Notice of request for more information

The Environmental Permitting (England & Wales) Regulations 2016

Company Secretary

Sharpsmart Limited
Unit 44 Enterprise City
Meadowfield Avenue
Spennymoor
County Durham
DL16 6JF

Application number: PP3707BB/V003

The Environment Agency, in exercise of its powers under paragraph 4 of Part 1 of Schedule 5 of the above Regulations, requires you to provide the information detailed in the attached schedule. The information is required in order to determine your application for a permit duly made on 30/10/2020.

Send the information to either the email or postal address below by 15/01/2021. If we do not receive this information by the date specified then we may treat your application as having been withdrawn or it may be refused. If this happens you may lose your application fee.

Email address: peter.chesney@environment-agency.gov.uk

Postal address:
Permitting and Support Centre
Quadrant 2
99 Parkway Avenue
Parkway Business Park
Sheffield
S9 4WF

Name	Date
Peter Chesney	04/12/2020

Authorised on behalf of the Environment Agency

Notes

These notes do not form part of this notice.

Please note that we charge £1,200 where we have to send a third or subsequent information notice in relation to the same issue. We consider this to be the first notice on the issues covered in this notice.

The notes in italics that appear after information requests in the attached schedule do not form part of the notice. The notes are intended to assist you in providing a full response.

Schedule

1. Air emissions risk assessment

The air emissions risk assessment (Appendix J AQIA) provided in support of the application has not considered emissions of sulphur dioxide (SO_2) from the proposed boiler. The Medium Combustion Plant Directive (MCPD) includes a SO_2 emission limit for new plant that burn gaseous fuels other than natural gas (35mg/m^3).

The risk assessment provided has only considered concentrations of Oxides of Nitrogen (NOx) at local ecological receptors and has not considered all relevant critical levels and loads for habitat sites (e.g. including Acid Deposition, Nutrient Deposition, Nitrogen Deposition). Also, the assessment has not considered the impact of emissions at local wildlife sites (identified in GIS screening report).

a) Provide an updated air emissions risk assessment (AQIA) that includes:
   - an assessment of SO_2 emissions from the facility's new boiler upon local sensitive receptors (human health and ecological)
   - an assessment of the impact of emissions from the facility upon all relevant ecological receptors, including local wildlife sites
   - consideration of all relevant critical loads and levels for ecological receptors
   - consideration of all relevant human health receptors, at locations (excluding work places) where the public may be reasonably likely to be present for the duration of the relevant assessment criteria (e.g. for more than 15 minutes for the SO_2 15 minute Air Quality Standard)

   Please provide the air dispersion modelling data files with the assessment report.

   Note, the existing air emissions risk assessment assumed that NOx emissions from the boiler were at a concentration of 101mg/m^3, rather than the emission limit set in the MCPD (200mg/m^3). Based upon the information provided to date, a NOx emission limit of 101mg/m^3 is likely to be set in the varied permit for the facility. If the boiler plant will not be able to operate below this emission limit during ongoing operation then an alternative emission concentration will need to be considered and assessed through an updated air emissions risk assessment (AQIA).

2. Wash plant

a) There will be an additional emission to sewer from the facility resulting from the operation of the proposed wash plant (i.e. generation and discharge of wash waters). Provide further information to describe this emission and to assess the potential environmental risk from its release, taking into account its quantity and nature/composition (i.e. presence of potentially polluting substances), including the potential for any chemical or medicinal contamination resulting from the treatment of contaminated waste sharps.

b) *The existing Thames Water discharge consent for the facility includes a number of limits and restrictions. For example, that it will not contain non-biodegradable detergents, the pH will be between 6 and 11, the temperature will be below 43°C, it will be within the limits stated in Appendix 1 of the consent and will not contain substances listed in Schedule 1 of the Trade Effluents Regulations at concentrations greater than background. The consent also states that 'no condensing water shall be discharged'.*

   Confirm that the discharge to sewer from the operation of the facility, as detailed in the variation application (i.e. including the proposed operation of the wash plant, new boiler and autoclaves), will continue to meet the conditions and limits of the existing Thames Water discharge consent.

c) There will be an additional emission to air from wash plant (of vapour/steam). Provide further information to describe this emission and to assess the potential environmental risk from its release, taking into account its quantity and nature/composition (i.e. presence of potentially polluting

substances), including the potential for the release of any chemical or medicinal substances resulting from the treatment of contaminated waste sharps.

d) Confirm the treatment capacity of the waste plant (tonnes per day) and the waste types (by description and EWC code) that will be treated by it.

e) Provide further information to explain how it will be ensured, through the operation of the wash plant, that the different types of waste that are repackaged will go for appropriate treatment (either on site or off site following transfer), including, but not limited to -
   - how it will be ensured that only sharps waste with EWC codes 18 01 03* or 18 01 03* with 18 01 09 will be repackaged together and treated through the autoclave, and that other sharps wastes will be transferred off-site for further treatment (e.g. incineration)
   - whether or not certain waste(s) will be managed and treated together in batches, so that the repackaged/bulked wastes are of a similar type or require the same disposal/recovery option

f) Provide further information to explain:
   - what happens to the wash water once used – for example, is it collected, recirculated and reused (with or without treatment), or is it discharged directly to sewer
   - what measures will be taken to ensure that the use of water by the wash plant is reduced and optimised, having regards to the relevant appropriate measures of our Healthcare Waste guidance

g) The application states that the emission to air from the wash plant will pass through HEPA and carbon filters prior to release, the same as emissions from the autoclave and shredder, and that the performance of these filters is monitored by the pressure differential. Confirm how often this monitoring is undertaken and how this information is assessed, recorded and acted upon (in terms of filter regeneration or replacement).

3. Treatment (shredding & autoclaving) of infectious sharps waste contaminated with non-hazardous medicines

a) Provide a systematic assessment of the proposed treatment process to explain and demonstrate how it will be ensured that any non-hazardous medicines (specifically, pharmaceutically active ingredients (APIs)) present in the proposed waste stream (i.e. waste received under EWC code 18 01 03* with 18 01 09) will be captured and contained and sent for destruction and will not be emitted to the environment.

   This should consider all potential sources of fugitive and point source emissions to the environment (to air and water), the expected efficacy of the emission control/abatement systems and the management of liquid effluents and solid residues generated by the treatment process (including HEPA and carbon filters).

   It should also include further information summarising operating procedures (including staff training) that will be in place to ensure that:

- only infectious waste contaminated with non-hazardous medicines will be autoclaved (i.e. excluding any other medicinally or chemically contaminated sharps)
- that all effluent and residues resulting from the treatment of non-hazardous medicinally contaminated infectious waste will be sent for incineration (and not to sewer or landfill), from generation to final disposal/recovery
- all relevant plant and equipment (e.g. shredders, autoclaves, tanks, containers, effluent and condensate collection systems etc.) are fully cleaned and disinfected after the treatment of any infectious medicinally contaminated waste before the treatment of infectious non-medicinally contaminated waste, and after the treatment of any infectious waste before the treatment of offensive waste

b) Provide further information to explain what measures will be in place to check and confirm through the waste management chain (from point of production to final disposal) that all potentially medicinally contaminated wastes will go and have gone for incineration. For example, will the waste code and description accompanying the waste identify potential medicinal contamination and the need for incineration? Will waste records be used to track the material to ensure that it ends up at an incinerator plant, and not in a landfill or discharged to sewer?

c) Provide further information to explain how the shredder, autoclave and other associated equipment (e.g. conveyors, compactors, tanks, bins/containers, effluent and condensate collection systems etc.) will be thoroughly cleaned after treating medicinally contaminated waste in order to prevent potential cross contamination of non-medicinally contaminated waste, including the residues and effluent resulting from its treatment. Also, explain how this cleaning will be done whilst minimising the generation of additional wastes and preventing/controlling potential fugitive emissions to air and water.

d) Provide further information to explain what process or emissions monitoring will be undertaken (as part of initial plant testing and validation and during ongoing operation) to demonstrate the effectiveness of the measures for preventing and controlling chemical emissions to air and water (i.e. of medicines and potential break-down products).

e) Confirm if the intention is to treat medicinally contaminated infectious sharps waste only, or if you also will treat bagged medicinally contaminated infectious waste. It is unclear from the application documentation, the majority of which refers to sharps only waste (e.g. section 3.1 of the BAT Assessment) whilst p.9 of the Supporting Statement also refers to bagged waste.

f) The application states that the medicinally contaminated infectious waste stream will either be pre-shredded or loaded directly into autoclave. Provide further information to explain how it will be determined if pre-shredding is or isn't required and who will make this decision.

g) Confirm whether 18 01 03*/09 waste will be treated with other 18 01 03* waste, or in separate batches and explain how plant validation tests will take into account the possible range of waste streams that will be treated at the same time through consideration of worst case challenge load (as detailed in our Healthcare Waste Guidance for plant validation tests).

h) The final paragraph on p.11 of the BAT Assessment suggests that confirmation has not yet been received from the proposed waste incinerator plant that they will be able to accept the medicinally contaminated effluent (i.e. that the effluent specification will be met) and that the operator is waiting on results from a US sample of effluent. Please confirm whether or not this is still the case, and why an effluent sample is required from a US plant when a similar treatment facility, taking similar waste, is already operating in the UK (i.e. at the Sharpsmart Stoke facility).

4. Autoclaving single use instruments, devices and equipment

a) The application refers to the treatment (autoclaving) of infectious single use instruments, medical devices, electrical medical instruments and 'laboratory wastes'.
Provide EWC codes and descriptions (along with examples, where possible) of the types of instruments, devices, equipment and laboratory wastes that will be accepted for treatment (autoclaving), along with any limits or exclusions that will be applied through waste pre-acceptance/acceptance procedures to ensure that only suitable wastes are accepted for treatment. For example, medical devices, electrical equipment and laboratory wastes could potentially contain hazardous substances or other components unsuitable for alternative treatment (e.g. batteries, LCDs, mercury, radioactive materials, pharmaceuticals, hazardous chemicals, microbiological cultures etc.).

b) Provide further information to explain how such single use wastes will be checked and inspected through your waste pre-acceptance and acceptance procedures to confirm that they are suitable for treatment (e.g. that they do not contain unsuitable waste types, components or properties).

c) Confirm where the containers holding the treated single use instruments, devices and electrical instruments will be stored on-site. Show the location on an updated site plan.

d) Provide further information to explain where the treated waste instruments, devices and equipment etc. will be sent for further recovery or disposal.

e) Confirm the maximum quantity of treated instruments, devices and equipment etc. that will be stored in containers (bins) at the facility and how long these wastes will be stored prior to transfer.

5. Shredding offensive wastes and storage of shredded material

a) Confirm the capacity of the offensive waste shredding activity (tonnes per day).

b) Confirm the maximum on site storage capacity and storage duration for shredded offensive waste (our Healthcare Waste guidance states waste should be stored for up to 1 week if stored externally). Confirm how many skips will be required on-site at any one time for the storage of this material and where the skips will be stored (inside building or yard), including the proposed location on a site plan.

c) The site plan currently provided shows there will be one skip for compacting offensive waste and another one for compacting autoclave floc, however the application documentation suggests the two materials may be compacted together in the same skip. Confirm whether or not the 3 treated waste streams (i.e. shredded offensive, autoclaved infectious, autoclaved infectious with non-hazardous medicine contamination) will be collected, compacted and stored in the same or different skips. If all waste streams could be collected in the same skip, explain how it will be ensured that all of the waste will go for appropriate disposal (i.e. incineration if it is contaminated by non-hazardous medicines).

d) Provide further information to explain how the shredded offensive material will be collected, transferred and loaded into the compactor skip (the autoclave floc compactor and/or the separate offensive waste compactor), and what measures will be in place to prevent and control fugitive emissions and odour.

e) Provide further information to explain how the shredder and associated plant/equipment (e.g. bins/containers, conveyors, compactors etc.) will be cleaned and disinfected before being used for offensive waste if previously used for treating infectious or medicinally contaminated hazardous wastes. Also, explain how this cleaning will be done whilst minimising the generation of additional wastes and preventing/controlling potential fugitive emissions to air and water.

f) Provide further information to explain how the following appropriate measures from the Environment Agency's Healthcare Waste Guidance will be met during the compaction of shredded offensive waste:

> 4. If you compact or compress any offensive wastes you must use detailed procedures to contain and minimise the release of body fluids, micro-organisms and liquid discharges. You must carry out monitoring to demonstrate that your procedures and associated measures are effective.
>
> 5. Heavier compaction is likely to result in bags splitting and lead to the release of emissions to air, or liquids to surface or groundwater. If you subject offensive waste to heavier compaction, you must have appropriate measures in place to make sure that you fully capture, contain and abate (if required) all such emissions.

6. Increasing annual waste throughput and floc storage capacity

The existing permit for the facility limits the total on site storage of hazardous and non-hazardous waste to 55 tonnes. The application (p.5 of Supporting Statement) states:

'The applicant can confirm that the existing storage limit of 55 tonnes remains applicable; this is constrained by the capacity of the building.'

The application proposes to increase the storage capacity for treated/compacted floc to 100 tonnes.

a) Provide further information to confirm:

- whether the existing and proposed 55 tonne site storage capacity is just for waste accepted at the facility for treatment and transfer, or whether it also includes the storage of waste produced (treated) at the facility
- what the proposed total waste storage capacity of the site is (including storage of waste accepted for treatment/transfer and waste produced by onsite treatment activities)
- if the proposed additional 100 tonnes storage capacity includes both the storage of compacted autoclave floc and shredded offensive waste

b) Provide further information to explain and justify the need for the increased 100 tonne storage capacity for treated/compacted floc, including the number of skips that would need to be held on site at any one time to store this quantity of material, where these skips would be stored (the site plan provided shows one compactor skip for floc and one for offensive), and the maximum duration waste stored in the skips would be held on site for. If stored externally, our Healthcare Waste guidance states that storage should be for no longer than 7 days.

c) Confirm whether or not you are proposing to increase the maximum total annual quantity of waste that can be accepted for treatment and transfer to 60,000 tonnes (i.e. up to 30,000 tonnes for treatment (of which up to 20,000 is hazardous) and, in addition, up to 30,000 tonnes for transfer), or an alternative annual quantity.

d) If proposing to increase annual waste acceptance of waste to 60,000 tonnes (or an alternative quantity), provide further information to explain how this can be achieved with existing storage infrastructure and a total waste storage capacity of 55 tonnes (which, according to the application, is constrained by the capacity of the building).

If the site treated and transferred 55 tonnes from the site every day (the maximum amount that can be accepted and stored on site at any one time), 365 days per year, this would total just over 20,000t for the year. To have a throughput of 60,000 tonnes per year, the site would need to receive, store, treat and transfer (on average) over 160 tonnes of waste per day (365 days per year), whilst operating with a storage capacity of 55 tonnes.

7. Odour management plan (OMP)

a) Review and where necessary update your OMP to account for any additional information or changes made as result of the responses to the previous sections above and to address the comments made below:

i. The OMP should provide an inventory of all potentially odorous solid, liquid and gaseous materials held on site across the full range of operating conditions. This should include waste received for treatment or transfer as well as wastes, residues, effluents and gases produced by the treatment processes undertaken at the facility. Along with the description of these materials, the inventory should detail the maximum quantities of the materials held on-site, how and where they will be stored on-site, the maximum length of time they will be held on-site, as well as any other specific odour controls that will be applied to them.

ii. Currently, the OMP largely focusses upon the treatment and storage/compaction of autoclaved waste and does not fully identify or consider the shredding, handling and compaction/storage of offensive waste as an additional source of odour.

iii. The OMP does not confirm the maximum quantities (i.e. in terms of tonnage and/or number of containers/skips etc.) of the potential odorous materials and wastes that will be held on-site.

iv. The current OMP states that the maximum storage period for any load of waste is 2 weeks, presumably before it is either treated or transferred off site. However it does not confirm how long treated wastes and other potentially odorous materials (including residues and effluents) will be stored on site before being removed. Our Healthcare Waste Guidance states that waste stored externally should not be stored for more than 7 days.

v. The OMP states that the waste compactor skip is within a building. However, the site plan provided with the application shows that the offensive waste compactor skip is outside. It is unclear if (and where) the skips of compacted waste (floc and offensive waste) will be stored inside the building and/or outside in the yard area.

vi. The OMP does not identify or consider the handling and storage of wash waters from the wash plant or effluent from the cleaning/disinfection of the site as potential of odour sources.

vii. The OMP should include a site plan showing the location of potential sources of odour, e.g. storage areas, equipment, abatement systems.

viii. The OMP should confirm the frequency, extent and methods of site inspection and cleaning activities.

ix. The OMP states that after the 1st month of operation olfactory monitoring will be undertaken monthly at four set locations, as well as at one additional location determined by wind direction. The OMP does not explain how this monitoring will be undertaken, who will do it, or why the frequency should be reduced after the first month of operation. At sites that store and treat potentially odorous waste, we would typically expect odour monitoring (e.g. sniff tests) to be undertaken at a higher frequency than that proposed, for example, as part of routine daily site inspections.