardous chemicals.

The orange bag bins will be repositioned so patients and visitors do not have access to them. They will be moved away from hand washing sinks to prevent municipal waste entering the waste stream.

Offensive hygiene bags will be introduced alongside the orange bags to capture the healthcare offensive waste stream and remove it from the clinical waste stream.

Procedures for IV bags will be 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) will be emptied down the sluice and the packaging disposed of in the offensive waste stream.

In addition, one of the experienced ward staff will be trained in internal waste management procedures. They will conduct monthly audits of the ward, support and train ward staff, and communicate with the waste manager on waste issues.

Follow up audit

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

- 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 additional elements that are not addressed here.

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

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