This publication was withdrawn on 23 November 2021

This standard rules permit is no longer available. You can use the revised <u>SR2008 No 24: standard rules for transfer of healthcare waste</u> for new applications.

Chapter 4, The Environmental Permitting (England and Wales) Regulations 2010



Standard rules SR2013 No.1 Treatment of 100 t/y of clinical & healthcare waste

Introductory note

This introductory note does not form part of these standard rules.

These rules allow an operator to operate one or more units in one or more suitably equipped rooms within a building at a medical practice or hospital to store and treat certain hazardous and non-hazardous clinical and healthcare waste that are

- (i) produced at that practice; and
- (ii) produced by staff from that medical practice providing care in the community (at premises other than a medical practice) and returned to that practice.

Treatment includes treatment by heat, chemicals and/ or irradiation in order to render the clinical waste safe. The definition of rendering safe is based on the Department of Health document HTM 07 01 'Safe management of healthcare waste' as treatment that:

- for infectious waste demonstrates the ability to reduce the number of infectious organisms present in the waste to a level that no additional precautions are needed to protect workers or the public against infection by the waste;
- b. for anatomical waste destroys anatomical waste such that it is no longer generally recognizable;
- c. for any clinical waste renders any syringes, needles or any other equipment or item unusable and no longer in their original shape and form; and
- d. for medicinal waste destroys the component chemicals of medicinal waste.

Treatment of infectious clinical waste must meet the State and Territorial Association on Alternative Treatment Technologies (STAATT) level III criteria demonstrating this either through validation and efficacy testing as specified in Environment Agency Guidance EPR5.07 or continuous monitoring which the Environment Agency accepts achieve the same level of protection.

All treatment activities must take place within a building with an impermeable surface and sealed drainage system. These rules will not permit the mixing of hazardous waste. The rules will also not permit the burning of any wastes, either in the open, inside buildings or in any form of incinerator.

These rules do not allow any point source emission into surface waters or groundwater.

Liquids may be discharged into a sewer by permission of the sewage undertaker or sent off-site in a tanker for disposal or recovery.

End of Introductory note

Rules

1 - Management

1.1 General management

- 1.1.1 The operator shall manage and operate the activities:
 - (a) in accordance with a written management system that identifies and minimises risks of
 pollution, including those arising from operations, maintenance, accidents, incidents,
 non- conformances, closure and those drawn to the attention of the operator as a result
 of complaints; and
 - (b) using sufficient competent persons and resources.
- 1.1.2 Records demonstrating compliance with rule 1.1.1 shall be maintained.
- 1.1.3 Any person having duties that are or may be affected by the matters set out in these standard rules shall have convenient access to a copy of them kept at or near the place where those duties are carried out.
- 1.1.4 The operator shall ensure a person meeting the requirements of an approved competence scheme is responsible for the operating arrangements, including training, operating instructions and support if any problems occur.

1.2 Avoidance, recovery and disposal of wastes produced by the activities

- 1.2.1 The operator shall take appropriate measures to ensure that:
 - (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities;
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.2.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 - Operations

Table 2.1 Activities

2.1 Permitted activities

2.1.1 The operator is only authorised to carry out the activities specified in Table 2.1 below ("the activities").

Description of activities	Limits of activities			
D15: Storage pending any of the disposal operations numbered D1 to D14 in the Waste Framework Directive (excluding temporary storage, pending collection, on the site where it is produced)	Activities covered by this permit are limited to the treatment of certain hazardous and non- hazardous clinical and healthcare waste at the place where the waste is produced, and the treatment of waste produced by staff from that medical practice providing			
D9: Physico-chemical treatment not specified elsewhere in Annex I of the Waste Framework Directive which results in final	care in the community (at premises other than a medical practice).			
compounds or mixtures which are discarded by means of any of the operations numbered D1 to D8 and D10 to D12	The total quantity of waste disposed of or recovered under this permit shall be less than 100 tonnes a year.			
R13: Storage of wastes pending any of the recovery operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where it is produced).	Treatment of waste that is not clinical waste is limited to R3 and R4 activities.			
R3: Recycling/reclamation of organic substances which are not used as solvents	The maximum quantity of waste treated shall not exceed, individually or aggregated, 2 tonnes per day. No more waste shall be stored prior to treatment at any one time than could be processed in 3 days.			
R4: Recycling/reclamation of metals and metal compounds	There shall be no mixing of hazardous waste.			
	The waste types permitted for treatment are set out in Table 2.2a. The treatment of wastes listed in Table 2.2b of this permit can only be undertaken subject to pre-operation condition 4.			

2.2 Waste acceptance

- 2.2.1 Waste shall only be accepted if:
 - (a) it is of a type and quantity listed in tables 2.2a and 2.2b below; and
 - (b) waste acceptance procedures are in place to determine (a) above.

Maximum Quantities

The total quantity of waste accepted at the site shall be less than 100 tonnes a year

Table 2.2a Waste types permitted for treatment				
Waste Code	Description			
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)			
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans			
18 01 03* ¹	wastes whose collection and disposal is subject to special requirements in order to prevent infection.			
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals			
18 02 02* ¹	wastes whose collection and disposal is subject to special requirements in order to prevent infection.			
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS			
20 01	separately collected fractions (except 15 01)			
20 01 99 ¹	other fractions not otherwise specified (comprising only of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).			

- ¹ The following wastes under this waste code are specifically excluded from waste treatment activities:
 - (i) **Any waste** containing waste medicines and chemicals, waste contaminated with cytotoxic and cytostatic medicines, anatomical waste (identifiable human or animal tissue arising from healthcare), or Dental amalgam;
 - (ii) **Sharps boxes** containing any of the excluded wastes from (i) and (iii) or Sharps that are contaminated with pharmaceuticals in any quantity (including syringes that are fully discharged, partially discharged or undischarged).
 - (iii) **Biohazard waste**: Any waste known or likely to contain ACDP Hazard Group 4 biological agents; any waste from a containment level 3 laboratory: and all Microbiological cultures from any source, and, any potentially infected waste from pathology departments and other clinical or research laboratories (unless autoclaved before leaving the site of production).

Table 2.2b Waste	types permitted for treatment with prior consent of the Environment Agency
Waste Code	Description
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	sharps (except 18 01 03)
18 01 03* (with or without 18 01 09)	medicinally contaminated infectious sharps/syringes
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers). (This is limited to non-clinical human offensive/hygiene waste only)
18 01 08*	cytotoxic and cytostatic medicines
18 01 09 ¹	medicines other than those mentioned in 18 01 08
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	sharps (except 18 02 02)
18 02 02* (with or without 18 02 08)	medicinally contaminated infectious sharps/syringes

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection. (This is limited to non-clinical animal offensive/hygiene waste only)
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	medicines other than those mentioned in 18 02 07
20 01 99	Offensive wastes from residential homes

*In order to treat non-infectious waste or medicines or medicinally contaminated waste a written justification must be submitted to the Environment Agency as per Table S2.4 section 4 and 2.1 of Environment Agency Sector Guidance EPR 5.07 (version 1.1).

18 01 01, 18 01 04, 18 02 01 and 18 02 03 entries are limited to those wastes that are not described, packaged, labeled or transported as infectious or clinical wastes.

2.3 Operating techniques

2.3.1 The activities shall be operated using the techniques and in the manner described in Table 2.3 below.

Table 2.3 Operating techniques

- 1. The wastes listed in Table 2.2a may be mixed during treatment. Any other mixing of hazardous waste with other categories of hazardous waste, or with non-hazardous waste is prohibited.
- 2. All waste treated must have been subjected to waste acceptance pre-acceptance and appropriate measures 4,5,6,14 and 17 for on-site acceptance checks in accordance with section 2.2 of EPR 5.07 (Version 1.1)
- 3. Only permitted wastes segregated in accordance with HTM 07 01, The Safe Management of Healthcare Waste (2013), may be treated
- 4. All permitted waste shall be stored in designated rooms within a building, within sealed containers located on an impermeable surface with sealed drainage system. Sealed containers shall be kept locked when not being loaded or unloaded.
- 5. All waste treatment activities shall take place within a building provided with an impermeable pavement and sealed drainage system.
- 6. Rigid containers for the storage of waste shall be of a design that:
 - will prevent the escape of any liquid;
 - has a lockable lid or other means of securing the container.
- Waste containing or contaminated with cytotoxic and cytostatic medicines shall be kept separate from other wastes.
- 8. Waste medicines, dental amalgam, medicinally contaminated sharps (including fully discharged syringes) and non-medicinally contaminated sharps shall be kept separate from each other and other wastes and stored in a secure place.
- 9. Body parts and organs shall be stored in designated refrigerated units within a building.
- 10. All surfaces where waste is handled and stored shall allow effective disinfection.
- 11. The operator shall use appropriate measures to disinfect surfaces, mobile and static containers before and after use for the storage and handling of clinical and healthcare wastes.
- 12. The treatment process must render any disposable items, equipment and sharps both unrecognisable and beyond use, and destroy any patient information within the waste.

Treatment process validation

- 13. Following commencement, the treatment process shall be revalidated:
 - periodically, at intervals no greater than 48 months during the operational life of the individual unit, or
 - if any process parameters (for example time, temperature, pressure, mass or type of waste and so on) are altered from those assessed during site commissioning, or
 - if mechanical or engineering changes are made to the treatment process, or
 - before recommencing treatment operations after a routine monitoring failure, or

- if the clinical waste stream changes such that the worst case scenario challenge load considered during the original site commissioning validation is no longer the worst case scenario.
- 14. The revalidation report may, by prior agreement with the Environment Agency, be based on use of spores or a check on continuous monitoring arrangements. Where no validation report is submitted within 14 days of the anniversary of the 4 yearly period, or the Environment Agency does not agree to the validation report, then the treatment process shall cease until the operator has received written confirmation from the Environment Agency that the treatment process can recommence.

Routine efficacy monitoring

- 15. Efficacy monitoring of the treatment process shall be undertaken to demonstrate the correlation between treatment parameters (e.g. temperature, pressure and residence time) and that microbial inactivation to STAATT level III is achieved during routine operation. The monitoring may, by prior agreement with the Environment Agency, be based on use of spores or a check on continuous monitoring arrangements.
- 16. In the event that the treatment process does not demonstrate the required microbial inactivation levels, the process shall be stopped until the problem has been rectified. The treatment process shall only recommence following agreement in writing by the Environment Agency.

Treatment process quality control

- 17. Continuous monitoring of treatment parameters shall be recorded during the waste treatment process. The results of this monitoring shall be checked to confirm that the waste has been treated to the required standard prior to disposal of the treated waste.
- 18. In the event that the treatment process does not reach the required parametric levels, the process shall be stopped until the problem has been rectified. The treatment process shall only recommence following agreement in writing by the Environment Agency.

2.4 The site

2.4.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan attached to the permit.

2.5 Hazardous waste storage and treatment

2.5.1 Hazardous waste shall not be mixed, either with a different category of hazardous waste or with other waste, substances or materials, unless it is authorised by table 2.1 and appropriate measures are taken.

2.6 Pre-operational rules

2.6.1 Treatment activities shall not be brought into operation, until the measures specified in table S2.4 have been completed.

Table S2.4 Pre-operational measures

Pre-operational measures

- 1. The operator shall submit a written site commissioning validation report to the Environment Agency for approval, unless the Environment Agency has confirmed in writing that a report is not required, that demonstrates:
 - (a) a microbial efficacy analysis, that demonstrates that the choice of test organism, the method of introduction to the plant, the choice of organism carrier, and the analytical method are adequate to demonstrate STAATT level III criteria for a worst case scenario challenge load;
 - (b) evidence that effective parametric controls, and procedures for real-time monitoring and assessment of outputs, are in place with respect to any waste treated;
 - (c) evidence that the parametric control data relates to microbial efficacy, so that waste can therefore be considered to be treated satisfactorily on the basis of parametric controls alone;
 - (d) an environmental monitoring assessment of the site that addresses emissions from permitted activities, including emissions from any macerator/shredder; and
 - (e) where procedures for operational efficacy monitoring are different from those in (a), evidence that such continuous monitoring arrangements are a sufficiently effective substitute.
 - 2. The operator receives written confirmation from the Environment Agency that the validation report has been agreed.
 - 3. The efficacy monitoring procedure or continuous monitoring procedure is sent to and agreed in writing by the Environment Agency prior to operations commencing.
 - 4. Pre-operational measure before treating waste listed in Table 2.2b.

A written justification for the treatment of wastes listed in Table 2.2b of this permit shall be submitted to the Environment Agency for approval. As a minimum, the justification shall take into account the principles specified in sections 2.1 and 2.3 of the sector guidance note for clinical waste EPR 5.07. It should address whether the treatment of each of the wastes listed in table 2.2b:

- is effective, including validation of the process using worst case scenario conditions;
- is an efficient use of energy and raw materials;
- impedes waste recovery or recycling;
- · compromises the treatment of any hazardous waste;
- has an effect on emissions from the activity; and
- is segregated in accordance with HTM 07 01, The Safe Management of Healthcare Waste.

No wastes specified in Table 2.2b shall be accepted for treatment unless the Environment Agency has given written approval under this condition.

3 – Emissions and monitoring

3.1 Emissions to air, water or land

3.1.1 There shall be no point source emissions to air, water or land, except from the sources and emission points listed in table 3.1.

3.1.2 The limits given in table 3.1 shall not be exceeded.

Table 3.1 Point source emissions					
Monitoring Location	Parameter	Monitoring frequencies	Limit (as colony forming units - cfu)	Unit	Monitoring standard and method
Point source process emissions to air	Bacillus spores	As specified in Table C1, Annex 3 of Clinical Waste (EPR 5.07), unless otherwise agreed with the Environment Agency	1000	Per cubic meter ²	In accordance with Annex 3 of Clinical Waste (EPR 5.07), unless otherwise agreed with the Environment Agency
	Chemicals ³	To be agreed with the Environment Agency (as part of pre-operational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)
Waste water	Bacillus spores (spiked organisms)	As specified in Table C1, Annex 3 of Clinical Waste (EPR 5.07), unless otherwise agreed with the Environment Agency	300	Per litre ²	In accordance with Annex 3 of Clinical Waste (EPR 5.07), unless otherwise agreed with the Environment Agency
	Chemicals ³	To be agreed with the Environment Agency (as part of pre-operational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)	To be agreed with the Environment Agency (as part of preoperational measure 4)

Note 1: This is an indicative benchmark based on a specific input dose. It will be reviewed periodically.

Note 2: These units relate to the overall monitoring period so the cfu benchmark applies to each individual sample of air or water taken, with a calculation made to report the result per cubic meter or litre. These are based on a seeding dose of 1 x 106 spores per gram of waste load and would need to be adjusted if the seed dose were higher or lower.

Note 3: Monitoring is required where chemically or medicinally contaminated waste is processed. This should address the range of chemicals and medicines treated, as well as any reaction or breakdown products. Monitoring is also required if the treatment process uses chemicals, in relations to those chemicals and any reaction or breakdown products. In other circumstances, monitoring is not required.

3.2 Emissions of substances not controlled by emission limits

3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this rule if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent, or where that is not practicable to minimise, those emissions.

3.2.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution, submit to the Environment Agency for approval within the period specified, an emissions management plan; and
- (b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 3.2.3 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.3 Odour

- 3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable, to minimise, the odour.
- 3.3.2 The operator shall:
 - (a) maintain and implement an odour management plan;
 - (b) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the specified period, a revised odour management plan; and
 - (c) implement any approved revised odour management plan from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.4 Noise and vibration

3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan, to prevent or where that is not practicable, to minimise, the noise and vibration.

3.4.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan; and
- (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

- 3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake monitoring for the parameters, at the locations and at not less than the frequencies specified in table 3.1 and 3.5
- 3.5.2 The operator shall maintain records of all monitoring required by these standard rules including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

Table 3.5 Fugitive bioaerosol emissions monitoring (spiked organisms)					
Monitoring Location	Parameter	Monitoring frequencies	Limit (cfu)	Unit	Monitoring standard and method
Air – sample points <10m from the treatment plant.	Bacillus spores	As specified in Table C1, Annex 3 of Clinical Waste (EPR 5.07), unless otherwise agreed with the	1000	Per cubic metre ¹	In accordance with Annex 3 of Clinical Waste (EPR
Air – sample points>10m from the treatment plant	Bacillus spores		300	Per cubic metre ¹	5.07) , unless otherwise agreed with the Environment
Surface – sample point < 10m from the treatment plant	Bacillus spores	Environment Agency	20000 ²	Per square metre , per hour 1	Agency
Surface – sample points > 10 m from the treatment plant.	Bacillus spores		5000°	Per square metre per hour ¹	

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

- Each individual sample of air taken, with a calculation made to report the result per cubic metre.
- For each individual settle plate (this is not an average)—a calculation made to adjust for surface area of a settle plate and exposure time (for example if settle plates are deployed for only 15 minutes of every hour then the result must be multiplied by 4).
- These are based on a seeding dose of 1 x 10⁶ spores per gram of waste load and would need to be adjusted accordingly if the seed dose were higher or lower.

Note 2: These benchmarks are indicative only, are based on a specific input dose, and will be reviewed periodically.

4 - Information

4.1 Records

- 4.1.1 All records required to be made by these standard rules shall:
 - (a) be legible;
 - (b) be made as soon as reasonably practicable;
 - (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible or are capable of retrieval; and
 - (d) be retained, unless otherwise agreed by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
 - (i) off-site environmental effects; and
 - (ii) matters which affect the condition of land and groundwater.
- 4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by these standard rules, unless otherwise agreed in writing by the Environment Agency.

4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by these standard rules to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 Within one month of the end of each quarter, the operator shall submit to the Environment Agency using the form made available for the purpose, the information specified on the form relating to the site and the waste accepted and removed from it during the previous quarter.

4.3 Notifications

- 4.3.1 The Environment Agency shall be notified without delay following the detection of:
 - (a) any malfunction, breakdown or failure of equipment or techniques, accident or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution;
 - (b) the breach of a limit specified in these standard rules; or
 - (c) any significant adverse environmental effects.
- 4.3.2 Written confirmation of actual or potential pollution incidents and breaches of emission limits shall be submitted within 24 hours.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters except where such disclosure is prohibited by Stock Exchange rules:
 - a) Where the operator is a registered company:
 - any change in the operator's trading name, registered name or registered office address;
 and
 - any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
 - b) Where the operator is a corporate body other than a registered company:
 - any change in the operator's name or address; and
 - any steps taken with a view to the dissolution of the operator.
 - c) In any other case:
 - the death of any of the named operators (where the operator consists of more than one named individual);
 - · any change in the operator's name(s) or address(es); and
 - any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership.

4.4 Interpretation

- 4.4.1 In these standard rules the expressions listed below shall have the meaning given.
- 4.4.2 In these standard rules references to reports and notifications mean written reports and notifications, except when reference is being made to notification being made "without delay", in which case it may be provided by telephone.

"authorised officer" means any person authorised by the Environment Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in Section 108(4) of that Act.

"building" means a construction that has the objective of providing sheltering cover and minimising emissions of noise, particulate matter, odour and litter.

"cytotoxic and cytostatic medicines" means any medicinal product that possesses one or more of the hazardous properties H6 Toxic, H7 Carcinogenic, H10 Toxic for Reproduction and H11 Mutagenic.

"D" means a disposal operation provided for in Annex I to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on Waste.

[&]quot;accident" means an accident that may result in pollution.

- "clinical waste" means waste from a healthcare activity (including veterinary healthcare) that—
- (a) contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms,
- (b) contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent, or (c) is a sharp, or a body fluid or other biological material (including human and animal tissue) containing or contaminated with a dangerous substance within the meaning of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(b), and waste of a similar nature from a non-healthcare activity;

"offensive waste" means waste that-

- (a) is not clinical waste.
- (b) contains body fluids, secretions or excretions, and
- (c) falls within code 18 01 04, 18 02 03 or 20 01 99 in Schedule 1 to The List of Wastes (England) Regulations 2005(d)

"emissions of substances not controlled by emission limits" means emissions of substances to air, water or land from the activities, either from emission points specified in these standard rules or from other localised or diffuse sources, which are not controlled by an emission limit.

"emissions to land", include emissions to groundwater.

"groundwater" means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

"hazardous waste" has the meaning given in the Hazardous Waste (England and Wales) Regulations 2005.

"healthcare waste" means a waste classified under Chapter 18 of Schedule 1 to The List of Wastes(England) Regulations 2005, which is waste from Human and Animal Health Care and/or Related Research.

"impermeable surface" means a surface or pavement constructed and maintained to a standard sufficient to prevent the transmission of liquids beyond the pavement surface, and should be read in conjunction with the term "sealed drainage system" (below).

"mixing of hazardous waste" means mixing hazardous waste as defined by Regulation 18 of the Hazardous Waste (England and Wales) Regulations 2005.

"pollution" means emissions as a result of human activity which may—

- (a) be harmful to human health or the quality of the environment,
- (b) cause offence to a human sense,
- (c) result in damage to material property, or
- (d) impair or interfere with amenities and other legitimate uses of the environment.

"quarter" means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

"R" means a recovery operation provided for in Annex II to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on Waste.

"requirements for carriage" means the requirements of the current Carriage Regulations, which implement the ADR.

"sealed container" means a container which is fully enclosed, weather proof, does not allow any solid or liquid content to escape and is lockable.

"sealed drainage system" in relation to an impermeable surface, means a drainage system with impermeable components which does not leak and which will ensure that:

- (a) no liquid will run off the surface otherwise than via the system;
- (b) except where they may lawfully be discharged to foul sewer, all liquids entering the system are collected in a sealed sump.

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

"STAATT Level III" means the level III criteria set by the State and Territorial Association on Alternative Treatment Technologies (STAATT), as interpreted by Environment Agency guidance EPR 5.07 Version 1.0. The STAATT Level III criteria requires the inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 log₁₀ reduction or greater; and inactivation of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores at a 4 log₁₀ inactivation or greater.

"waste acceptance": appropriate measures to determine if waste is of a type and quantity listed in table 2.2 as set out in Environment Agency guidance EPR 5.07 Version 1.1, (XXXXXX) which includes both preacceptance and on site acceptance checks.

"waste code" means the six digit code referable to a type of waste in accordance with the List of Wastes (England) Regulations 2005, as appropriate, and in relation to hazardous waste, includes the asterisk.

"year" means calendar year commencing on 1st January.

End of standard rules