Reva Environmental Ltd

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Environment Agency Permitting and Support Centre
Environmental Permitting Team
Quadrant 2
99 Parkway Avenue
Parkway Business Park
Sheffield
S9 4WF

Application Reference: EPR/PP3707BB/V003
Permit Variation Application for Rainham Clinical Waste Treatment Facility

Dear Pete,

Thank you for your email dated 4 December 2020 regarding the application referenced above. The following information is provided to you in response to the Schedule 5 request for further information. A copy of the Schedule 5 Notice is provided in **Annex Sc5-1** to this response letter, for completeness.

Question 1 – Air Emissions Risk Assessment

You have requested an update to the AQIA provided, to consider emissions of SO2 and critical levels for habitat sites.

A copy of the updated AQIA is provided in **Annex Sc5-2** of this letter, and a copy of the model input files has been sent separately via email.

Question 2 – Wash Plant

a. Emission to Sewer

The current discharge consent covers the effluent produced from the washing of the 770 ltr carts on site. The operation of the new wash plant presents a new discharge to sewer from the wash plant. Sharps waste is currently received but within UN containers so the effluent will be slightly different as a result of the wash plant being operational. The same process is currently permitted and carried out at Sharpsmart's Stoke facility; a copy of discharge sample results for that site is provided in **Annex Sch5-3** to this response letter.

The wash detergent used is Solid Hero Plus. The specification for this confirms that it is biodegradable and accords with the requirements of the detergent regulation 648/2004/EC.

b. Discharge consent compliance

Please see our response to Question 2a and Stoke effluent samples provided as an equivalent example in Annex Sch5-3. Sharpsmart has reviewed the existing discharge consent and contacted one of their sewerage undertakers to confirm the intent of the condition excluding condensed waters, as the discharging of condensing water (from the steam) has been practice on the site for many years and the intention is for this to continue. The only caveat on this would be that it would not be discharged to sewer when the plant is processing a batch of sharps.

The response from Thames Water confirms that this condition was required to be added to all consents issued, due to the Water Industry Act 1991, however that it is only applicable (and specifically) for old traditional steam engines, not condensation. A copy of this communication can be provided to the EA if required.

c. Emission to Air

There is a local exhaust ventilation (LEV) system which is installed over the head/tipping area. This is directed to atmosphere via a filtration system, as detailed in the application documentation. The extraction on the hot wash area is purely steam; it does not contain any potentially polluting substances so does not pose a risk to the environment from its release.

d. Treatment Capacity and Waste Types

The wash plant is capable of processing 150 – 160 containers per hour. Containers are 2.5 kg so this is a capacity of up to 0.4 tonnes per hour. The following containers are processed:

- 18 01 03/09 yellow lidded – typically this makes up 80% of the throughput;
- 18 01 09 blue lidded – typically this makes up 5% of the throughput
- 18 01 03 orange lidded – typically this makes up 5% of the throughput
- 18 01 08 purple lidded – typically this makes up 10% of the throughput

The autoclaves can treat 800 kg per cycle, running 25 cycles per day, 24 hours a day, 7 days a week. This equates to 140 tonnes per week of 18 01 03 and 18 01 03/09.

e. Waste Processing

In essence, the incoming containers are batched by container colour/waste so that there is only one waste type decanted into a single bulk container to allow correct onward processing (treatment or transfer). The incoming containers are stored/staged in the red painted area of the processing building to allow batch processing of each waste type / producer and to keep wastes appropriately segregated.

f. Wash Water

Wash water in the wash plant is mains supplied and is only used once. Recirculation is not considered appropriate given that the intent is to ensure the cleanliness and sterility of the containers because they are used in a clinical context.

Whilst water use is therefore inevitable, it is minimised via the plant control systems which are programmed to utilise the correct quantity of water and detergent for the batch. Programmes are timed and dosing of detergents is fully controlled. The wash plant meets, and is accredited to, ISO 23907.

g. Filter Management

Daily site checks are completed across the site, and the filter systems are included in these. The units have pressure gauges on them which are visible so can be checked as part of this daily site audit.

In addition to this, regular checks are undertaken by the maintenance teams and the filters are on a service contract with the equipment supplier to ensure that regular maintenance and filter changes take place. These measures together ensure that the filter efficiency is maintained.

Question 3 – Treatment of Infectious Sharps

a. BAT Assessment

The BAT Assessment provided with the application was updated and resubmitted in October 2020 (ref. SHSMT_2020.02/05). Section 3.1.1 provides the information that was submitted for the same activity at the Stoke facility which has been successfully permitted for the treatment of this waste stream. The level of detail of the BAT assessment reflects the understanding of the applicant of the concern that the EA has with respect to the potential for sharps to have a level of pharmaceutical contamination present. Extensive pre-application discussions were held with the EA for the Stoke facility in order to establish those concerns and ascertain the level of detail required to reassure the regulator sufficiently for the EP to be granted.

In summary, the BAT assessment refers to pre-acceptance audits to confirm that pure pharmaceutical waste will be segregated and not treated; it recognises that the potential for pharmaceutical contamination in infectious waste is likely to be <5% and that this would be limited to a residual level on packaging which is arguably negligible. The BAT assessment (Table BAT1) presents details for the five most commonly use prescribed medicines and sets out the potential pathway for emission, and the capture/control method.

It confirms that the majority of pharmaceuticals used within the UK have boiling/melting (and decomposition) points much higher than those that the waste will be exposed to in the autoclave process. The compounds

will therefore not change form/characteristics so any residual contamination will be found within the floc and the autoclave liquid effluent, not in the steam. Irrespective of the type of pharmaceutical products present in the waste, the waste stream is still ultimately disposed of in a similar way to that which it currently it, i.e. incineration.

For this specific application, the presence of residual pharmaceutical content in the floc and liquid effluent is acceptable for disposal at the designated R1 energy from waste facilities as it will be subject to sufficient incineration temperatures for the destruction of pharmaceutical content. The use of alternative treatment for this waste stream is therefore considered to be appropriate.

With respect to ensuring that the waste is appropriately identified, segregated and processed along the correct route at the site, and that staff are fully aware of the requirements with regard to control of emissions and cleaning/disinfecting of key plant and equipment, site personnel are fully trained in accordance with Sharpsmart's certified EMS.

The EMS is followed and led by the Management Team to ensure that employees have the necessary training, skills and equipment required to carry out their work and that internal audits are conducted regularly to review this. The company maintains a competency/training matrix to support this.

New starters are provided with induction checklists to check and ensure understanding of requirements of their roles, but also of the EMS and the EP under which the facility is regulated. On the job reviews are carried oud to check/ensure high levels of competence.

Sharpsmart ensures that all employees are aware of the EMS policy, manual, and documents and their contribution to the effectiveness of it through:

- Notice Boards
- Employee Handbook
- Awareness Training
- Induction
- CPD
- SOP's
- Incident reports and reviews
- Risk assessments
- Method Statements

b. Waste Duty of Care

Sharpsmart adheres to its duty of care procedures to ensure compliance with requisite identification, tracking and transfer requirements. It has a single national agreement/contract in place to ensure that all potentially medicinally contaminated wastes only go to the correct facility (for incineration). Sharpsmart does not use landfill for any floc; this avoids the risk of any errors.

c. Cleaning Procedures

Equipment	Cleaning Procedure
Shredder	• The final waste shredded between 18 01 03/09 and 18 01 03 cycle will be non-medicinally contaminated this will be either 18 01 03 bagged wastes or waste cardboards. These wastes remove any solid residues remaining in the teeth, hopper or screen areas. • The Shredder will be sprayed with water to wash the shredder removing further residues. All effluent will be captured for off site disposal.
Carts	• The shredder carts are lined with heavy duty plastic liners removing the need decontaminate. • The liners enter the autoclave with the wastes.
Autoclave	• The autoclave and condenser system will have a mains water flushing system installed to allow the system to be flushed between 18 01 03/09 and 18 01 03 cycle if required • All effluent will be captured and sent for off-site recovery/disposal. • Operationally the two on site autoclaves will solely process one type of waste 18 01 03 or 18 01 03/09.

Tanks	• The system is designed to divert medicinally contaminated effluent mechanically to a separate tank to that of effluent from the treatment of orange bags. There is no mixing of effluent in the storage tanks. • The divert values are controlled through the PLC on the autoclaves and will open/shut dependant on the cycle parameters/waste stream selected. • Operationally the autoclaves will process a single stream unless capacity constraints/breakdowns require alternative processing. Only one clave will process sharps, both claves could process orange.
Conveyor Systems and Compactor	• Wastes exiting the autoclaves via the conveyors and within the conveyors will be mixed from either treatment process (18 01 03 or 18 01 03/09) will all residue floc being recovered at the same facility so no requirement for cleaning between cycles. • During maintenance and cleaning all residues and liquid from the process will be captured and sent for off-site disposal.

d. Process & Emissions Monitoring

The following commissioning plan is proposed; this is consistent with that approved and implemented at the Stoke facility.

Equipment	Commissioning Plan

Shredder	• Testing of difficult known wastes in mixed bulk loads to ensure complete destruction (opening) and rendering unusable
	  ○ 10 mm syringes
	  ○ Scissors/blades
	  ○ Vacuum/suction canisters
	  ○ Guide wires
	  ○ IV tubing and bags
	• Smoke bomb test of the shredder extraction to ensure no escape and all air is drawn through the filtration systems
	• Safety interlocks work
	• Capture of all liquids within the system
	• Spore aerosol testing in line with *Healthcare waste: appropriate measures for permitted facilities V1*

Compactor	• Compaction of material with the addition of 20 litres of water to ensure the door seals work and that the water can be drained and retained prior to transport.

Autoclave	• Validation of cycles to ensure complete treatment of waste in line with *Healthcare waste: appropriate measures for permitted facilities V1*
	  ○ Cycle length to achieve required log reduction
	  ○ Temperatures settings – temperature strips used in different parts of the waste load
	  ○ Vacuum cycles required to achieve penetration and steam removal
	  ○ Waste types
	  ▪ Shredded and un-shredded Yellow waste – 18 01 03, 18 01 03/09
	  • Maximum quantity/volume per cart to achieve log reduction required
	  ▪ Shredded orange bagged waste 18 01 03
	  • Maximum quantity/volume per cart to achieve log reduction required
	  ▪ Un-shredded medical instruments (metal)
	  ▪ Un-shredded wastes in bags/containers
	  ○ Spore strips used in different parts of the load and autoclave to ensure complete treatment throughout the load.

	• Spore aerosol testing around the opening/prep and movement of carts from the shredder. To ensure containment prior to treatment.
Condenser and Effluent retention	• Heat exchanger completely condenses all steam to the required temperature and time frame to not affect the cycle process • Buffer tanks safety, overflow are functional

An outline of monitoring that will be carried out during operations is included in Section 4.2 of the October BAT Assessment. In addition, the following details are provided:

- Daily checking of filter units. These units have pressure gauges on them which are visible so can be checked as part of the daily site audit.
- 3 yearly stack monitoring of the boiler exhaust to be completed by an accredited third party, in accordance with MCERTS.
- Daily olfactory monitoring at specified points around the site, in accordance with EA's H4 guidance.
- Regular checks of all waste containers (incoming and post-treatment materials) to ensure integrity and fitness for use.
- Monitoring of wash plant effluent by the sewerage undertaker; results provided to Sharpsmart monthly.
- Monitoring of the shredder abatement plant on a monthly basis (for total and speciated VOCs) – only during the treatment of contaminated sharps.
- Monitoring of the autoclave abatement plant on a monthly basis (for total and speciated VOCs) – only during the treatment of contaminated sharps.
- Monitoring of particulate matter at the shredder abatement plant on a six monthly basis.
- Routine monitoring of efficacy of the treatment process, at <10 m and >10 m from the treatment plant in line with *Healthcare waste: appropriate measures for permitted facilities V1*

e. Waste Types

We apologise for any lack of clarity on this subject; the applicant would like to treat medicinally contaminated infectious bagged waste in addition to the sharps waste stream.

f. Pre-Shredding Determination

The request to include both options was to allow either option to be tested during commissioning and to give plant contingency (shredder breakdown etc.). In reality, one of the options will be the primary one; the result of testing and validation will enable Sharpsmart to confirm which one this is. It is considered likely that the loading of the waste directly into the autoclave will be the primary solution as this will reduce handling/processing and the rotary nature of the clave will make the waste unidentifiable/unusable. Following testing/validation if both options are successful a safe operating procedure (SOP) will be written and incorporated into the site EMS, clearly stating which is the primary processing option and setting out circumstance in which the other option can be used (this will require the approval from the national Operations Manager or Technical Manager for each instance).

g. Waste Batches

It is confirmed that 18 01 03 bagged waste will be treated separately; this is pre-shredded and already validated.

Processing will be on a batch basis; only one clave will be used to treat 18 01 03/09 whilst both are capable of treating 18 01 03. This ensure flexibility to allow for the varying volume differences that are received at the site. For testing 18 01 03/09 as a worst case, spores will be placed within typical items (syringes, handles etc.) to prove that they are still treated for the (primary) non-shredded process option, at the maximum load weight ~800kg. On a shredded load, all waste will be of uniform size and therefore the worst case load will be in terms of the maximum waste volume that can fit into the claves ~800kg.

h. Effluent Disposal Route

This reference was included in the BAT Assessment in error and was mis-copied from the Stoke facility application which included a reference to the US facility as that was the situation at the time. There are now two facilities in the UK already taking the effluent from the Stoke facility and both have ample capacity to also take the Rainham effluent; both are also set up to do so.

Question 4 – Autoclaving of Single Use Instruments

a. Waste Types

The request to include autoclaving of single use instruments/equipment is limited to 18 01 03, to enable them to be recycled.

The waste stream will not include any batteries or lab cultures. Sharpsmart has a dedicated green container which is provided to customers for use in areas of high single-use metal waste production (theatres, podiatry, material, SSD etc.). These containers are clearly labelled with details and instruction to ensure correct segregation at the producer site. Audits will be undertaken as part of waste acceptance and pre-acceptance processes; as the containers are decanted at the Rainham facility, if the waste is observed to be unsuitable for recovery the waste is transferred to an appropriately licensed facility for the correct disposal solution.

b. Waste Inspection

As referred to in response to Question 4a, the applicant has an "Auditsmart" auditing process that checks the containers. The waste is also subjected to visual inspection when it is decanted from the reusable containers.

c. Waste Storage – Single Use Instruments/Equipment

Treated single use instruments/equipment will be stored in either palletised rigid boxes or skips. The containers (whichever type used) will be delivered as needed, in preparation for the batch being processed. As they are filled they will be removed from site. The filled containers will be stored within the building, in the waste reception area and they will not be on site for more than a day. Current expectation is that only small quantities of this waste stream will be processed; approximately 3 – 4 cycles per month.

d. Waste Recovery/Disposal Route

The treated waste will be transferred off site to an appropriately licensed facility for metal recycling/recovery.

e. Waste Quantity

As referred to in response to Question 4c, the treated waste will be removed from site within 24 hours; this is necessary due to space constraints within the building. Typically 2 – 3 tonnes will be treated at any one time.

Question 5 – Shredding of Offensive Waste

a. Activity Capacity

The shredder can process a maximum of 1 tonne per hour. The processing of offensive waste through the shredder will only be when this is necessary for contingency and alternative disposal requirements.

b. Storage Capacity & Duration

Skips of shredded material (a mixture of floc / shredded offensive waste) are moved every day excluding Sundays. This means that the maximum period that this waste would be stored on site would be 48 hours. Further details of the skip arrangements are provided in response to Question 6 of this document.

c. Compaction Skips

It is confirmed that all shredded material can be mixed together in the same skip; the outlet for all floc/shredded material is the same and is incineration. This ensures no issues/mistakes can occur. The only landfill outlet that Sharpsmart uses is for compacted un-shredded offensive bags; an existing permitted activity. There is a dedicated compactor skip located in the yard area for this.

d. Movement of Shredded Offensive Waste

The shredded offensive waste is loaded via the same autoclave conveyor system as the floc into the compactor. Emissions will be controlled through air extraction of the same type as is used on the autoclaves.

e. Cleaning Procedures

Please refer to response to Question 3c.

Specifically in relation to the offensive waste shredding activity, Section 3.1.2 of the October BAT Assessment details how, prior to the shredding of any non-hazardous waste, the shredder will be thoroughly cleaned and disinfected in order to prevent any cross-contamination of this waste from preceding hazardous loads. Disinfected would be sprayed into the shredder, hopper and screen. The same section also confirms that this cleaning activity could result in the generation of potentially contaminated effluent and therefore this would not be discharged to sewer but instead collected in a sealed tank and pumped into IBCs for transfer to a permitted energy from waste facility for recovery.

In the event that general housekeeping cleaning around the area of the shredder is required (e.g. due to waste spillage), any effluent would also be directed to the sealed tank.

f. BAT for Shredding Activity

The shredding activity removes the risk of bags splitting; these concerns relating to heavy compaction are therefore irrelevant. The bags cease to exist after shredding. The shredding and compactor loading is carried out with active air extraction, with odour controls (carbon filtration). Whilst liquid discharge isn't in reality observed (as other wastes act as an absorbent once shredded), any that is generated would be capture and discharged through either the drainage process or captured as effluent and managed via the IBC collection and transfer off site route.

Question 6 – Waste Throughput Increase & Floc Storage Capacity

a. Storage Clarification

The application seeks to retain the existing 55 tonnes storage limit for waste received on site (pre-treatment) for either treatment or onward transfer.

The application seeks to add to this a further 100 tonnes to allow the storage of treated floc and/or offensive (either shredded or direct compaction, the latter being an existing permitted activity). This would be in a maximum of 10 compactor skips.

The total storage on site would therefore be 155 tonnes.

b. Justification for Increase

The reason for the increased storage capacity for treated/compacted floc is that it is a contingency requirement. Compactor skips are collected on a wagon and drag system at a rate of two compactors per day. This means that there will always be a minimum of four on site (two full awaiting collection, one being filled, one being offensive). In the event that compactor skip collection is delayed or missed this would result in six being needed within 24 hours (four full awaiting collection, one being filled, one being offensive). With this in mind, the request for ten skips gives the applicant sufficient capacity to allow processing to continue if there is a breakdown in the skip exchange service. If the storage was limited to less than four skips, the facility could need to cease processing for minor vehicle breakdowns etc. Note that floc is not going to be stored for more than 7 days and older wastes will be always be prioritised for exchange over newer wastes.

c. Confirmation of Throughput Increase

To confirm, the request is not necessarily to increase the existing limit from 30,000 tonnes per year, but to allow for 100% of that limit to be applied to treatment. At the moment treatment is only allowed for up to 20,000 tonnes of the 30,000 tonnes.

d. Throughput vs Storage Capacity

Please see the response to Question 6c; the intention is not to increase to 60,000 tonnes but to allow treatment to be applied to 100% of the 30,000 tonne limit should it need it.

Question 7 – Odour Management Plan (OMP)

a. OMP Update

i. Inventory of all potentially odorous solid, liquid and gaseous materials.

Section 2 of the OMP submitted in June 2020 (ref. SHSMT_2020.02/07, revised in October 2020, v2) identifies the odour sources and presents them in a text form but also tabulated in Table OMP3. Table OMP3 has been updated to include maximum quantities of odorous materials, how and where they will be stored and the maximum storage duration.

Table OMP4 of the October OMP comprises a risk assessment and includes the specific odour controls that are applied to the odour sources set out in Section 2.

The revised OMP (ref. SHSMT_2020.02/07 v3) is provided in **Annex Sc5-4** of this response letter.

ii. Consideration of shredding, handling and compaction/storage of offensive waste.

Sections 2.2, 2.4 and 2.6 have been augmented to specifically include offensive waste as an additional odour source. This has been reflected also in the updated Table OMP3.

iii. Maximum Quantities for Odorous Materials

See response to i) above. Quantities have been added into Table OMP3.

iv. Storage duration for treated and other potentially odorous materials.

It is confirmed that floc storage is limited to 7 days. Effluent storage (in IBCs or a tank) could be for up to 2 weeks but this storage will always be within the confines of the building. The OMP has been amended to include storage durations (in Table OMP3).

v. Compactor skip locations/types

There is one external compactor skip in which compaction is actively undertaken, as shown on the site plan; this is used for compaction of un-shredded offensive bags and is an existing activity on the permit. Shredded offensive wastes (if/when this is carried out for contingency purposes) will be loaded into the internal compactor (within the building) along with autoclave floc and then stored outside once full, awaiting collection which is typically within 24 hours. The locations of the compactors/skips is given in the updated Table OMP3 and on the site plan provided in Annex OMP2.

vi. Consideration of the handling and storage of wash waters from the wash plant and effluent from the cleaning/disinfection of the site as potential of odour sources.

The odour source table, Table OMP3 has been updated to specifically include these potential odour sources.

vii. Location of potential sources of odour.

Location identifiers have been added into Table OMP3 and cross referenced by way of inclusion on a copy of the Site Layout Plan, provided in Annex OMP2.

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

It is confirmed that daily site inspections are undertaken; these include housekeeping and cleanliness checks which are of a visual nature and focus on the key areas of plant/equipment and potential pollution. Equipment is cleaned at the end of shifts prior to handover or at the point of process cessation if it is not running 24/7.

The OMP has been amended to reflect this.

ix. Olfactory monitoring

The applicant can confirm that that odour checks are in fact carried out daily as part of the site managers/supervisors daily checks, which are recorded on an app/electronic system. Wider audits are undertaken by the compliance departments as a secondary check, and this is typically monthly.

The daily checks will be carried out in accordance with EA guidance (H4) – collecting the information as presented in Annex OMP1 of the Odour Management Plan submitted in June and revised in October 2020.

Section 5 of the OMP has been amended to reflect this.

Close Out

We hope that this response addresses your queries and enables you to determine the application; we look forward to hearing from you soon.

Yours sincerely

Rebecca Hodkinson
Reva Environmental Limited