Permitting Decisions- Environment Agency Initiated Variation

We have issued an Environment Agency initiated variation for Rainham Clinical Treatment Centre operated by Sharpsmart Limited following a review of the permit in accordance with Environmental Permitting (England and Wales) Regulations 2016, regulation 34(1).

The variation number is EPR/PP3707BB/V004.

Permit Review

This Environment Agency has a duty, under the Environmental Permitting (England and Wales) Regulations 2016 (EPR), regulation 34(1), to periodically review permits. Article 21(3) of the Industrial Emissions Directive (IED) also requires the Environment Agency to review conditions in permits to ensure that they deliver compliance with relevant standards, within four years of the publication of updated decisions on Best Available Techniques (BAT) Conclusions.

We have reviewed the permit for this [regulated facility and varied the permit to make a number of changes to reflect relevant standards and best practice. These changes principally relate to the implementation of our technical guidance Healthcare waste: appropriate measures for permitted facilities and the relevant requirements of the BAT Conclusions for Waste Treatment, which have been incorporated into our guidance.

In this decision document, we set out the reasoning for the variation notice that we have issued.

It explains how we have reviewed and considered the techniques used by the operator in the operation and control of the plant and activities of the installation (operating techniques) against our technical guidance.

As well as considering the review of the operating techniques used by the Operator for the operation of the plant and activities of the installation, the consolidated variation notice takes into account and brings together in a single document all previous variations that relate to the original permit issue. Where this has not already been done, it also modernises the entire permit to reflect the conditions contained in our current generic permit template.

Purpose of this document

This decision document provides a record of the decision making process. It:

- explains how the Environment Agency initiated variation has been determined;
- summarises the decision making process in the decision considerations section to show how the main relevant factors have been taken into account;
- highlights key issues in the determination.

Read the permitting decisions in conjunction with the environmental permit and the variation notice.

Key issues of the decision

Environment Agency led variation – permit review

We have carried out an Environment Agency initiated variation to the permit following a permit review as required by legislation to ensure that permit conditions deliver compliance with relevant legislative requirements and appropriate standards to protect the environment and human health.

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. Relevant existing facilities must be in compliance with the BAT Conclusions within 4 years (i.e. by August 2022).

On 13 July 2020, Healthcare waste: appropriate measures for permitted facilities guidance was published on gov.uk. This technical guidance explains the standards that are relevant to regulated facilities with an environmental permit to treat or transfer healthcare waste, providing relevant standards (appropriate measures) for those sites and incorporating the relevant requirements of the BAT Conclusions.

We issued a notice under regulation 61(1) of the Environmental Permitting (England and Wales) Regulations 2016 (a Regulation 61 Notice) on 26/11/2020

requiring the operator to provide information to confirm that the operation of their facility currently meets, or how it will subsequently meet, the standards (appropriate measures) described in our technical guidance.

The notice required that where the revised standards are not currently met, the operator should provide information that:

- Describes the techniques that will be implemented to ensure operations meet the relevant standards and by when, or
- Explains why they are not applicable to the facility in question, or
- Justifies why an alternative technique is appropriate and will achieve an equivalent level of environmental protection to the standards described in our guidance

The standards described in our technical guidance are split into 7 chapters:

- General management appropriate measures
- Waste pre-acceptance, acceptance and tracking appropriate measures
- Waste storage, segregation and handling appropriate measures
- Waste treatment appropriate measures
- Emissions control appropriate measures
- Emissions monitoring and limits appropriate measures
- Process efficiency appropriate measures

We have set emission limit values (ELVs) and monitoring requirements for relevant substances in line with our technical guidance, unless a tighter, i.e. more stringent, limit was previously imposed and these limits have been carried forward.

The Regulation 61 notice required the operator to confirm whether they could comply the standards described in each of these chapters. Table 1 below provides a summary of the response received and our assessment of it. The overall status of compliance with the standards (appropriate measures) is indicated in the table as:

NA – Not Applicable

CC – Currently Compliant

FC – Compliant in the future (through improvement conditions set in permit)

NC – Not Compliant

In accordance with Article 22(2) of the Industrial Emissions Directive, the Regulation 61 notice asked the operator to provide a soil and groundwater risk assessment, along with a baseline report or summary report confirming the current state of soil and groundwater contamination, where listed activities are undertaken that involve the use, production of release of relevant hazardous substances.

The Regulation 61 notice also asked the operator to confirm whether they operate a medium combustion plant or specified generator (as per Schedule 25A or 25B of EPR 2016) and whether they had considered how their operations could be affected by climate changes (e.g. through a climate change adaptation plan).

Our assessment of the responses received from the operator regarding soil and groundwater risk assessment, medium combustion plant and specified generators, and consideration of climate change are also summarised in Table 1.

The Regulation 61 notice response from the Operator was received on 10/03/2021.

We considered that the response did contain sufficient information for us to commence determination of the permit review.

Although we were able to consider the Regulation 61 notice response generally satisfactory at receipt, we needed more information in order to complete our permit review assessment. We requested this by email and the operator provided further information on (summary of information) on 22/04/2022. We made a copy of this information available on our public register.

Appropriate measures	Compliance status	Assessment of the installation's compliance with relevant standards (appropriate measures) and any alternative techniques proposed by the operator
General management appropriate measures	CC	The operator confirmed that they currently meet the requirements of all appropriate measures in this section. Compliance with the appropriate measures in this section of the guidance has been incorporated into the varied permit through the updated operating techniques listed in Table S1.2.
Waste pre-acceptance, acceptance and tracking appropriate measures	FC	The operator has confirmed that they are not in compliance with this appropriate measure. As such, an improvement condition has been incorporated into the varied permit through an updated Table S1.3, which must be addressed within 2 months of permit issue.
Waste storage, segregation and handling appropriate measures	FC	The operator confirmed that they currently meet the requirements of the appropriate measures in this section – However, we have set an Improvement Condition (IC7) to require a waste storage plan, in accordance with the waste storage, segregation and handling appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020, which must clearly establish the maximum storage capacity of the site and the designated individual storage areas. They must define capacity in terms of numbers of carts, containers or pallets, as well as by tonnage
Waste treatment appropriate measures	CC	The operator confirmed that they currently meet the requirements of the appropriate measures in this section. Compliance with the appropriate measures in this section of the guidance has been incorporated into the varied permit through the updated operating techniques listed in Table S1.2.
Emissions control appropriate measures	FC	The pre-shredder is served by a high efficiency particulate air (HEPA) filter and carbon filter. Air is extracted from the autoclaves and passed through a condenser, HEPA filter and carbon filter prior to discharge. These are 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. Table S3.1 of the permit states that the abated exhaust system for the autoclave features HEPA and carbon filters. However, within the Regulation 61 response it states new extraction is required and will be abated through carbon to control VOCs. As a result of this, a request for information was submitted to the operator requesting information on the new extraction referenced. The operator's response stated that additional extraction would be required if pharmaceutical waste were to be processed and this would be required above the autoclaves and compactor – currently the shredder has a 3 stage pre/HEPA/carbon system, and that something similar would be replicated for the autoclaves and compactor. Due to the uncertainty as to what abatement is currently in place for the autoclaves, it was deemed appropriate to insert an improvement condition to require the operator to submit a written report to the

		Environment Agency for approval detailing the current extraction and abatement methods in place for the autoclaves on site, and a comparison with the requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020. If improvements are needed to meet the requirements of Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020; then proposed timescales must be provided detailing when they will be installed. The revised guidance states: To reduce point source emissions to air (for example, dust, volatile organic compounds and odour) from the treatment of waste, you must use an appropriate combination of abatement techniques, including one or more of the following systems: • adsorption (for example, activated carbon) • biofiltration • wet scrubbing • fabric filters • high efficiency particulate filtration (HEPA) • condensation • cyclonic separation • electrostatic precipitation The guidance goes on to state: You must use HEPA filters to prevent bioaerosol emissions from relevant point sources. The revised guidance contains appropriate measures for the provision of HEPA filters for microbial/bioaerosol emissions.
Emissions monitoring and limits appropriate measures	CC	The operator confirmed that they currently meet the requirements of the appropriate measures in this section. Compliance with the appropriate measures in this section of the guidance has been incorporated into the varied permit through the updated operating techniques listed in Table S1.2.

Process efficiency appropriate measures	FC	The operator has confirmed that they are not in compliance with this appropriate measure. An improvement condition was previously inserted into the permit during variation V003 (Issued 24/03/2021) requiring the operator to 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 is required to submit a written report to the Environment Agency for approval, detailing the findings of the review and including a timetable for implementing any recommendations or improvements. The date for completion of this improvement condition has elapsed, and therefore it has been retained within the revised permit, with the date for submission of the relevant report being set at the issue date +1 day.
Reg 61 requirement	**Assessment of response received**	
Soil and groundwater risk assessment	N/A according to Regulation 61 response: By extension, they are therefore accepting that there is zero pre-existing contamination and accepting the risk that they may be required to clean up any pre-existing contamination when they surrender their permit.	
Medium combustion plant and specified generators	During the previous variation (V003, issued 24/03/2021), the application replaced the previously permitted 0.7 megawatt (MW) LPG boiler with a new 2.5 MW LPG boiler. Emission limits and monitoring requirements were included in the permit at that time, for relevant emissions to air from the boiler. The emission limits are set at the concentrations specified in the MCPD and assumed in the application's air impact assessment. The permit includes a requirement to carry out annual monitoring of emissions because the facility is located in an air quality management area for relevant emissions (Nitrogen Dioxide) with high existing background concentrations.	
Climate change	Operator has stated there are targets for emission reduction. Climate Change Adaptation will be delivered through the EMS condition and an improvement condition is not required.	
Summary of other changes made to the permit as a result of our assessment of the Reg 61 response		
Change	**Reason for change**	
Table S1.3 Improvement Programme requirements	We have added new improvement conditions, which relate to: IC4 Waste pre-acceptance or acceptance procedures – see table above.	

	IC5 Updated emissions inventory and H1 (air and water) - To ensure that a written report is provided to the Environment Agency for approval within 2 months of the issue of the permit. This needs to detail a proposed monitoring programme to characterise and assess the facility's point source emissions. This will ensure the emissions form the process are in line with Healthcare waste: appropriate measures for permitted facilities and BAT-AELs. IC6 Autoclave extraction and abatement – see table above. IC7 Waste storage plan - The operator shall submit a waste storage plan, in accordance with the waste storage, segregation and handling appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020 to the Environment Agency for approval, which must clearly establish the maximum storage capacity of the site and the designated individual storage areas. They must define capacity in terms of numbers of carts, containers or pallets, as well as by tonnage. IC8 Washing of carts - The operator shall cease to clean carts by hand held jet washer or other non-official equipment. The replacement washer system must meet the requirements set out in Healthcare waste: appropriate measures for permitted facilities dated 13 July 2020.
Table S1.3 and S1.4 Existing improvement and pre-operational programme requirements	During the permit review process, it was apparent that there were outstanding improvement and pre-operational conditions. These has been retained as follows: IC1 (Labelled as IC7 in the previous variation (EPR/PP3707BB/V003) - The operator shall provide the Environment Agency with a written report for approval on the emissions monitoring and assessment required by table S3.1 and pre-operational condition PO3. The report shall detail the monitoring undertaken and the results and conclusions obtained from it, specifically: I. the composition of the monitored emissions; II. an assessment of the potential environmental impact of any chemical emissions resulting from the treatment of medicinally contaminated wastes (following our H1 risk assessment methodology, unless an alternative is agreed) and a comparison to relevant emission limits provided in technical guidance; III. an assessment of the effectiveness of the control measures in place to prevent and minimise emissions to air;

	IV. the proposal of any additional appropriate measures or improvements that could be implemented to prevent or minimise emissions further. Based upon the monitoring undertaken, the operator shall also propose emission limits (or 'benchmarks') for ongoing emissions monitoring of the treatment process in accordance with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020. IC2 (Labelled as IC8 in the previous variation (EPR/PP3707BB/V003) - The operator shall submit a written report to the Environment Agency for approval that includes the results of an updated assessment of the impact of any sanitary or hazardous pollutants in the facility's emissions to sewer using the Environment Agency's 'H1 Environmental Risk Assessment' tool (or equivalent as agreed with the Environment Agency). A monitoring and assessment plan shall be submitted to the Environment Agency for approval prior to commencing testing. The monitoring and assessment shall be undertaken in accordance with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities (dated 13 July 2020) and shall be undertaken when all relevant plant that produce a process effluent are fully operational (i.e. boiler, wash plant, shredder and autoclaves). IC3 (Labelled as IC9 in the previous variation (EPR/PP3707BB/V003) - 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. PO1 – Steam treatment of infectious waste single use instruments in Table S2.2 (18 01 03*). The operator shall submit a written validation report to the Environment Agency for approval, that demonstrates and confirms: I. the treatment efficacy of the waste facility for the additional waste types (infectious waste single use instruments (18 01 03*)), in accordance with the Waste treatment appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020;

	II. the proposals for routine monitoring of treatment efficacy comply with the Waste treatment appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020; III. the installation's emissions, in accordance with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020; and IV. the proposals for routine monitoring of emissions comply with the Emissions monitoring an limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020. The treatment efficacy tests must take into account the range of permitted waste types that the plant may treat at the same time as the additional waste in question (18 01 03* single use instruments). The operation shall not be made operational until the Environment Agency has given prior written approval under this condition. PO2 - Shredding and steam treatment of infectious waste contaminated with non-hazardous medicines (18 01 03* with 18 01 09), alone or with other permitted types of waste. The operator shall submit a written validation report to the Environment Agency for approval, that demonstrates and confirms: I. the treatment efficacy of the waste facility for the additional waste types (infectious waste contaminated with non-hazardous medicines (18 01 03* with 18 01 09)), in accordance with the Waste treatment appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020; II. the proposals for routine monitoring of treatment efficacy comply with the Waste treatment appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020; III. the installation's emissions, in accordance with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020; and IV. the proposals for routine monitoring of emissions comply with the Emissions monitoring and limits appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities, dated 13 July 2020. The treatment efficacy tests must take into account the range of permitted waste types that the plant may treat at the same time as the additional waste in question (18 01 03* with 18 01 09 infectious waste with non-hazardous medicines).

	Any alternative operating scenarios where the waste in question would be steam treated without first being shredded must also be fully assessed and validated in accordance with the waste treatment appropriate measures of technical guidance Healthcare waste: appropriate measures for permitted facilities (dated 13 July 2020) as part of this pre-operational measure prior to operation. The operation shall not be made operational until the Environment Agency has given prior written approval under this condition. PO3 - Shredding and steam treatment of waste contaminated with non-hazardous medicines (18 01 03* with 18 01 09). The operator shall submit a written report to the Environment Agency for approval, that: I. proposes a sampling and testing programme for characterising and assessing emissions to air from the abatement systems of the shredder and autoclaves for total and speciated VOCs and dust; II. considers emissions resulting from both the treatment of waste contaminated with non-hazardous medicines (18 01 03* with 18 01 09) and waste not contaminated with non-hazardous medicines (18 01 03*); III. proposes measures to demonstrate that effective clean down occurs between processing of medicinally contaminated sharps and other waste; IV. proposes measures and a sampling and testing regime for demonstrating that pharmaceutically contaminated autoclave liquors or condensate is not discharged to sewer as a result of the treatment of medicinally contaminated waste (i.e. all pharmaceutically contaminated liquids from the treatment of medicinally contaminated sharps are captured for off-site disposal by incineration). No medicinally contaminated waste shall be accepted for shredding and/or steam treatment unless the Environment Agency has given prior written approval under this condition. PO4 - Shredding and/or autoclaving of waste contaminated with non-hazardous medicines (18 01 03* with 18 01 09). The operator shall submit to the Environment Agency for approval a copy of the written procedures that will be followed at the facility in order to ensure that relevant plant and equipment are cleaned between treatment cycles of waste contaminated with non-hazardous medicines and waste not contaminated with non-hazardous medicines. PO5 - Shredding of non-hazardous offensive waste (18 01 04). The operator shall submit to the Environment Agency for approval a copy of the written procedures that will be followed at the facility in order to ensure that relevant plant

	and equipment are cleaned and disinfected between treatment cycles of infectious waste and non-infectious offensive waste.
Table S1.3 Improvement programme requirements **Completed improvement programme requirements**	The following improvement condition has been completed (Labelled as IC10 in the previous variation (EPR/PP3707BB/V003): The operator shall submit a written report to the Environment Agency for approval that proposes a monitoring programme to characterise and assess point source emissions to air from the sharps bin wash plant 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 monitoring and assessment undertaken, along with any proposals for ongoing monitoring or further assessment. This was confirmed in correspondence with Area dated 31/01/2022. The previous variation (EPR/PP3707BB/V004) also had a suite of Improvement Conditions which had been marked as completed in that variation. They have therefore been removed and they are not in the permit. For completeness, they were as follows: IC1 VOC and Microbes/Bioaerosols Assessment A written assessment of the Volatile Organic Compounds (VOCs) emitted from the process shall be submitted to the Agency. The written assessment shall include: • a scale drawing showing location of the emission points monitored; • sampling of the emission and comparison against the benchmark values listed in the Sector Guidance Note S5.07, to assess their significance; • proposal of any necessary modelling of the emission; and • details of how any emissions are to be prevented during the operation of the facility.

	Where on-going routine VOC monitoring is proposed as a result of the above, the written assessment, shall also include: 1. a scale drawing showing the proposed monitoring locations 2. a proposed sampling frequency 3. proposed trigger levels for the parameters monitored 4. an action plan that identifies actions to be taken should trigger levels be exceeded The proposals for modelling, emission prevention and any proposed monitoring shall be implemented by the operator, from the date of approval by the Agency in writing. IC2 Drainage The operator shall colour code the drainage covers on site to clearly indicate which discharge to the foul sewer system and which drain is to watercourse. The direction of flow should also be shown with an arrow. IC3 Energy efficiency An energy efficiency plan shall be submitted to the Agency, detailing the measures to comply with the requirements set out in the Agency's Sector Guidance Note S5.07. Where appropriate the plan shall include dates for the implementation of individual improvement measures. The plan shall be implemented by the operator from the date of approval by the Agency. IC4 Justification and procedure for pre-acceptance, acceptance and treatment of selected bio hazardous waste. Before any waste from clinical laboratories is accepted, a written justification and procedure shall be submitted to the Agency for approval for the pre-acceptance, acceptance and treatment of all microbiological cultures from any source and any potentially infected waste from pathology departments and research establishments. As a minimum, these will take into account the principles specified in the Clinical Waste sector guidance note (EPR 5.07), the research and

	laboratory section of the Safe Management of Healthcare Waste, and should be consistent with the recommendations of current HSE guidance for laboratories. IC5 A revised validation report should be agreed with the Environment Agency, following the introduction of shredding waste prior to treatment on site. The report should contain the following: (a) a microbial efficacy analysis that demonstrates that the choice of test organism, the method of introduction to the plant, the choice of organism carrier, and the analytical method are adequate to demonstrate State and Territorial Association on Alternative Treatment Technologies (STAATT) level III criteria for a worst case scenario challenge load. IC6 The operator shall submit a report demonstrating that the area of land to be used for the compaction of wastes has an impermeable surface with a sealed drainage system. This report shall include the details of waste types to be compacted for Environment Agency approval. The operator shall also submit details of a management system covering the cleaning and maintenance of the compactor. The report shall be submitted to the Environment Agency in writing for approval.

Table 1 – Summary of our assessment of the operator's Reg 61 response