

# Permitting decisions

## Variation

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We have decided to grant the variation for Sharpsmart Ltd operated by Sharpsmart Limited.

The variation number is EPR/XP3493VP/V006

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

### Purpose of this document

This decision document provides a record of the decision making process. It summarises the decision making process in the decision checklist to show how all relevant factors have been taken in to account.

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

- summarises the decision making process in the decision checklist to show how all relevant factors have been taken into account
- shows how we have considered the consultation responses

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Read the permitting decisions in conjunction with the environmental permit and the variation notice. The introductory note summarises what the variation covers.

# Decision checklist

Aspect considered	Decision
<b>Receipt of application</b>	
Confidential information	<p>A claim for commercial or industrial confidentiality has been made.</p> <p>We have not accepted the claim for confidentiality. We consider that the inclusion of the relevant information on the public register would not prejudice the applicant's interests to an unreasonable degree. The reasons for this are given in the notice of determination for the claim.</p> <p>A CinC report was issued to the Applicant/Operator, informing them of our decisions and the reasons behind the decisions. They did not choose to appeal these decisions.</p> <p>The decision was taken in accordance with our guidance on confidentiality.</p>
Identifying confidential information	<p>We have not identified information provided as part of the application that we consider to be confidential.</p> <p>The decision was taken in accordance with our guidance on confidentiality.</p>
<b>Consultation/Engagement</b>	
Consultation substantial change installations	<p>The consultation requirements were identified in accordance with the Environmental Permitting Regulations and our public participation statement.</p> <p>The application was publicised on the GOV.UK website.</p> <p>We do not consider this application to be of high public interest.</p> <p>We consulted the following organisations:</p> <p><i>Public Health England</i></p> <p><i>Local Authority</i></p> <p><i><u>Health</u> and Safety Executive</i></p> <p><i>Sewerage Authority – Severn Trent Water</i></p> <p><i>Canal and Rivers Trust</i></p> <p>The comments and our responses are summarised in the <u>consultation section</u>.</p>
<b>The facility</b>	
The regulated facility	<p>We considered the extent and nature of the facility at the site in accordance with RGN2 'Understanding the meaning of regulated facility', Appendix 2 of RGN 2 'Defining the scope of the installation', Appendix 1 of RGN 2 'Interpretation of Schedule 1', guidance on waste recovery plans and permits.</p> <p>The extent of the facility is defined in the site plan and in the permit. The activities are defined in table S1.1 of the permit.</p>
<b>The site</b>	

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Extent of the site of the facility	<p>The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility. The plan is included in the permit.</p> <p>The plan and other documents describe or show the emission monitoring points in regard to the proposed autoclaving activity on site.</p>
Site condition report	<p>The operator has provided a description of the condition of the site, which we consider is satisfactory. The decision was taken in accordance with our guidance on site condition reports and baseline reporting.</p> <p>The SCR was provided with the Application documents at Appendix G.</p>
Biodiversity, heritage, landscape and nature conservation	<p>The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat.</p> <p>We have assessed the application and its potential to affect all known sites of nature conservation, landscape and heritage and/or protected species or habitats identified in the nature conservation screening report as part of the permitting process.</p> <p>We consider that the application will not affect any sites of nature conservation, landscape and heritage, and/or protected species or habitats identified. The nature of the SSSI within the screening distance (Metallic Tileries) is unlikely to be affected by the potential emissions from the site; notwithstanding the control measures that the operator will have in place. Similarly, the Local Wildlife Sites and nature reserves are also unlikely to be affected by the emissions from site, due both to their nature and control measures in place.</p> <p>We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.</p>
<b>Environmental risk assessment</b>	
Environmental risk	<p>We have reviewed the operator's assessment of the environmental risk from the facility.</p> <p>The operator's risk assessment is satisfactory.</p> <p>NOx emissions were discussed in a H1 assessment – PHE carried out its own assessment of the modelling/assessment and were satisfied that the risk was insignificant, confirming as such via email (dated 16<sup>th</sup> May 2019 from Haymond Lam).</p>
<b>Operating techniques</b>	
General operating techniques	<p>We have reviewed the techniques used by the operator and compared these with the relevant guidance notes and we consider them to represent appropriate techniques for the facility.</p> <p>The BAT Assessment Report submitted as part of the Application (at Appendix I) includes an options appraisal and justification for the use of the selected treatment method/technology. This report was submitted to address the requirements of the guidance "Best Available Techniques (BAT) Reference Document for Waste Treatment", dated 2018.</p>

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	<p>Additional comments for the Fire Prevention Plan were submitted via a Schedule 5 Notice response. These have been incorporated with the Fire Prevention Plan as part of the Operating Techniques.</p> <p>The operating techniques that the applicant must use are specified in table S1.2 in the environmental permit.</p>
Operating techniques for emissions that screen out as insignificant	<p>Emissions of NO<sub>x</sub> (from the steam generator) have been screened out as insignificant, and so we agree that the applicant's proposed technique is BAT for the installation.</p> <p>We consider that the emission limits included in the installation permit reflect the BAT for the sector.</p>
Odour management	<p>As the Activities proposed at the site are for Clinical waste treatment, an Odour Management Plan is required. The Operator has provided a plan and we have reviewed the odour management plan in accordance with our guidance on odour management.</p> <p>We consider that the odour management plan is satisfactory.</p>
<b>Permit conditions</b>	
Updating permit conditions during consolidation	<p>We have updated permit conditions to those in the current generic permit template as part of permit consolidation. The conditions will provide the same level of protection as those in the previous permits.</p> <p>The process flow diagram at the end of this document has been drafted to aid understanding of the AR codes and the waste codes that are permitted to undergo the treatment/DAA. This was used and conceived internally at the Environment Agency for internal use only.</p>
Use of conditions other than those from the template	<p>Based on the information in the application, we consider that we do not need to impose conditions other than those in our permit template.</p>
Waste types	<p>We have specified the permitted waste types, descriptions and quantities, which can be accepted at the regulated facility.</p> <p>We are satisfied that the operator can accept these wastes for the following reasons:</p> <ul style="list-style-type: none"> <li>• they are suitable for the proposed activities</li> <li>• the proposed infrastructure is appropriate; and</li> <li>• the environmental risk assessment is acceptable.</li> </ul> <p>We have restricted the following wastes for the following reasons:</p> <ul style="list-style-type: none"> <li>• 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection</li> </ul> <p><i>This code can be repackaged (AR1) [existing activity allowance], shredded (AR2) and autoclaved (AR3) as part of the site Activities, for onward treatment or disposal. Justification was provided by the Operator for its inclusion in the autoclaving treatment process.</i></p>

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	<ul style="list-style-type: none"> <li>18 01 03*/09 [dual coded] - Medicines other than those mentioned in 18 01 06 (<b>dual coded with 18 01 03* only</b>)</li> </ul> <p><i>This code can be shredded (AR2) and autoclaved (AR3) as part of the site Activities, for onward treatment or disposal. Justification was provided by the Operator for its inclusion in the autoclaving treatment process. The Pre-Operational conditions in the Permit ask for extra information during commissioning in regard to monitoring emissions based on API residues that may potentially be part of this waste stream. The treatment plant also should be flushed between treatments including this code to ensure no cross-contamination with potential API residues.</i></p> <ul style="list-style-type: none"> <li>18 02 02* - wastes whose collection and disposal is subject to special requirements in order to prevent infection</li> </ul> <p><i>This code can be repackaged (AR1) [existing activity allowance], shredded (AR2) and autoclaved (AR3) as part of the site Activities, for onward treatment or disposal. Justification was provided by the Operator for its inclusion in the autoclaving treatment process.</i></p> <ul style="list-style-type: none"> <li>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)</li> </ul> <p><i>This code can undergo Activities AR7, AR8 and AR10. AR10 allows for this waste to undergo shredding and compaction and was part of this variation. The Environment Agency is satisfied with the control and abatement measures proposed as part of managing these wastes.</i></p> <p>All liquor or floc that is produced from wastes that potentially contain any residual APIs (18 01 03*/09) will be sent for incineration to ensure destruction of the residues. No autoclave liquor from the treatment process involving this waste code will be discharged to sewer. The floc will be disposed of at an EfW Facility.</p> <p>We made these decisions with respect to waste types in accordance with Environment Agency guidance "How to comply with your environmental permit" Clinical waste (EPR 5.07 version 1.1).</p>
Pre-operational conditions	<p>Based on the information in the application, we consider that we need to impose pre-operational conditions.</p> <p>PO1 – Requires submission of a commissioning validation report in line with sector guidance note EPR5.07 on clinical wastes. Treatment Activity AR3 shall not be made Operational until the Environment Agency provides written approval.</p> <p>PO2 – Shredding and Autoclaving Activity; provision should be made for testing and monitoring/abatement for VOCs, measures for 'clean down' and testing of pharmaceutically autoclave liquors. Prior approval in writing from the Environment Agency is required under this condition.</p>
Improvement programme	<p>Based on the information on the application, we consider that we need to impose an improvement programme.</p>

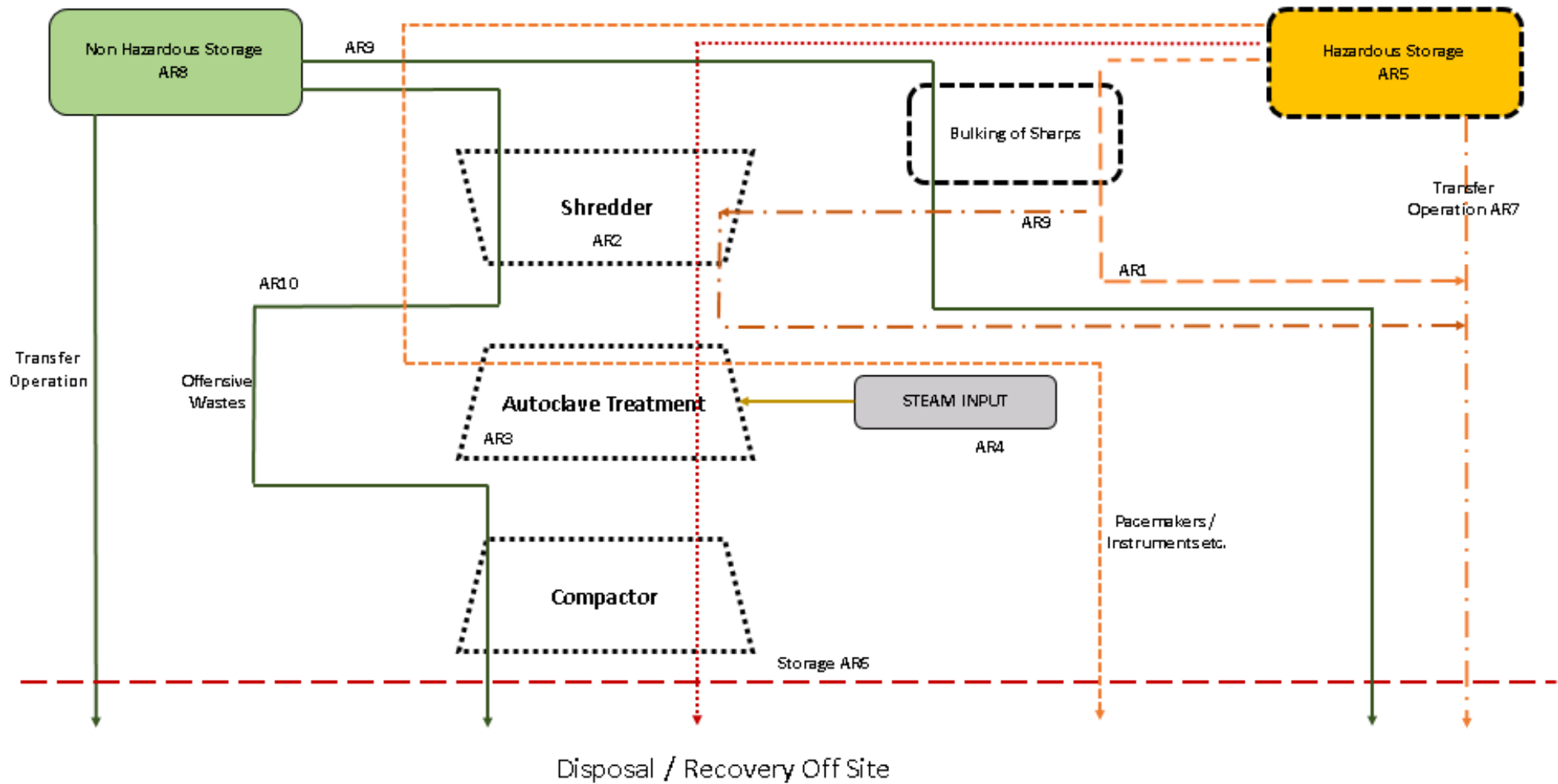
Aspect considered	Decision
	<p>We have imposed an improvement programme to ensure that:</p> <p>The treatment process is monitored for ongoing emissions of VOCs in line with PO2 (discussed above) in line with sector guidance note EPR 5.07. Compliance dates are stipulated (IC1).</p>
Emission limits	<p>ELVs and equivalent parameters or technical measures [based on BAT] have been added for the following substances:</p> <p>Oxides of Nitrogen (NO and NO<sub>2</sub> expressed as NO<sub>2</sub>) [100 mg/m<sup>3</sup>] – steam generator (as the generator is covered by MCP)</p> <p>Particulate Matter [5 mg/m<sup>3</sup>] - shredder</p> <p>Bacillus Spores [1000 cfu/m<sup>3</sup>] - shredder</p> <p>Bacillus Spores [300 cfu litre<sup>-1</sup>] - condensate</p> <p>Fugitive bioaerosol emissions:</p> <p>Bacillus Spores –</p> <p>Air &lt;10m from plant [1000cfu/m<sup>3</sup>]</p> <p>Air &gt;10m from plant [300 cfu/m<sup>3</sup>]</p> <p>Surface &lt;10m from plant [20,000 cfu/m<sup>3</sup>]</p> <p>Surface &gt;10m from plant [5000 cfu/m<sup>3</sup>]</p> <p>These limits were imposed in line with guidance note EPR5.07 and the relevant BREF.</p>
Monitoring	<p>We have decided that monitoring should be added for the following parameters, using the methods detailed and to the frequencies specified:</p> <p>Table S3.1:</p> <p>Carbon Monoxide (from steam generator) as an hourly average, every 3 years.</p> <p>Total TVOCs and Speciated VOCs (from shredder abatement and from Autoclave Extraction) as an hourly average on a monthly basis.</p> <p>Table S3.4:</p> <p>Treatment efficiency, in accordance with Annex 2 of sector guidance note EPR 5.07</p> <p>These monitoring requirements have been imposed in order to ensure that the treatment activities are effective and do not cause pollution or pose greater environmental risk.</p> <p>We made these decisions in accordance with sector guidance note EPR 5.07.</p>
Reporting	<p>We have added reporting in the permit for the following parameters:</p> <p>Treatment Efficiency – quarterly/from as agreed in PO1.</p> <p>Emissions to Air – every 12 months.</p>

Aspect considered	Decision
	<p>Emissions to sewer – every 6 months.</p> <p>Tonnages for:</p> <p>Hazardous waste treated and accepted for transfer; and</p> <p>Non-hazardous waste treated/produced.</p> <p>Performance parameters for water usage, energy usage and total raw materials used.</p> <p>We made these decisions in accordance with sector guidance notes EPR5.07 and EPR5.06.</p>
<b>Operator competence</b>	
Management system	<p>There is no known reason to consider that the operator will not have the management system to enable it to comply with the permit conditions. The Operator has supplied evidence in the form of a Management Systems document and competency certificates as part of their Application to vary the Permit.</p>
Technical competence	<p>Technical competence is required for activities permitted.</p> <p>The operator is a member of an agreed scheme.</p> <p>We are satisfied that the operator is technically competent – Operator provided up to date WAMITAB certificates for their appropriate members of staff.</p>
Relevant convictions	<p>The Case Management System has been checked to ensure that all relevant convictions have been declared.</p> <p>No relevant convictions were found. The operator satisfies the criteria in our guidance on operator competence.</p>
Financial competence	<p>There is no known reason to consider that the operator will not be financially able to comply with the permit conditions.</p>
<b>Growth Duty</b>	
Section 108 Deregulation Act 2015 – Growth duty	<p>We have considered our duty to have regard to the desirability of promoting economic growth set out in section 108(1) of the Deregulation Act 2015 and the guidance issued under section 110 of that Act in deciding whether to grant this permit.</p> <p>Paragraph 1.3 of the guidance says:</p> <p>“The primary role of regulators, in delivering regulation, is to achieve the regulatory outcomes for which they are responsible. For a number of regulators, these regulatory outcomes include an explicit reference to development or growth. The growth duty establishes economic growth as a factor that all specified regulators should have regard to, alongside the delivery of the protections set out in the relevant legislation.”</p> <p>We have addressed the legislative requirements and environmental standards to be set for this operation in the body of the decision document above. The guidance is clear at paragraph 1.5 that the growth duty does not</p>

Aspect considered	Decision
	<p>legitimise non-compliance and its purpose is not to achieve or pursue economic growth at the expense of necessary protections.</p> <p>We consider the requirements and standards we have set in this permit are reasonable and necessary to avoid a risk of an unacceptable level of pollution. This also promotes growth amongst legitimate operators because the standards applied to the operator are consistent across businesses in this sector and have been set to achieve the required legislative standards.</p>



## Flow Process



## Consultation

The following summarises the responses to consultation with other organisations, our notice on GOV.UK for the public, newspaper advertising and the way in which we have considered these in the determination process.

### Responses from organisations listed in the consultation section

<b>Response received from</b>
Public Health England
<b>Brief summary of issues raised</b>
Concerns over modelling of NOx from the steam raising generator were raised.
<b>Summary of actions taken or show how this has been covered</b>
The Operator re-submitted H1 Assessment from the Emissions to Air, which proved satisfactory for the PHE Assessment. Emissions to air were not significant.

No other responses were received.