

Notice of variation and consolidation with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Sharpsmart Limited

Sharpsmart Limited
9 Longport Enterprise Centre
Scott Lidgett Road
Stoke on Trent
ST6 4NQ

Variation application number

EPR/XP3493VP/V009

Permit number

EPR/XP3493VP

Sharpsmart Limited

Permit number EPR/XP3493VP

Introductory note

This introductory note does not form a part of the permit

Under the Environmental Permitting (England & Wales) Regulations 2016 (schedule 5, part 1, paragraph 19) a variation may comprise a consolidated permit reflecting the variations and a notice specifying the variations included in that consolidated permit.

Schedule 1 of the notice specifies the conditions that have been varied and schedule 2 comprises a consolidated permit which reflects the variations being made. All the conditions of the permit have been varied and are subject to the right of appeal.

This permit variation has been issued to implement guidance "Healthcare waste: appropriate measures for permitted facilities".

Changes introduced by this variation notice/statutory review

The Industrial Emissions Directive (IED) came into force on 7 January 2014 with the requirement to implement all relevant Best Available Techniques (BAT) Conclusions as described in the Commission Implementing Decision. Article 21(3) of the IED requires the Environment Agency to review conditions in permits that it has issued and to ensure that the permit delivers compliance with relevant standards, within four years of the publication of updated decisions on Best Available Techniques (BAT) Conclusions. The BAT Conclusions for Waste Treatment (the BREF) was published on 17 August 2018 following a European Union wide review of BAT, implementing decision (EU) 2018/1147 of 10 August 2018.

On 13 July 2020, Healthcare waste: appropriate measures for permitted facilities guidance was published on gov.uk. The guidance explains the standards that are relevant to regulated facilities with an environmental permit to treat or transfer healthcare waste, providing indicative BAT for those sites.

This variation has been issued to update some of the conditions following a statutory review of the permits in the healthcare waste treatment and transfer sector. The opportunity has also been taken to consolidate the original permit and subsequent variations where appropriate.

Brief description of the process

The regulated facility comprises:

- pre-shredding and steam disinfection of infectious waste, storage of treatment residues;
- repackaging of hazardous waste, including repacking reusable sharps containers;
- cleaning and disinfection of reusable sharps containers;
- temporary storage of hazardous waste;
- steam generation, container washing and raw material storage;
- repackaging of non-hazardous waste;
- temporary storage of non-hazardous waste.

The steam disinfection plant consists of a pre-shredder, an autoclave, compaction and storage of treated floc, and pollution abatement equipment. Waste is shredded under negative pressure before transfer to the treatment chamber where a combination of heat, moisture and residence time is sufficient to disinfect the waste to produce a waste floc. Steam is supplied to the autoclave from the natural gas-fired steam raising plant, which is a medium combustion plant.

Off-gases from the autoclave are cooled in a condenser with the resulting water being discharged to foul sewer – If the condensate arises from the treatment of medically contaminated infectious waste, it is sent for incineration. Air from the shredder and autoclave is extracted and abated through a high efficiency particulate air (HEPA) filter and carbon filter. The abatement system is designed to remove any infectious

bio-aerosols, excess moisture and any residual organic compounds and odours from the off-gases before their release to atmosphere.

The schedules specify the changes made to the permit.

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

Status log of the permit		
Description	Date	Comments
Application EPR/XP3493VP/A001	Duly made 19/07/2011	Application for clinical waste transfer station.
Permit determined	14/11/2011	Permit for clinical waste transfer station issued.
Variation Application EPR/XP3493VP/V002	02/07/2013	Application for administrative variation.
Variation Application returned EPR/XP3493VP/V002	16/08/2013	Application returned.
Variation Application EPR/XP3493VP/V003	Duly Made 04/10/2013	Application to vary/increase site boundary.
Variation Application EPR/XP3493VP/V003	15/11/2013	Varied permit issued.
Administrative variation Application EPR/XP3493VP/V004	Received 28/03/2017	Application to add waste codes.
Variation determined EPR/XP3493VP/V004	19/06/2017	Varied permit issued.
Variation Application EPR/XP3493VP/V005	Duly Made 14/11/2018	Application to vary/increase site boundary.
Additional information provided for Schedule 5 Notice, dated 23/11/2018	29/11/2018	Updated Site Condition Report submitted.
Variation determined EPR/XP3493VP/V005	29/11/2018	Varied permit issued
Application EPR/XP3493VP/V006 (variation and consolidation)	Duly made 21/03/2019	Application to vary and update the permit to modern conditions.
Additional information provided for Schedule 5 Notice, dated 24/05/2019	24/05/2019	Received additional Fire Prevention Plan information, updated disposal criteria, Risk Assessment (H1) and information on receipt of proposed pharmaceutical waste.
Additional information provided for Schedule 5 Notice, dated 02/08/2019	02/08/2019	Received additional information relating to process flow and controls for treatment, pharmaceutical elements of wastes and commissioning of plant.
Variation determined EPR/XP3493VP/V006	25/10/2019	Varied permit issued.
Notified of change of Registered Office address	18/09/2020	Registered Office address changed to Unit 1 Enterprise Point, Enterprise City, Meadowfield Avenue, Spennymoor, Durham, DL16 6JF.
Variation issued EPR/XP3493VP/V007	14/10/2020	Varied permit issued to Sharpsmart Limited.

Status log of the permit		
Description	Date	Comments
Variation Application EPR/XP3493VP/V008	Duly Made 03/02/2021	Minor technical variation to add additional waste streams to existing shredding activities AR2 and AR10.
Additional information provided for Schedule 5 Notice, dated 23/04/2021	29/04/2021	Additional information relating to controls and cleaning procedures for the shredder under activity AR10 only to prevent cross contamination.
Variation determined EPR/XP3493VP/V008	18/05/2021	Varied permit issued to SharpSmart Limited.
Regulation 61 Notice sent to Operator	26/11/2021	Regulation 61 Notice requiring information for statutory review of permit.
Regulation 61 Notice response	10/03/2021	Response received from the operator.
Application EPR/XP3493VP/V009 (variation and consolidation)	Environment Agency Initiated Variation	Statutory review of permit occasioned by Waste Treatment BAT Conclusions published on 17 August 2018 and Healthcare waste: appropriate measures for permitted facilities published 13 July 2020.
Additional information received	22/04/22	Response to request for further information.
Additional information received	22/08/22	Response to request for further information.
Environment Agency Waste Treatment Sector Permit Review Variation determined EPR/XP3493VP/V009 (PAS Billing Ref: CP3948QZ EAWML Billing Ref. EAWML 102731)	14/12/22	Varied and consolidated permit issued.

End of introductory note

Notice of variation and consolidation

The Environmental Permitting (England and Wales) Regulations 2016

The Environment Agency in exercise of its powers under regulation 20 of the Environmental Permitting (England and Wales) Regulations 2016 varies and consolidates

Permit number

EPR/XP3493VP

Issued to

Sharpsmart Limited (“the operator”)

whose registered office is

**Unit 1 Enterprise Point
Enterprise City
Meadowfield Avenue
Spennymoor
Durham
England
DL16 6JF**

company registration number **04261387**

to operate regulated facilities at

**Sharpsmart Limited
9 Longport Enterprise Centre
Scott Lidgett Road
Stoke on Trent
ST6 4NQ**

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

Name	Date
Anne Lloyd	14/12/2022

Authorised on behalf of the Environment Agency

Schedule 1

All conditions have been varied by the consolidated permit as a result of an Environment Agency initiated variation.

Schedule 2 – consolidated permit

Consolidated permit issued as a separate document.

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/XP3493VP

This is the consolidated permit referred to in the variation and consolidation notice for application EPR/XP3493VP/V009 authorising,

Sharpsmart Limited (“the operator”),

whose registered office is

Unit 1 Enterprise Point

Enterprise City

Meadowfield Avenue

Spennymoor

Durham

England

DL16 6JF

company registration number **04261387**

to operate an installation and waste operations at

Sharpsmart Limited

9 Longport Enterprise Centre

Scott Lidgett Road

Stoke on Trent

ST6 4NQ

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

Name	Date
Anne Lloyd	14/12/2022

Authorised on behalf of the Environment Agency

Conditions

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 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.
- 1.1.4 The operator shall comply with the requirements of an approved competence scheme.

1.2 Energy efficiency

- 1.2.1 For the following activities referenced in schedule 1, table S1.1 (AR1 to AR7) the operator shall:
- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
 - (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
 - (c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

- 1.3.1 For the following activities referenced in schedule 1, table S1.1 (AR1 to AR7) 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 four 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 further appropriate measures identified by a review.

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

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.

- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

- 2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the "activities").
- 2.1.2 For the following activities referenced in schedule 1, table S1.1 (AR1 to AR7) waste authorised by this permit shall be clearly distinguished from any other waste on the site.

2.2 The site

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 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 Environment Agency.
- 2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation ("plan") specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.4 Waste shall only be accepted if:
- (a) it is of a type and quantity listed in schedule 2 tables S2.2, S2.3, S2.4 and S2.5; and
 - (b) it conforms to the description in the documentation supplied by the producer and holder.
- 2.3.5 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and
 - (e) the waste code of the waste.
- 2.3.6 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.
- 2.3.7 Hazardous waste shall not be mixed, either with a different category of hazardous waste or with other waste, substances or materials, unless it is authorised by schedule 1 table S1.1 and appropriate measures are taken.

2.4 Improvement programme

- 2.4.1 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 Environment Agency.
- 2.4.2 Except in the case of an improvement which consists only of a submission to the Environment Agency, the operator shall notify the Environment Agency within 14 days of completion of each improvement.

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 3 tables S3.1 and S3.2.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

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 condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.2.2 The operator shall:
- (a) if notified by the Environment Agency that the activities are giving rise to pollution, submit to the Environment Agency for approval within the period specified, an emissions management plan which identifies and minimises the risks of pollution from emissions of substances not controlled by emission limits;
 - (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.

3.4 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 which identifies and minimises the risks of pollution from noise and vibration;
- (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 the monitoring specified in the following tables in schedule 3 to this permit:
 - (a) point source emissions specified in tables S3.1 and S3.2;
 - (b) fugitive microbial emissions specified in table S3.3;
 - (c) process monitoring specified in table S3.4;
- 3.5.2 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.
- 3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.
- 3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2 and S3.3 unless otherwise agreed in writing by the Environment Agency.

3.6 Pests

- 3.6.1 The activities shall not give rise to the presence of pests which are likely to cause pollution, hazard or annoyance outside the boundary of the site. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved pests management plan, have been taken to prevent or where that is not practicable, to minimise the presence of pests on the site.
- 3.6.2 The operator shall:
 - (a) if notified by the Environment Agency, submit to the Environment Agency for approval within the period specified, a pests management plan which identifies and minimises risks of pollution from pests;
 - (b) implement the pests management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.7 Fire prevention

- 3.7.1 The operator shall take all appropriate measures to prevent fires on site and minimise the risk of pollution from them including, but not limited to, those specified in any approved fire prevention plan.

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 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 the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, 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 the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 For the following activities referenced in schedule 1, table S1.1 (AR1 to AR7) a report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment 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 the permit including an interpretive review of that data;
- (b) the annual production/treatment data set out in schedule 4 table S4.2; and
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment 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 4 table S4.1;
- (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six 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 Within 1 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 In the event:

- (a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—

- (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
- (b) of a breach of any permit condition the operator must immediately—
- (i) inform the Environment Agency, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
- (c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.

4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.

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:

Where the operator is a registered company:

- (a) any change in the operator's trading name, registered name or registered office address; and
- (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

Where the operator is a corporate body other than a registered company:

- (a) any change in the operator's name or address; and
- (b) any steps taken with a view to the dissolution of the operator.

In any other case:

- (a) the death of any of the named operators (where the operator consists of more than one named individual);
- (b) any change in the operator's name(s) or address(es); and
- (c) 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 of them being in a partnership, dissolving the partnership.

4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:

- (a) the Environment Agency shall be notified at least 14 days before making the change; and
- (b) the notification shall contain a description of the proposed change in operation.

4.3.6 The Environment Agency shall be given at least 14 days' notice before implementation of any part of the site closure plan.

4.4 Interpretation

- 4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.
- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made “immediately”, in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity and WFD Annex I and II operations	Limits of specified activity and waste types
AR1	Section 5.3 Part A(1)(a)(ii) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving physico-chemical treatment.	Treatment by shredding of infectious waste prior to on-site treatment (AR2). R3 Recycling / reclamation of organic substances which are not used as solvents. D9 Physico-chemical treatment.	From treatment of infectious waste to storage of shredded waste prior to on-site treatment. All treatment shall take place within a building on an impermeable surface with sealed drainage. No more than 50 tonnes per day of hazardous waste shall be shredded. Shredded waste shall be stored within fully enclosed, waterproof and leak-proof containers. The shredding of waste shall not change either the maximum storage times for waste on site or the amount that can be stored. There shall be no shredding of waste single use instruments. No waste types shall be submitted to this activity other than those hazardous wastes specified in Schedule 2, Table S2.2.
AR2	Section 5.3 Part A(1)(a)(ii) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving physico-chemical treatment.	Treatment of infectious waste by batch thermal treatment in autoclaves, including post-treatment compaction of treated floc. R3 Recycling / reclamation of organic substances which are not used as solvents. R4 Recycling/ reclamation of metals and metal compounds (treatment of single-use instruments) D9 Physico-chemical treatment.	From treatment of waste to storage of treated floc. All treatment shall take place within a building on an impermeable surface with sealed drainage. The autoclave shall be operated in accordance with Note 1. No more than 50 tonnes per day of infectious waste shall be treated. Treated floc shall be stored within fully enclosed, waterproof and leak-proof containers in a building and for no longer than 14 days. No more than 13 tonnes of treated floc shall be stored on site at any one time. All waste (including residues, condensate and effluent) resulting from the treatment of waste contaminated with non-hazardous medicines must be sent for incineration. No medicinally contaminated waste or effluent shall be discharged to sewer from this process. Aqueous effluent from the process shall be stored in leak-proof containers for no longer than 7 days within a building on an impermeable surface with sealed drainage. No waste types shall be submitted to this activity other than those infectious

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity and WFD Annex I and II operations	Limits of specified activity and waste types
			wastes specified in Schedule 2, Table S2.2.
AR3	Section 5.3 Part A(1)(a)(iv) Disposal of hazardous waste with a capacity exceeding 10 tonnes per day involving repackaging.	Operation of sharps bin wash plant and repackaging (bulking) of emptied sharps. R12 Exchange of waste for submission to any of the operations numbered R1 to R11. D14 Repackaging prior to submission to any of the operations numbered D1 to D13.	From repackaging of waste to storage of repackaged waste, washing and disinfection of empty packages and disposal of washings to sewer. Waste may only be removed from its original packaging if it has been designed to be re-used. The maximum quantity of sharps bin waste treated through the wash plant shall not exceed 50 tonnes per day. Washing and disinfection of reusable sharps bins and repackaging of wastes shall take place within a building on an impermeable surface with sealed drainage. Repackaging of waste shall not change either the maximum storage times for waste on site or the amount that can be stored. No waste types shall be submitted to this activity other than those hazardous wastes specified in Schedule 2, Table S2.3.
AR4	Section 5.3 Part A(1)(a)(iv) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving repackaging.	Repackaging of hazardous waste. R12 Exchange of waste for submission to any of the operations numbered R1 to R11. D14 Repackaging prior to submission to any of the operations numbered D1 to D13.	Repackaging is limited to: <ul style="list-style-type: none"> taking a waste package from a cart or bulk container (for example, skip) and placing it onto a pallet or vehicle transferring, removing or separating waste from its primary packaging into another container Other than waste received in reusable sharps bins that are emptied and cleaned for re-use, waste shall not be transferred, removed or separated from its primary packaging (for example bags, bins, boxes and blister packs). Repackaging of waste shall not change either the maximum storage times for waste on site or the amount that can be stored. No waste types shall be submitted to this activity other than those hazardous wastes specified in Schedule 2, Table S2.4.
	Directly Associated Activity		
AR5	Steam supply (Medium Combustion Plant)	<1.8 MWth natural gas fired boiler.	Steam generator for provision of steam for autoclave treatment.
AR6	Raw material handling and storage.	Raw material handling and storage.	From receipt and storage to point of use.

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity and WFD Annex I and II operations	Limits of specified activity and waste types
AR7	Cleaning and disinfection of containers and carts.	Automated bin wash that cleans and disinfects.	Handling, cleaning and storage of containers and carts prior to dispatch. Washing and disinfection of mobile containers shall only take place in designated areas with an impermeable surface and a sealed drainage system.
<p>Note 1 - The autoclave shall only be operated:</p> <p>(i) at the time, temperature and pressure settings the plant was validated at</p> <p>(ii) for a total load weight of waste no greater than that proven during validation</p> <p>(iii) for waste types and where relevant quantities of each type proven during validation</p> <p>(iv) if it passes plant validation requirements, including repeated plant validation and routine efficacy monitoring (Table S3.4), as set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.</p>			
Waste Operations			
Activity reference	Description of activities for waste operations	Limits of activities	
AR8	Treatment by shredding of non-hazardous waste and subsequent compaction of shredded waste. R3 Recycling / reclamation of organic substances which are not used as solvents. D9 Physico-chemical treatment.	<p>From shredding of waste to storage of shredded waste.</p> <p>No more than 50 tonnes per day of non-hazardous waste shall be shredded.</p> <p>No more than 13 tonnes of shredded non-hazardous waste shall be stored on site at any one time.</p> <p>The aggregated maximum quantity of non-hazardous waste treated for disposal on site shall not exceed 50 tonnes per day.</p> <p>All shredding shall take place within a building on an impermeable surface with sealed drainage.</p> <p>Shredded and compacted floc shall be stored within fully enclosed, waterproof and leak-proof containers in a building and for no longer than 14 days.</p> <p>The shredding of waste shall not change either the maximum storage times for waste on site or the amount that can be stored.</p> <p>Waste shall be shredded inside a building, using an enclosed and abated shredder with HEPA and carbon filters.</p> <p>Any shredded waste containing or contaminated with non-hazardous medicines (18 01 09) must be sent for incineration.</p> <p>Bin, container or cart washing equipment shall be purpose-built, contained and located in a designated area of the facility provided with self-contained drainage. The cart or bin wash must be designed to collect and contain all wash waters, including any spray.</p> <p>No waste types shall be submitted to this activity other than those non-hazardous wastes specified in Schedule 2, Table S2.5.</p>	
AR9	Repackaging of non-hazardous waste. R12 Exchange of waste for submission to any of the	<p>Repackaging is limited to:</p> <ul style="list-style-type: none"> taking a waste package from a cart or bulk container (for example, skip) and placing it onto a pallet or vehicle 	

	<p>operations numbered R1 to R11.</p> <p>D14 Repackaging prior to submission to any of the operations numbered D1 to D13.</p>	<ul style="list-style-type: none"> transferring, removing or separating waste from its primary packaging into another container <p>Other than waste received in reusable sharps bins that are emptied and cleaned for re-use, waste shall not be transferred, removed or separated from its primary packaging (for example bags, bins, boxes and blister packs).</p> <p>Washing and disinfection of reusable sharps bins and repackaging of wastes shall take place within a building on an impermeable surface with sealed drainage.</p> <p>Repackaging shall take place within a building on an impermeable surface with sealed drainage.</p> <p>Repackaging of waste shall not change either the maximum storage times for waste on site or the amount that can be stored.</p> <p>Bin, container or cart washing equipment shall be purpose-built, contained and located in a designated area of the facility provided with self-contained drainage. The cart or bin wash must be designed to collect and contain all wash waters, including any spray.</p> <p>No waste types shall be submitted to this activity other than those non-hazardous wastes specified in Schedule 2, Table S2.4.</p>
AR10	<p>Storage of hazardous and non-hazardous waste.</p> <p>R13 Storage of waste pending any of the operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where it is produced).</p> <p>D15 Storage pending any of the operations numbered D1 to D14 (excluding temporary storage, pending collection, on the site where the waste is produced).</p>	<p>From receipt and storage of hazardous waste on site, to its treatment or repackaging on site; or its transfer off-site.</p> <p>The total amount of waste stored on site at any one time, including both hazardous and non-hazardous waste, shall not exceed 50 tonnes.</p> <p>All hazardous waste shall be stored inside a building and on impermeable surfacing with sealed drainage.</p> <p>Waste shall not be stored in vehicles or vehicle trailers, unless they are being received for immediate offloading or prepared for imminent transfer (that is, they will be removed from site within 24 hours, or 72 hours if over a weekend).</p> <p>Infectious clinical waste shall be stored for no longer than 14 days.</p> <p>Refrigerated anatomical waste shall be stored for no longer than 14 days.</p> <p>Unrefrigerated anatomical waste shall be stored for no longer than 24 hours, or up to 72 hours if over a weekend.</p> <p>Pharmaceutical, chemical and palletised hazardous waste shall be stored securely within designated areas of the building.</p> <p>The following hazardous waste types shall be stored on site for no longer than 6 months:</p> <ul style="list-style-type: none"> non-infectious medicines (including cytotoxic and cytostatic medicines) dental amalgam other chemicals or other wastes <p>Notwithstanding the limits given above where a shorter storage time period is given in an agreed management plan then that time period shall take precedence.</p> <p>No waste types shall be submitted to this activity other than those hazardous wastes specified in Schedule 2, Table S2.4.</p>

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application	All	Duly Made 21/03/2019
	Odour Management Plan Document Reference HSMT_2018.01/08 and dated 15th March 2019.	21/03/2019
Response to Schedule 5 Notice dated 24/05/2019	All Parts – Additional information provided for Fire Prevention Plan and clarification on waste acceptance procedures and criteria.	24/05/2019
Response to Schedule 5 Notice dated 02/08/2019	All parts – Additional information provided on autoclave treatment protocol and waste management procedures.	02/08/2019
	All Parts – Non-Technical Summary SHSMT_2021.01/01, excluding proposals for treatment of yellow bagged wastes and amendment of table S2.4, which have not been accepted under this variation.	11/02/2021
Response to Schedule 5 Notice dated 23/04/2021	Response to question 1 only and additional information on shredder cleaning provided in “Annex 1 Shredder cleaning SOP” provided on autoclave treatment protocol and waste management procedures.	29/04/2021
Healthcare waste: appropriate measures for permitted facilities Version published 13 July 2020	All parts of the appropriate measures guidance shall apply other than: Those parts to which an improvement programme requirement applies in Table S1.3 and until the agreed completion date for that improvement.	N/A

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1 Waste pre-acceptance or acceptance procedures	The operator shall review and update their waste pre-acceptance and/or waste acceptance procedures to ensure that they meet the requirements of our guidance Healthcare waste: appropriate measures for permitted facilities. Specifically, they must demonstrate that the following appropriate measure(s) of the guidance will be met: Waste pre-acceptance, acceptance and waste tracking appropriate measures. A copy of the updated procedure(s) shall be submitted to the Environment Agency for approval.	14/02/2023
IC2 Updated emissions inventory and H1 (air and water)	The operator shall submit a written report to the Environment Agency for approval that proposes a monitoring programme to characterise and assess the facility’s point source emissions to air and water (including sewer) in accordance with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020. The report shall detail the parameters and substances that will be tested for, the monitoring methods and equipment that will be used, and a timetable for undertaking the monitoring. The monitoring programme shall be carried out as approved by the Environment Agency. A written report shall submitted to the Environment Agency for approval detailing the results and conclusions of the emissions monitoring and assessment undertaken, including a completed H1 Environmental Risk Assessment and proposals for any ongoing monitoring or further assessment.	Submission of written report proposing monitoring programme by 14/02/2023 Submission of subsequent written report detailing monitoring and assessment results by 14/06/2023.

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC3 Process efficiency	The operator shall carry out a review of the raw material, water and energy usage of the facility, including new and existing activities and plant against the Process efficiency appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020. The operator shall submit a written report (or reports) to the Environment Agency for approval, detailing the findings of the review and including a timetable for implementing any recommendations or improvements.	14/03/2023
IC4 Site layout and emission points plan	<p>The operator shall submit a site layout and emissions point plan to the Environment Agency for approval that clearly identifies existing point source emissions to air and discharges to sewer (showing the point at which the discharge is made to sewer, where it leaves the permit boundary and responsibility of the operator).</p> <p>The site plan must also show as a minimum:</p> <ul style="list-style-type: none"> - buildings, and other main constructions, like treatment plants, incinerators, storage silos and security fences - storage facilities for hazardous materials like oil and fuel tanks, chemical stores, waste materials - location of items for use in accidents and emergencies, like absorbents for chemical spills - entrances and exits that can be used by emergency services - points designed to control pollution, for example inspection or monitoring points - trade effluent or sewage effluent treatment plants - effluent discharge points - land that you believe is contaminated, for example areas of your site that have previously been used for industrial purposes. 	14/03/2023

Schedule 2 – Waste types, raw materials and fuels

Raw materials and fuel description	Specification
-	-

Maximum quantity	The total quantity of wastes accepted at the site shall not exceed 8,000 tonnes per year. No more than 50 tonnes per day of infectious waste shall be shredded. No more than 50 tonnes per day of infectious waste shall be subject to thermal treatment via the autoclave.
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*	infectious waste, not contaminated with chemicals or medicines (Note 1)
18 01 03* and 18 01 09	infectious waste, medicinally contaminated (not cytotoxic or cytostatic) (Note 2)
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	infectious waste, not contaminated with chemicals or medicines (Note 1)
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	infectious waste, not contaminated with chemicals or medicines – municipal, separately collected fractions, not from healthcare or research-related sources (Note 1)
<p>Note 1: Excluding: anatomical waste; waste known or likely to contain ACDP Hazard Group 4 biological agents; any waste from a containment level 3 laboratory; all microbiological cultures from any source; and any potentially infected waste from pathology departments and other clinical or research laboratories.</p> <p>Note 2: Entries dual-coded under 18 01 03* and 18 01 09 are limited to wastes received in yellow lidded, rigid yellow containers or yellow bags that are contaminated with non-hazardous medicines only and do not include other pharmaceutical or pharmaceutically contaminated wastes.</p>	

Table S2.3 Permitted waste types and quantities for sharps bin wash plant and associated repackaging (AR3)	
Maximum quantity	The total quantity of wastes accepted at the site shall not exceed 8,000 tonnes per year. The maximum quantity of sharps bin waste treated through the wash plant shall not exceed 50 tonnes per day.
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*	infectious waste, not contaminated with chemicals or medicines (contains sharps)
18 01 03* and 18 01 08*	infectious waste, medicinally contaminated (cytotoxic or cytostatic) (contains sharps)
18 01 03* and 18 01 09	infectious waste, medicinally contaminated (not cytotoxic or cytostatic) (contains sharps)
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	infectious waste, not contaminated with chemicals or medicines (contains sharps)
18 02 02* and 18 02 07*	infectious waste, medicinally contaminated (cytotoxic or cytostatic) (contains sharps)
18 02 02* and 18 02 08*	infectious waste, medicinally contaminated (not cytotoxic or cytostatic) (contains sharps)

Table S2.4 Permitted waste types and quantities for repackaging (AR4 and AR9) and storage (AR10)	
Maximum quantity	The total quantity of wastes accepted at the site shall not exceed 8,000 tonnes per year. Combined storage capacity of hazardous and non-hazardous waste on site shall not exceed 50 tonnes at any one time.
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
09 01 02*	water-based offset plate developer solutions
09 01 03*	solvent based developer solutions
09 01 04*	fixer solutions
09 01 05*	bleach solutions and bleach fixer solutions
09 01 07	photographic film and paper containing silver or silver compounds
15	WASTE PACKAGING, ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED
15 01	packaging (including separately collected municipal packaging waste)
15 01 04	Metallic packaging (lead foils from dental care)
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)

Table S2.4 Permitted waste types and quantities for repackaging (AR4 and AR9) and storage (AR10)	
Maximum quantity	The total quantity of wastes accepted at the site shall not exceed 8,000 tonnes per year. Combined storage capacity of hazardous and non-hazardous waste on site shall not exceed 50 tonnes at any one time.
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	non-infectious sharps, not contaminated with chemicals or medicines
18 01 01 and 18 01 09	non-infectious sharps from vaccines delivered in mass vaccination centres, in the community and in care homes
18 01 02	non-infectious anatomical waste, not chemically preserved
18 01 02 and 18 01 06*	non-infectious anatomical waste, chemically preserved, hazardous chemicals
18 01 02 and 18 01 07	non-infectious anatomical waste, chemically preserved, non-hazardous chemicals
18 01 03*	infectious waste, not contaminated with chemicals or medicines (may contain sharps) infectious anatomical waste, not chemically preserved infectious gypsum wastes (for example, plaster casts and moulds)
18 01 03* and 18 01 06* or 18 01 07	infectious waste, contaminated with chemicals infectious anatomical waste, chemically preserved
18 01 03* and 18 01 08* or 20 01 31*	infectious waste, contaminated with cytotoxic and cytostatic medicines – (may contain sharps)
18 01 03* and 18 01 09	infectious waste, medicinally contaminated (not cytotoxic or cytostatic) – (may contain sharps)
18 01 04	non-infectious offensive waste – human healthcare non-infectious gypsum wastes (for example, plaster casts and moulds)
18 01 06*	chemicals consisting of or containing hazardous substances
18 01 07	chemicals other than those mentioned in 18 01 06
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	other waste medicines, excluding cytotoxic and cytostatic medicines – human healthcare
18 01 10*	amalgam waste from dental care
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	non-infectious sharps, not contaminated with chemicals or medicines
18 02 02*	infectious waste, not contaminated with chemicals or medicines (may contain sharps) infectious anatomical waste, not chemically preserved infectious gypsum wastes (for example, plaster casts and moulds)
18 02 02* and 18 02 05* or 18 02 06	infectious waste, contaminated with chemicals infectious anatomical waste, chemically preserved
18 02 02* and 18 02 07* or 20 01 31*	infectious waste, contaminated with cytotoxic and cytostatic medicines (may contain sharps)

Table S2.4 Permitted waste types and quantities for repackaging (AR4 and AR9) and storage (AR10)	
Maximum quantity	The total quantity of wastes accepted at the site shall not exceed 8,000 tonnes per year. Combined storage capacity of hazardous and non-hazardous waste on site shall not exceed 50 tonnes at any one time.
18 02 02* and 18 02 08	infectious waste, medicinally contaminated (not cytotoxic or cytostatic) (may contain sharps)
18 02 03	non-infectious anatomical waste, not chemically preserved non-infectious offensive waste non-infectious gypsum wastes (for example, plaster casts and moulds)
18 02 03 and 18 02 05*	non-infectious anatomical waste, chemically preserved, hazardous chemicals
18 02 03 and 18 02 06	non-infectious anatomical waste, chemically preserved, non-hazardous chemicals
18 02 05*	chemicals consisting of or containing dangerous substances
18 02 06	chemicals other than those mentioned in 18 02 05
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	other waste medicines, excluding cytotoxic and cytostatic
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 – municipal, separately collected fractions not from healthcare or research-related sources
20 01 32	other waste medicines, excluding cytotoxic and cytostatic medicines – municipal, separately collected fractions not from healthcare or research-related sources
20 01 99	non-infectious offensive waste – municipal, separately collected fractions not from healthcare or research-related sources non-infectious sharps, not contaminated with chemicals or medicines – not from healthcare or research-related sources infectious waste, not contaminated with chemicals or medicines – municipal, separately collected fractions, not from healthcare or research-related sources (may contain sharps)

Table S2.5 Permitted waste types and quantities for shredding and compaction of non-hazardous waste (AR8)	
Maximum quantity	Treatment by shredding of non-hazardous waste and subsequent compaction of shredded waste shall not exceed 50 tonnes per day.
Waste code	Description
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	non-infectious sharps, not contaminated with chemicals or medicines
18 01 04	non-infectious offensive waste – human healthcare

Table S2.5 Permitted waste types and quantities for shredding and compaction of non-hazardous waste (AR8)	
Maximum quantity	Treatment by shredding of non-hazardous waste and subsequent compaction of shredded waste shall not exceed 50 tonnes per day.
Waste code	Description
18 01 09	other waste medicines, excluding cytotoxic and cytostatic medicines – human healthcare
18 01 01 and 18 01 09	non-infectious sharps from vaccines delivered in mass vaccination centres, in the community and in care homes
20 01 99	non-infectious offensive waste – municipal, separately collected fractions not from healthcare or research-related sources non-infectious sharps, not contaminated with chemicals or medicines – not from healthcare or research-related sources

Schedule 3 – Emissions and monitoring

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 Boiler Plant (as shown on drawing in schedule 7)	Boiler Plant	Oxides of Nitrogen (NO and NO ₂ expressed as NO ₂)	100 mg per cubic metre	Hourly average	Every 3 years	BS EN 15267-3
		Carbon Monoxide (CO)	No limit set	Hourly average	Every 3 years	BS EN 15058
A2 Shredder and slave shredder (as shown on drawing in schedule 7)	Local Exhaust Ventilation (LEV) system fitted to shredder with carbon and HEPA filters	Bacillus Spores	1000 cfu per cubic metre (Note 1)	In accordance with Emissions monitoring and limits appropriate measures of Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020	Annually	In accordance with Emissions monitoring and limits appropriate measures of Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020
		Total volatile organic compounds (TVOC)	30 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 3)	BS EN 12619
		Speciated volatile organic compounds	No limit set	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 3)	BS CEN/TS 13649
		Particulate matter	5 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Every 6 months (Note 4)	BS EN 13284-1
A3 Autoclave Extraction (as shown on	Abated exhaust system from autoclave,	Bacillus Spores	1000 cfu per cubic metre (Note 1)	In accordance with Emissions monitoring and limits appropriate	Annually	In accordance with Emissions monitoring

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
drawing in schedule 7) via carbon filter	with HEPA and carbon filters			measures of Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020		and limits appropriate measures of Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020
		Total volatile organic compounds (TVOC)	30 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 3)	BS EN 12619
		Speciated volatile organic compounds	No limit set	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 3)	BS CEN/TS 13649
		Particulate matter	5 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Every 6 months (Note 4)	BS EN 13284-1
A4 Extraction Flue (as shown on drawing in schedule 7) via carbon filter	Compactor loading Area	Total volatile organic compounds (TVOC)	No limit set (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 4)	BS EN 12619
		Speciated volatile organic compounds	No limit set	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 4)	BS CEN/TS 13649
A5 Extraction Flue from washer head (as shown on drawing in schedule 7) HEPA filtration	Washing plant	Total volatile organic compounds (TVOC)	30 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 4)	BS EN 12619

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
A6 Extraction Flue from washer drying process (as shown on drawing in schedule 7) no abatement / water vapour only	Washing plant	Total volatile organic compounds (TVOC)	30 mg per cubic metre (Note 2)	Average value of 3 consecutive measurements of at least 30 minutes each	Monthly (Note 4)	BS EN 12619

Note 1 - These units relate to the overall monitoring period so the colony-forming units (cfu) benchmark applies to each individual sample of air or water to be taken, with a calculation made to report the results per cubic metre or litre. These are based on a seeding dose of 1×10^6 spores per gram of waste load, and would need to be adjusted if the seed dose were higher or lower. The units of the limit (per cubic metre) relate to the overall monitoring period so the limit applies to each individual sample of air, with a calculation made to report the result per cubic metre.

Note 2 – This limit, or an alternative limit agreed in writing with Environment Agency following completion of IC2, is applicable.

Note 3 – Monitoring for Total VOCs is to be undertaken on a 6 monthly frequency during the treatment of non-medicinally contaminated waste.
Monitoring for total and speciated VOCs is to be undertaken on a monthly basis during the treatment of medicinally contaminated waste (18 01 03* with 18 01 09).

Note 4 - An alternative monitoring frequency may be agreed in writing with Environment Agency following completion of IC2.

Table S3.2 Point source emissions to sewer, effluent treatment plant or other transfers off-site – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
Emission point location to be confirmed under IC4	Effluent discharge Condensate from treatment chamber and wash waters from bin cleaning process	Bacillus Spores (spiked organisms)	300 cfu per litre (Note 1)	-	Annually	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020

Table S3.2 Point source emissions to sewer, effluent treatment plant or other transfers off-site – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference period	Monitoring frequency	Monitoring standard or method
		Any additional monitoring to be agreed in writing following completion of Improvement condition IC2				
<p>Note 1: These units relate to the overall monitoring period so the colony-forming units (cfu) benchmark applies to each individual sample of air or water to be taken, with a calculation made to report the results per cubic metre or litre. These are based on a seeding dose of 1×10^6 spores per gram of waste load, and would need to be adjusted if the seed dose were higher or lower. These units relate to the overall monitoring period so the cfu limit applies to each individual sample of water taken, with a calculation made to report the result per litre.</p>						

Table S3.3 Fugitive microbial emissions monitoring (spiked organisms)				
Emission point ref. & location	Parameter	Limit (incl. unit)	Monitoring frequency	Monitoring standard or method
Air – sample points <10 m from the treatment plant	Bacillus Spores	1,000 cfu per cubic metre (Note 1)	Annually	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.
Air – sample points >10 m from the treatment plant	Bacillus Spores	300 cfu per cubic metre (Note 1)	Annually	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.
Surface – sample point <10 m from the treatment plant	Bacillus Spores	20,000 cfu per square metre per hour (Note 1)	Annually	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.
Surface – sample point >10 m from the treatment plant	Bacillus Spores	5,000 cfu per square metre per hour (Note 1)	Annually	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.
<p>Note 1: These units relate to the overall monitoring period so the cfu benchmark applies to:</p> <ul style="list-style-type: none"> • each individual sample of air taken, with a calculation made to report the result per cubic metre. • for each individual settling plate (this is not an average) - a calculation made to adjust for surface area of settle plate and exposure time (for example if settle plates are deployed for only fifteen minutes of every hour then the result must be multiplied by four). <p>The limit is based on a seeding dose of 1×10^6 spores per gram of waste load. You should adjust it accordingly if you use a higher or lower seeding dose.</p> <p>The units relate to the overall monitoring period so the cfu limit applies to each individual:</p> <ul style="list-style-type: none"> • sample of air – a calculation is made to report the result per cubic metre. • settle plate (this is not an average) a calculation is made to adjust for surface area of a settle plate and exposure time (for example, if you use settle plates for only 15 minutes of every hour then you must multiply the result by 4). 				

Table S3.4 Process monitoring requirements				
Emission point reference or source or description of point of measurement	Parameter	Monitoring frequency	Monitoring standard or method	Other specifications
Shredding of waste and subsequent steam treatment in autoclaves	Treatment efficacy (routine monitoring)	In accordance with requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020	In accordance with Waste treatment appropriate measures of Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020	The Environment Agency shall be notified immediately of any test failures.
	Repeated plant validation	<p>Plant commissioning validation must be repeated in accordance with Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020:</p> <ul style="list-style-type: none"> • periodically, at intervals of 4 years or less during the operational life of the plant <p>and if:</p> <ul style="list-style-type: none"> • any process parameters or conditions change from those assessed and approved during plant commissioning or plant validation • any changes are made to plant design or engineering • changes to the waste types accepted for treatment mean that the challenge load considered during plant commissioning or plant validation is no longer the worst case scenario <p>the plant fails routine treatment efficacy monitoring</p>		Results of repeated plant validation shall be submitted to the Environment Agency for approval.

Schedule 4 – Reporting

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

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	First period begins
Emissions to air Parameters as required by condition 3.5.1.	A1, A2, A3, A4, A5, A6	Every 6 months	1 January
Emissions to sewer Parameters as required by condition 3.5.1	S1	Annually	1 January
Fugitive microbial emissions Parameters as required by condition 3.5.1	Air and surface monitoring points as detailed in table S3.3	Annually	1 January
Routine efficacy monitoring Parameters as required by condition 3.5.1	Steam treatment of waste in autoclaves	Quarterly	1 January
Repeated plant validation Parameters as required by condition 3.5.1	Steam treatment of waste in autoclaves	Every 4 years or less, as required by table S3.4	1 January

Table S4.2 Annual production/treatment	
Parameter	Units
Hazardous waste thermally treated	tonnes
Non-hazardous waste thermally treated	tonnes
Treated floc produced	tonnes

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Total raw material used	Annually	tonnes

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Emissions to air	Form air 1 or other form as agreed in writing by the Environment Agency	08/03/2021
Fugitive microbial emissions	Form Microbial 1 or other form as agreed in writing by the Environment Agency	17/06/2021

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Emissions to Sewer	Form Sewer 1 or other form as agreed in writing by the Environment Agency	08/03/2021
Water usage	Form Water usage 1 or other form as agreed in writing by the Environment Agency	08/03/2021
Energy usage	Form Energy 1 or other form as agreed in writing by the Environment Agency	08/03/2021
Other performance indicators	Form Performance 1 or other form as agreed in writing by the Environment Agency	08/03/2021
Treatment efficacy monitoring	Monitoring report submitted in writing to the Environment Agency	-
Repeated plant validation	Validation report submitted in writing to the Environment Agency	-

Schedule 5 – 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 EP Regulations.

Part A

Permit Number	
Name of operator	
Location of Facility	
Time and date of the detection	

(a) Notification requirements for 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	
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	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
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 breach of permit conditions not related to limits	
To be notified within 24 hours of detection	
Condition breached	
Date, time and duration of breach	
Details of the permit breach i.e. what happened including impacts observed.	
Measures taken, or intended to be taken, to restore permit compliance.	

(d) 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 facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

“accident” means an accident that may result in pollution.

“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 5 to the EP Regulations.

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

“building” is a covered structure enclosed on all vertical sides that provides sheltered cover and contains emissions of, for example, noise, particulate matter, odour and litter

“clinical” waste means waste from a healthcare activity (including veterinary healthcare) that:

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

and waste of a similar nature from a non-healthcare activity.

“container” is a receptacle for waste for example bags, bins, boxes, drums, IBCs and blister packs. Wastes may be packaged in more than one receptacle for example a bag in a box.

“cytotoxic and cytostatic medicines” are medicinal products that possess one or more of the hazardous properties acutely toxic, carcinogenic, mutagenic or toxic for reproduction.

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

“disposal” means any of the operations provided for in Annex I to the Waste Framework Directive.

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

“emissions to land” includes emissions to groundwater.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2016 No.1154 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“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.

“hazardous property” has the meaning in Annex III of the Waste Framework Directive.

“hazardous substance” means a substance classified as hazardous as a consequence of fulfilling the criteria laid down in parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008.

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

“healthcare waste” means waste produced during human or animal healthcare, or related research activities. It covers both clinical and offensive waste. Wastes produced by healthcare in the community, and similar types of waste produced by non-healthcare activities are included, for example:

- cosmetic body piercing and body art

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

“impermeable surface” means a surface or pavement constructed and maintained to a standard sufficient to prevent the transmission of liquids beyond the pavement surface

“Industrial Emissions Directive” means Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions, as read in accordance with Schedule 1A to the Environmental Permitting (England and Wales) Regulations 2016.

“List of Wastes” means the list of wastes established by Commission Decision 2000/532/EC replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

“Medium Combustion Plant” or “MCP” means a combustion plant with a rated thermal input equal to or greater than 1 MW but less than 50 MW.

“Medium Combustion Plant Directive” or “MCPD” means Directive 2015/2193/EU of the European Parliament and of the Council on the limitation of emissions of certain pollutants into the air from medium combustion plants, as read in accordance with Schedule 1A to the Environmental Permitting (England and Wales) Regulations 2016.

“medicines” are “medicinal products” as defined in Regulation 130 of Part VIII of the Medicines Act 1968. Waste medicines (or pharmaceutical waste) include:

- expired, unused, spilt and contaminated medical products that are no longer required and need to be disposed of appropriately;
- discarded items contaminated with medicines such as bottles or boxes with residues, gloves, masks, connecting tubing, syringe bodies and drug vials.

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

“offensive waste” is waste that:

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

“pests” means birds, vermin and insects.

“pollution” includes pollution of the environment, harm to human health and serious detriment to the amenities of the locality, resulting from the permitted activities.

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

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

“recovery” means any of the operations provided for in Annex II to the Waste Framework Directive.

“repackaging” is:

- taking a waste package for example a bag, drum or box out of one cart or bulk container for example, skip and placing it into another cart or bulk container for example, skip
- taking a waste package from a cart or bulk container for example, skip and placing it onto a pallet or vehicle
- taking a waste package from a pallet and placing it into a cart or bulk container for example, skip
- transferring, removing or separating waste from its primary packaging into another container

“sealed container” for the purposes of this permit, means a container which is fully enclosed, weather proof, does not allow any solid or liquid content to escape and is lockable.

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

- no liquid will run off the surface otherwise than via the system
- 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.

“waste code” means the six digit code referable to a type of waste in accordance with the List of Wastes and in relation to hazardous waste, includes the asterisk.

“Waste Framework Directive” or “WFD” means Waste Framework Directive 2008/98/EC of the European Parliament and of the Council on waste, as read in accordance with Schedule 1A to the Environmental Permitting (England and Wales) Regulations 2016.

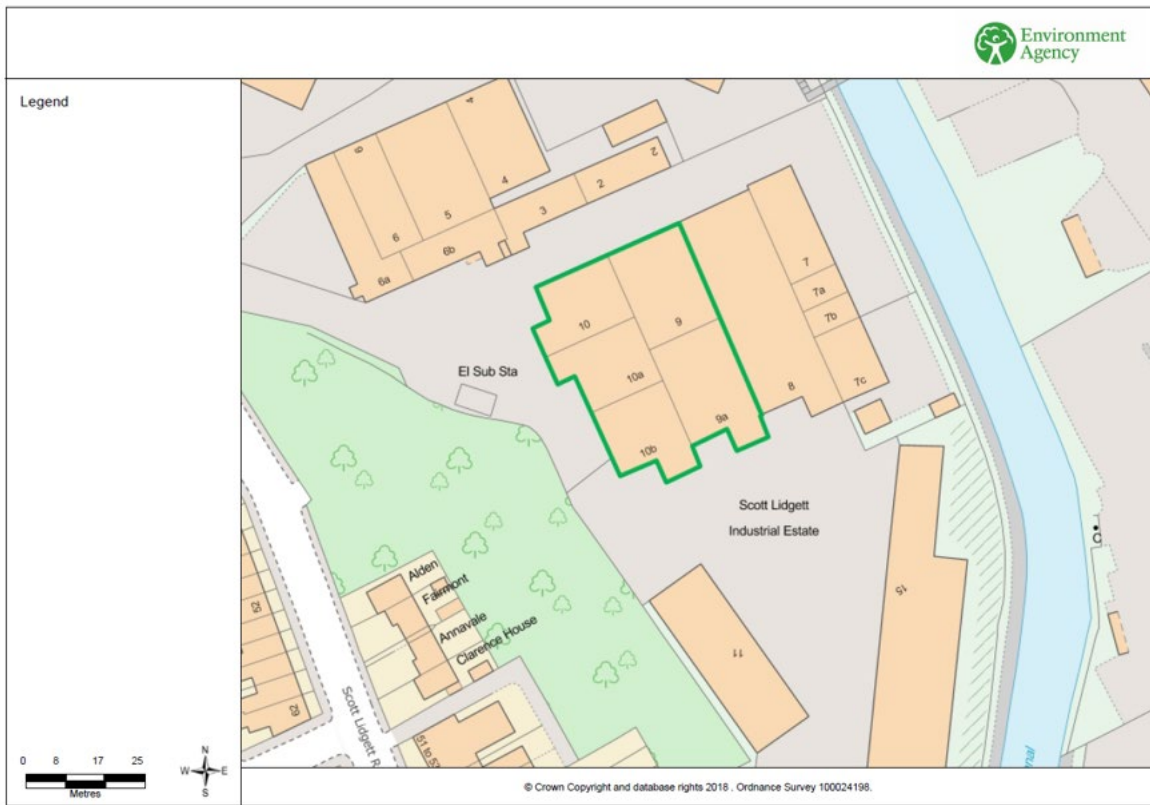
“year” means calendar year ending 31 December.

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:

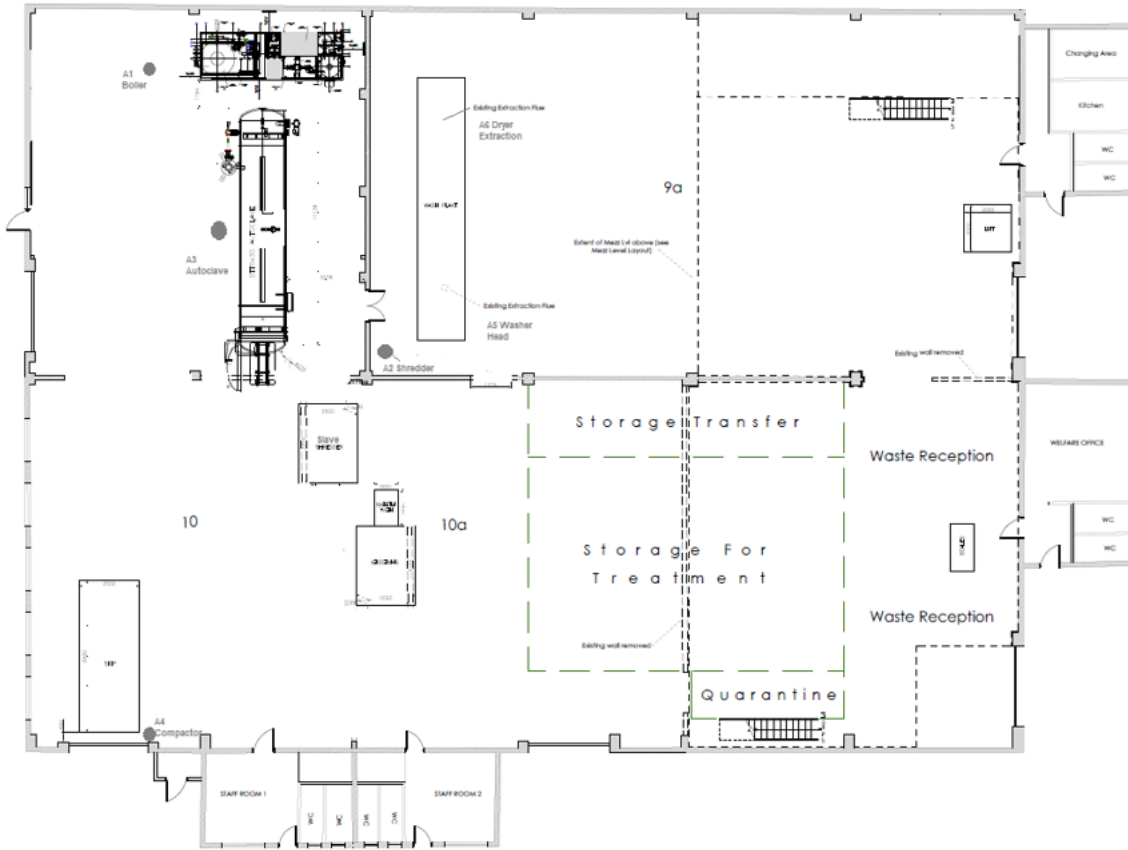
- in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- in relation to emissions from non-combustion sources, the concentration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

Schedule 7 – Site plan



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Site layout plan (including emission points to air)



END OF PERMIT