

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/V006

Permit number

EPR/XP3493VP

Sharpsmart Limited

Permit number EPR/XP3493VP

Introductory note

This introductory note does not form a part of the notice

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. Only the variations specified in schedule 1 are subject to a right of appeal.

This variation authorises the Operator to treat wastes (as specified in schedule 2) via shredder and/or autoclave. The quantity of wastes for treatment has been set at 8,000 tonnes per year. New Operating Techniques, emissions monitoring and reporting have been amended as a result of the new activities at the site.

The variation also covers new discharges to air (covered as medium combustion plant directive, for the steam generator [approximately 1.78MW] to feed the autoclave, the shredder extraction system and the Autoclave extraction) and to sewer (a discharge from the autoclave liquor/condensate).

There will be no discharge to sewer from the autoclave treatment process (for treatment emissions produced whilst the treatment plant is operational on restricted waste codes) to ensure all pharmaceutical contamination is captured and sent for incineration. Treatment liquors (which may be pharmaceutically contaminated) produced from the plant 'flush' cycle following treatment of these restricted waste codes will be captured and sent for incineration.

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.

Status log of the permit		
Description	Date	Comments
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.

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

Permit number

EPR/XP3493VP

Issued to

Sharpsmart Limited (“the operator”)

whose registered office is

Unit 44

Enterprise City

Meadowfield Avenue

Spennymoor

County Durham

United Kingdom

DL16 6JF

company registration number **04261387**

to operate a regulated facility at

Sharpsmart Limited

9 Longport Enterprise Centre

Scott Lidgett Road

Stoke on Trent

ST6 4NQ

to the extent set out in the schedules.

The notice shall take effect from 25/10/2019

Name	Date
Mark Jones	25/10/2019

Authorised on behalf of the Environment Agency

Schedule 1

All conditions have been varied by the consolidated permit as a result of the application made by the operator.

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/V006 authorising,

Sharpsmart Limited (“the operator”),

whose registered office is

Unit 44

Enterprise City

Meadowfield Avenue

Spennymoor

County Durham

United Kingdom

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
Mark Jones	25/10/2019

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 AR6) 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 AR6) 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 AR6) 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 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, S2.5, S2.6 and S2.7; and
 - (b) it conforms to the description in the documentation supplied by the producer and holder.
- 2.3.4 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.
- 2.3.5 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.
- 2.3.6 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.

2.5 Pre-operational conditions

2.5.1 The operations specified in schedule 1 table S1.4 shall not commence until the measures specified in that table have been completed.

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) air monitoring for fugitive 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 and S3.2 unless otherwise agreed in writing by the Environment Agency.

3.6 Fire prevention

3.6.1 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 AR6) 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 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.
- 4.3.4 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.
- 4.3.5 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
AR1	Section 5.3 Part A(1)(a)(iv) Repackaging prior to submission to any of the other activities listed in this Section or in Section 5.1	D14 Repackaging prior to submission to any of the operations numbered D1 to D13. R12 Exchange of wastes for submission to any of the operations numbered R1 to R11.	The maximum quantity of hazardous waste repackaged shall not exceed 50 tonnes/day. Washing and disinfection of mobile containers shall only take place on areas of impermeable surface with a sealed drainage system. All waste repackaging activities shall take place within a building, provided with an impermeable pavement and sealed drainage system. Sealed containers shall be kept locked when not being emptied. Only the hazardous wastes specified in Schedule 2, Table S2.3.
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.	D9 Physico-chemical treatment of waste. R12 Exchange of wastes for submission to any of the operations numbered R1 to R11. Shredding of waste.	The maximum quantity of hazardous waste shredded shall not exceed 50 tonnes/day. Only the wastes specified in Schedule 2, Table S2.4.
AR3	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.	D9 Physico-chemical treatment of waste. R3 Recycling/ reclamation of organic substances which are not used as solvents. Steam treatment in autoclaves with subsequent compaction of the waste stream.	From receipt of waste to storage and despatch of treated waste and storage of the effluent from the autoclave. The maximum quantity of hazardous waste autoclaved shall not exceed 50 tonnes/day. No pharmaceutically contaminated waste shall discharged to sewer from this process. Only the wastes specified in Schedule 2, Table S2.5.
Directly Associated Activity			
AR4	Steam supply (Medium Combustion Plant)	<1.8 MWth natural gas fired boiler.	Steam generator for provision of steam for autoclave treatment.
AR5	Storage of hazardous waste	D15/R13: Storage of hazardous waste.	Storage of hazardous waste prior to repackaging or treatment on site. All waste shall be stored within sealed containers. All waste shall be stored within a building provided with an impermeable surface with sealed drainage system.

Table S1.1 activities			
			<p>The aggregated maximum storage capacity for all hazardous waste on site shall not exceed 50 tonnes at any time.</p> <p>Waste shall not be stored for longer than 14 days.</p> <p>Only the wastes specified in Schedule 2, Table S2.2.</p>
AR6	Storage of treated floc	D15/R13: Storage of non-hazardous waste.	<p>Storage of treated floc produced by activity AR3 prior to removal from site.</p> <p>All waste shall be stored within sealed containers.</p> <p>All waste shall be stored within a building provided with an impermeable surface with sealed drainage system.</p> <p>Waste shall not be stored for longer than 14 days.</p>
Activity reference	Description of activities for waste operations		Limits of activities
AR7	D15/R13: Storage of hazardous waste.		<p>Storage of hazardous waste prior to transfer off-site for disposal or recovery.</p> <p>All waste shall either be stored within a building provided with an impermeable surface with sealed drainage system or within sealed containers located on an impermeable surface with sealed drainage system.</p> <p>The aggregated maximum storage capacity for all hazardous waste on site shall not exceed 50 tonnes at any time.</p> <p>Waste shall not be stored for longer than 14 days.</p> <p>Only the hazardous wastes specified in Schedule 2, Table S2.2.</p>
AR8	D15/R13: Storage of non-hazardous waste.		<p>Storage of non-hazardous waste prior to treatment and/or transfer off-site for disposal or recovery.</p> <p>All waste shall either be stored within a building provided with an impermeable surface with sealed drainage system or within sealed containers located on an impermeable surface with sealed drainage system.</p> <p>Waste shall not be stored for longer than 14 days.</p> <p>Only the non-hazardous wastes specified in Schedule 2, Table S2.6.</p>
AR9	D14/R13: Repackaging prior to submission to any of the operations numbered D1 to D13.		<p>The aggregated maximum quantity of non-hazardous waste treated for disposal on site shall not exceed 50 tonnes/day.</p> <p>All waste repackaging activities shall take place within a building, provided with an impermeable pavement and sealed drainage system.</p>

Table S1.1 activities		
		<p>Washing and disinfection of mobile containers shall only take place on areas of impermeable surface with a sealed drainage system.</p> <p>Sealed containers shall be kept locked when not being loaded or unloaded.</p> <p>Only the non-hazardous wastes specified in Schedule 2, Table S2.6.</p>
AR10	D9/R12: Shredding and compaction of non-hazardous wastes.	<p>The aggregated maximum quantity of non-hazardous waste treated for disposal on site shall not exceed 50 tonnes/day.</p> <p>Only the non-hazardous wastes specified in Schedule 2, Table S2.7.</p>

Table S1.2 Operating techniques		
Description	Parts	Date Received
How to comply with your Environmental Permit	All	N/A
Application	Risk Assessment Matrix (Appendix E) – All Parts	21/04/2011
	Odour Management Plan S11-039/OMP June 2011 – All Parts	14/07/2011
The Management of Clinical Waste (EPR5.07)	All	N/A
Application	All	Duly Made 21/03/2019
	Odour Management Plan Document Reference HSMT_2018.01/08 and dated 15 th 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

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1	<p>The operator shall provide a report to the Environment Agency on the speciated volatile organic compounds monitoring required by table S3.1 and pre-operational condition PO2.</p> <p>The operator shall also propose emission limits (or 'benchmarks') for ongoing emissions monitoring of the treatment process in accordance with the requirements of sector guidance note EPR 5.07 on clinical wastes.</p>	Within 8 months of the commencement of treatment (with a minimum of 6 months of monitoring)

Table S1.4 Pre-operational measures		
Reference	Operation	Pre-operational measures
PO1	Steam treatment of wastes specified in Table S2.3	<p>The operator shall submit a written commissioning validation report to the Environment Agency for approval, that demonstrates:</p> <p>(i) the treatment efficacy of the waste facility, in accordance with the appropriate measures in Sections 2.1, 2.3 and Annex 1 of the sector guidance note EPR 5.07 on clinical wastes;</p> <p>(ii) the proposals for routine monitoring of treatment efficacy comply with the appropriate measures in section 3.2 and Annex 2 of the sector guidance note EPR 5.07 on clinical wastes;</p> <p>(iii) the installation's emissions, in accordance with the appropriate measures in Section 3.3 and Annex 3 of the sector guidance note EPR 5.07 on clinical wastes; and</p>

Table S1.4 Pre-operational measures		
Reference	Operation	Pre-operational measures
		<p>(iv) the proposals for routine monitoring of emissions comply with the appropriate measures in section 3.3 and Annex 3 of the sector guidance note EPR 5.07 on clinical wastes.</p> <p>The treatment process under activity AR3 shall not be made operational until the Environment Agency has given prior written approval under this condition.</p>
PO2	Shredding and/or Autoclaving of contaminated sharps (18 01 03* (with 18 01 09).	<p>The operator shall submit a written report to the Environment Agency for approval, that:</p> <p>(i) proposes a sampling and testing regime for speciated volatile organic compounds from the abatement systems for the shredder and autoclave;</p> <p>(ii) proposes measures to ensure that effective clean down occurs between processing of medicinally contaminated sharps and other waste;</p> <p>(ii) proposes measures and a sampling and testing regime for demonstrating that only pharmaceutically uncontaminated autoclave liquors or condensate is discharged to sewer (i.e. all pharmaceutically contaminated liquids from the treatment of medicinally contaminated sharps are captured for off-site disposal by incineration).</p> <p>No medicinally contaminated sharps shall be accepted for shredding and/or steam treatment unless the Environment Agency has given prior written approval under this condition.</p>

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
-	-

Table S2.2 Permitted waste types and quantities for storage (Activities AR5, AR7)	
Maximum quantity	The quantity of waste accepted at the site shall be no more than 8000 tonnes per annum aggregate across hazardous and non-hazardous wastes
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
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
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* (with or without 18 01 09)	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 06*	chemicals consisting of or containing dangerous substances
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	Medicines other than those mentioned in 18 01 06 (dual coded with 18 01 03*only)
18 01 10*	amalgam waste from dental care
18 02	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 05*	chemicals consisting of or containing dangerous substances
18 02 07*	cytotoxic and cytostatic medicines
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

Table S2.3 Permitted waste types and quantities for repackaging (Activity AR1)	
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
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
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*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 06*	chemicals consisting of or containing dangerous substances
18 01 08*	cytotoxic and cytostatic medicines
18 01 10*	amalgam waste from dental care
18 02	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 05*	chemicals consisting of or containing dangerous substances
18 02 07*	cytotoxic and cytostatic medicines
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

Table S2.4 Permitted waste types and quantities for shredding (Activity AR2)	
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* (with or without 18 01 09)	wastes whose collection and disposal is subject to special requirements in order to prevent infection ¹
18 01 09	Medicines other than those mentioned in 18 01 06 (dual coded with 18 01 03* only) ¹
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals

Table S2.4 Permitted waste types and quantities for shredding (Activity AR2)	
Waste code	Description
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
¹ Note: – Entries dual-coded under 18 01 03 and 18 01 09 are limited to wastes received in yellow lidded, rigid yellow containers that are contaminated with non-cytostatic/non-cytotoxic medicines only (including those that are fully, partially, or un-discharged) and do not include other pharmaceutical or pharmaceutically contaminated wastes.	

Table S2.5 Permitted waste types and quantities for autoclaving (Activity AR3)	
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* (with or without 18 01 09)	wastes whose collection and disposal is subject to special requirements in order to prevent infection ¹
18 01 09	Medicines other than those mentioned in 18 01 06 (dual coded with 18 01 03* only) ¹
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
¹ Note: – Entries dual-coded under 18 01 03 and 18 01 09 are limited to wastes received in yellow lidded, rigid yellow containers that are contaminated with non-cytostatic/non-cytotoxic medicines only (including those that are fully, partially, or un-discharged) and do not include other pharmaceutical or pharmaceutically contaminated wastes.	

Table S2.6 Permitted waste types and quantities for storage and repackaging (Activities AR8, AR9)	
Maximum quantity	Description
	The quantity of waste accepted at the site shall be no more than 8000 tonnes per annum aggregate across hazardous and non-hazardous wastes.
Waste code	Description
09	Wastes from the photographic industry
09 01	wastes from the photographic industry
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
18	Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)
18 01	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	Sharps (except 18 01 03)
18 01 02	Body parts and organs including blood bags and blood preserves (except 18 01 03)

Table S2.6 Permitted waste types and quantities for storage and repackaging (Activities AR8, AR9)	
18 01 04	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)
18 01 07	Chemicals other than those mentioned in 18 01 06
18 01 09	Medicines other than those mentioned in 18 01 06
18 02	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	Sharps (except 18 02 02)
18 02 03	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection
18 02 06	Chemicals other than those mentioned in 18 02 05
18 02 08	Medicines other than those mentioned in 18 02 07
20	Municipal wastes (household waste and similar commercial, industrial and institutional wastes) including separately collected fractions
20 01	Separately collected fractions (except 15 01)
20 01 32	medicines other than those mentioned by 20 01 31*

Table S2.7 Permitted waste types and quantities for shredding and compaction (Activity AR10)	
Waste code	Description
18	Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) ¹
¹ Note: These wastes are to be shredded in isolation from other waste streams, with the plant to be disinfected between uses to prevent contamination.	

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 SHSMT-SoT2)	Boiler Plant	Oxides of Nitrogen (NO and NO ₂ expressed as NO ₂)	100 mg/m ³	Hourly average	Every 3 years	BS EN 15267-3
		Carbon Monoxide (CO)	No limit set	Hourly average	Every 3 years	-
A2 – Shredder (as shown on drawing SHSMT-SoT2)	Shredder abatement plant	Particulate matter	5 mg/m ³	Hourly average	Every 6 months	BS EN 13284-1
		Bacillus Spores (spiked organisms)	1000 cfu/m ³	-	To be agreed in writing as part of pre-operational condition PO2 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.
		Total volatile organic compounds (TVOC)	No limit set	Hourly average	Monthly ^{NOTE1}	BS EN 12619
		Speciated volatile organic compounds	No limit set	Hourly average	Monthly ^{NOTE1}	BS CEN/TS 13649
A3 – Autoclave Extraction (as shown on drawing SHSMT-SoT2)	Autoclave abatement plant	Total volatile organic compounds (TVOC)	No limit set	Hourly average	Monthly ^{NOTE1}	BS EN 12619
		Speciated volatile organic compounds	No limit set	Hourly average	Monthly ^{NOTE1}	BS CEN/TS 13649
NOTE 1: This monitoring requirement shall apply only during the treatment of contaminated sharps once approved under pre-operational condition PO2. The ongoing monitoring frequency may be reduced subject to completion of IC1 and the agreement of the Environment Agency.						

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
S1	Condensate from Steam treatment and condensers ¹	Bacillus Spores (spiked organisms)	300 cfu ² per litre	-	To be agreed in writing as part of pre-operational condition PO1 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.
	Wash waters from bin cleaning process	None	-	-	-	-

¹ Note: No pharmaceutically contaminated condensate shall be discharged to sewer.

² Note: These benchmarks are indicative only, and will be reviewed periodically.

Table S3.3 Fugitive bioaerosol 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 ¹	To be agreed in writing as part of pre-operational condition PO1 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.
Air – sample points >10 m from the treatment plant	Bacillus Spores	300 cfu per cubic metre ¹	To be agreed in writing as part of pre-operational condition PO1 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.
Surface – sample point <10 m from the treatment plant	Bacillus Spores	20,000 ² cfu per square metre per hour ¹	To be agreed in writing as part of pre-operational condition PO1 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.
Surface – sample point >10 m from the treatment plant	Bacillus Spores	5,000 ² cfu per square metre per hour ¹	To be agreed in writing as part of pre-operational condition PO1 in table S1.4	In accordance with the sector guidance note for Clinical Waste EPR 5.07.

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

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

For each individual 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).

² Note: These benchmarks are indicative only, and will be reviewed periodically.

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
Steam treatment of waste in autoclaves	Treatment efficacy (routine monitoring)	-	-	In accordance with guidance in Annex 2 of the sector guidance note for Clinical Waste EPR 5.07.

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	Period begins
Treatment efficacy (routine monitoring) as specified in Table S3.3	Steam treatment of waste in autoclaves with subsequent compaction	Quarterly	To be agreed in writing as part of pre-operational condition PO1 in table S1.4.
Emissions to air Parameters as required by condition 3.5.1.	A1, A2, A3	Every 12 months	1 January
Emissions to sewer Parameters as required by condition 3.5.1	S1	Every 6 months	1 January, 1 July

Table S4.2 Annual production/treatment	
Parameter	Units
Hazardous waste treated	tonnes
Hazardous waste accepted for transfer	tonnes
Non-hazardous waste treated	tonnes
Non-hazardous waste 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
Air	Form air 1 or other form as agreed in writing by the Environment Agency	25/10/2019
Bioaerosols	Form Bioaerosol 1 or other form as agreed in writing by the Environment Agency	25/10/2019
Sewer	Form sewer 1 or other form as agreed in writing by the Environment Agency	25/10/2019
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	25/10/2019
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	25/10/2019

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 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.

“background concentration” means such concentration of that substance as is present in:

- for emissions to surface water, the surface water quality up-gradient of the site; or
- for emissions to sewer, the surface water quality up-gradient of the sewage treatment works discharge.

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

- contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms;
- contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent; or
- 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.

“Cytotoxic and cytostatic medicines” are medicinal products that possess one or more of the hazardous properties toxic, carcinogenic, mutagenic or toxic for reproduction. Cytotoxic and cytostatic waste is the fraction of waste medicines, as described below for ‘medicines’, that contains or is contaminated with cytotoxic and cytostatic medicines.

“disposal” means any of the operations provided for in Annex I to Directive 2008/98/EC of the European Parliament and of the Council on waste.

“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.

“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 schedule 3 or from other localised or diffuse sources, which are not controlled by an emission or background concentration 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 waste” has the meaning given in the Hazardous Waste (England and Wales) Regulations 2005 (as amended).

“Healthcare waste” means a waste classified under Chapter 18 of the List of Wastes that is both produced by human and animal healthcare and/or related activities; and is of a type specifically associated with such activities.

“Industrial Emissions Directive” means Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions.

“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, as amended from time to time.

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

“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.

“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.

“offensive waste” means waste that:

- is not clinical waste;
- contains body fluids, secretions or excretions; and
- falls within the description of code 18 01 04, 18 02 03 or 20 01 99 in the list of wastes.

“Pests” means Birds, Vermin and Insects.

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

“recovery” means any of the operations provided for in Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste.

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

“STAATT” State and Territorial Association on Alternate Treatment Technologies. Now “iSTAATT”, the International Society of Analytical Assessment of Treatment Technologies.

“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.

“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.

When the following terms appear in the waste code list in Schedule 2, tables S2.2, S2.3, S2.4, S2.5, S2.6 and S2.7, for those tables, they have the meaning given below:

‘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.

'heavy metal' means any compound of antimony, arsenic, cadmium, chromium (VI), copper, lead, mercury, nickel, selenium, tellurium, thallium and tin, as well as these materials in metallic form, as far as these are classified as hazardous substances.

'PCBs' means

- polychlorinated biphenyls
- polychlorinated terphenyls
- monomethyl-tetrachlorodiphenyl methane, Monomethyl-dichloro-diphenyl methane, Monomethyldibromo-diphenyl methane
- any mixture containing any of the above mentioned substances in a total of more than 0.005% by weight

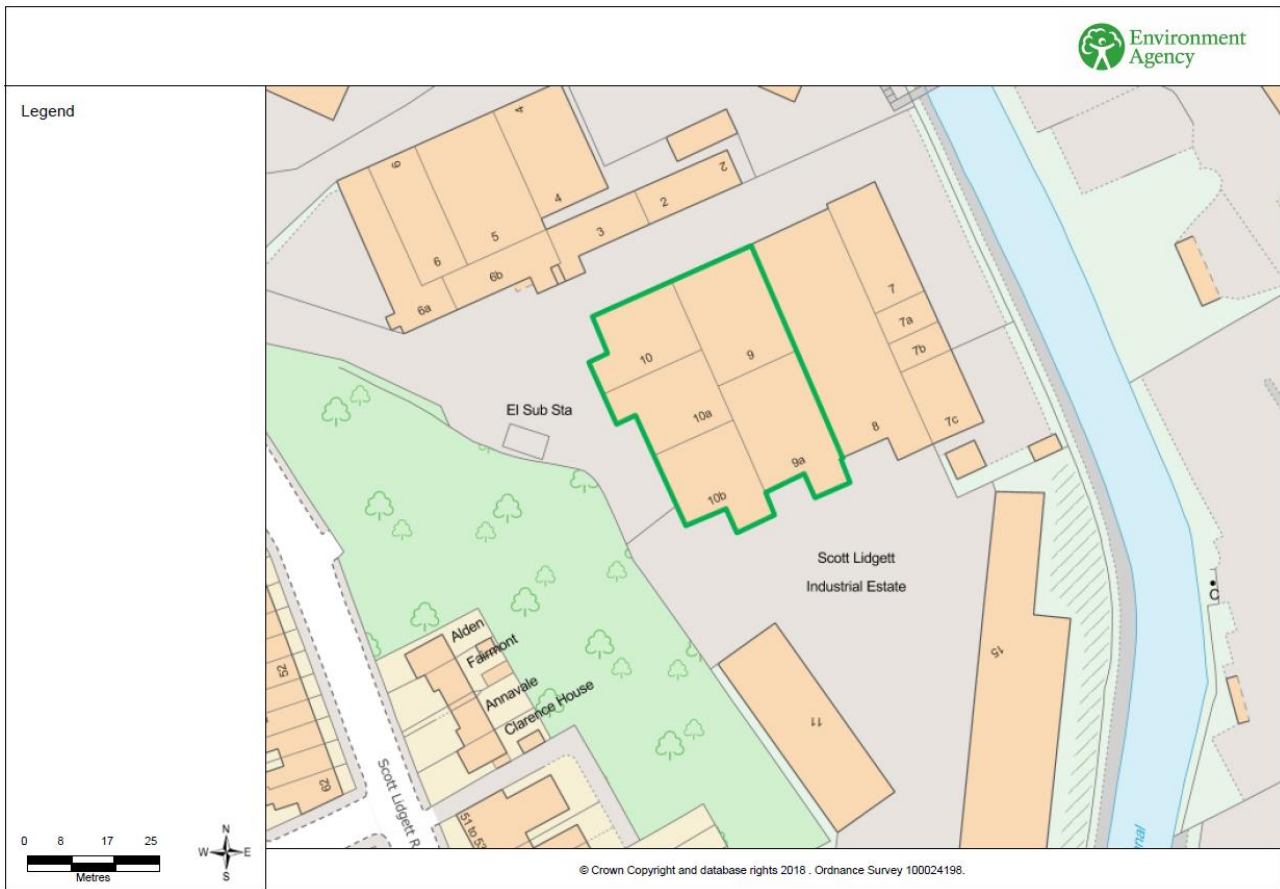
'transition metals' means any of the following metals: any compound of scandium, vanadium, manganese, cobalt, copper, yttrium, niobium, hafnium, tungsten, titanium, chromium, iron, nickel, zinc, zirconium, molybdenum and tantalum, as well as these materials in metallic form, as far as these are classified as hazardous substances.

'stabilisation' means processes which change the hazardousness of the constituents in the waste and transform hazardous waste into non-hazardous waste.

'solidification' means processes which only change the physical state of the waste by using additives without changing the chemical properties of the waste.

'partly stabilised wastes' means wastes containing, after the stabilisation process, hazardous constituents which have not been changed completely into non-hazardous constituents and could be released into the environment in the short, middle or long term.

Schedule 7 – Site plan



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END OF PERMIT