



**ENVIRONMENT
AGENCY**

Permit with introductory note

Pollution Prevention and Control (England & Wales) Regulations 2000

Sterile Technologies (Newcastle) Limited
Wrexham Clinical Waste Treatment
Plant and Transfer Station
Marlborough Road
Wrexham Industrial Estate
Wrexham
Clwyd
LL13 9RJ

Permit number

RP3237SZ

Wrexham Clinical Waste Treatment Plant and Transfer Station Permit Number RP3237SZ

Introductory note

This introductory note does not form a part of the permit

The main features of the installation are as follows:

Sterile Technologies (Newcastle) Limited accepts hazardous and non-hazardous waste which consists mainly of clinical waste. The Operator either treats the waste in the Heat Disinfecting Unit (HDU) or transfers it to a suitably licensed/permitted facility. The transfer of non-hazardous waste activity is regulated under the residual part of the waste management licence

The HDU consists of a shredder, a waste treatment chamber and abatement equipment. It shreds the waste under negative pressure to prevent the release of dust, odours and pathogens. The collected gases are passed through a three-stage HEPA filter before being released to the atmosphere. The shredded material is heated in the treatment chamber and the off-gases, including water vapour, are cooled in a condenser. Condensed water is discharged to a foul sewer and the gases are passed through a scrubber and biofilters to abate odours before being released to the atmosphere.

The waste leaves the HDU as a non-hazardous residue/flock that is landfilled. The treatment of waste takes place within a building. No waste activities are undertaken outside the building apart from the storage of some wastes in sealed containers.

The site is located on an industrial estate in Wrexham Industrial Estate, Wrexham and it is on the same site as an incinerator operated by the company. The incinerator holds a separate IPPC Permit and it has been deemed that both sites are not technically connected with one another. The site is more than 1km from a Natura 2000 designated site. It is anticipated that there will be no effect on the designated sites. There are no SSSI's within 2km of the facility.

There is a discharge to foul sewer from the installation and this is regulated through the consent to discharge issued by the sewerage undertaker.

The clean and uncontaminated surface water for the site discharges to the Red Whither Brook.

There are three point source emissions to air: the shredder hood, which is fitted with a HEPA filter; the HDU which has a condenser, a scrubber and biofilters; and the gas-fired oil heating system

The Operator has an environmental management system in place and is accredited to ISO14001.

The Operator is audited annually by LRQA .

Status Log of the permit

Detail	Date	Response Date
Application RP3237SZ	Duly made 31/08/05	
Schedule 4 Notice	03/03/06	20/03/06, 28/03/06, 31/03/06 and 11/04/06
Request to extend determination period	02/03/06	10/03/06
Permit determined	23/06/06	

Other PPC permits relating to this installation

Operator	Permit Number	Date of Issue
Not Applicable		

Superseded or Partially Superseded Licences/Authorisations/Consents relating to this installation

Holder	Reference Number	Date of Issue	Fully or Partially Superseded
Sterile Technologies (Newcastle) Limited	Waste Management Licence EAWML37223	09/02/04	Partially Superseded

The waste management licence shall cease to have effect if and to the extent that treatment, keeping or disposal of waste authorised by the licence is authorised by this permit.

Other existing Licences/Authorisations/Registrations relating to this site

Holder	Reference Number	Date of issue
Sterile Technologies (Newcastle) Limited	Waste Management LicenceEAWML37223	09/02/04

End of Introductory Note

Permit

Pollution Prevention and Control
(England and Wales) Regulations 2000

Permit

Permit number

RP3237SV

The Environment Agency (the Agency) in exercise of its powers under Regulation 10 of the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No 1973) hereby authorises **Sterile Technologies (Newcastle) Limited ("the operator")**,

whose registered office is :

Sterile Technologies (Newcastle) Limited
Lindfield House
Stuart Road
Gravesend
Kent
DA11 0BZ

company registration number **5018899**

to operate an installation at:

Wrexham Clinical Waste Treatment Plant and Transfer Station
Marlborough Road
Wrexham Industrial Estate
Wrexham
Clwyd
LL13 9RJ

to the extent authorised by and subject to the conditions of this permit.

Signed

Date

	
---	---

R Holland

Authorised to sign on behalf of the Agency

Conditions

1 Management

1.1 General management

1.1.1 The activities shall be managed and operated:

- (a) in accordance with a management system, which identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents and non-conformances and those drawn to the attention of the operator as a result of complaints; and
- (b) by sufficient persons who are competent in respect of the responsibilities to be undertaken by them in connection with the operation of the activities.

1.1.2 Records demonstrating compliance with condition 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 this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Accidents that may cause pollution

1.2.1 The operator shall:

- (a) maintain and implement an accident management plan;
- (b) review and record at least every 4 years or as soon as practicable after an accident, (whichever is the earlier) whether changes to the plan should be made;
- (c) make any appropriate changes to the plan identified by a review.

1.3 Energy efficiency

1.3.1 The operator shall:

- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
- (b) review and record at least every 4 years whether there are suitable opportunities to improve the energy efficiency of the activities; and
- (c) take any further appropriate measures by a review.

1.4 Efficient use of raw materials

1.4.1 The operator shall:

- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
- (b) maintain records of raw materials and water used in the activities;
- (c) review and record at least every 4 years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and

- (d) take any appropriate further measures identified by a review.

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

1.5.1. The operator shall:

- (a) take appropriate measures to ensure that waste produced by the activities is avoided or reduced, or where waste is produced it is recovered wherever practicable or otherwise disposed of in a manner which minimises its impact on the environment;
- (b) review and record at least every 4 years whether changes to those measures should be made; and
- (c) take any further appropriate measures identified by a review.

1.6 Site security

1.6.1. Site security measures shall prevent unauthorised access to the site, as far as practicable.

2. Operations

2.1 Permitted activities

- 2.1.1 The operator is authorised to carry out the activities specified in schedule 1 table S1.1 (the "activities").
- 2.1.2 Where there are wastes on site that are not subject to this permit then the wastes subject to the activities authorised under condition 2.1.1, shall be clearly identified.

2.2 The site

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in red on the site plan at schedule 2 to this permit.

2.3 Operating techniques

- 2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1 table S1.2, unless otherwise agreed in writing by the Agency.
- 2.3.2 No raw materials or fuels listed in schedule 3 table S3.1 shall be used unless they comply with the specifications set out in that table.
- 2.3.3 Waste shall only be accepted if:
- (a) it is of a type and quantity listed in schedule 3 tables S3.2 and S3.3; and
 - (b) it conforms to the description in the documentation supplied by the producer and holder; and
 - (c) it is only processed in the activity specified in Table S1.1 of Schedule 1.
- 2.3.4 Records shall be kept of all waste accepted onto the site.
- 2.3.5 The Operator shall ensure that where waste produced at the Permitted Installation(s) is sent to a waste recovery or disposal facility, the facility in question is provided with the following information, prior to receipt of the waste:
- The nature of the process producing the waste
 - The composition of the waste
 - The handling requirements of the waste
 - The hazard classification associated with the waste
 - The waste code of the waste
- 2.3.6 The Operator shall ensure that where waste produced at the Permitted Installation(s) is sent to a landfill site, it meets the waste acceptance criteria for that landfill.
- 2.3.7 Measures shall be implemented and maintained throughout the operational life of the installation to monitor and control the presence of pests on the installation. Such measures shall prevent pests being attracted to the installation in numbers that are likely to:
- cause harm to human health or the quality of the environment,
 - cause offence to any human senses,
 - result in damage to material property, or

- impair or interfere with amenities and other legitimate uses of the environment.
- 2.3.8 Measures shall be implemented and maintained throughout the operational life of the installation to control and monitor the presence of scavenging birds and other scavengers on the installation. Such measures shall prevent scavenging birds and other scavengers from gathering on operational areas or scavenging wastes in a manner likely to
- cause harm to human health or the quality of the environment,
 - cause offence to any human senses,
 - result in damage to material property, or
 - impair or interfere with amenities and other legitimate uses of the environment

2.4 Off-site conditions

- 2.4.1 There are no off-site conditions under this section.

2.5 Improvement programme

- 2.5.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Agency.
- 2.5.2 Except in the case of an improvement which consists only of a submission to the Agency, the operator shall notify the Agency within 14 days of completion of each improvement.

2.6 Pre-operational conditions

- 2.6.1 There are no pre-operational conditions in this permit.

2.7 Closure and decommissioning

- 2.7.1 The operator shall maintain and operate the activities so as to prevent or where that is not practicable, to minimise, any pollution risk on closure and decommissioning.
- 2.7.2 The operator shall maintain a site closure plan which demonstrates how the activities can be decommissioned to avoid any pollution risk and return the site to a satisfactory state.
- 2.7.3 The operator shall carry out and record a review of the site closure plan at least every 4 years.
- 2.7.4 The site closure plan (or relevant part thereof) shall be implemented on final cessation or decommissioning of the activities or part thereof.

2.8 Site protection and monitoring programme

- 2.8.1 The operator shall, within 2 months of the issue of this permit, submit a site protection and monitoring programme.
- 2.8.2 The operator shall implement and maintain the site protection and monitoring programme and shall carry out and record a review of it at least every 4 years.

3. Emissions and monitoring

3.1 Emissions to water, air or land

3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 4 tables S4.1, S4.2 and S4.3.

3.1.2 The limits given in schedule 4 shall not be exceeded.

3.2 Transfers off-site

3.2.1 Records of all the wastes sent off site from the activities, for either disposal or recovery, shall be maintained.

3.3 Fugitive emissions of substances

3.3.1 Fugitive emissions of substances (excluding odour, noise and vibration) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures have been taken to prevent or, where that is not practicable, to minimise those emissions.

3.3.2 Litter or mud arising from the activities shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures have been used to prevent or, where that is not practicable, to minimise the litter and mud.

3.3.3 Litter or mud arising from the activities shall be cleared from affected areas outside the site as soon as practicable.

3.3.4 All liquids, 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.

3.4 Odour

3.4.1 Emissions from the activities shall be free from odour at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or, where that is not practicable, to minimise the odour.

3.5 Noise and vibration

3.5.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or, where that is not practicable, to minimise the noise and vibration.

3.6 Monitoring

3.6.1 The operator shall, unless otherwise agreed in writing by the Agency, undertake monitoring for the parameters, at the locations and at not less than the frequencies specified in the following tables in schedule 4 to this permit:

- (a) point source emissions specified in tables S4.1, S4.2 and S4.3; and;

- (b) ambient air monitoring specified in table S4.4.
- 3.6.2 The operator shall maintain records of all monitoring required by this permit 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.
- 3.6.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.6.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate) unless otherwise agreed in writing by the Agency.
- 3.6.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 4 tables S4.1, S4.2 and S4.3 unless otherwise specified in that schedule.

4. Information

4.1 Records

4.1.1 All records required to be made by this permit 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 in writing by the 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) the site protection and monitoring programme.

4.1.2 Any records required to be made by this permit shall be supplied to the Agency within 14 days where the records have been requested in writing by the Agency.

4.1.3 All records required to be held by this permit shall be held on the site and shall be available for inspection by the Agency at any reasonable time.

4.2 Reporting

4.2.1 A report or reports on the performance of the activities over the previous year shall be submitted to the Agency by 31 January (or other date agreed in writing by the Agency) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with this permit against the relevant assumptions, parameters and results in the assessment of the impact of the emissions submitted with the application;
- (b) where the operator's management system encompasses annual improvement targets, a summary report of the previous year's progress against such targets;
- (c) the annual production /treatment data set out in schedule 5 table S5.2;
- (d) the performance parameters set out in schedule 5 table S5.3 using the forms specified in table S5.4 of that schedule; and
- (e) details of any contamination or decontamination of the site which has occurred.

4.2.2 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

- (a) in respect of the parameters and emission points specified in schedule 5 table S5.1;
- (b) for the reporting periods specified in schedule 5 table S5.1 and using the forms specified in schedule 5 table S5.4; and

- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.
- 4.2.3 A summary report of the waste types and quantities accepted and removed from the site shall be made for each quarter. It shall be submitted to the Agency within one month of the end of the quarter and shall be in the format required by the Agency.
- 4.2.4 The operator shall, unless notice under this condition has been served within the preceding 4 years, submit to the Agency, within 6 months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.
- 4.2.5 All reports and notifications required by the permit shall be sent to the Agency using the contact details supplied in writing by the Agency.
- 4.2.6 The results of reviews and any changes made to the site protection and monitoring programme shall be reported to the Agency, within 1 month of the review or change.

4.3 Notifications

- 4.3.1 The Agency shall be notified without delay following the detection of:
 - (a) any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution;
 - (b) the breach of a limit specified in the permit;
 - (c) any significant adverse environmental effects.
- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 6 to this permit within the time period specified in that schedule.
- 4.3.3 Prior written notification shall be given to the Agency of the following events and in the specified timescales:
 - (a) as soon as practicable prior to the permanent cessation of any of the activities;
 - (b) cessation of operation of part or all of the activities for a period likely to exceed 1 year; and
 - (c) resumption of the operation of part or all of the activities after a cessation notified under (b) above.
- 4.3.4 The Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.
- 4.3.5 Where the 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 Agency when the relevant monitoring is to take place. The operator shall provide this information to the Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.6 The Agency shall be notified within 7 days of any changes in technically competent management and the name of any incoming person together with evidence that such person has the required technical competence.
- 4.3.7 The Agency shall be provided, within 14 days of the operator or any relevant person being convicted of a relevant offence, (unless such information has already been notified to the Agency), with details of the nature of the offence, the place and date of conviction, and the sentence imposed.

- 4.3.8 The Agency shall be notified within 14 days of the operator and/or any relevant person lodging an appeal against a conviction for any relevant offence and of the outcome when the appeal is decided.
- 4.3.9 The 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) any change in the operator's trading name, registered name or registered office address;
 - (b) any change to particulars of the operator's ultimate holding company (including details of an ultimate holding company where an operator has become a subsidiary); and
 - (c) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

4.4 Interpretation

- 4.4.1 In this permit the expressions listed in schedule 7 shall have the meaning given in that schedule.

Schedule 1 - Operations

Table S1.1 activities		
Activity listed in Schedule 1 of the PPC Regulations	Description of specified activity and WFD Annex IIA and IIB operations	Limits of specified activity and waste types
Section 5.3 Part A(1)(a): The disposal of hazardous waste (other than by incineration or landfill) in a facility with a capacity of more than 10 tonnes per day.	D9 Physico-chemical treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any operations numbered D1 to D12 (in the heat disinfecting unit.)	<p><u>Waste types</u></p> <p>180103*, 180202*</p> <p>Excluding: pharmaceutical waste in any form or containers; anatomical waste (identifiable human or animal tissue); carcasses; any waste known or likely to contain ACDP Hazard Group 4 biological agents; any waste from a containment level 3 laboratory; other microbial cultures unless an appropriate treatment methodology has been submitted and agreed by the Agency that demonstrates adequate containment and disinfection procedures; cytotoxic and cystostatic contaminated waste; medicinally contaminated sharps.</p> <p><u>Limits</u></p> <p>Maximum of 24 tonnes per day of hazardous and non- hazardous waste</p>
Section 5.3 Part A(1)(a): The disposal of hazardous waste (other than by incineration or landfill) in a facility with a capacity of more than 10 tonnes per day.	D15 Storage of Hazardous waste	<p><u>Waste types</u></p> <p>150202*, 180103*, 180106*, 180108*, 180110*, 180202*, 180205*, 180207*, 200131*</p> <p><u>Limits</u></p> <p>Maximum storage of 91.25 tonnes at any one time as follows:-</p> <p>Area in front of the HDU : 125 x 770 litre carts = 6.25 tonnes</p> <p>Yard Area : 25 x 1500 litre carts = 2.5 tonnes</p> <p>Yard Area : 450 x 770 litre carts = 22.5 tonnes</p> <p>Yard Area : 15 trailers = 60 tonnes</p>

Table S1.1 activities cont'd

Activity listed in Schedule 1 of the PPC Regulations	Description of specified activity and WFD Annex IIA and IIB operations	Limits of specified activity and waste types
Directly Associated Activity		
Disposal of non-hazardous waste	D9 Physico-chemical treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any operations numbered D1 to D12 (in the heat disinfecting unit.)	<p><u>Waste types</u></p> <p>150101, 150105, 150106, 150203, 180101, 180102, 180104, 180107, 180109, 180201, 180203, 180206, 180208, 200101, 200110, 200132 and 200199 (only to include: municipal sharps collection; substances and good seized/confiscated by police and customs; soiled surgical dressings, swabs, nappies, feminine hygiene, incontinence pads and other similar soiled wastes collected from households, institutions and commercial and industrial premises; drugs related litter.)</p> <p>Excluding: pharmaceutical waste in any form or containers; anatomical waste (identifiable human or animal tissue); carcasses; any waste known or likely to contain ACDP Hazard Group 4 biological agents; any waste from a containment level 3 laboratory; other microbial cultures unless an appropriate treatment methodology has been submitted and agreed by the Agency that demonstrates adequate containment and disinfection procedures; cytotoxic and cystostatic contaminated waste; medically contaminated sharps.</p> <p><u>Limits</u></p> <p>Maximum of 24 tonnes per day of hazardous and non- hazardous waste</p>
Disposal of non-hazardous waste	D15 Storage of non hazardous waste	<p><u>Waste types</u></p> <p>150101, 150105, 150106, 150203, 180101, 180102, 180104, 180107, 180109, 180201, 180203, 180206, 180208, 200101, 200110, 200132 and 200199 (only to include: municipal sharps collection; substances and good seized/confiscated by police and customs; soiled surgical dressings, swabs, nappies, feminine hygiene, incontinence pads and other similar soiled wastes collected from households, institutions and commercial and industrial premises; drugs related litter.)</p> <p><u>Limits</u></p> <p>Maximum storage of 20 tonnes at any one time</p>
Washing of Clinical Waste Containers	Washing of containers used for clinical waste storage.	No limit on capacity
Combustion plant	Gas fuelled boiler <0.5MW	From receipt of fuel to emission of combustion gases.
The air abatement equipment for the treatment process	HEPA filters, condenser, scrubber and bio-filter	

The storage and handling of residues from the treatment process	<u>Waste types</u> 190203 only to include waste generated from the treatment of hazardous waste in the installation.
	<u>Limits</u> Maximum of 60 tonnes at any one time as follows: 5 x skips for residue = 60 tonnes

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application	The response to questions 2.1.4 to 2.1.10, 2.1.12 to 2.1.14, 2.1.17 to 2.1.24 and 2.2 of the application, (excluding answers to question 2.2.9) and excluding attachment 5 parts 8(2) and 9.	31/08/05
Response to Schedule 4 Notice Request dated 03/3/06	Answers to points 5,9-12, 14-27 only	20/03/06, 28/03/06, 31/03/06, 11/04/06
Email from Stuart Budd, Sterile Technologies, dated 08/12/05	All	08/12/05
Email from Stuart Budd Sterile Technologies, dated 25/01/06	Hazardous and non-hazardous waste storage for Wrexham Plant only.	25/01/06
Email from Colm Harkin Sterile Technologies, dated 15/06/06	Storage quantities for Wrexham facility only and description of wastes to be included.	15/06/06

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1	The Operator shall revise and re-submit the plan which details air emissions to ensure that it has an accurate scale.	01/10/06
IC2	The Operator shall implement procedures to ensure that waste is stored in bins with closed lids except during loading and unloading. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedures.	01/10/06
Any proposed improvement shall be implemented from the date of approval by the Agency in writing.		

IC3	The Operator shall repair the oil leak on the screw conveyor. The operator shall submit a validation report to the Agency for approval.	01/10/06
IC4	The Operator shall revise and re-submit the plan which details site drainage to ensure that it has an accurate scale and clearly references all surface water discharge point(s) on site as W1, W2 etc..	01/10/06
IC5	A written justification for the treatment of non-hazardous waste listed in tables S1.1 and S3.2 of this permit, shall be submitted to the Agency for approval. As a minimum, the justification shall take into account the principles specified in section 2.1.1 of Sector Guidance Note IPPC 5.06 dated December 2004. The justification should address whether the treatment of each non-hazardous waste listed in tables S1.1 and S3.2: <ul style="list-style-type: none"> • is an efficient use of energy; • impedes waste recovery or recycling; and • compromises the treatment of any hazardous waste . <p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the justification.</p> <p>Following review of the justification by the Agency, only those non-hazardous wastes approved shall be accepted for treatment at the installation.</p>	01/10/06
IC6	A written plant efficacy testing procedure shall be submitted to the Agency for approval. As a minimum the procedure shall include: <ul style="list-style-type: none"> • the frequency of sampling; • minimum number of spore strips or sub-samples to be used; • number of control strips; • details of the indicator strips and/or multipoint data loggers to be used; • the quantitative and qualitative success criteria; and • an action plan that details actions to be taken if the success criteria are exceeded. <p>The notification requirements of condition 2.5.2 shall deemed to have been complied with on submission of the procedure.</p> <p>The efficacy testing procedure shall be implemented from the date of approval by the Agency in writing. Until such time that the written procedure for efficacy testing is approved by the Agency, the minimum frequency for efficacy testing to demonstrate microbial inactivation shall be weekly.</p>	01/10/06
IC7	The Operator shall review the storage of waste and the site surfacing at the facility in accordance with section 2.1.3 of Sector Guidance Note IPPC S5.06, dated December 2004. Once the review has been conducted the Operator shall submit their findings to the Agency in writing and a timetable of remediation works if required. <p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the review.</p> <p>Any proposed improvements shall be implemented by the Operator from the date of approval by the Agency in writing.</p>	01/01/07
IC8	The Operator shall review the bunding at the facility in the vicinity of the scrubbing tower and the oil storage facility in zone 12 and ensure that it meets the requirements of section 2.2.5 of the Agency Sector Guidance Note, dated December 2004. <p>The operator shall submit a written timetable of repairs to be undertaken to the Agency for approval.</p>	01/07/07
IC9	The Operator shall develop a written Site Closure Plan with regard to the requirements set out in Section 2.11 of Sector Guidance Note IPPC S5.06, dated December 2004. Upon completion of the plan, a summary of the document shall be submitted to the Agency for approval in writing.	01/07/07
IC10	A written assessment of the Volatile Organic Compounds (VOCs) emitted from the process shall be submitted to the Agency. The written assessment shall include, but need not be	01/07/07

restricted to:

- a scale drawing showing location of the emission points monitored;
- sampling of the emission and comparison against the benchmark values listed in Section 3.11 of the Sector Guidance Note IPPC S5.06, dated December 2004, to assess their significance;
- proposal of any necessary modelling of the emission; and
- details of how any emissions are to be prevented during the operation of the facility.

The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the written assessment.

The proposals for modelling and emission prevention shall be implemented by the Operator, from the date of approval by the Agency in writing.

IC11	A written report considering discharges to sewer shall be submitted to the Agency for approval. The report shall include, but need not be restricted to:	01/07/07
------	--	----------

- The probability of sewer bypass, via storm/emergency overflows or at intermediate sewage pumping stations
- The percentage of the time the Wastewater Treatment Works is bypassed;
- An estimate of the increased annual load of metals and persistent substances which will result from bypassing;
- A summary of action plans in the event of bypass such as knowing when bypass is occurring, or shutting down, or justification if there is to be no action taken;
- Summary of the events that could cause a release which could adversely effect the sewage treatment works and what actions (e.g. holding tanks, monitoring, batch release etc.) and actions taken to prevent this;
- Details of the treatment provided at the wastewater treatment works and how this compares to that which would be achieved if the effluent were treated on-site, based on reduction of load (not concentration) of each substance to the receiving water; and
- Any improvements identified, where appropriate the report shall contain different dates for implementing different measures.

The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.

Any improvements shall be implemented by the Operator from the date of approval by the Agency in writing.

IC12	The Operator shall undertake a waste minimisation audit in accordance with section 2.4.2 of the Sector Guidance Note IPPC S5.06, dated December 2004.	01/07/07
------	---	----------

The audit shall be submitted to the Agency in writing with a timetable of improvements to be undertaken, for approval by the Agency.

IC13	The Operator shall undertake an energy use audit in accordance with section 2.7.2 of the Sector Guidance Note IPPC S5.06, dated December 2004.	01/07/07
------	--	----------

The audit shall be submitted to the Agency in writing with a timetable of improvements to be undertaken, for approval by the Agency.

IC14	<p>A written report considering the cleaning and disinfecting of all clinical waste re-usable containers that have been delivered to and emptied at the installation should be provided to the Agency. The report shall include but need not be restricted to:</p> <ul style="list-style-type: none"> • the type and frequency of cleaning and disinfection necessary to prevent fugitive emissions of odour and biological contaminants; • a scale drawing showing location of the cleaning and disinfecting; • details of the disinfectant to be used, including strength and contact time; • details of the disposal of the wash water or waste arising; and • details of how fugitive emissions are to be prevented during the cleaning and disinfecting activity. <p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.</p> <p>The procedure shall be implemented by the Operator from the date of approval by the Agency in writing.</p>	01/07/07
IC15	<p>A written waste pre-acceptance procedure shall be submitted to the Agency for approval. The procedure shall take account of the principles specified in section 2.1.1 of Sector Guidance Note IPPC 5.06 dated December 2004. As a minimum the procedure shall:</p> <ul style="list-style-type: none"> • ensure that only waste suitable for treatment is accepted for treatment at the installation; • provide details of the waste producer and process that produced the waste; • include the quantity and type of each waste; and • include a reliable audit of the waste, prior to acceptance, at the site that shows that waste has been appropriately segregated and identified. <p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure.</p> <p>The procedure shall be implemented by the Operator from the date of approval by the Agency in writing.</p>	01/07/07
IC16	<p>A written waste acceptance procedure shall be submitted to the Agency for approval. The procedure shall take account of the principles specified in section 2.1.2 of Sector Guidance Note IPPC 5.06 dated December 2004. As a minimum the procedure shall include:</p> <ul style="list-style-type: none"> • a record of the inspection regime for each load and justification for the selection of this option; • visual inspection before offloading where safety is not compromised. <p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure.</p> <p>The procedure shall be implemented by the Operator from the date of approval by the Agency in writing.</p>	01/07/07

IC17	<p>A written validation report of the existing plant operation should be provided to the Agency. The report shall include, but need not be restricted to:</p> <ul style="list-style-type: none"> • a microbial efficacy analysis, that demonstrates that the choice of test organisms, 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; • evidence that the parametric controls, and procedures for real-time monitoring and assessment of outputs, are in place with respect to any waste treated; • evidence that the parametric control data relate to microbial destruction efficacy so that waste can therefore be considered to be treated satisfactorily on the basis of parametric control alone; and • an environmental monitoring assessment of the site that addresses process emissions; and • an assessment of any improvements identified. 	01/07/07
<p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.</p>		
<p>Any improvements shall be implemented by the Operator from the date of approval by the Agency in writing.</p>		
IC18	<p>A written risk assessment considering the risk of fugitive emissions from the installation and the need to undertake ambient air monitoring should be provided to the Agency. The report shall include but need not be restricted to:</p> <ul style="list-style-type: none"> • Necessary preventative measures for fugitive emissions; • a recommendation about undertaking ambient air monitoring including monitoring in the vicinity of the HDU maintenance/access points; • a scale drawing showing any proposed monitoring locations; • any proposed sampling frequencies; • any proposed trigger levels for the parameters monitored; • an action plan that identifies actions to be taken should trigger levels be exceeded if monitoring is proposed; 	01/07/07
<p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.</p>		
<p>Any proposed preventative measures and monitoring shall be implemented by the Operator from the date of approval by the Agency in writing.</p>		
IC19	<p>The operator shall consider the subsurface structures present at the site in relation to their potential to cause fugitive emissions to surface and ground water. The assessment will take into account the requirements of section 2.2.5 of the Sector Guidance Note IPPC S5.06, dated December 2004. A written report summarising the findings shall be submitted to the Agency. A time-scale for implementation of any improvements shall be submitted to the Agency for approval in writing.</p>	01/07/07
<p>The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.</p>		
<p>Any improvements shall be implemented by the Operator from the date of approval by the Agency in writing.</p>		
IC20	<p>The Operator shall submit a written procedure for approval by the Agency, in conjunction with the site pre-acceptance and acceptance criteria, to ensure that none of the following are present in the sharps boxes accepted for treatment :</p> <ul style="list-style-type: none"> • syringes contaminated with any quantity of pharmaceutical waste; • other pharmaceutical waste; • cytotoxic and cytostatic contaminated waste; and 	01/07/07

-
- any other excluded waste.

The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.

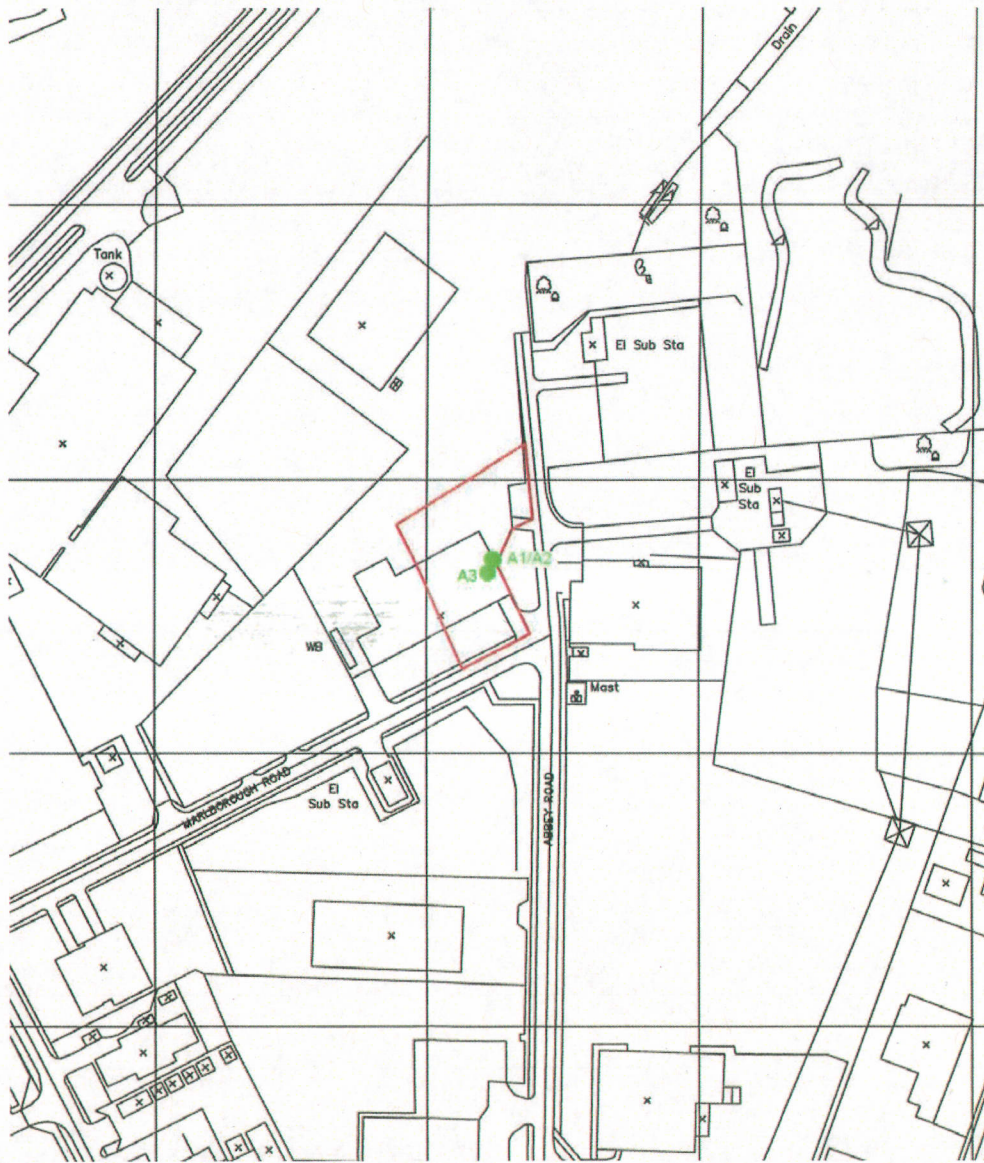
The procedure shall be implemented by the Operator from the date of approval by the Agency in writing.

IC21	The operator shall provide a report in writing to the Agency detailing the current monitoring method used to determine effluent flow at S1 and having regard to EN, ISO and BS standards. The monitoring method shall be agreed in writing with the Agency.	01/11/07
IC22	The Operator shall undertake a water use audit in accordance with section 2.4.3 of the Sector Guidance Note IPPC S5.06, dated December 2004.	01/07/08
	The audit shall be submitted to the Agency in writing with a timetable of improvements to be undertaken for approval by the Agency.	
IC23	The Operator shall ensure that a maintenance and inspection programme of impervious surfaces and containment kerbs is established in accordance with section 2.2.5 of the Sector Guidance Note IPPC S5.06, dated December 2004.	01/09/08
IC24	The Operator shall assess the method for effluent flow as agreed in IC21 with the requirements given in MCERTS standard 'Minimum requirements for self-monitoring effluent flow' version 1 August 2004. A written report shall be provided to the Agency detailing how this standard is to be achieved and shall include time-scales for implementation.	01/03/09

The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report.

The standard shall be implemented by the Operator from the date of approval by the Agency in writing.

Schedule 2 - Site plan



Schedule 3 - Waste types, raw materials and fuels

Table S3.1 Raw materials and fuels

Raw materials and fuel description	Specification
-	-

Table S3.2 Permitted waste types and quantities for treatment of waste in the Heat Disinfection Unit

Maximum quantity of	24 tonnes per day
Waste code	Description
150101	Paper and cardboard packaging
150105	Composite packaging
150106	Mixed packaging
150203	Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 150202*
180101	Sharps (except 180103*)
180102	Body Parts and organs including blood bags and blood preserves (except 180103*)
180103*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
180104	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen and disposable clothing, diapers)
180107	Chemicals other than those mentioned in 180106*.
180109	Medicines other than those mentioned in 180108*.
180201	Sharps (except 180202*)
180202*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
180203	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection
180206	Chemicals other than those mentioned in 180205*.
180208	Medicines other than those mentioned in 180207*.
200101	Paper and cardboard
200110	Clothes.
200132	Medicines other than those mentioned in 200131*
200199	Municipal sharps collection; substances and goods seized/confiscated by police and customs; soiled surgical dressings, swabs, nappies, feminine hygiene, incontinence pads and other similar soiled wastes collected from households, institutions and commercial and industrial premises; drugs related litter

Table S3.3 Permitted waste types and quantities for storage

Waste codes	No more than 91.25 tonnes of hazardous waste and 20 tonnes of non-hazardous waste to be stored at any one time
EWC Code	Description
150101	Paper and cardboard packaging
150105	Composite packaging
150106	Mixed packaging
150202*	Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths and protective clothing contaminated by dangerous substances
150203	Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 150202*
180101	Sharps (except 180103*).
180102	Body Parts and organs including blood bags and blood preserves (except 180103*)
180103*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
180104	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection.
180106*	Chemicals consisting of or containing dangerous substances
180107	Chemicals other than those mentioned in 180106*.
180108*	Cytotoxic and cytostatic medicines
180109	Medicines other than those mentioned in 180108*.
180110*	Amalgam waste from dental care
180201	Sharps (except 180102*).
180202*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
180203	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection.
180205*	Chemicals consisting of or containing dangerous substances
180206	Chemicals other than those mentioned in 180205*.
180207*	Cytotoxic and cytostatic medicines
180208	Medicines other than those mentioned in 180207*.
200101	Paper and cardboard
200110	Clothes.
200131*	Cytotoxic and cytostatic medicines
200132	Medicines other than those mentioned in 200131*
200199	Municipal sharps collection; substances and goods seized/confiscated by police and customs; soiled surgical dressings, swabs, nappies, feminine hygiene, incontinence pads and other similar soiled wastes collected from households, institutions and commercial and industrial premises; drugs related litter

Schedule 4 – Emissions and monitoring

Table S4.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Parameter	Source	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 as detailed on 'Air Emissions Points' Plan	Total aerobic bacteria	Shredder hood via HEPA filter	1000cfu/m ³		Quarterly	To be agreed with the Agency
A1 as detailed on 'Air Emissions Points' Plan	Total coliform bacteria	Shredder hood via HEPA filter	300 cfu/m ³		Quarterly	To be agreed with the Agency
A1 as detailed on 'Air Emissions Points' Plan	Total fungi	Shredder hood via HEPA filter	1000cfu/m ³		Quarterly	To be agreed with the Agency
A2 as detailed on 'Air Emissions Points' Plan	Total aerobic bacteria	Heat disinfection unit, via scrubber	1000cfu/m ³		Quarterly	To be agreed with the Agency
A2 as detailed on 'Air Emissions Points' Plan	Total coliform bacteria	Heat disinfection unit, via scrubber	300 cfu/m ³		Quarterly	To be agreed with the Agency
A2 as detailed on 'Air Emissions Points' Plan	Total fungi	Heat disinfection unit, via scrubber	1000cfu/m ³		Quarterly	
A3 as detailed on 'Air Emissions Points' Plan	-	Gas fired oil heating system	-	-	-	-

Table S4.2 Point Source emissions to water (other than sewer) – emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
W1, shown as point "leaves site" on 'Drainage Plan'	-	Clean uncontaminated surface water only	-	-	-	-

Table S4.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site – emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 shown as "to sewer" on 'drainage plan'	Flow	Drainage from within the building and process water	-	-	Reported as daily average over 1 month	To be agreed with the Agency by IC 21

Table S4.4 Ambient air monitoring requirements

Location or description of point of measurement	Parameter	Monitoring frequency	Monitoring standard or method ¹	Other specifications
Monitoring points to be agreed with the Agency by IC18	Bio aerosols	To be agreed with the Agency	To be agreed with the Agency	To be agreed with the Agency
Monitoring points to be agreed with the Agency by IC10	VOC's	To be agreed with the Agency	To be agreed with the Agency	To be agreed with the Agency

Schedule 5 - Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S5.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air Parameters as required by condition 3.6.1	A1, A2	Every 12 months	01/01/06
Emissions to sewer Parameters as required by 3.6.1	S1	Every 3 months	Upon completion of IC 21
Ambient air monitoring Parameters as required by condition 3.6.1	To be agreed with the Agency by ICs 10 and 18	Every 6 months	Upon completion of ICs 10 and 18

Table S5.2: Annual production/treatment	
Parameter	Units
Amount of waste treated in the Heat disinfection unit per year	tonnes

Table S5.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	m ³ /tonnes
Energy usage	Annually	MJ/tonne

Table S5.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Air	Form air 1 or other form as agreed in writing by the Agency	01/06/06
Waste Returns	WMS1 or other form as agreed in writing by the Agency	N/A
Sewer	Form Sewer 1 or other form agreed in writing with the Agency	01/06/06
Water usage	Form water usage1 or other form as agreed in writing by the Agency	01/06/06
Energy usage	Form energy 1 or other form as agreed in writing by the Agency	01/06/06
Other performance indicators	Form performance 1 or other form as agreed in writing by the Agency	01/06/06

Schedule 6 - Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the PPC Regulations.

Part A

Permit Number	RP3237SZ
Name of operator	Sterile Technologies (Newcastle) Limited
Location of Installation	Marlborough Road, Wrexham Industrial Estate
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution

To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit

To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B - to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of Sterile Technologies (Newcastle) Limited

Schedule 7 - Interpretation

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

"*accident management plan*" means a documented procedure (or procedures) that set out the measures necessary to prevent accidents occurring within the permitted installation, during both normal and abnormal operations, and limit the consequences to human health or the environment of any such accidents that do occur.

"*annually*" means once every year.

"*application*" means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 4 to the PPC Regulations.

"*authorised officer*" means any person authorised by the 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.

"*disposal*" shall mean any of the operations provided for in Annex IIA to Directive 75/442/EEC.

"*emissions to land*", includes emissions to groundwater.

"*fugitive emission*" means an emission to air, water or land from the activities which is not controlled by an emission limit.

"*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.

"*land protection guidance*", means Agency guidance "H7 - Guidance on the protection of land under the PPC Regime: application site report and site protection monitoring programme".

"*MCERTS*" means the Environment Agency's Monitoring Certification Scheme.

"*notify*" means that a telephone call can be used, whereas all other reports and notifications must be supplied in writing, either electronically or on paper.

"*notified without delay*" means that a telephone call can be used, whereas all other reports and notifications must be supplied in writing, either electronically or on paper.

"*PPC Regulations*" means the Pollution, Prevention and Control (England and Wales) Regulations SI 2000 No.1973 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

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

"*recovery*" shall mean any of the operations provided for in Annex IIB to Directive 75/442/EEC.

"*relevant person*" and "*relevant conviction*" shall have the meanings given to them in the Environmental Protection Act 1990

"*site protection and monitoring programme*" means a document which meets the requirements for site protection and monitoring programmes described in the Land Protection Guidance.

"*technically competent management*" and "*technical competence*" shall have the meanings given to them

in the Environmental Protection Act 1990.

“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
“WFD” means Waste Framework Directive (75/442/EEC).

“year” means calendar year ending 31 December.

Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- (a) in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- (b) in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content

END OF PERMIT