Variation notice with introductory note

Environmental Permitting (England & Wales) Regulations 2010

Britcare (Yorkshire) Treatment Facility

Britcare Ltd
Bankwood Lane Industrial Estate
Bankwood Lane
Rossington
Doncaster
DN11 0PS

Variation notice number
EPR/EP3497ED/V002

Permit number
EPR/EP3497ED

Britcare (Yorkshire) Treatment Facility
Permit number EPR/EP3497ED

Introductory note

This introductory note does not form a part of the permit

The following notice, which is issued pursuant to regulation 20 and Part 1 of Schedule 5 of the Environmental Permitting (England and Wales) Regulations 2010 S.I.2010 No. 675 (the Regulations), gives notice of the variation of an environmental permit to operate a regulated facility.

The changes introduced by this variation notice are to allow Britcare Ltd to vary their existing permit to a Standard Rules Permit to operate a Clinical waste and Healthcare waste treatment and transfer station with a annual throughput of less than 75,000 tonnes per annum.

Schedule 1 of this notice lists any deleted conditions, Schedule 2 lists any amended conditions, Schedule 3 lists any conditions that have been added and Schedule 4 shows any changes to the plan.

The status log of a permit sets out the permitting history, including any changes to the permit reference number.

Status Log of the permit

Detail	Date	Response Date
Application EPR/EP3497ED (partial transfer of permit EPR/SP3990CM)	Duly made 10/03/10	
Partial transfer determined EPR/EP3497ED	16/06/10	
Application EPR/EP3497ED/V002	24/05/10	
Variation issued EPR/EP3497ED/V002	25/06/10	

End of Introductory Note

Notice of variation

Environmental Permitting
(England and Wales) Regulations 2010

Permit number
EPR/EP3497ED

The Environment Agency in exercise of its powers under Regulation 20 of the Environmental Permitting (England and Wales) Regulations 2010 (SI 2010 No 675) varies the permit as set out below.

Britcare Ltd ("the operator"),

whose registered office is

Kelham House
Kelham St
Doncaster
DN1 3RE

company registration number **3376733**

holds a permit to operate a regulated facility at
Britcare Ltd
Bankwood Lane Ind Est
Bankwood Ln
Rossington
Doncaster

DN11 0PS

and that permit is varied to the extent set out in Schedules 1 to 4 of this notice.

The notice shall take effect from 25/06/10

Name	Date
J McNamara	25/06/10

Jane McNamara

Authorised on behalf of the Environment Agency

Schedule 1 – conditions to be deleted

The following conditions are deleted

All Conditions from EPR/EP3497ED

Schedule 2 – conditions to be amended

None.

Schedule 3 – conditions to be added

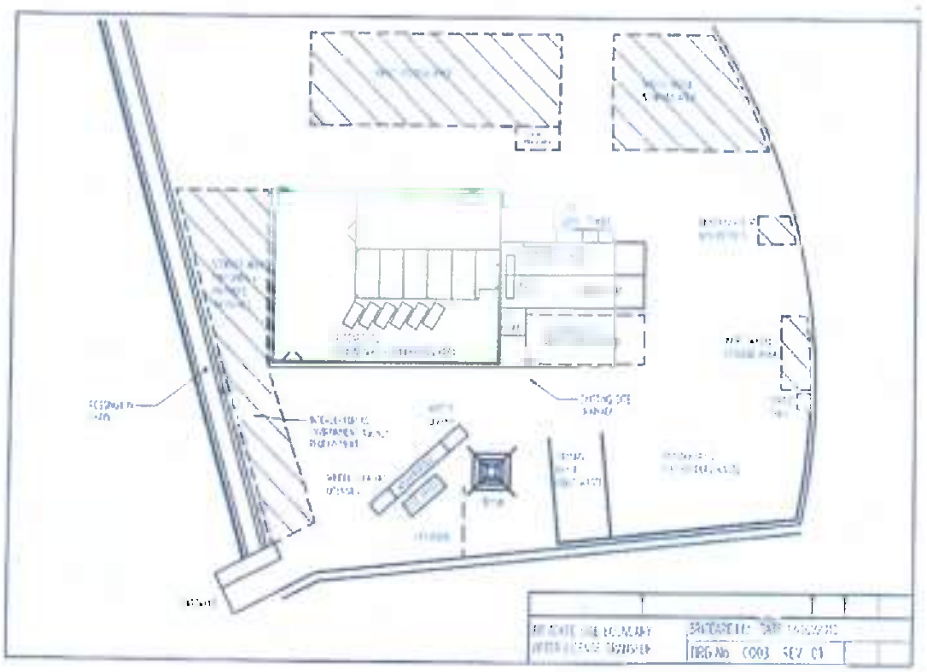
The following conditions are added to the permit

SR2008No25 75kte

Schedule 4 – amended plan

Amended plan attached

This is the plan referred to in the standard rules SR2008No25_75kte



Standard rules

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

Environment Agency

Standard rules SR2008No25_75kte – clinical waste & healthcare waste treatment and transfer station

Introductory note

This introductory note does not form part of these standard rules

When referred to in an environmental permit, these rules will allow the operator to operate a site for the treatment of clinical waste to render the waste safe and the storage and transfer of hazardous and non-hazardous clinical and healthcare waste at a specified location, provided that the permitted activities are not carried out within 200 metres of a European Site[1], Ramsar site or a Site of Special Scientific Interest (SSSI).

Permitted wastes are limited to non-hazardous and hazardous clinical and healthcare waste. The total quantity of waste that can be accepted at a site under these rules must be less than 75,000 tonnes a year. Treatment includes treatment by heat, chemicals and 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:

a. 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;

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 in the manner specified in Environment Agency Guidance.

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. These 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. However, under the emissions of substances not controlled by emission limits rule:

- Liquids may be discharged into a sewer subject to a consent issued by the local water company.
- Liquids may be taken off-site in a tanker for disposal or recovery.
- Clean surface water from roofs, or from areas of the site that are not being used in connection with storing and treating waste, may be discharged directly to surface waters, or to groundwater by seepage through the soil via a soakaway.

[1] A candidate or Special Area of Conservation (cSAC or SAC) and proposed or Special Protection Area (pSPA or SPA) in England and Wales.

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 comply with the requirements of an approved competence scheme.

2 – Operations

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").

Table 2.1 activities	
Description of activities	**Limits of activities**
D15: Storage pending any of the operations numbered D1 to D14 (excluding temporary storage, pending collection, on the site where it is produced) D9: Physico-chemical treatment not specified elsewhere in Annex IIA which results in final compounds or mixtures which are discarded by means of any of the operations numbered D1 to D8 and D10 to D12 R13: Storage of wastes pending any of the operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where it is produced) D14: Repackaging prior to submission to any of the operations numbered D1 to 13	The maximum quantity of hazardous waste received, stored, treated or repackaged for disposal shall not exceed, individually or aggregated, 10 tonnes per day. The treatment of non-hazardous waste for disposal shall not exceed 50 tonnes per day. The D9 treatment of hazardous waste shall include both thermal/chemical disinfection and shredding/maceration. There shall be no mixing of hazardous waste. The waste types permitted for treatment (D9), storage (D15 and R13), and repackaging (D14) are set out in tables 2.2a, 2.2b and 2.2c.

2.2 Waste acceptance

2.2.1 Waste shall only be accepted if:

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

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

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

Table 2.2 Waste types and quantities

Maximum Quantities

The total quantity of waste accepted at the site shall be less than 75,000 tonnes a year

Exclusions

Dangerous Goods: Any waste, otherwise permitted by table 2.2a or 2.2b, that is either transported in a vehicle, or is packaged in a manner that does not meet the requirements for carriage of that waste, unless agreed in writing with the Environment Agency for that individual consignment or batch of waste.

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 are specifically excluded from waste treatment activities from this waste code:

(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 storage (permitted activities D15 and R13)	
Waste Code	Description
09	WASTES FROM THE PHOTOGRAPHIC INDUSTRY
09 01	Wastes from the photographic industry
09 01 01*	water-based developer and activator solutions[2]
09 01 02*	water-based offset plate developer solutions[2]
09 01 03*	solvent based developer solutions[2]
09 01 04*	fixer solutions[2]
09 01 05*	bleach and bleach fixer solutions[2]
09 01 07	photographic film and paper containing silver or silver compounds[2]
09 01 08	photographic film and paper free of silver or silver compounds[2]
[2] This is limited to wastes of this type arising from medical practices or associated research activities.	
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 02	body parts and organs including blood bags and blood preserves (except 18 01 03)
18 01 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) (This is limited to non-clinical human offensive/hygiene waste and autoclaved waste from laboratories only)
18 01 06*	chemicals consisting of or containing dangerous substances (excluding X-ray photochemicals)
18 01 07	chemicals other than those mentioned in 18 01 06 (excluding X-ray photochemicals)
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	medicines other than those mentioned in 18 01 08
18 01 10*	amalgam waste from dental care
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	sharps (except 18 02 02)
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection. (This is limited to non-clinical animal offensive/hygiene waste and autoclaved waste from laboratories only)
18 02 05*	chemicals consisting of or containing dangerous substances (excluding X-ray photochemicals)
18 02 06	chemicals other than those mentioned in 18 02 05 (excluding X-ray photochemicals)
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	medicines other than those mentioned in 18 02 07
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 31*	cytotoxic and cytostatic medicines
20 01 32	medicines other than those mentioned in 20 01 31
20 01 99	other fractions not otherwise specified (comprising of separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection).
	other fractions not otherwise specified (comprising only of non-clinical human and

	animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection)

Table 2.2c Waste types permitted for repackaging (D 14)

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 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 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
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)
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS
20 01	separately collected fractions (except 15 01)
20 01 99	other fractions not otherwise specified (comprising only of non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection)

2.3 The site

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

2.3.2 The activities shall not be carried out within 200 metres of a European Site SSSI.

2.4 Pre-operational rules

2.4.1 Treatment activities shall not be brought into operation until the measures specified in table 2.4 have been completed.

Table S2.4 Pre-operational measures
Pre-operational measures
1. The operator's confirmation that the construction and installation of the plant has been carried out in accordance with the manufacturer's recommendations, shall be sent to the Environment Agency.
2. A validation report is sent to the Environment Agency that contains the following: (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 the macerator/shredder; (e) where procedures for operational efficacy monitoring are different from those in (a), evidence that these procedures are appropriate.
3. The operator receives written confirmation from the Environment Agency that the validation report has been agreed.
4. The efficacy monitoring procedure is sent to and agreed in writing by the Environment Agency prior to operations commencing.

2.5 Waste labelling and tracking

2.5.1 Containers shall be adequately and securely labelled at all times so that the producer, source of the wastes, contents and date of receipt can be identified.

2.5.2 The operator shall maintain a tracking system which can identify wastes prior to their onward dispatch.

2.6 Disinfection procedures

2.6.1 The operator shall use appropriate measures to disinfect surfaces and static containers used for the storage of clinical and healthcare wastes.

2.6.2 All surfaces where waste is handled and stored shall allow effective disinfection.

2.7 Shredding/maceration

2.7.1 Treatment shall be capable of reducing the waste to a particle size of less than or equal to 50mm and no particle shall exceed 80mm in any dimension.

2.8 Treatment process validation

2.8.1 Following commencement, the treatment process shall be revalidated at 4 yearly intervals and a validation report submitted within 14 days of the anniversary of each 4 yearly period. 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.

2.9 Routine efficacy monitoring

2.9.1 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.

2.9.2 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.

2.10 Treatment process quality control

2.10.1 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.

2.10.2 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.

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 (cfu)	Unit	Monitoring standard and method
Point source process emissions to air	Bacillus spores	Where the introduction of Bacillus spores is required by the Environment Agency to assess emissions from any part of the process.	To be agreed with the Environment Agency	To be agreed with the Environment Agency	To be agreed with the Environment Agency
	Chemicals	To be agreed with the Environment Agency	To be agreed with the Environment Agency	To be agreed with the Environment Agency	To be agreed with the Environment Agency
Waste water	Bacillus spores (spiked organisms)	To be agreed with the Environment Agency	$(300)^2$	Per litre	To be agreed with the Environment Agency

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

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 Table 3.2 below and in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.

Table 3.2 Appropriate measures for emissions not controlled by emission limits
Measures
1. All permitted waste shall either be stored: ◦ within a building provided with an impermeable surface with sealed drainage system; or ◦ within sealed containers located on an impermeable surface with sealed drainage system. Sealed containers shall be kept locked when not being loaded or unloaded.
2. All waste treatment activities shall take place within a building provided with an impermeable pavement and sealed drainage system.
3. Compaction shall be limited to treated wastes.
4. Wastes which arrive in bags or other non-rigid containers shall be transferred into rigid containers immediately.
5. 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.
6. Waste containing or contaminated with cytotoxic and cytostatic medicines shall be kept separate from other wastes.
7. 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.
8. Body parts and organs shall be stored in designated refrigerated units within a building.
9. The transfer of waste from vehicles or containers into other vehicles or containers shall only take place on areas with an impermeable surface with sealed drainage system.
10. Waste dispatched from the site shall be packaged in accordance with, and loaded onto vehicles that meet, the appropriate requirements for the carriage of dangerous goods.
11. Washing and disinfection of mobile containers shall take place on areas of impermeable surface with sealed drainage system.

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;

(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;

(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;

(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	To be agreed with the Environment Agency	1000	Per cubic metre[1]	To be agreed with the Environment Agency
Air – sample points>10m from the treatment plant	Bacillus spores	To be agreed with the Environment Agency	300	Per cubic metre[1]	To be agreed with the Environment Agency
Surface – sample point < 10m from the treatment plant	Bacillus spores	To be agreed with the Environment Agency	(20000)[2]	Per square metre , per hour [1]	To be agreed with the Environment Agency
Surface – sample points > 10 m from the treatment plant.	Bacillus spores	To be agreed with the Environment Agency	(5000) [2]	Per square metre per hour [1]	To be agreed with the Environment Agency

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).
- Each individual sample of water taken, with a calculation made to report the result per litre.

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.

"accident" means an accident that may result in pollution.

"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.

"Annex IIA" means Annex IIA to Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on Waste.

"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 IIA to Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on Waste.

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

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

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

"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.

"European Site" means Special Area of Conservation or candidate Special Area of Conservation or Special Protection Area or proposed Special Protection Area in England and Wales, within the meaning of Council Directives 79/409/EEC on the conservation of wild birds and 92/43/EEC on the conservation of natural habitats and of wild flora and fauna and the Conservation (Natural Habitats &c) Regulations 1994.

Internationally designated Ramsar sites are dealt with in the same way as European sites as a matter of government policy and for the purpose of these rules will be considered as a European Site.

"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 the List of Wastes, 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 IIB to Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 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.

"SSSI" means Site of Special Scientific Interest within the meaning of the Wildlife and Countryside Act 1981 (as amended by the Countryside and Rights of Way Act 2000).

"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 $\log_{10}$ reduction or greater; and inactivation of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores at a 4 $\log_{10}$ inactivation or greater.

"waste acceptance": appropriate measures to determine if waste is of a type and quantity listed in table 2.2 and conforms to the description in the documentation supplied by the producer and holder is set out in Environment Agency guidance EPR 5.07 Version 1.0.

"waste code" means the six digit code referable to a type of waste in accordance with the List of Wastes (England)Regulations 2005, or List of Wastes (Wales) 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