Stericycle Knowsley

Healthcare Waste Treatment Plant and Transfer Station

Environmental Permit Variation

Permit Reference KP3436NL

Application Document Number 06

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Version v1.1

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Part A – Overview

1. Permit Changes & Non-Technical Summary

1.1 Permit Changes

1.1.1 Summary – existing

Knowsley Healthcare Waste Treatment and Transfer Station is currently permitted (permit number KP3436NL) as an installation for the treatment and storage of hazardous healthcare waste and as a waste operation for the treatment and storage of non-hazardous healthcare waste.

The Knowsley installation comprises the following activities:

- (AR1) - Section 5.3 A(1)(a)(ii) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving physico-chemical treatment.
- (AR2) - Section 5.3 Part A(1)(a)(iv) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving repackaging.
- (AR3) - Section 5.6 Part A(1)(a) Temporary storage of hazardous waste with a total capacity exceeding 50 tonnes.

The following directly associated activities:

- (AR4) - Steam Supply
- (AR5) - Cleaning and disinfection of carts
- (AR6) – Raw material handling and storage

The following waste operations:

- (AR7) - Treatment of offensive waste by thermal treatment in one steam auger.
- (AR8) - Light compaction of nonhazardous waste.
- (AR9) - Repackaging of non-hazardous waste
- (AR10) - Storage of non-hazardous waste

1.1.2 Site Redevelopment Plan

Stericycle are completing a whole site refurbishment which includes alterations to the existing building; extension of the existing building; creation of seven new loading/unloading bays; the installation of two new heat treatment lines and repurposing of the existing heat treatment line.

The project is being driven by the improvement condition 2 (IC2) banning the storage of waste in trailers and Stericycle Knowsley will serve as the primary hub in Northern England for processing of clinical waste. The project increases processing capacity from 48 tonnes per day to 188 tonnes per day and includes the processing of medicinal sharps through the heat treatment lines to align with the recent permit variation at our sister facility in Telford, permit number MP3303SQ.

1.1.3 Variation purpose

The purpose of this variation is to:

1. Add additional treatment capacity to the installation (AR1) through the addition of two new heat treatment lines each capable of processing 55-70 tonnes per day. This will increase the sites total processing capability to 188 tonnes per day.

2. Alter the existing line to run as an installation for the processing of clinical waste (existing AR1) and as a waste operation activity (AR TBC) for the shredding of non-hazardous healthcare wastes for disposal or recovery interchangeably and update Table 2.5 to reflect the change.
3. Alter the storage areas and storage capacity (AR3 and AR10) to reflect the future site layout.
4. Add an additional activity for the medium combustion plant serving the two new heat treatment lines.
5. Permit the treatment of sharps waste classified as both infectious (180103) and medicinally contaminated (180109) within the installation activity (AR1) and make the necessary update to Table 2.2 to reflect the change.
6. Add storage of medicinally contaminated effluent to the directly associated activities to serve AR1 and point 5 above.
7. Add a wastewater treatment plant to the directly associated activities to serve AR1 and point 5 above.

With reference to the permitted activity references in table S1.1 of the permit the following changes will be made:

- Activity AR1 – Additional treatment capacity and permitting for the treatment of sharps waste (180103/180109)
- Activity AR2; AR9 – No change
- Activity AR3; AR10 – Updates to the storage areas and capacities
- Activity AR4; AR5; AR6 – No change
- Activity AR7 – Removal of the treatment of offensive waste by thermal treatment. This will be replaced by the new activity for mechanical treatment below.
- Activity AR8 – No change although AR TBC (1) and AR8 will be interchangeable.
- Activity AR TBC (1) – New activity. Mechanical treatment of non-hazardous (offensive) waste.
- Activity AR TBC (2) – New DAA. Addition of new combustion plant serving the two new installation plants which falls into scope under the Industrial Emissions Directive.
- Activity AR TBC (3) – New DAA. Storage of medicinally contaminated effluent.
- Activity AR TBC (4) – New DAA. Addition of a wastewater treatment plant to treat medicinally contaminated effluent before emissions to sewer.
- Activity AR TBC (5) – New DAA (not included in existing permit). Storage of treatment residues.

1.1.4 Future State Overview

The proposed development changes the way in which Stericycle handle and process healthcare wastes and has been designed to incorporate resilient and adaptable plants which are capable of operating in several modes. The purpose of this change is to enable better adaptation to processing capacity when waste inputs vary and to displace wastes that would be traditionally incinerated via alternative treatment to enable recovery/recycling options and move towards zero waste to landfill.

For context, Figure 1, Figure 2 and Figure 3 below explain the sites current and future configuration:

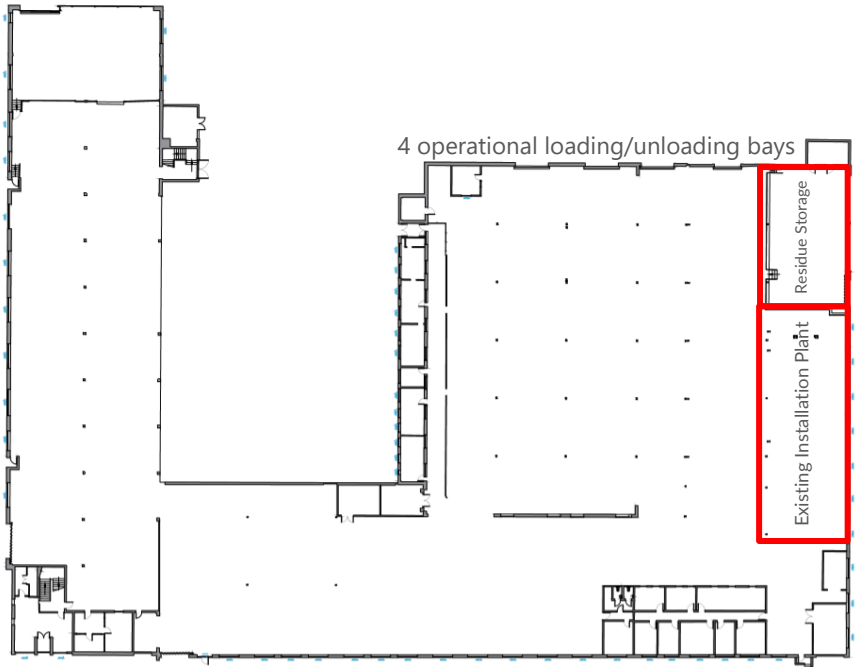


Figure 1 - Current Site Layout

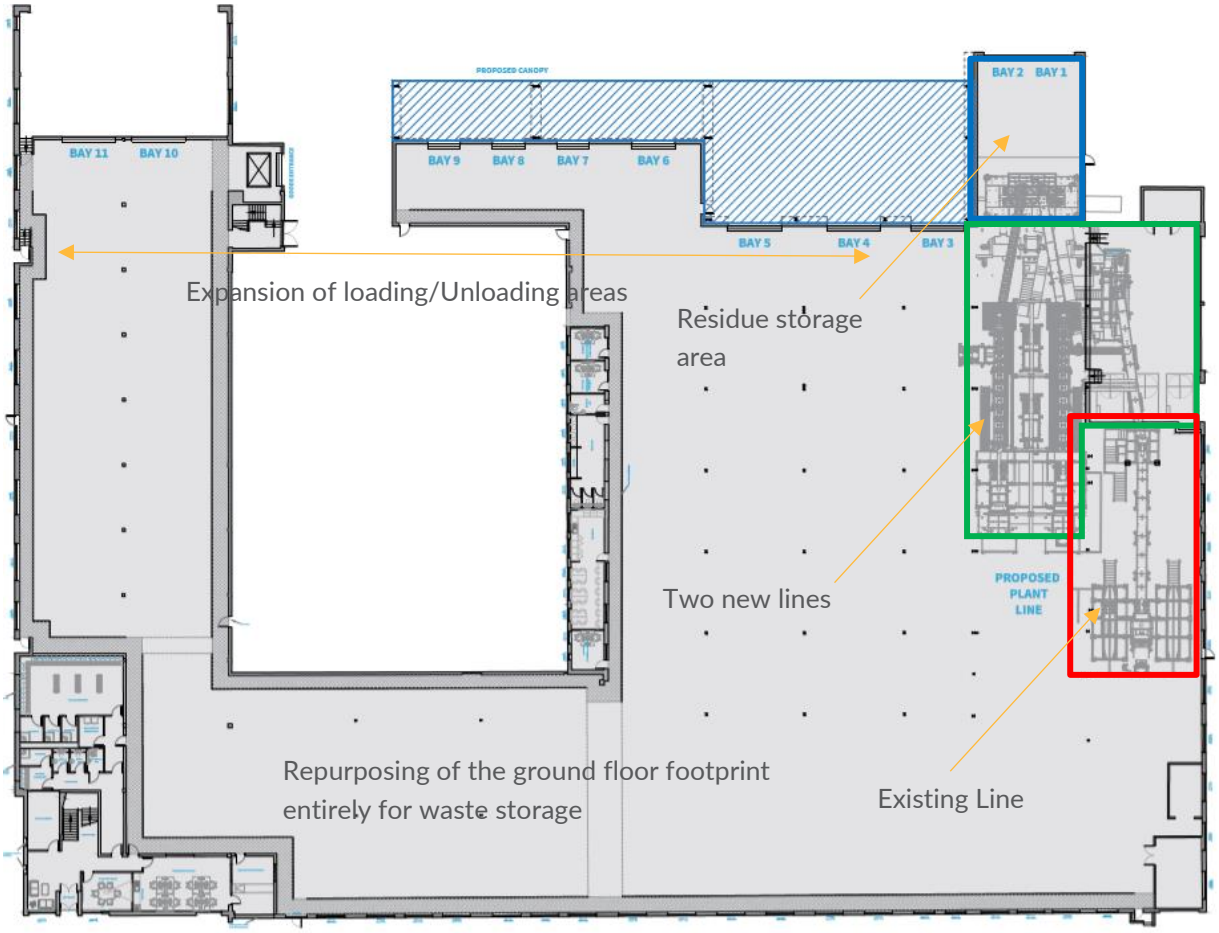
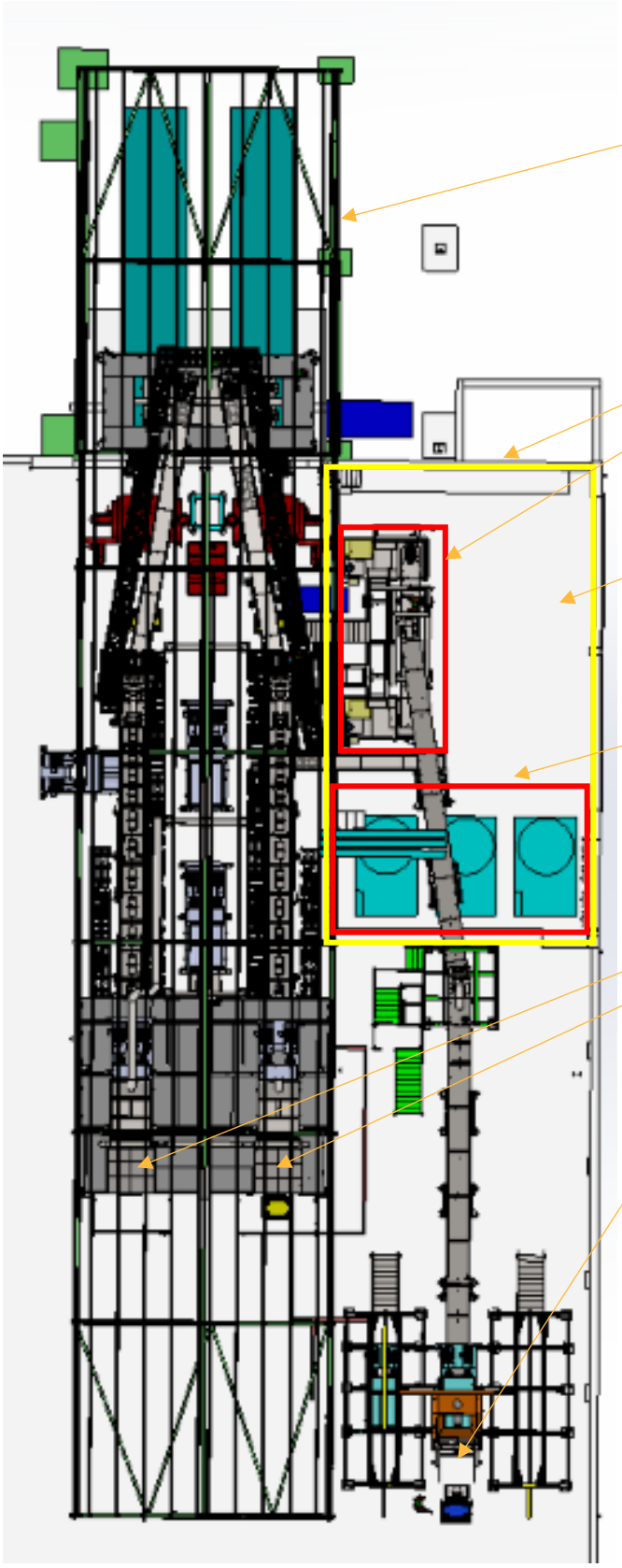


Figure 2 - Future Site Layout



Residue storage to be relocated into a new extension to the building and loaded directly into walking floor trailers from the two new lines and the existing line which currently loads into compactor skips.

The current residue storage area will be repurposed and the feed system to compactor skips and the compactor skips to be removed once Line 1 is operational.

The area currently occupied by compactor skips will house the effluent storage area and wastewater treatment plant.

The currently unused area to the south of this area will house three new abatement plants. The abatement plant on the existing line will be upgraded to match the new lines to meet the VOC emission limits.

Two new lines to be branded line 1 and 2 (Left to right) and the existing line will be rebranded as Line 3.

Lines will be able to operate in several different processing modes:

Mode 1 – Infectious waste

Mode 2 – Medicinally contaminated infectious waste

Mode 3 – Non-hazardous offensive waste

Line 1 and 2 will be capable of operating in processing modes 1 and 2.

Line 3 will be capable of operating in processing modes 1 and 3.

Figure 3 - Detailed Future Plant Layout

1.1.4.1 Plant Mode Configuration

Each plant will be capable of operating in several different modes controlled via the plants Programmable Logic Controller (PLC) and Supervisory Control and Data Acquisition (SCADA) system. The logic results in the automatic control of plant operating parameters, loading restrictions and effluent capture capabilities depending on which mode the plant is being operated in. This methodology ensures that each waste type is effectively treated, and emission pathways robustly controlled. The operating modes are as follows:

- Mode 1 – Heat treatment of infectious waste streams (as per the existing permit).
- Mode 2 – Heat treatment of waste allowable under Mode 1 plus medicinally contaminated sharps (180103/180109).
- Mode 3 – Mechanical processing of non-hazardous healthcare waste to facilitate recovery/disposal.

As way of a summary, parameters for each mode will be controlled as follows (Table 1):

Mode	Allowable Waste Types	Heat Settings	Effluent Pathway
Mode 1	Orange clinical waste stream (as per existing permit)	As per validated parameters	Sewer
Mode 2	As per mode 1 plus medicinally contaminated infectious sharps (180103/180109)	As per validated parameters	Effluent capture for offsite treatment/wastewater treatment plant
Mode 3	Offensive (tiger bagged) clinical waste streams	Heat turned off	Sewer

Table 1 - Processing Mode Summary

Each plant will operate within the following modes:

- Line 1 - Modes 1 and 2
- Line 2 –Modes 1 and 2
- Line 3 –Modes 1 and 3

1.1.4.2 Control Logic for Plant Operation

Following on from Table 1, the control logic for the plant operation is detailed and ensures emission pathways are controlled both during operation within a mode and when switching between modes. This results in the need for clean down time frames and delay timers to ensure medicinally contaminated effluents continue to be captured and appropriately treated between clean downs. Clean down regimes emission pathways will be discussed further throughout this application but for context, Figure 4 shows the detailed logic for the operation of the plant within each mode.

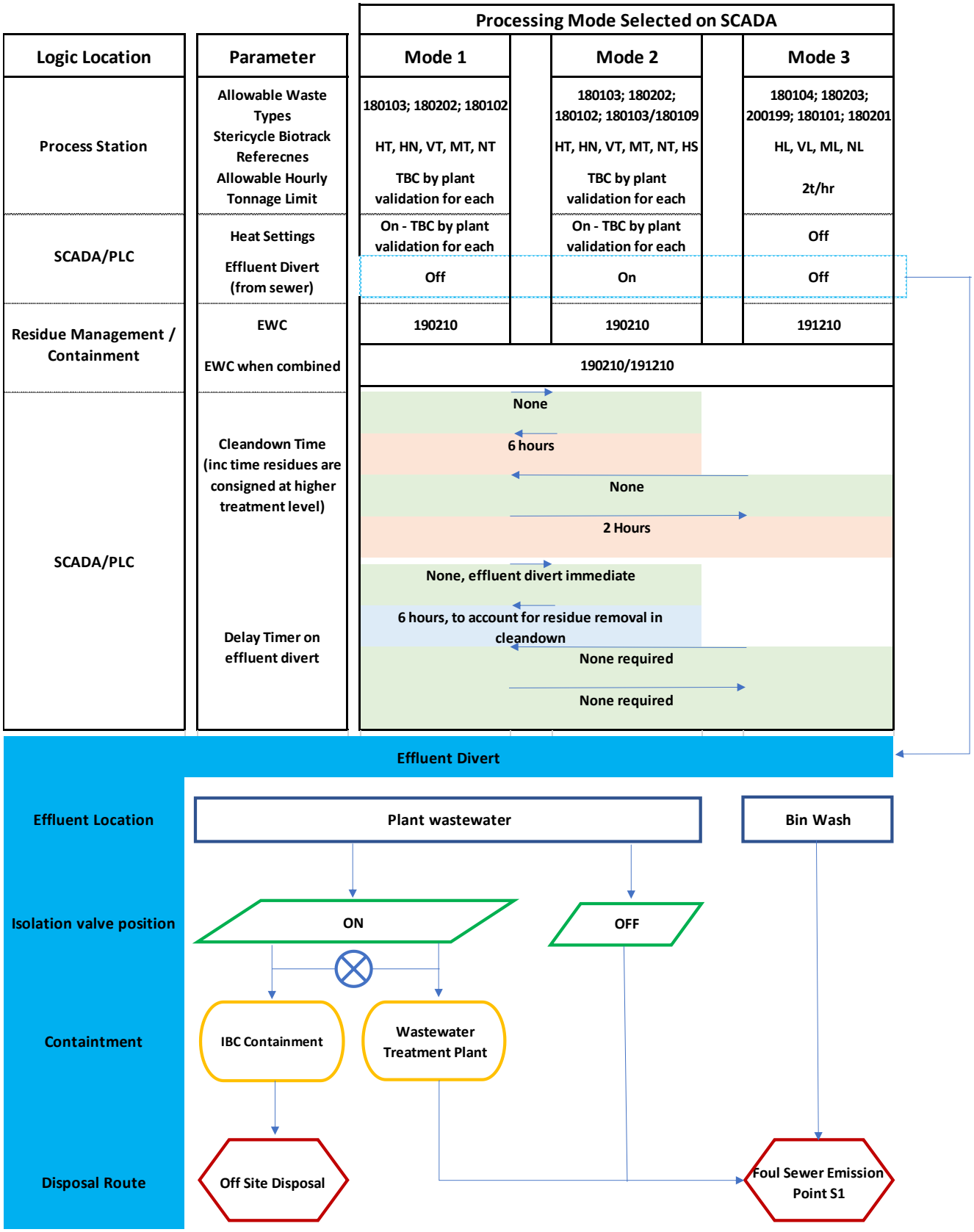


Figure 4 - Control Logic for Plant Operation

1.2 Non-technical Summary (New)

1.2.1 Overview

The proposed redevelopment development comprises a healthcare waste treatment plant and transfer station. The site will receive packaged healthcare and related wastes that are suitable for either on-site treatment (physio-chemical or mechanical) or transfer off-site to other disposal or recovery facilities.

The on-site treatment will comprise of three treatment lines, each consisting of a single steam auger with integral shredder for the following activities:

- Installation - Section 5.3 A(1)(a)(ii) Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving physico-chemical treatment. (Lines 1-3).
- Waste operation - the mechanical re-processing of non-hazardous healthcare wastes for disposal or recovery. (Line 3).

The following are directly associated activities to the treatment plant:

- Existing gas fired steam raising plant to supply the steam auger (Line 3). New gas fired stream raising plant to supply the stream auger (Line 1 and 2). New plant falls into the medium combustion plant category of the industrial combustion plant directive.
- Bin washing system for re-usable waste containers.
- Raw material handling and storage
- Storage of treatment plant residues pending transfer off-site for disposal or recovery.
- Storage of medicinally contaminated effluent produced by the installation pending offsite disposal/recovery.
- Wastewater treatment plant to treat medicinally contaminated effluent prior to discharge to sewer.

The transfer station consists of the following activities:

- Installation - Section 5.6 A(1)(a) Temporary storage of hazardous waste with a total capacity exceeding 50 tonnes.
- Waste operation - the storage of non-hazardous wastes pending on-site treatment or transfer off-site for disposal or recovery.
- Waste operation – repackaging of offensive waste (light compaction) pending transfer off site for disposal or recovery.
- Repackaging of hazardous waste.
- Repackaging of non-hazardous waste.

1.2.2 Main Features

Each treatment line consists of a shredder, a single chamber steam auger and pollution control equipment/abatement plant. Waste is shredded under negative pressure before transfer to the auger chamber where a combination of heat, moisture and residence time is sufficient to disinfect the waste. Steam is supplied to the auger from the gas fired steam raising plant. The steam can also be turned off to allow the mechanical only treatment of non-hazardous waste.

Off-gases from the auger and shredder pass through the abatement plant. The abatement plant consists of an air-to-air heat exchanger and condenser which condense the moisture from the gas stream into liquid and discharges them as wastewater which is either captured, treated and/or discharged to foul sewer.

The gas stream is then reheated via a duct heater before passing through a course, high efficiency particulate air (HEPA) and carbon (three-stage) filter. Together, the abatement plant has been designed to remove volatile

organic compounds (VOCs), any infectious bio-aerosols, moisture and any odours from the off-gases before their release to atmosphere.

Each treatment line has its own emission point to air from the treatment process where the final off-gases are released. There are a further three emission points to air from the existing and new gas fired steam raising plant. The wastewater treatment plant consists of a raw effluent tank, an oxidation tank, an adsorption and oxidation tank and a treated effluent tank. The treatment plant has a single point source emission to air for trace carbon dioxide and hydrogen off-gasses,

There is also an emission point to foul sewer for effluent arising from the treatment process condensate (directly or via the effluent treatment plant) and for effluent arising from the container washing process. There are no emissions to surface water arising from the activities at the site.

The shredded and treated residue is stored on site in walking floor trailers pending transfer off-site for recovery/recycling, use as a solid derived fuel or landfill (wastes from mode 1 and 3 only).

The thermal waste treatment process and mechanical treatment of offensive waste is undertaken wholly within the process building with no treatment activities being undertaken outside the building. Light compaction of offensive waste is the only activity which occurs externally however this is conducted on a loading bay which is under a canopy enclosed on three sides.

Waste is stored in designated storage areas inside the building and within a designated storage area for residues externally. All designated storage areas have impermeable surfaces with sealed drainage and all waste is stored in fully enclosed, leak-proof containers.

2. Permitted Activities

2.1 Activity Flowchart

Figure 5 shows the activity flowchart of the waste treatment and waste transfer operations and where the installation sites within both. AR's in green are existing but may require modification and AR's in red are new.

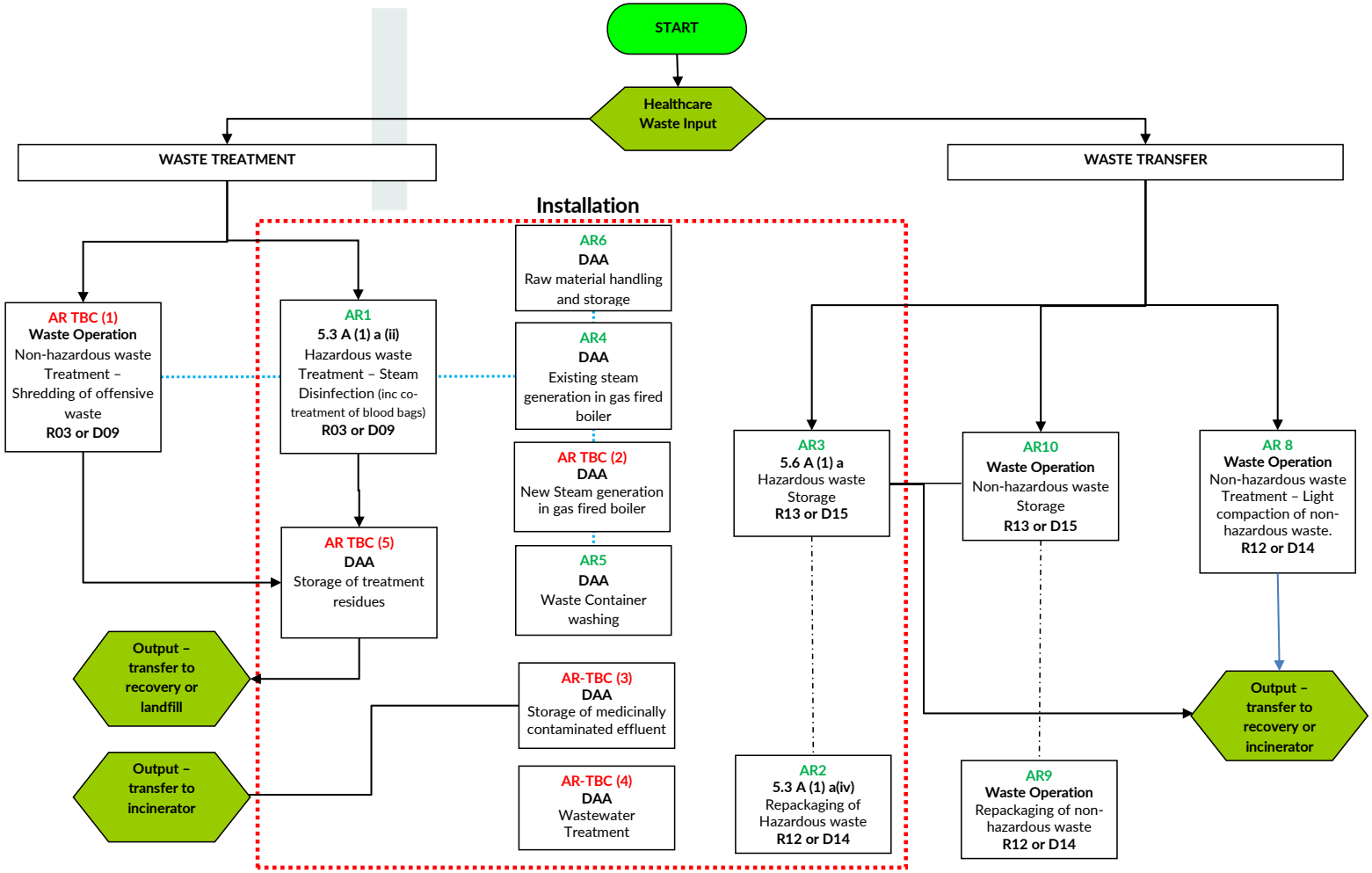


Figure 5 - Activity Flowchart

2.2 Installation and Waste Operation Activity Table

Name	Location	Description of the activity	Schedule 1 Ref	Activity Capacity	Annex IIA or IIB codes	Operating Modes
Installation Activities						
AR1 Hazardous Treatment	Treatment Plant	Steam Auger - Disinfection	5.3 A (1) a (ii)	Line 1 – 70 tonnes/day Line 2 - 70 tonnes/day Line 3 – 48 tonnes/day* 68,500 tonnes per annum combined	R03 or D09	Mode 1 or Mode 2
AR2 –Hazardous Waste Repackaging	Transfer Station	Transferring waste packages from one bulk container to another	5.3 A (1) (a) (iv)	N/A	R12 or D14	N/A
AR3 – Hazardous Waste Storage	Transfer Station	Waste storage in bulk containers e.g. carts	5.6 A (1) a	390 tonnes	R13 or D15	N/A
Directly Associated Activities						
AR4 – Steam Supply	Treatment Plant	Gas fired stream-raising boiler to Line 3 (existing)	N/A	Net thermal input 0.8 MWth	N/A	Mode 1 or Mode 3
AR TBC (2) – Steam Supply	Treatment Plant	Gas fired stream-raising boilers x 2 to Line 1 and 2	N/A	Net thermal input 1.25 MWth each	N/A	Mode 1 or Mode 2
AR5 – Cleaning and disinfection of carts	Treatment Plant/ Transfer Station	Automated washers that clean and disinfect reusable containers	N/A	N/A	N/A	N/A
AR6 – Raw material handling and storage	Treatment Plant/ Transfer Station	Oils, chemicals, detergents supporting the wider operation	N/A	N/A	N/A	N/A
AR TBC (5) – Storage of Process Residues	Treatment Plant	Storage of treated residues in walking floor trailers	N/A	212 tonnes	N/A	N/A
AR TBC (3) – Storage of Effluent	Treatment Plant	Storage of effluent contaminated with medicines for offsite disposal	N/A	60 tonnes in 60 IBC's	N/A	Mode 2
AR TBC (4) – Wastewater Treatment	Treatment Plant	Treatment of wastewater for organic and API content	N/A	N/A	N/A	N/A
Waste Operations						
AR TBC (1) – Mechanical treatment of non-hazardous waste	Treatment Plant	Shredding of non-hazardous offensive waste within the installation to facilitate recovery or disposal	N/A	Line 3 - 48 tonnes/day* 17,500 tonnes per annum	R03 or D09	Mode 3

AR8 – Light compaction of non-hazardous waste	Transfer Station	Light compaction of offensive wastes	N/A	48 tonnes/day	R12 or D14	N/A
AR9 – Non-hazardous Waste Repackaging	Transfer Station	Transferring waste packages from one bulk container to another	N/A	N/A	R12 or D14	N/A
AR10 – Non-hazardous Waste Storage	Transfer Station	Waste storage in bulk containers e.g. carts	N/A	93 tonnes	R13 or D15	N/A
*AR1 Line 3 and AR TBC (1) (Mechanical treatment of non-hazardous waste) are interchangeable i.e. the Line 3 of the installation can only operate in one mode and with one waste type at a time. When switching between modes the plant will be subject to clean town protocols as set out in this application.						

Table 2 - Installation and Waste Operation Activities

2.3 BAT and Supplementary Information

All activities will be operated in accordance with Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities', and as a consequence Stericycle believes that the operational processes and techniques to be used represent best available techniques (BAT). Where an operation deviates from Bat, this is discussed as follows.

2.3.1 AR1 – Processing of medicinally contaminated sharps

Justification for the deviation from BAT is set out in section 3.2 of this application.

2.3.2 AR TBC (1) – Mechanical treatment of non-hazardous waste

This activity does not deviate from BAT but is conducted within the treatment installation when operating in Mode 3 i.e. with no heat or steam being applied to the waste. Section 9 of this report details the operational techniques to clean down the installation between operational modes and ensure there is no cross contamination of waste streams. All abatement and emission control techniques do not differ from that of the treatment activity.

3. Permitted Wastes

3.1 Alternations to Waste Codes

3.1.1 Activity Reference AR1 – Medicinally Contaminated Sharps Processing

The following codes need altering on installation Activity Reference AR1:

- Sharps waste classified as both infectious (18 01 03) and medicinally contaminated (18 01 09).

To allow for this EWC code 18 01 09 will need to be added to table S2.2; and the text against code 18 01 03 and Note 1 amended to allow for the processing of sharps contaminated with non-hazardous medicines (whether fully discharged, partially discharged or undischarged).

This change will only apply to 18 01 03 / 18 01 09 infectious medicinal sharps waste. We do not propose to treat either of the following waste streams:

- Any hazardous medicinal wastes (cytotoxic / cytostatic 18 01 08)
- Any pharmaceutical waste that is not also infectious sharps waste (non-hazardous medicines 18 01 09)

3.1.2 Activity Reference TBC (1)

The following codes need adding into a new table for the proposed activity reference AR TBC (1), the mechanical processing of non-hazardous wastes when the plant operates in Mode 3.

Waste Types for Mechanical Processing – Activity AR TBC	
Maximum Quantity	48 tonnes per day (Interchangeable with the maximum quantity within AR1 for Line 3)
Hazard Properties	None
Waste Code	**Description**
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	non-infectious sharps
18 01 04	non-infectious offensive waste – human healthcare
18 02	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	non-infectious sharps
18 02 03	non-infectious offensive waste
20	MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS

20 01	separately collected fractions (except 15 01)
20 01 99	non-infectious offensive waste – municipal, separately collected fractions not from healthcare or research-related sources

Table 3 – AR TBC Waste Codes

3.2 Bat and Supplementary Information

3.2.1 Activity Reference AR1 – Medicinally Contaminated Sharps Processing

Stericycle are innovating to permit the treatment of medicinally contaminated sharps within an alternative technology treatment process. This change proposes alternatives to the following BAT points defined in Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities':

- Waste treatment appropriate measures (section 5)
- Emissions control appropriate measures (section 6)
- Emissions monitoring and limits appropriate measures (section 7)

This change has recently been permitted at our Telford facility, permit reference MP3303SQ. Part C (Section 14) of this report provides and assessment of the pharmaceutical inputs to and outputs from the process, and the relevant sections of this report describe how the emissions will be controlled and worst-case scenario tested. This change increases opportunities for this waste stream to be recovered/recycled. Together, this demonstrates that heat disinfection treatment of the infectious medicinal sharps waste stream represents BAT and that risks to the environment are controlled.

The changes proposed do not result in the installation deviating from waste treatment BAT (other than where specified in the original permit application) with the exceptions set out in Table 4 below. Where a new deviation from BAT applies, a justification is provided with reference to the corresponding sections of this report.

Section	BAT Point	Deviation	Justification	Report Reference
5.1 General Waste Treatment	5. For a relevant waste to be considered rendered safe, your treatment process must: - reduce the number of infectious organisms present in any infectious waste to a level that no additional precautions are needed to protect workers or the public against infection by the waste - destroy any anatomical waste (human or animal tissue) so that it is no longer recognisable - make any clinical waste (including any medical equipment and items) unusable and unrecognisable - destroy the component substances of any chemical, or medicinal and medicinally-contaminated waste - make any patient information within the waste unrecognisable	Process will not destroy the component substances of medicinal products within the medicinally contaminated sharps waste.	Process is not designed to do this, but ensures abatement and containment so there are no emissions of medicinal products. Destruction of residual medicinal products is achieved in the downstream recovery process.	8) Waste Treatment Process 9) Techniques for Pollution Control
5.1 General Waste Treatment	11. You must exclude the following wastes from alternative treatment activities – unless you have provided us with additional written justification for their treatment and we have specifically permitted and approved your plant for the treatment of these wastes: - waste medicines and chemicals wastes contaminated with or containing residual medicines or other chemicals,	Wastes contaminated with residual medicines will not be excluded from alternative treatment activities.	This application provides written justification for their treatment, and this variation is to seek approval to vary the permit to allow	3) Permitted Wastes 8.4 Commissioning and Validation

Section	BAT Point	Deviation	Justification	Report Reference
	including syringes that are fully discharged, partially discharged or undischarged (for example 18 01 03* infectious waste contaminated with 18 01 09 medicines) - non-infectious wastes (for example 18 01 04 offensive hygiene wastes) - anatomical waste - dental amalgam Justification for the alternative treatment of these wastes must assess any impact on emissions to air and water from the facility and demonstrate that the treatment: - is effective (including validation of worst-case scenario wastes and conditions) - is an efficient use of energy and raw materials - enhances the recovery or recycling of the waste where possible - does not impede the treatment of any other wastes		treatment of these wastes. This application assesses the impact on emissions to air and water from the facility and also demonstrates that the process will be effective, is an efficient use of energy and raw materials, does not impede the treatment of any other wastes and allows for the continued recovery of the waste.	11 Raw Materials 12 Resource Efficiency and Climate Change
5.1 General Waste Treatment	14. You must correctly describe, classify and code waste from alternative treatment using the appropriate LoW codes to make sure that it reflects the residual characteristics and properties. Here are some examples of different treatment scenarios, and the LoW codes to use for the wastes produced. **Waste hazardous by 'infectious' property only** If you are treating (rendering safe) waste that is hazardous by 'infectious' property only (orange stream waste – 18 01 03, 18 02 02 and 20 01 99) use these waste codes: 19 02 10 (if combustible) 19 02 06 or 19 02 99 depending upon nature of output material **Waste contaminated with or containing hazardous chemicals or medicines** If you are treating infectious waste containing or contaminated with hazardous chemicals or medicines, which are not specifically treated (removed or destroyed) by the treatment process, use the waste code 19 02 04*. You can only use waste codes 19 02 06, 19 02 10, or 19 02 99 if the treatment plant validation demonstrates that the process renders the waste safe and treats all chemical and medicines (including pharmaceutically active substances).	The BAT text does not include a scenario that is relevant to this application. Options are provided that cover: - when only infectious waste is treated. - when waste contaminated with hazardous medicines which have not been removed or destroyed has been treated. - when waste contaminated with any medicines has been treated, and the treatment process does remove or destroy the medicines. In the scenario proposed in this application, waste contaminated with non-hazardous medicines which the process does not destroy will be treated. The BAT guidance does not specify coding in this scenario.	The BAT text does not specify a code for the output material in the scenario proposed in this application. We therefore propose to code the output material as 19 02 10 because the pharmaceutical content present will be negligible. This is consistent with what has been agreed at other Stricycle facilities.	1.1.4.1) Plant Mode Configuration
5.2 Plant Commissioning and validating the efficacy of treatment	7. You must repeat plant validation and send a validation report to the Environment Agency at these points: periodically throughout the operational life of the plant and at intervals of 4 years or less if any process parameters (for example, treatment duration, temperature, pressure, mass or type of waste) differ from those assessed during site commissioning	No deviation but a plant validation will be required for each waste type to demonstrate effectiveness.	Plant validation will be completed with new challenge load including medicinally contaminated sharps waste. When switching between processing modes, the plant will be	8.4) Commissioning and Validation 1.1.4.1) Plant Mode Configuration

Section	BAT Point	Deviation	Justification	Report Reference
	if you make any changes to the design or engineering of the treatment plant before restarting treatment operations after a routine monitoring failure if changes to the healthcare waste stream mean that the worst case scenario challenge load considered during the original site commissioning validation is no longer the worst case scenario		capable of changing set points to ensure it operates within the validated parameters for that operational mode. This is consistent with what has been agreed at other Stricycle facilities.	
5.4 Validation tests treating wastes contaminated with or containing medicines	1. Validation tests must demonstrate that the plant is capable of destroying the range of pharmaceuticals and active ingredients that may be present in the waste stream. You must base your identification of potential substances (including potential breakdown products), and assessment of their thermal stability and decomposition, on an initial review of available literature. This must be supported by laboratory scale trials, where appropriate, to define a worst case challenge load.	Point 1 is not relevant as the treatment process is not capable of destroying the active pharmaceutical ingredients in the waste, and we do not claim that it is. The purpose of the treatment process is to disinfect the waste while containing any pharmaceutical content.	As the purpose of the treatment is to disinfect the waste, the validation process for infectious wastes is relevant and will be followed. We have however completed a detailed assessment of the potential pharmaceutical substances present, and an assessment of their thermal stability and decomposition. The purpose of this assessment is determine the fate of the pharmaceutical content in the process to ensure that emissions can be controlled.	Part C 14) Processing of Medicinally Contaminated Sharps – Supporting Evidence
5.4 Validation tests treating wastes contaminated with or containing medicines	2. Validation tests must assess and demonstrate the efficacy of each plant. These must involve: - a control run - a minimum of 3 test runs considering at least 3 worst case substances The 3 worst case substances are those that literature reviews and trials have identified as being the most thermally resistant. You must dose the waste with the substances so the concentration is significantly higher than the limit of detection and the background level of any potentially interfering pharmaceuticals or other chemicals. 3. You should introduce chemical tracer dyes resistant to the treatment process with the pharmaceuticals to demonstrate the treated waste is homogenous and material sampling is appropriate. 4. You must consider and assess any effect on plant emissions that may result from the treatment of the pharmaceuticals.	Validation test will be undertaken as specified with a single deviation from BAT point 2. Because the process is not designed to destroy the active pharmaceutical compounds present there is no need to use the most thermally resistant substances as an appropriate worst case.	The challenge load substances will be selected from the shortlist of target substances outlined in Part C of this report on the basis that the substance must be stable in either solid phase or liquid phase at the process operating temperatures, and that the substance can be obtained to undertake quantitative analysis.	Part C 14) Processing of Medicinally Contaminated Sharps – Supporting Evidence
Emissions Monitoring appropriate measures - Point Source	3. If your treatment plant treats pharmaceutically or chemically contaminated wastes, for example, medicinally contaminated sharps (even if fully discharged), you must propose and agree with the Environment Agency emission limits and monitoring	No specific deviation however monitoring requirements proposed are	The assessment of the fate of pharmaceutical products in the waste stream demonstrates that the residual	Part C 14) Processing of Medicinally Contaminated

Section	BAT Point	Deviation	Justification	Report Reference
Emissions to air	requirements for relevant substances. This will be based on an assessment of the range of pharmaceuticals and chemicals in use and their: - occurrence and concentration within the waste - properties and behaviour when subjected to - - the treatment process predicted environmental impact	the same as for infectious waste treatment.	quantities present will be fully retained in the output waste, the process effluent or the abatement system filters. There will be no additional emissions to air as a consequence of this application and therefore we do not propose monitoring for any additional substances (other than specified under BAT point 4 in the same section).	Sharps – Supporting Evidence Part A/B 4) Emissions 0) Emissions Monitoring
Emissions Control appropriate measures - Point Source Emissions to water and sewer	4. To reduce emissions to water and sewer, if you need to treat waste water before discharge or disposal, you must use an appropriate combination of treatment techniques, including one or more of the following: - preliminary or primary treatment – for example, equalisation, neutralisation or physical separation - physico-chemical treatment – for example, adsorption, distillation or rectification, precipitation, chemical oxidation or reduction, evaporation, ion exchange, or stripping - biological treatment – for example, activated sludge process or membrane bioreactor - nitrogen removal – for example, nitrification and denitrification - solids removal – for example, coagulation and flocculation, sedimentation, filtration or flotation 6. You must not discharge sharps or medicines (for example, resulting from the washing of reusable sharps bins) to surface water, storm drainage or foul sewer.	Proposed wastewater treatment is in line with BAT point 4 (adsorption and oxidation) and wastewater controls ensure that Bat point 6 is met.	No deviation from BAT.	4) Emissions 9) Techniques for Pollution Control 0) Emissions Monitoring
Emissions Monitoring appropriate measures - Point Source Emissions to water and sewer	4. If your treatment plant is authorised to process medicinally or chemically contaminated waste, for example, medicinally contaminated sharps (even if fully discharged), you must propose and agree with the Environment Agency emission limits and monitoring requirements for relevant substances. You will need to assess the range of chemicals and pharmaceuticals in use and their: - occurrence and concentration within the waste - properties and behaviour when subjected to the treatment process - predicted environmental impact	Emission limits and monitoring requirements not yet agreed, to be determined through trial process.	No deviation from BAT. Emission limits for API's in wastewater to be agreed with Environment Agency.	4) Emissions 9) Techniques for Pollution Control 0) Emissions Monitoring

Table 4 - Medicinally Contaminated Sharps Processing BAT Justification

4. Emissions

4.1 Overview

4.1.1 Existing

The facility currently has three emission points as follows:

- A1 – Point source emission from process abatement
- A2 – Point source emission from gas fired boiler exhaust
- S1 – Point source emission for effluent to sewer

A1 and A2 arise from the treatment plant activities (installation and operation) and S1 arises from a directly associated activity to the installation.

4.1.2 Proposed

The installation of two new treatment lines will result in the addition of 5 new point source emissions to air. The existing plant will retain two-point source emissions to air but the location of A1 will alter slightly due to the roof alterations taking place. S1 will remain but the location will change due to the reconfiguration of the drainage infrastructure and addition of a wastewater treatment plant. Table 5 below outlines all of the emission points and notes which are existing, new and/or moved location. Emission parameters for each emission point are also defined in section 0.

Ref	Location	Source	Pathway	Existing/New	Moved location
A1	Treatment plant exhaust	Treatment plant abatement system for Line 1	Air	New	N/A
A2	Treatment plant exhaust	Treatment plant abatement system for Line 2	Air	New	N/A
A3	Treatment plant exhaust	Treatment plant abatement system for Line 3	Air	Existing (currently A1)	No
A4	Boiler exhaust	Steam raising boiler for Line 1	Air	New	N/A
A5	Boiler exhaust	Steam raising boiler for Line 2	Air	New	N/A
A6	Boiler exhaust	Steam raising boiler for Line 3	Air	Existing (currently A2)	Yes
A7	Wastewater treatment plant exhaust	Wastewater treatment plant serving lines in isolation or collectively	Air	New	N/A
S1	Wastewater discharge point	Treatment plant, wastewater treatment plant and bin wash effluent	Sewer	Existing	Yes

Table 5 - Emission Points

4.2 Emission Parameters, Limits & Controls

4.2.1 Emission Parameters and Limits

Ref	Source	Parameter	Limit
A1	Treatment plant abatement system for Line 1	Bacillus spores	1000 cfu per cubic metre
		Total volatile organic compounds (TVOC)	30 mg per cubic metre
		Speciated volatile organic compounds	None
		Particulate matter	5 mg per cubic meter* * See section 4.4
A2	Treatment plant abatement system for Line 2	Bacillus spores	1000 cfu per cubic metre
		Total volatile organic compounds (TVOC)	30 mg per cubic metre
		Speciated volatile organic compounds	None
		Particulate matter	5 mg per cubic meter* * See section 4.4
A3	Treatment plant abatement system for Line 3	Bacillus spores	1000 cfu per cubic metre
		Total volatile organic compounds (TVOC)	30 mg per cubic metre
		Particulate matter	5 mg per cubic meter* * See section 4.4
A4	Steam raising boiler for Line 1	NOx	100 mg per cubic metre
A5	Steam raising boiler for Line 2	NOx	100 mg per cubic metre
A6	Steam raising boiler for Line 3	N/A	N/A
A7	Wastewater treatment plant	N/A	N/A
S1	Treatment plant, wastewater treatment plant and bin wash effluent	Bacillus Spores (spiked organisms)	300 cfu per litre
		API Concentration (paracetamol) (future requirement, emission from wastewater treatment plant)	To be agreed

Table 6 - Emissions Monitoring Parameters

4.2.2 Point Source Emissions to Air

4.2.2.1 Treatment Plant Abatement (A1-A3)

Each new treatment line (Line 1 and 2) will be served by a pollution control system designed to reduce and minimise any impact from the emissions listed in Table 6. The existing pollution control system on Line 3 will be upgraded to mirror those on the new lines. This will result in a repositioning of the emission point to facilitate routine monitoring positioning the monitoring point for each line together. The pollution control system is outlined in section 9.

4.2.2.2 Steam raising boiler (A4-6)

New (A4 and A5)

Emissions arising from the new steam raising boiler fall under the medium combustion plant category of the Industrial Emission Directive. As such may require monitoring within 4 months of first operation then periodic monitoring every three years thereafter. The boiler is of a modern high efficiency design with self-modulating boilers designed to optimize combustion. The maximum thermal rating of each boiler is 1.25 megawatts thermal with a NOx emission of <100mg/m^3.

Combustion plant emissions modelling has been completed as part of the planning application. A copy of the report is attached as Appendix 6 – Air Quality Assessment.

Existing

Emissions arising from the steam raising boiler will be below thresholds requiring further assessment. The boiler will be of a modern high efficiency design with self-modulating burners designed to optimise combustion. The maximum thermal rating of the boiler is 854 kilowatts. The existing plant was included in the combustion plant emissions modelling has been completed as part of the planning application. A copy of the report is attached as Appendix 6 – Air Quality Assessment.

4.2.2.3 Wastewater Treatment Plant

The wastewater treatment plant will serve any of the lines in isolation or collectively depending on which mode they are operating in. Process control of these emissions is detailed within the control logic outlined in Figure 4 (Section 1.1.4.2). Emissions result from the oxidation process within the treatment vessels and are at trace concentrations only. No routine monitoring is proposed. The system is outlined further in section 9.4.

4.2.3 Point Source Emissions to Sewer

Effluent entering the sewer discharge point originates from one of the following locations:

- Condensate from the treatment plant pollution control systems
- Effluent from the bin washing process
- Treated discharge from the wastewater treatment plant
- Boiler blowdown

Process control of these emissions is detailed within the control logic outlined in Figure 4 (Section 1.1.4.2). Operating techniques for the management of medicinally contaminated effluent is outlined in section 9.4.

Mode 1 and 3 Operation

Condensate arising from the treatment plant pollution control system and effluent from the bin washing process is transferred directly to foul sewer. Experience at other Stericycle facilities indicates that clinical waste

treatment effluents routinely comply with all terms of the discharge consents for the facilities and are also within benchmark thresholds for microbial emissions. Table 7 provides character data for effluent from a comparable steam auger facility operated by Stericycle. The character is defined separately between for that produce when operating in Mode 1 and 3 and that when operating in Mode 2.

Parameter	Mode 1/3 Operation	Mode 2 Operation
Chemical oxygen demand (COD)	1000-8000 mg/l	5000-20000 mg/l
Biological oxygen demand (BOD)	100-1000 mg/l	100-2000 mg/l
Suspended solids	< 100 mg/l	< 100 mg/l
pH	7.5 – 9.5	7.5-10.5
Anionic detergents	< 50 mg/l	< 50 mg/l
Sulphate	< 50 mg/l	< 50 mg/l
Sulphide	<0.01 mg/l	<1 mg/l
Phosphorous	<1 mg/l	<1 mg/l
Arsenic	<0.01 mg/l	<0.01 mg/l
Cadmium	<0.01 mg/l	<0.01 mg/l
Chromium	<0.01 mg/l	<0.01 mg/l
Copper	<0.01 mg/l	<0.01 mg/l
Mercury	<1 µg/l	<1 µg/l
Nickel	<0.01 mg/l	<0.01 mg/l
Lead	<0.01 mg/l	<0.01 mg/l
Zinc	<0.01 mg/l	<0.01 mg/l
Volume	<3m3 per day	<29m3 per day

Table 7 - Typical Effluent Parameters

Stericycle already operate a trade effluent discharge consent with the sewerage undertaker (United Utilities) to cover discharge of these effluents plus vehicle washings and will undertake any monitoring as required by the consent. Monitoring of general characteristics required within the emission monitoring and limits section of the Healthcare Waste: appropriate measures for permitted facilities guidance.

Monitoring of microbial emissions to sewer is undertaken annually and Stericycle propose no change to this frequency.

Mode 2 Operation

When operating in Mode 2, the plant will initially capture condensate generated from the pollution control system for off-site disposal. When switching from Mode 2 to Mode 1 or 3, effluent will divert back to foul sewer. Operational techniques for the capture system are outlined in section 9.4.

Once the plant is operational, Stericycle will install a wastewater treatment plant which will abate API and organic concentration in the wastewater prior to discharge to the sewer. It is expected that the wastewater treatment plant will be added to the permit with a pre-operational condition to define the monitoring parameter for API concentration outlined in Table 6.

When operating in Mode 2, effluent from the bin washing process will continue to drain directly to foul sewer.

Wastewater Treatment Plant

Stericycle may use the wastewater treatment plant for treatment of effluent in any mode according to operational preferences but it will be mandatory when operating in Mode 2.

4.2.4 Other Point Source Emissions

This variation has no change to other point source emissions. There are no point source emissions to groundwater, surface water or land as a result of the activities at the site.

4.2.5 Fugitive Emissions

This variation has no change to fugitive emissions on site.

The loading of process resides is conducted within the building and the new treatment lines are designed to the same philosophy as the existing as outlined within the original application.

4.2.6 Waste Transfers Off-Site

Treated waste residue and the shredded offensive waste (known as flock) will be transferred off-site for recovery as a solid derived fuel or recycling of metal/polymer components. Recovery/recycling of the flock using this method is subject to operational viability and regulatory approval at the receiving sites.

It may at periods be necessary to transfer the flock to disposal via landfill if the receiving recovery outlet cannot accept waste e.g. during shutdowns. This will only take place for wastes produced during Mode 1 and 3 i.e. wastes with no medicinal contamination. Medicinally contaminated flock produced in Mode 2 will only be sent to recovery facilities. The pre-acceptance and acceptance measures in place will ensure that the treated flock contains no hazardous components and will not have any adverse impact on land or groundwater.

Additional controls are in place for residues produced in Mode 2 or mixed residues when Mode 2 waste is present. These residues will be destined for energy to waste recovery or via an intermediatory recovery facility for the removal of metals and polymers from the flock for recycling. Remaining residues will be subject to energy to waste recovery.

Figure 4 in section 1.1.4.2 of this report shows the residue management of each waste in isolation and when combined.

Captured medicinally contaminated effluent will be transferred off-site for high temperature incineration. Processing of effluent using this method is subject to operational viability and regulatory approval at the receiving sites.

4.3 Location of Point Source Emissions Points

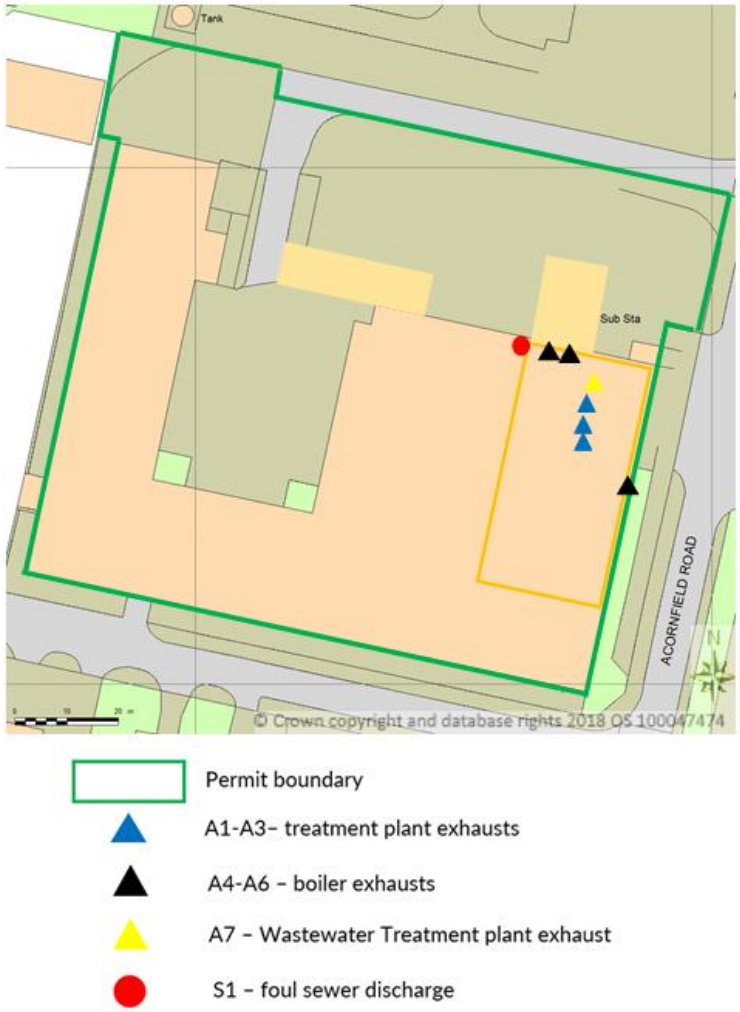


Figure 6 - Emission Points (Basic Plan)

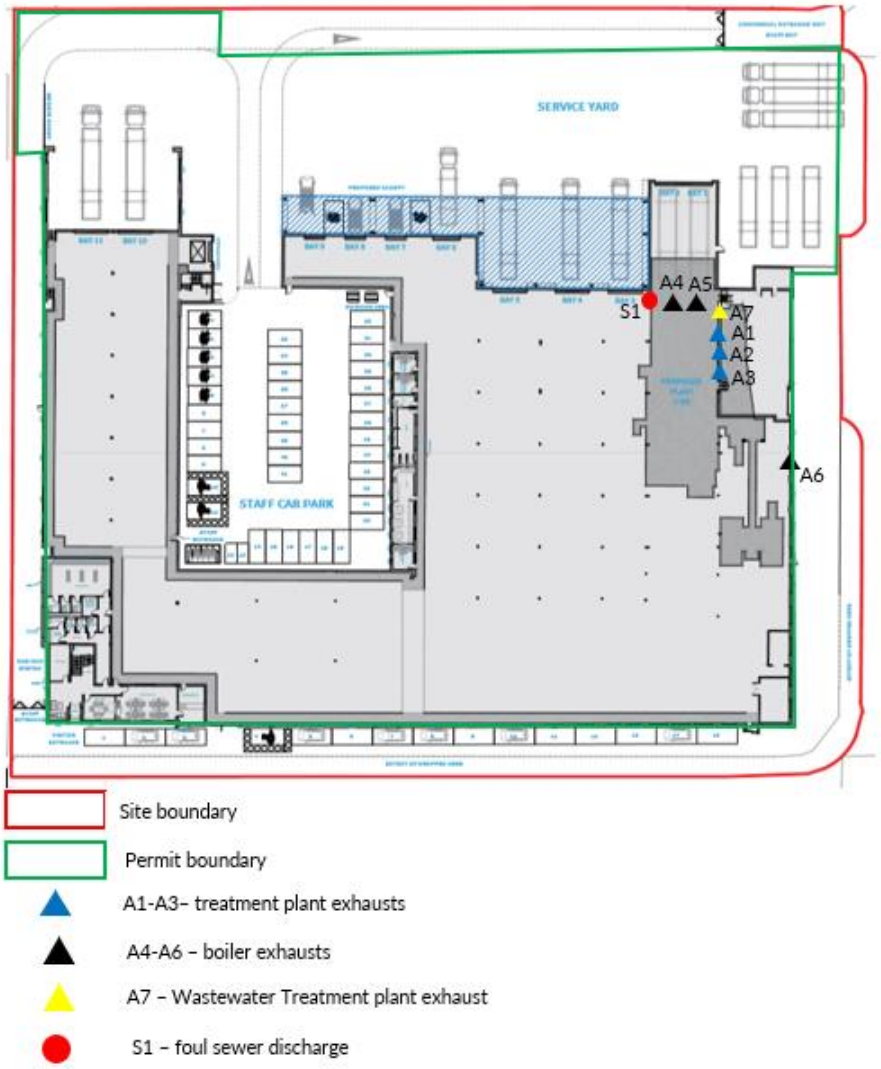


Figure 7 - Emission Points (Detailed Plan)

4.4 BAT and Supplementary Information

4.4.1 Particulate Matter

*Stericycle believe this emission parameter can be screened out from the monitoring requirements. Emissions points A1, A2 and A3 are all linked to both the shredder hopper and the steam auger of line 1, 2 and 3 respectively. Neither the shredder nor the steam auger generates dust due to the material being processed (healthcare wastes tend to be heavy in plastics and have high moisture content). All emissions pass through an abatement system fitted with a H13 HEPA filter with a 99.95% efficacy rate before being discharged to atmosphere. This system will not allow dust through the HEPA to reach the emission point and the filters are subject an annual LEV test to assess their lifespan then routine replacement as a result. It is expected that this parameter will be screened out via Improvement Condition IC4 by the time this variation is determined and as such can be omitted from the varied permit.

4.4.2 Stack and Monitoring BAT

All stacks have been designed to take account of the relevant sections of the Environment agency guidance document M1 Monitoring Stack Emissions and all sampling ports are designed to meet the relevant sections of BS EN 15259.

Part B – Operating Techniques

5. Technical Standards and General Requirements

The site will operate as it does currently with no change of use. As such, the Healthcare Waste: appropriate measures for permitted facilities guidance remains the only relevant sector guidance.

The site will operate in accordance with the sector guidance except where alternative measures are currently listed within Table S1.2 of the permit or alternative measures are proposed as part of this application document.

The company's Business Management System (BMS) includes policies, procedures and work instructions designed to ensure compliance with all permit conditions and that meet the BAT requirements for general management specified within the Healthcare Waste: appropriate measures for permitted facilities guidance.

6. Waste Pre-Acceptance and Acceptance

6.1 Waste Pre-Acceptance

There are no fundamental changes to the waste pre-acceptance measures submitted for the existing permit but Stericycle have made some additions following issue of a permit to process sharps waste at another Stericycle facility. These measures ensure that healthcare waste producers are aware that their medicinal sharps waste may no longer go for incineration and may be subject to alternative treatment. As such, accurate segregation becomes more prevalent. Stericycle have implemented the following:

- Completed a customer awareness campaign (through direct customer contact via our Account Management team) to ensure that waste producers know that sharps waste may be disposed via technology other than incineration.
- Ensured that checks on the presence of non-sharps medicinal waste in sharps containers is included on the pre-acceptance audit protocol for audits undertaken by our own team, and that the checks on the same are included on the audit review protocol for audits received from customers.

6.2 Waste Acceptance

There are no changes to the acceptance measures submitted for the existing permit.

7. Waste Storage

7.1 Description

7.1.1 Justification

The storage area designations and capacities within AR3 and AR10 require amendment to reflect the future site layout. All waste will be stored and dispatched from the facility in accordance with the requirements of Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities' except where currently referenced in Table S1.2 Operating Techniques of the current permit. In addition to this, the redevelopment will not alter the deadline currently listed for improvement condition IC2. The redevelopment is phased and will require all phases to be completed before IC2 can be discharged.

7.1.2 Process residues

The permit variation will also change the method in which process residues are stored for the new and existing lines. The compaction of residues into skips will cease and all residues will be loaded into walking floor trailers inside the building. The walking floor enclosure (which is an extension to the existing building) is fully enclosed with a roller shutter door for access when changing trailers. It will house two trailers with the external area adjacent to it capable of holding an additional six either empty or full walking floor trailers pending off-site disposal.

7.1.3 Trailers

The external area for the process residues as outlined in 7.1.2 will be combined with the trailer holding area for receipted trailers or those loaded awaiting dispatch. This is not a storage area and the timeframes outlined within Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities' will be adhered to following discharge of IC2.

7.1.4 Internal Storage

The reconfiguration of the site layout allows for the entire internal area to be used for the storage of waste pending processing or transfer. This facilitates full utilisation of the site, provides the floor space for trailers to be unloaded within 24 hours of receipt and allows Stericycle to store waste inside of the building opposed to within trailers as is the case at present. Each internal area will be sectioned and labelled accordingly so wastes that can be processed on site and wastes being transferred off-site are grouped together according to hazard type. Each area is flexible so the site can flex up and down depending on waste type volumes and operating conditions at any one time. A typical configuration is shown in more detail within Figure 9.

7.2 Storage Area Capacity

Storage area capacities have been calculated based upon floor area and the number of wheel carts that can fit into the space. The maximum weight per cart is applied to calculate the tonnage quantity and ensures that when the site is full, the permit limit will not be exceeded. Storage area designations are shown in Figure 8 (section 7.3) with capacities for each area listed in Table 8 below:

Area	Corresponding activities	Capacity	Description
A	AR1, AR2, AR3, AR8, AR9, AR10, AR TBC (1) (shredding of non-haz offensive waste)	465 tonnes	Internal storage area with impermeable surface and sealed drainage for storage of waste in wheeled carts or other approved containers. 372 tonnes hazardous 93 tonnes non-hazardous Refer to Table 9 for the calculation determining the total storage volume. Storage area A includes two designated, signed quarantine areas for the temporary quarantine storage of up to 46 waste carts (approx. 7 tonne). These areas are marked in purple on Figure 8.
B	AR TBC (3) (storage of medicinally contaminated effluent)	60 tonnes	Internal storage area with impermeable surface and sealed drainage for storage of medicinally contaminated residues. This area will be surrounded by an ACO drain with its own isolation point so in the event of a leak/spill the drainage system can be isolated. Storage of effluent will meet secondary containment (bunding) requirements set out in the healthcare waste appropriate measures guidance. Up to 60 IBC's containing effluent pending offsite disposal.
C	AR TBC (5) (Storage of treatment residues) AND AR1, AR2, AR3, AR8, AR9, AR10, AR TBC (1) (shredding of non-haz offensive waste)	230 tonnes	This area will be used interchangeably for the storage of process residues; storage of lightly compacted offensive wastes pending transfer; and as a holding area for trailers containing loose waste pending unloading or transfer. Each will meet the required timeframes within Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities'. Area C consists of the following: • An internal area for the loading/storage of process residues into walking floor trailers. This area has an impermeable surface and sealed drainage. • An external area designated for the storage of treatment residues in walking floor trailers pending off-site recovery/disposal. This area has an impermeable surface and sealed drainage.

			• The external area will be combined with a holding area for trailers containing loose waste and skips/RCV's containing lightly compacted offensive waste pending unloading or off-site recovery/disposal. Total Tonnages for Area C: 18 tonnes hazardous 212 tonnes non-hazardous This consists of the follow: Residues (non-hazardous): • 2 x 24 tonne walking floor trailers (internally) • 6 x 24 tonne walking floor trailers (externally) Trailers (Hazardous): • 3 x 6 tonne BK2 trailers containing waste (externally) Offensive Waste (non-hazardous): • 2 x 10 tonne static skips or mobile compactor vehicles (RCV's) containing waste

Table 8 - Storage Area Capacity

7.3 Storage Area Schematic

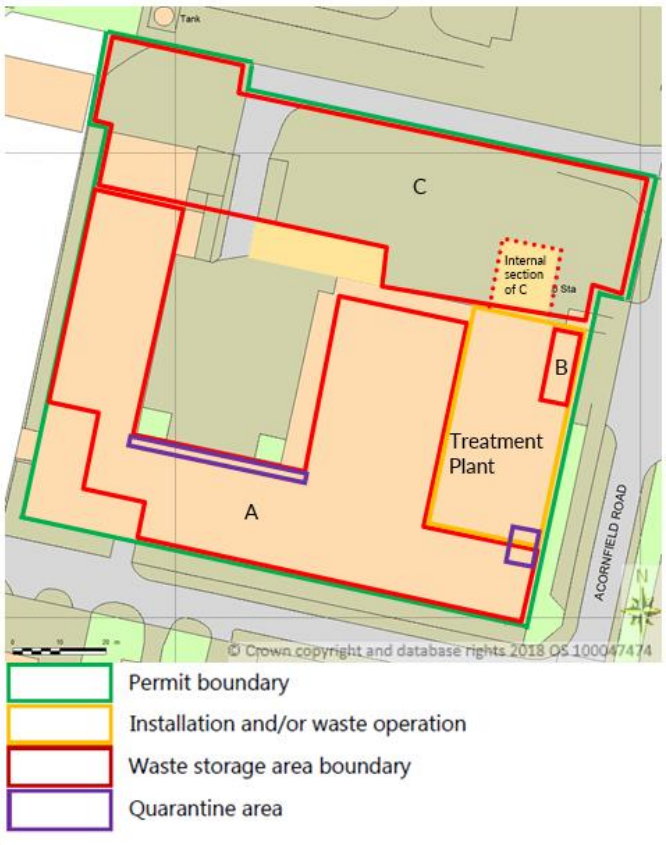


Figure 8 - Storage Area Schematic (Basic)

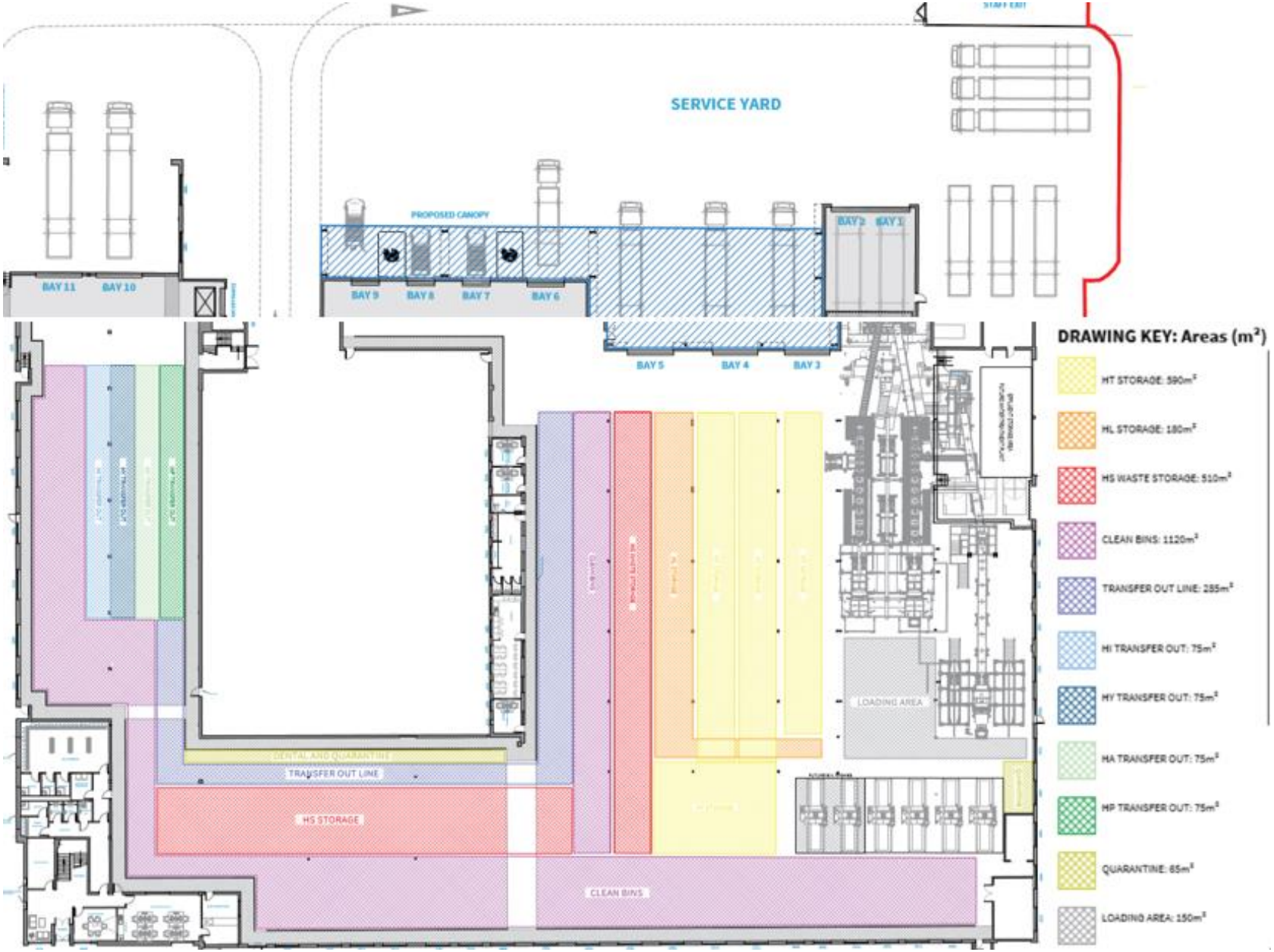


Figure 9 - Storage Area Schematic (Detailed)

7.4 BAT and Supplementary Information

Justification for the waste quantity stored in Area A:

Waste Storage Calculation	
Total area available	3,100 m^2
Area occupied per carts	1 m^2 (1.26*0.76 = 0.96m2)
Estimated number of carts and/or pallets	3,100
Estimated maximum weight per cart/pallet	150 kg
Total estimated weight	465 tonnes

Table 9 - Waste Storage Calculation

8. Waste Treatment Process

8.1 Steam Disinfection Auger (Mode 1 and 2)

8.1.1 Overview

The two new treatment lines (Line 1 and 2) will be a Steam Auger design with a throughput of up to 70 tonnes per day or up to 2.9 tonnes per hour each. The existing line (Line 3) will remain as existing with a throughput of up to 48 tonnes per day or up to 2 tonnes per hour. Line 1 and 2 can operate in Mode 1 and 2. Line 3 can operate in Mode 1 and 3.

When any of the lines are operating in Mode 1 and 2 the following process is relevant:

a) Waste is loaded into the inspection hopper directly from the 770ltr wheeled carts used to transport and store the waste. This is a mechanical process to minimise manual handling of the waste. The waste is then visually inspected in the hopper, with any non-conformant waste identified being removed and reported as specified in the relevant management system procedure. One or two carts are loaded into the inspection hopper at a time.
b) After inspection the waste is transferred from the inspection hopper and into the treatment process loading hopper above the shredder. This is a mechanical process to minimise manual handling of the waste. The waste is tipped directly into the shredder. The hopper above the shredder is enclosed and operates under negative pressure to contain bioaerosols created through the waste shredding process and divert them to the pollution control system.
c) The waste then passes directly through a four-shaft shredder designed to a 50mm cut. The shredder is designed to cope with all permitted wastes including sharps waste.
d) The shredded waste is then transferred through the treatment chamber, an enclosed elongated tube containing an auger screw which mechanically moves the waste flock (the shredded waste material is known as flock) through the process. Steam is injected into the chamber at several points along the auger to provide the necessary heat and moisture to disinfect the waste. Temperature monitoring points are located along the auger and at the discharge point.
e) An integrated SCADA system monitors and controls the plant temperatures, steam injection rates and auger rotation speed to ensure that the plant is maintained within validated parameters during all hours of operation. The system records and archives all data.
f) The shredded, inactivated waste flock is then discharged into a walking floor trailer where it is stored prior to transfer off-site to be recovered, used as a solid recovered fuel or for disposal at a permitted landfill site (landfill disposal not relevant when operating in Mode 2).

When operating within or switching between operational modes; waste inputs, tonnage limits, heat settings and relevant cleandown/effluent divert processes are controlled using the SCADA and the process logic outlined in section 1.1.4 of this report. Section 9 of this report outlines the measures for pollution control when operating in each mode.

8.2 Mechanical (Cold) Shredding of Non-Hazardous Offensive Waste (Mode 3)

The existing line (Line 3) will be capable of switching between Mode 1 (operating as a steam disinfection auger) and Mode 3 (operating cold as a mechanical treatment only).

When operating in Mode 3, the following process is relevant:

a) Waste is loaded into the inspection hopper directly from the 770ltr wheeled carts used to transport and store the waste. This is a mechanical process to minimise manual handling of the waste. The waste is then visually inspected in the hopper, with any non-conformant waste identified being removed and reported as specified in the relevant management system procedure. One or two carts are loaded into the inspection hopper at a time.
b) After inspection the waste is transferred from the inspection hopper and into the treatment process loading hopper above the shredder. This is a mechanical process to minimise manual handling of the waste. The waste is tipped directly into the shredder. The hopper above the shredder is enclosed and operates under negative pressure to contain bioaerosols created through the waste shredding process and divert them to the pollution control system
c) The waste then passes directly through a four-shaft shredder designed to a 50mm cut.
d) The shredded waste is then transferred through the treatment chamber which operates cold. The chamber consists of an elongated tube containing an auger screw which mechanically moves the waste flock (the shredded waste material is known as flock) through the chamber. All steam injectors and the steam jacket are turned off, so no heat or moisture is added to the waste as it travels though the auger to the discharge point.
e) The shredded waste flock is then transferred to a transportation screw combined with Line 2 (post treatment) and then discharged into a walking floor trailer where it is stored prior to transfer off-site to be recovered, used as a solid recovered fuel or for disposal at a permitted landfill site.

When operating within or switching between operational modes; waste inputs, tonnage limits, heat settings and relevant cleandown/effluent divert processes are controlled using the SCADA and the process logic outlined in section 1.1.4 of this report. Section 9 of this report outlines the measures for pollution control when operating in each mode.

8.3 Treatment Plant Process Schematic

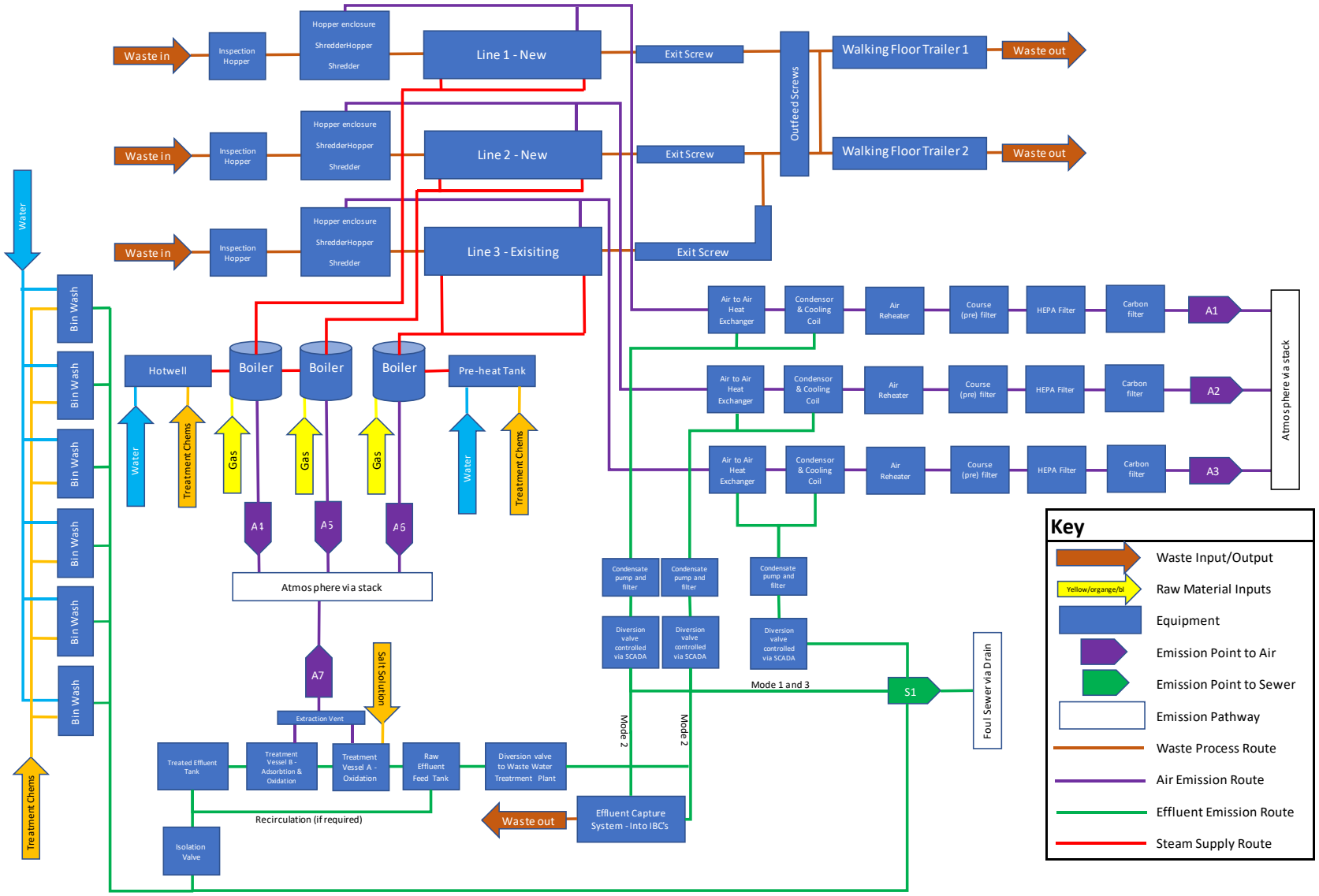


Figure 10 - Treatment Plant Process Schematic

8.4 Commissioning and Validation

8.4.1 Overview

Commissioning and validation of the treatment plant will be undertaken to demonstrate the following criteria specified in Healthcare waste: appropriate measures for permitted facilities:

- **Infectious waste** - the treatment must demonstrate the ability to reduce the number of organisms present in the waste to a level that no additional precautions are needed to protect workers or the public against infection by the waste;
- **for any clinical waste** – renders any syringes, needles or any other equipment or item unusable and no longer in their original shape and form (un-recognisable);

The criteria for anatomical and pharmaceutical wastes are not relevant. The treatment plant does not accept anatomical waste and Stericycle does not claim to treat the medicinal component of the waste stream through the process. Control of the pharmaceutical emission element is outlined in section 9 of this report.

The efficacy of the treatment process is controlled by time and temperature. The waste must reach a certain temperature for a certain length of time to ensure that bacteria within the waste are inactivated to the required level. The required treatment level, as defined in the Healthcare waste: appropriate measures for permitted facilities guidance, is a minimum of STAATT Level III inactivation of the waste.

The treatment temperature is controlled by the injection of steam into the process and monitored at the waste entry point into the auger, the mid-point of the auger and the waste exit point from the auger. The residence time is controlled by the speed of rotation of the auger screw. During commissioning of the treatment plant the optimum temperatures, steam injection volumes and screw rotation speeds will be defined, and will then be subject to external validation by an independent contractor.

The validation tests, to be undertaken by a suitably qualified independent contractor, will be carried out in accordance with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance. The test method to be employed is that for microbial validation for pre-maceration thermal technologies where spore strip integrity can be guaranteed.

After completion of the validation test ongoing routine microbial efficacy tests will be undertaken by Stericycle in accordance with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance. Additional monitoring required due to the mode operation of the plants is outlined in section 8.5 of this report. The routine efficacy test method to be employed is that where monitoring using spore strips is appropriate.

The technology to be employed is not novel as Stericycle already operates a steam auger at this facility and a further two at other facilities in England including one that processes medicinal sharps. These facility consistently exceeds the STAATT Level III inactivation criteria during both validation tests and routine operations, and produces a flock residue with no recognisable components. As such the process to be employed demonstrates BAT for the relevant treatment criteria.

8.4.2 Commissioning and validation proposals for each operational mode

Commissioning and validation of the treatment plant is standard operating practice at Stericycle however the proposed facility will operate three separate treatment lines capable of operating in three separate modes. As such, it is appropriate to set out the proposals for demonstrating the criteria outlined in section 8.4.1 is met when operating within each mode.

- When operating in mode 1, Stericycle propose commissioning and testing in line with the frequencies outlined in the Healthcare waste: appropriate measures for permitted facilities guidance.
- When operating in mode 2, Stericycle intend on remaining flexible on whether the medicinal sharps are continually processed, or batch processed. As such, plant validations will be completed using worst case

load profiles to demonstrate that the plant can treat the waste during any combination of loading. Stericycle propose commissioning and testing in line with the frequencies outlined in the Healthcare waste: appropriate measures for permitted facilities guidance.

- When operating in Mode 3, no treatment validation is required as this is mechanical treatment only.

Table 10 below, sets out the validation schedule for each line and each mode. Each validation will be completed in line with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance.

Mode/Line	Mode 1	Mode 2	Mode 3
Line 1	1 Validation using 100% heat treatable (orange) waste streams	1 validation using 100% 180103/180109 medicinally contaminated infectious sharps	N/A – No validation is required for the mechanical processing of non-hazardous waste
Line 2	1 Validation using 100% heat treatable (orange) waste streams	1 validation using 100% 180103/180109 medicinally contaminated infectious sharps	
Line 3	1 Validation using 100% heat treatable (orange) waste streams	N/A – Line does not process in this mode	

Table 10 - Validation Schedule

By completing a validation within each mode at worst case challenge load, this will demonstrate that each line is capable of processing the waste types listed in the control logic (Figure 4) collectively or in isolation.

8.5 Routine Treatment Monitoring

8.5.1 Routine efficacy monitoring

Routine efficacy monitoring is completed routinely at Stericycle facilities to comply with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance. In order to demonstrate routine efficacy monitoring within each mode of operation, it is appropriate to define the monitoring schedule. Table 11 sets out the routine efficacy schedule for each line. Line 1 and 2 are new therefore are subject to weekly testing during the first six months of operation whereas Line 3 is existing and is subject to monthly monitoring. Neither line is subject to testing in Mode 3 because no validation is required for mechanical processing of non-hazardous waste.

The Healthcare waste: appropriate measures for permitted facilities guidance does not specify a minimum number of spore strips to be recovered and tested for plants with an hourly throughput of more than 1000kg however in line with the approach taken for sampling frequency, Stericycle propose a minimum of 5 spore strips and 1 control is adopted for each separate test.

Timeframe	Mode/Line	Line 1	Line 2	Line 3
		Number of efficacy tests consisting of 5 spores plus 1 control per test		
First six months of operation	Mode 1	None	1 per week	N/A – Line is existing
	Mode 2	1 per week	None	
After six months of operation	Mode 1	1 per month on scheduled test date i.e. not defined by processing mode	1 per month on scheduled test date i.e. not defined by processing mode	1
	Mode 2			N/A

Table 11 - Routine Efficacy Monitoring Schedule

The schedule ensures that each mode is tested on at least one of the two new plants at a weekly frequency required by the Healthcare waste: appropriate measures for permitted facilities guidance. Monitoring frequency after six months of operation reflects the frequencies agreed at Stericycle's other facility permitted for processing of Medicinal sharps.

9. Techniques for Pollution Control

9.1 Existing techniques

There are no changes to existing techniques for waste pre-acceptance, acceptance, storage or odour management unless referenced elsewhere in this report.

9.2 Proposed techniques - Overview

The pollution control systems comprise of the following:

- An air abatement system treating the off gasses from the shredder hopper and treatment auger before emitting to atmosphere.
- An effluent capture system capable of either storing effluent in IBC's pending off-site treatment or diverting through an onsite wastewater treatment plant capable of abating API's down to an acceptable level and reducing the organic content of the effluent prior to discharging to sewer.

This section describes each system in detail and should be read in conjunction with other sections of this report, specifically sections 1.1.4 Future State Overview; 4.2 Emission Parameters, Limits & Controls; and 8.3 Treatment Plant Process Schematic.

9.3 Air abatement system

9.3.1 Overview

The air abatement system will be installed on the new line 1 and 2 with the existing abatement plant on line 3 replaced with an identical system. The system has been designed to minimise point source emissions to air, specifically the emission of any infectious bio-aerosols, any compounds with the potential to cause odour, and any volatile organic compounds. The system complies with the measures specified in Environment Agency sector guidance note 'Healthcare waste: appropriate measures for permitted facilities'.

Each line has a dedicated system, and the process flow is detailed in section 9.3.2:

9.3.2 Process Flow

For each line, off-gases from the treatment plant are transferred to a single abatement plant from the following sources:

- Shredder hopper enclosure
- Treatment auger

The combined air emissions are transferred via ducting under negative pressure to an air-to-air heat exchanger and condenser fitted with a cooling coil. This process quickly reduces the gas temperatures to constate any moisture in the gas flow. Condensate is filtered to remove solids then pumped to one of the following pathways:

- Sewer (When operating in mode 1 or 3)
- Effluent capture system (when operating in mode 2)

Once the gas stream has passed the air-to-air heat exchanger and condenser system, it will pass through an air reheater to optimise the dew point and reduce the relative humidity of the gas flow before it enters the filters.

The filters consist of three separate stages:

1. Pre filter (course filter) – Of a typical paper filter design, the purpose of the course filter is to protect the HEPA filter by filtering any larger particulates from the gas steam.
2. HEPA filter – The high efficiency HEPA filter removes any particulates and any infectious bioaerosols.
3. Carbon filter – The high efficiency carbon filter operates using an adsorption technique to abate VOC's to the required concentrations and any residual odorous organic compounds.

The final off-gases are then released to atmosphere via a vertical stack through the roof of the facility. All elements of the pollution control system are subject to routine planned preventative maintenance as specified in the Company business management system.

9.3.3 Filter Specifications and Active Monitoring

Filters have been specified to abate VOC's down to the required levels as outlined in Table 6 - Emissions Monitoring Parameters.

- HEPA - The high efficiency HEPA filters are H13 rated with a 99.97% removal efficiency for particulates.
- Carbon – The high efficiency carbon filters are 60CTC loose fill pellet design.

Electronic magnahelic gauges are used to monitoring pressure gradients across the filter system to monitor ensure maintenance of negative pressure and provide visual indication of when both the HEPA and carbon filters become blocked and/or require replacement. Filter maintenance is also subject to routine planned preventive maintenance.

9.3.4 Abatement Plant Schematic

Figure 10 - Treatment Plant Process Schematic details how the abatement system operates in conjunction with the wider plant. Figure 11 shows a detailed abatement plant schematic.

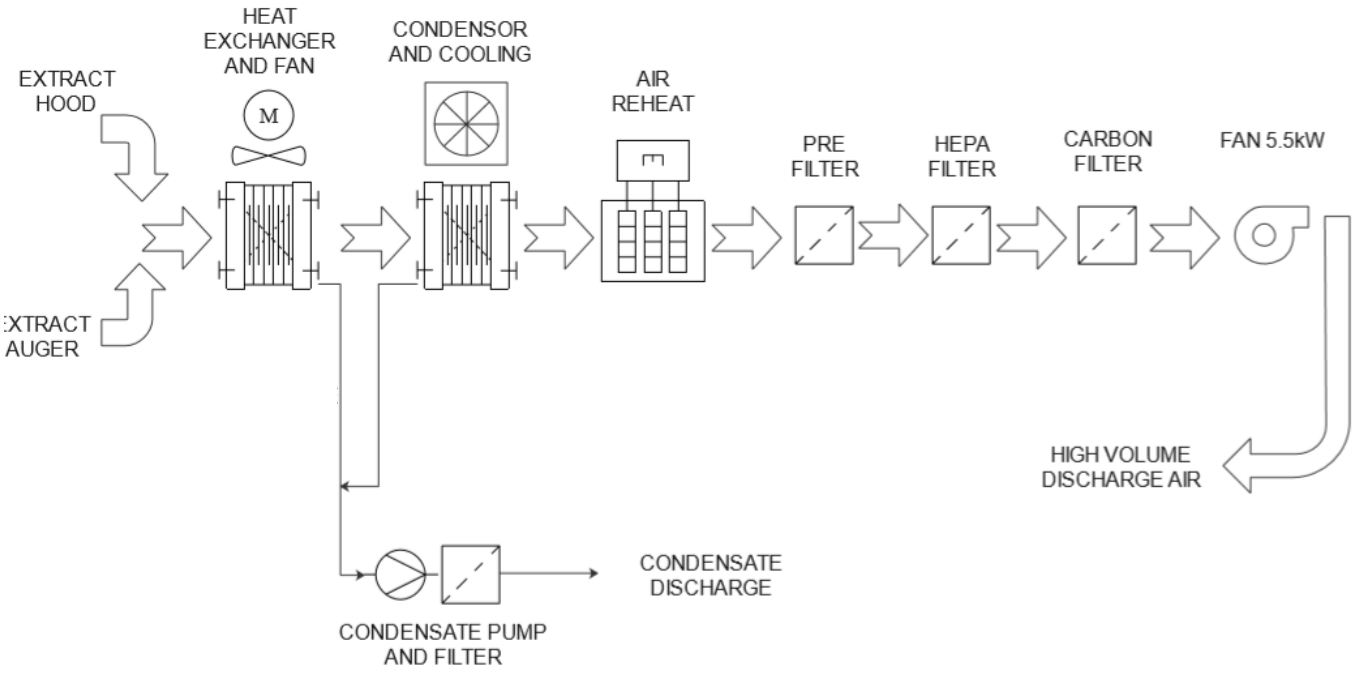


Figure 11 - Abatement Plant Schematic

9.4 Water capture/abatement system

9.4.1 Overview

The water capture/abatement system will be installed on the new line 1 and 2 however the existing line 3 will have the capacity to use the system if operational circumstances require it. The system is not required by BAT when processing infectious waste steams however when processing medicinal sharps (Line 1 and 2 in Mode 2) there is the potential for active pharmaceutical ingredients (API's) to be present within the effluent generated. As such, this system has been primarily designed to capture and/or abate API's for either off site treatment or emission to sewer respectively.

The system has been designed to completely control effluent pathways to sewer and when treating the effluent, minimising point source emissions to sewer.

The process logic in Figure 4 details how and when the plant operates in effluent capture/abatement mode. It also details the clean down protocols when switching between modes to ensure all API's are removed from the plant before effluent pathways are automatically switched via the PLC/SCADA system. A description of each of these processes is discussed in this section of the report.

9.4.2 Process Flow

Effluent is generated from the following sources:

- Air-to-air heat exchanger and condenser
- Bin washes

Effluent from the bin washes passes directly to the foul sewer. Effluent from the air-to-air heat exchanger and condenser is filtered via a particulate filter and pumped into the effluent capture system. The effluent capture system sends the effluent in one of two directions as follows:

- Directly to sewer (Mode 1 or 3)
- To the effluent capture/abatement system (Mode 2)

The directional control of the effluent is via an automated diversion valve controlled by the PLC/SCADA logic.

When operating in Mode 2

Effluent produced when operating in mode 2 or within the clean down timeframe when switched from mode 2 to mode 1 or 3 is pumped into the effluent capture and abatement system. The system has been designed to initially operate capturing effluent in IBC's for off-site disposal whilst a wastewater treatment plant is installed. Once the wastewater treatment plant is installed, this will be the default route with IBC capture present as a contingency operation i.e. treatment plant down for maintenance. The diversion to either the capture or treatment system will be controlled via an automated diversion valve controlled by the PLC/SCADA logic.

Capture

When effluent is captured there is a duel IBC system in place where one IBC is filled and the other sits empty. Both IBC's are situated within or on a secondary containment bund. The IBC's utilise an automatic filling mechanism that operates using an automated diversion valve and a fill sensor. The fill sensor produces an alarm on the operator's screen when each IBC is 80-90% full and automatically switches the filling direction when one IBC is full. This provides the operator with the opportunity to swap the full IBC with an empty and ensures that the system can continuously capture effluent when operating in mode 2. The PLA/SCADA logic has numerous alarm thresholds that produce warnings and in the event of two IBC's being full the plant will automatically turn to idle mode and stop waste being loaded.

All full IBC's are moved to the effluent storage area pending offsite transfer. The area is contained within a dedicated section of the plant and surrounded by an ACO drain. The ACO drain has a shut off valve so in the event of spillage, this can be shut and no effluent will enter the sewer system.

Treatment

When effluent is treated it is pumped directly into the treatment plant which is containerised within a shipping container. The system works completely independently and automatically and is linked to the PLC/SCADA system, so any alarms or faults are flagged up on the operator's screen. The effluent is pumped directly into a raw effluent feed tank where it is held until there is enough effluent to pump through the treatment plant. Effluent is then transferred to the first treatment vessel where it is exposed to an electrochemical oxidation process to reduce the total organic content (COD). It is then transferred to a second treatment vessel where it is exposed to a carbon adsorption and electrochemical oxidation process to target the elimination of trace organic compounds including API's. Trace quantities of CO2 and H2 are emitted from these vessels and pass through the extraction vent and the point source emission point. Following the treatment process, effluent is transferred to a treated effluent tank. At this point, the effluent can either be discharged to sewer or recirculated back to the raw effluent tank for multiple passes through the treatment process. The number of passes through the treatment processes will be determined by the agreed API concentrations proposed in Table 6 - Emissions Monitoring Parameters and the proposed pre-operational condition for the wastewater treatment plant outlined in section 9.4.6.

9.4.3 Effluent capture system Schematic

Figure 10 - Treatment Plant Process Schematic details how the abatement system operates in conjunction with the wider plant. Figure 12 shows a detailed schematic of the effluent capture system.

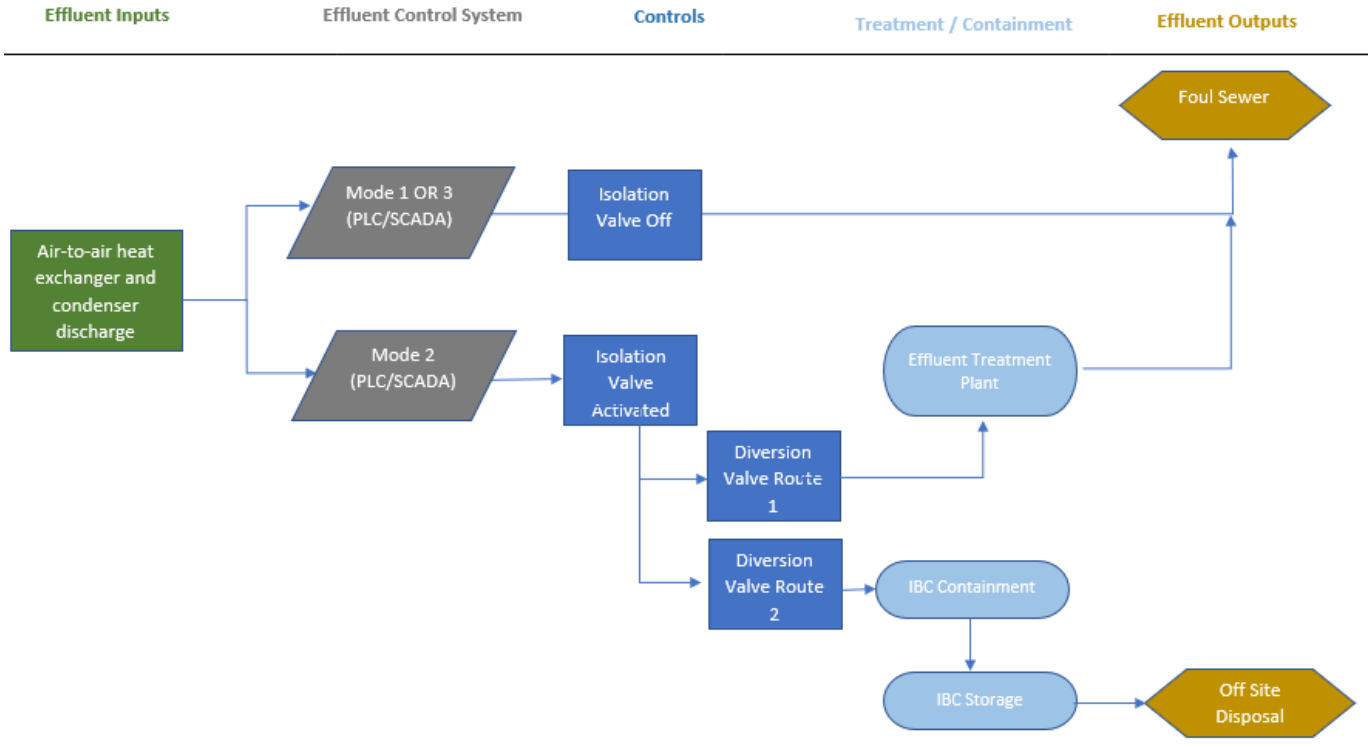


Figure 12 - Effluent Capture Schematic

9.4.4 Wastewater Treatment Plant Schematic

Figure 10 - Treatment Plant Process Schematic details how the abatement system operates in conjunction with the wider plant. Figure 13 shows a detailed schematic of the wastewater treatment plant.

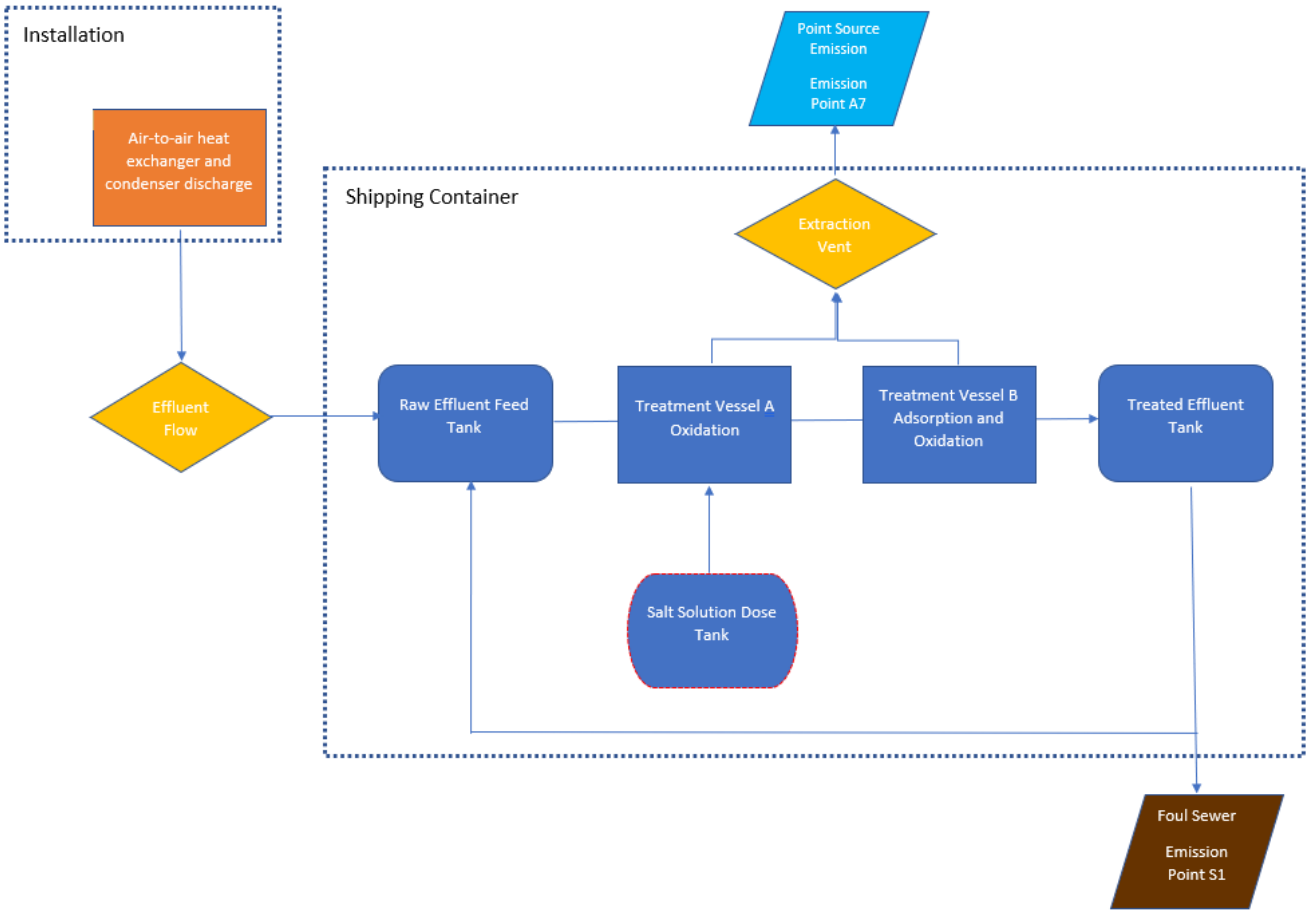


Figure 13 - Wastewater Treatment Plant Schematic

9.4.5 Wastewater Treatment Plant

The effluent treatment process within the wastewater treatment plant occurs in treatment vessel A and B as shown in Figure 13. The treatment is twofold as follows:

- Treatment vessel (A) – An electrochemical oxidation process occurs to reduce the total organic content (as measured by COD) of the raw effluent.
- Treatment vessel (B) – A combined carbon adsorption and electrochemical oxidation process to target elimination of trace organic components including APIs

Both treatment vessels contain an anode and cathode. Voltage is supplied to these electrodes which then transfers current through the effluent in the vessel. This process forms hydroxyl radicals in the effluent at and around the anode surface. The hydroxyl radicals then react with the organic species present in the effluent in an oxidation reaction, ultimately fully converting them into carbon dioxide and water. The basic formula for this process is as follows:

S[·OH] + R > S + mCO2 + nH2O + H+ + e- Where S represents the anode surface and R represents the organic compound.

In treatment vessel A, the oxidation reaction occurs non-selectively for all organic compounds in the reaction vessel on and around the anode. This acts as a pre-treatment step to reduce the total organic concentration of the effluent. Treatment vessel B contains an activated carbon product with a porous structure designed to capture trace organic pollutants (in the molecular size range for APIs) in the carbon porous matrix. The oxidation reaction within treatment vessel B primarily takes place on the surface of the carbon matrix, selectively targeting the trace organics adsorbed onto the carbon surface.

A salt solution (sodium sulphate) is added to treatment vessel A to increase the efficiency of the electrochemical oxidation process. Activated carbon in treatment vessel B is constantly recharged by the electrochemical oxidation process and only a small amount (approximately 5%) of the activated carbon requires replenishment annually.

9.4.6 Wastewater Treatment Plant Pre-Operational Conditions

Stericycle propose a two staged pre-operational condition prior to the treatment plant being put into operation.

Pre-operational Condition 1

- Define the success criteria for the wastewater treatment plant i.e. which API's to test for and what an acceptable concentration would be (Stericycle suggest using paracetamol as the most commonly used API and that most likely to be within the effluent at a concentration level similar to that of background concentration).
- Define the routine monitoring requirement proposed in *Table 6 - Emissions Monitoring Parameters*.
- Stericycle install the treatment plant but will continue to pump wastewater into IBC's whilst testing and commissioning takes place.

Pre-operational Condition 2

- Stericycle to submit a written report presenting the commissioning data, demonstrating the plant is effective and request that the operation of the wastewater treatment plant is approved i.e. discharge of treated wastewater to emission point S1.

9.5 Contamination Pathways & Controls

9.5.1 Pathways

The following sets out contamination pathways from the processing of medicinally contaminated sharps (mode 2) and non-hazardous offensive wastes (mode 3) within the same installation as infectious healthcare wastes (mode 1). It also highlights where contamination pathways require control when switching between modes which is outlined further in section 9.5.2.

Point source emissions to air

As discussed in Part C of this report, there will be no emissions to air of APIs from the process. Emissions from the processing of non-hazardous offensive waste will pass through the same abatement plant as when processing infectious waste therefore emissions are adequately treated above that required by BAT.

Point source emissions to wastewater / sewer

As discussed earlier in section 9, API's require control/treatment which is adequately dealt with. When switching between modes where medicinally contaminated wastes are being treated to non-medicinal wastes there is the potential for residual API's to be present in the effluent until a satisfactory clean down process has been completed. As such, a clean down protocol is required and outlined in section 9.5.2. Emissions from the

processing of non-hazardous offensive waste will be emitted to sewer which is adequate for the purposes of BAT.

9.5.2 Operational Mode Switching

9.5.2.1 Overview

When switching between operational modes, protocols will be controlled by the PLC/SCADA logic to ensure there is no cross contamination of contaminants within the auger or outputs from the auger. The potential scenarios for mode switching and contamination pathways are as follows:

- Switching from mode 1 to 2 – No potential of cross-contamination. Contaminants requiring control are higher in mode 2 than they are in mode 1.
- Switching from mode 1 to 3 – Treatment of hazardous infectious waste to non-hazardous offensive waste. Controls required.
- Switching from mode 3 to 1 - No potential of cross-contamination. Contaminants requiring control are higher in mode 1 than they are in mode 3.
- Switching from mode 2 to 1 – Treatment of medicinally contaminated infectious waste to infectious only waste. Controls required.

No clean down or additional controls other than these listed within this report are required when switching from modes 1 to 2; or modes 3 to 1. When switching from mode 1 to 3, the process must be effective at treating the infectious waste before heat is turned of and non-hazardous waste is mechanically processed. When switching from mode 2 to 1, the process must be effective at controlling API's and ensuring that API's are cleaned down within the auger before controls revert to these required when processing infectious only waste. The clean down protocol is automatically controlled by the PLC/SCADA logic as described in Figure 4 with a clean down time of 2 hours between modes 1 to 3 and 6 hours between modes 2 and 1. The protocols and justification for these timeframes are discussed in sections 9.5.2.2 and 9.5.2.3 below.

9.5.2.2 Protocols

Mode 1 to 3 – Control of Infectious Waste

1. Mode switched to Mode 3 on the SCADA
2. Bin loading of infectious waste ceases
3. Two-hour timer commences.
4. Heat continues to be applied as per validated parameters for one hour
5. At one hour, the heat supply to the installation is switched off.
6. The auger is allowed to cool for one hour
7. At two hours, bin loading of non-hazardous offensive waste will begin
8. The plant will continue to operate in mode 3.

Mode 2 to 1 – Control of API's

1. Mode switched to Mode 1 on the SCADA
2. Bin loading is restricted to those waste types allowable in Mode 1 i.e. no medicinally contaminated waste streams
3. Six-hour timer commences where waste being processed is still classified as medicinally contaminated and effluent continues to be captured in the system outlined in section 9.4.
4. Once six hours is reached, the effluent capture will cease and will divert directly to sewer.
5. The plant will continue to operate in mode 1.

9.5.2.3 Justification

Mode 1 to 3 – Control of Infectious Waste

When switching between mode 1 and 3, the installation will be effectively treating infectious waste with heat as per the validated parameters before switching to the mechanical processing of non-hazardous wastes within the same auger. No API's require control however the infectious waste within the installation must be adequately treated before the heat is turned off and non-hazardous waste is processed. As such a two hour 'clean down' will be implemented as outlined in section 9.5.2.2.

The two hours has been determined to take account of the following:

- Residence time of 45 minutes – This is the time it takes for a bin of waste to be loaded into the shredder to reach the end of the treatment process and exit the auger into one of the exit conveyors. 45 minutes from item 2 in the protocol, the treatment auger will be free of waste.
- Heat disinfection – A 15-minute period has been allocated for the application of steam to the empty auger to ensure any residue waste has been exposed to adequate heat for 10 minutes to ensure adequate disinfection before it is turned off.
- Heat dissipation - The auger operates at circa 100°C. It takes 1 hour for heat to dissipate to ensure the non-hazardous offensive waste is not being exposed to heat treatment.

Mode 2 to 1 – Control of API's

When switching between mode 2 and 1, the installation will stop processing medicinally contaminated sharps and begin processing infectious only waste. As a result, there will be waste potentially containing API's in the auger at the same time as non-medicinally contaminated wastes and control of the API's is required. As such a six hour 'clean down' will be implemented as outlined in section 9.5.2.2.

The six hours has been determined to take account of the following:

- Residence time of 45 minutes – This is the time it takes for a bin of waste to be loaded into the shredder to reach the end of the treatment process and exit the auger into one of the exit conveyors. i.e. after 45 minutes all medicinally contaminated waste will have exited the auger.
- Clean down of residual API residues within the auger – A 5-hour 15-minute period has been allocated where non-medicinal waste will be shredded and loaded into the process. This will absorb medicinal residues from the shredder and auger and transfer them to the walking floor trailer along with the other medicinal contaminated residues.
- Clean down of residual API residues within the abatement system - During the above point, the air-to-air heat exchangers and condensers will be processing non-medicinal contaminated process air for at least 5-hours and 15-minutes. This results in the natural cleaning and flushing of all medicinal residues in the process and associated pipework to the point of discharge where the effluent diversion valve is located.

The six-hour clean down time of the auger has been determined by testing at another Stericycle facility which is of an identical design to the line 1 and 2. The test was completed by loading a challenge load of pharmaceuticals into the process and taking samples from the process effluent periodically. The results demonstrate that the pharmaceutical concentrations in the process effluent return to baseline concentrations four hours after loading. As such the four hours plus an additional two to act as a buffer was considered appropriate. This has been accepted by the Environment Agency at Stericycle's Telford site where the processing of sharps has been permitted.

A summary of the testing, interpretation of the results and accompanying charts are contained within Appendix 4 – API Contamination Controls - Testing.

10. Emissions Monitoring

10.1 Emissions to Air

10.1.1 Emissions from treatment plant

Line 1 and 2

Monitoring of emissions to air (emission point A1 and A2) will be undertaken during commissioning and validation of the treatment plant, then routinely thereafter.

The emissions monitoring conducted will be of microbial emissions to air and surfaces, TVOC's and speciated VOCs as specified in 'Healthcare Waste: appropriate measures for permitted facilities'. The method to be employed will be that using tracer spore suspensions with air, surface and effluent monitoring all being undertaken. TVOC and speciated VOC testing will meet monitoring standards BS EN 12619 and BS CEN/TS 13649 respectively. The monitoring will be undertaken by an external independent contractor.

Microbial emissions to air, surfaces and wastewater will be completed annually as described in section 10.1.2 of this report.

TVOC will be completed six monthly when processing in Mode 1 and TVOC and speciated VOC testing will be completed six monthly when processing in Mode 2.

Pharmaceutical emissions monitoring is completed as part of the TVOC and speciated VOC emissions when operating in Mode 2.

Line 3

Monitoring of emissions to air (emission point A3) will continue to be undertaken routinely.

The emissions monitoring conducted will be of microbial emissions to air and surfaces, and TVOC's as specified in 'Healthcare Waste: appropriate measures for permitted facilities'. The method to be employed will be that using tracer spore suspensions with air, surface and effluent monitoring all being undertaken. The monitoring will be undertaken by an external independent contractor.

Microbial emissions to air, surfaces and wastewater will be completed annually for operation in Mode 1 as described in section 10.1.2 of this report.

TVOC testing will be completed six monthly when processing in Mode 1.

No emissions monitoring is proposed when operating in Mode 3 as this fall outside of the 'Healthcare Waste: appropriate measures for permitted facilities' guidance.

10.1.2 Microbial Emissions Monitoring

Microbial emissions monitoring is completed routinely at Stericycle facilities to comply with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance. The processing mode does not have any direct impact on bioaerosol containment, and the system has been designed and manufactured for full bioaerosol containment during operation. This has been demonstrated at another Stericycle facility which is permitted for medicinal sharps processing. As such the frequency of the microbial emissions monitoring will be carried out in accordance with the requirements of the Healthcare waste: appropriate measures for permitted facilities guidance. One test will be completed annually for each line to demonstrate compliance with the limits set out in Table 6 - Emissions Monitoring Parameters.

10.1.3 Emissions from steam raising boilers

Monitoring of emissions to air (emission point A4 and A5) will be undertaken within four months of first operation, then every three years thereafter.

The emissions monitoring conducted will be of NOx emissions as required by the industrial emissions directive. The monitoring will be undertaken by an external independent contractor.

We do not propose to undertake any monitoring of emissions from emission point A6 as this existing steam raising boilers falls under the 1MWt threshold for monitoring within the industrial emissions directive.

10.2 Emissions to Sewer

Monitoring of emissions to sewer (emission point S1) will be undertaken during commissioning and validation of the treatment plant, then routinely on annual basis thereafter.

The emissions monitoring conducted will be of microbial emissions to wastewater as specified in 'Healthcare Waste: appropriate measures for permitted facilities'. The method to be employed will be that using tracer spore suspensions with effluent monitoring all being undertaken. The monitoring will be undertaken by an external independent contractor.

Periodic monitoring of paracetamol will be completed by Stericycle during the first six months of operation when the plant operates in Mode 2 to demonstrate effective containment of effluent containing API's as outlined in the management techniques section 9 of this report. This is not proposed to be a formal monitoring requirement as it is for validation purposes only.

It is expected that the wastewater treatment plant will be added to the permit with a pre-operational condition to define the monitoring parameter for API concentration outlined in Table 6 and section 4.2.3.

Any monitoring required by any condition of the trade effluent discharge consent issued by the sewerage undertaker will also be completed as required.

11. Raw Materials

11.1 Overview

As part of the variation, there are updates to the types and volumes of raw materials used. An updated list is included in Table 12 below.

Activity	Description of raw material and composition material	Maximum amount on site	Annual throughput	How material used
AR4 and AR TBC (2) for AR1	Natural gas	n/a	Approx. 12,000 MWh	To fire steam raising boiler for treatment plant
AR4, AR5 (indirect for all activities)	Water	n/a	Approx. 30,000 m^3	To supply the boiler and the container washer
AR1, AR TBC (1)	Activated carbon granules	Approx. 1 m^3	Approx. 12 m^3	Carbon adsorption filter unit
AR TBC (4)	Salt Solution (sodium sulphate)	200 litres	2000 litres	Salt solution for wastewater treatment plant
AR4 and AR TBC (2) for AR1	Boiler water treatment chemical	420 litres	1000 litres	Dosed to boiler water to reduce hardness / scaling
All activities	Detergents	5,000 litres	20,000 litres	Use for container washing and cleaning of site surfaces
All activities	Hydraulic and silicone based oils	1500 litres	3,000 litres	Used for general site maintenance

Table 12 - Raw Materials

12. Resource Efficiency and Climate Change

12.1 Energy Efficiency

There are no changes to the energy efficiency measures outlined within the existing permit application.

With regards to the new plant, energy efficient parts and equipment will be used to ensure efficient operation. A comprehensive commissioning program will ensure the plant is optimized and the basic energy requirements of both new and existing plants combined is expected to as defined in Table 13.

Energy source	Energy consumption (primary energy)	% of total
Gas	76 kWh per tonne waste treated	51.4%
Electricity	72 kWh per tonne waste treated	48.6%

Table 13 - Energy Requirements

All new equipment has been specified to current energy efficiency standards and the facility will be required to review energy efficiency on an annual basis by comparing monthly energy use data for the preceding year. The site will also be included in any ESOS driven improvements.

12.2 Climate change

There are no changes to the climate change measures outlined within the existing permit application.

12.3 Raw Material Justification

The raw materials outlined in section 11 of this report are considered to be the most efficient and effective for the operation of a steam auger.

Gas is considered to be the best material to use to fire the boiler as it achieves more efficient combustion than other fossil fuels with corresponding lower carbon emissions (and emission of other pollutants, specifically NOx and particulate) per unit of energy required. The boiler will be of a modern high efficiency design with self modulating burners designed to optimise combustion.

Water use is minimised as far as possible, however it is not possible to recycle steam from the treatment process and steam injection volumes cannot be reduced below that which is necessary to maintain the required treatment temperatures.

Electricity use is essential to drive the treatment plant shredders, conveyors and compactors, and to provide lighting for the facility. There is no alternative to this however all drives, motors, lights etc are selected to be the most energy efficient and are subject to routine preventative maintenance.

Carbon used for the carbon adsorption filter system is a bespoke product designed for use in air abatement systems.

All other raw materials used are off the shelf products used for cleaning or maintenance purposes.

12.4 Avoidance of waste production

The treated waste residue, or flock and the shredded offensive waste, arising from the treatment plant is suitable for recovery as a solid recovered fuel. Stericycle has demonstrated the viability of this process with full recovery of flock material in effect at a number of other company facilities in the UK and Ireland including Knowsley.

The intention moving forward is to explore recycling options for the metal and polymer elements of the flock to further improve the position on the waste hierarchy.

A range of initiatives are underway to achieve this objective, including the following:

- Diversion of treatment residues (flock) from landfill to recovery as a solid recovered fuel.
- Diversion of offensive healthcare waste from landfill by mechanically processing and combining with the flock for use as a solid recovered fuel.
- Exploration of recycling opportunities for metal and polymer segments of the treatment resides (flock).
- Diversion of medicinally contaminated sharps waste from incineration to treatment facilities to increase recycling options
- Promoting the use of re-usable sharps containers to reduce the use of single use polymer.

Progress against objectives and targets is tracked through management system reviews, audits and KPI monitoring.

13. Environmental Risk Assessment & Accident Management Plan

13.1 Environmental Risk Assessment

The environmental risk assessment for the facility has been updated and attached as Appendix 5 - Environmental Risk Assessment.

13.2 Accident Management Plan

There are no changes to the existing accident management plan.

All incidents and actions will be managed in accordance with our existing management system arrangements as outlined within the original application. The accident management plan and risk assessments will be updated accordingly throughout expansion project and into permanent operation.

The maintenance and checking of any new components will be added to the daily infrastructure checks and preventative maintenance regimes prescribed by our management system that are in place at the facility. Any updates will take account of and comply with the Healthcare Waste: Appropriate measures for permitted facilities sector guidance.

PART C - Processing of Medicinally Contaminated Sharps

14. Processing of Medicinally Contaminated Sharps – Supporting Evidence

This report provides and assessment of the pharmaceutical inputs to and outputs from the process.

14.1 Assessment of pharmaceutical inputs and their fate within the heat treatment process

14.1.1 Assessment of Active Pharmaceutical Ingredient (API) Input

To determine the potential for active pharmaceutical ingredients to be present in the waste stream a literature review was undertaken to assess what medicines are commonly used and what the potential is for them to be present in the medicinally contaminated sharps waste stream.

This was an iterative process completed in the following stages:

i. Determination of the most commonly prescribed medicines in the UK
ii. Assessment of the delivery methods for the most common medicines
iii. Assessment of whether the waste arising from the medicines is hazardous or non-hazardous
iv. Development of a target shortlist of medicines likely to be present in the waste input using stages i) to iii) as a screening tool.
v. Review of the chemical and physical properties of each active pharmaceutical ingredient on the target shortlist to allow its interactions and fate in the treatment process to be assessed.

For stage i) a web search was undertaken to find sources of information on the most commonly used medications in the UK. Numerous data sources are available based on prescription frequency, market value and other data points. The data source chosen is a 2018 study published in the British Journal of Pharmacology. This source was selected for the following reasons:

- It is based on an analysis of both primary and secondary care datasets, so is representative of the sharps waste stream which is received from both primary and secondary care producers. Most other data sources are based on either primary or secondary care data but not both.
- It is based on prescription data and does not include any data on off-the-shelf or over-the-counter medicines. This is representative of the sharps waste stream as non-prescribed medicines are not generally purchased in formats that would give rise to sharps waste.
- It is a comprehensive list covering the top 100 drugs and drug groups.
- It is a relatively recent dataset, having been published in 2018.

For stage ii) the British National Formulary was interrogated to determine, for each medicine on the list, whether or not it can be administered using a method that gives rise to sharps waste (essentially any form of infusion or injection, intravenous and other mechanisms).

For stage iii) sources of information (including HTM07-01 Safe Management of Healthcare Waste) on the hazard classification for each medicine were interrogated to determine whether or not the waste arising from the medicine is hazardous or non-hazardous.

For stage iv), the information gathered in stages i) to iii) was used to create a target shortlist for medicines likely to be present in the medicinally contaminated sharps waste stream. Medicines were screened out if either or both of the following is true:

- The medicine is not delivered by any injection or infusion method, and does not therefore give rise to sharps waste.

- The medicine is hazardous, and is therefore not deposited into sharps bins for waste contaminated with non-hazardous medicines.

The screening exercise resulted in a total of 36 drugs / drug groups out of the initial 100 being taken forward to stage v). The full list of 100 drugs / drug groups and screening exercise is shown in appendix 1 of this report.

For stage v) a web search was completed to determine the chemical and physical properties of the drugs / drug groups on the target shortlist of 36. Where the shortlisted item was a drug group, rather than an individual drug, only one of the drugs in the group was selected for review. It was not necessary to evaluate each drug in a group as the groups are by definition comprised of active pharmaceutical ingredients that have the same basic mechanism of action and have very similar chemical and physical characteristics.

The following properties of each active pharmaceutical ingredient were determined:

- Methods of administration for the medicine
- Molecular weight of the API
- Physical form of the API
- Melting, boiling and decomposition temperatures of the API

The data for stage v) was obtained from a range of sources including the British National Formulary (administration data), the European Chemicals Agency substance database, the US National Institutes of Health open chemistry database and the US Environmental Protection Agency CompTox chemicals dashboard (chemical and physical data). Where available experimental data points are referenced in preference to computational data points.

The full dataset for stage v) of the assessment is included in appendix 2 of this report. The following section (14.1.2) interprets the findings of this assessment.

14.1.2 Assessment of the Fate of API's in the Process

Most commonly used medicines in the UK are made from an active pharmaceutical ingredient (API) that is a complex organic compound with a molar mass exceeding 150. As they are relatively large molecules their physical state at room temperature and standard pressure is generally solid. In most cases the API will remain in solid state and will not decompose significantly when subjected to the alternative treatment process. This is because their melting point, boiling point and decomposition temperatures are significantly greater than the temperatures at which the treatment plant operates. There is no differential effect of pressure on this as the system is not pressurised (unlike an autoclave) and operates at ambient pressure. The only exception to this is for synthetic hormonal products (i.e. insulin, enoxaparin) which are unstable unless stored in a temperature-controlled environment and which may start to decompose in the treatment process. As these drugs are synthetic versions of naturally occurring chemical compounds from the human body, the decomposition products can be compared to the presence of other body fluids and excreta that may be present in the waste and are not therefore of concern in terms of emissions.

For all other common APIs, their possible fate is to accumulate via one of the following routes:

- Contained within the treated solid waste (flock) produced by the process
- Contained within the liquid effluent produced by the process
- Contained within the off-gases / steam vapour produced by the process

To determine the probable route consideration must be given to both the chemical and physical characteristics of the API, and to the physical characteristics of the drug preparation and likely presentation in the waste. The chemical and physical characteristics of the APIs themselves would indicate that they accumulate almost entirely in the flock, as they are solid state molecules that will not be volatilised within the process. However

consideration must also be given to the physical form that the API is delivered in. Drugs delivered by injection or infusion are prepared as aqueous solutions or suspensions containing the API (and other non-pharmaceutically active ingredients – saline, dextrose etc), so the API will be suspended or dissolved in liquid form within the waste stream. For drugs delivered by injection this liquid will be present in residual quantities in needles, syringes and single dose vials. For drugs delivered by infusion this liquid will be present in residual quantities in tubing, cannulae and single dose vials. The waste is shredded prior to treatment so it is not considered that the differing sources and material in which the API is contained will have a significant impact on the fate of the API.

The first stage of the treatment process is the pre-shred. It is possible that a very small proportion of the API content could become airborne through the mechanical action of the shredding process. Any API subject to this fate would be extracted by the abatement process and would be captured by the HEPA filter. In the event that any API was able to bypass the HEPA filter it would transfer to the main plant abatement system and would either be condensed or captured by the carbon filter.

After shredding any APIs present will enter the steam auger where the heat disinfection process takes place. The process works by direct injection of steam into the waste bed which is mechanically moved through the vessel by a rotating auger screw. The steam injected into the process is either absorbed by the waste, condenses within the base of the auger vessel or enters the off-gas abatement system. The approximate proportions for each route are shown in the following table (Table 14).

	Absorbed into Flock	**Condensed in auger vessel**	**Off-gas to abatement system**
Proportion of steam/moisture	90%	<1%	10%

Table 14 - Medicinal Pathways

These proportions have been estimated by calculating the steam injection capacity of the system and comparing this to the effluent production volumes and moisture content analysis of the flock. Each of these parameters is variable but the ranges given have been determined with a relatively high degree of accuracy.

As the API content within the waste is present in aqueous suspensions or solutions we expect that the fate of the APIs will essentially mirror that of the steam injected in the waste. This is a reasonable and cautious approach as it assumes that API content can effectively be washed / leached from the waste in aqueous solution by the combination of heat/steam injection and mechanical mixing within the auger vessel. Given the stability of the API molecules at the temperature and pressure of operation this will be an entirely physical and not a chemical process. In reality some of the API content may be retained in the waste bed and therefore the total proportion retained in the flock may be even higher than the estimated value.

For any API content transferred in suspension or solution to the off-gas abatement system, the fate of this will be split between the condensate generated in the coalescing vessel and capture in the carbon filters. Carbon filters are designed to filter organic compounds at a range of molecular weights including relatively low molecular weight VOC's. Any residual APIs which are non-volatile and of higher molecular weight should therefore be captured by the carbon filters to a very high degree of efficacy. In summary the following table (Table 15) provides an estimate of the proportions for each possible fate for APIs entering the treatment process.

Fate of APIs entering the process	**Flock**	**Effluent** (auger and abatement	**Carbon Filter** (Shredder & plant abatement combined)	**HEPA Filter** (Shredder Abatement)

		condensate combined)		
Estimated Proportion	87-93%	5-10%	<2%	<0.5%

Table 15 - Fate of API's entering the process

The Sankey diagram shown in Figure 14 provides a visual representation of the API flow the process. As shown in the diagram and as described above the API content will be retained in the flock, the effluent, the carbon filter or the HEPA filter.

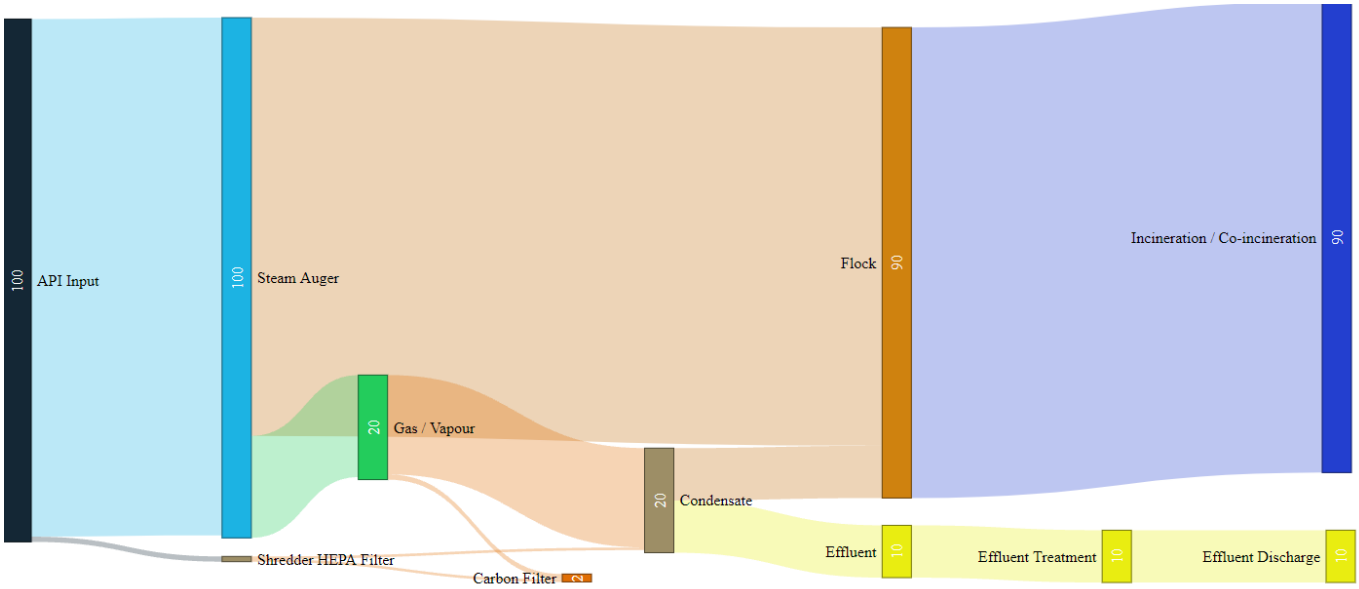


Figure 14 - Sankey diagram representation of API inputs, process flow and outputs (diagrammatic only)

PART D – Appendices

15. Appendix 1 – Scoping Exercise – assessment of top 100 commonly used drug groups

Table 16 below shows the list of 100 most commonly prescribe drugs / drug groups, and the screening exercise to determine whether they are likely to be present in the sharps waste stream. Rows with the text in green are in scope for the next stage of the assessment outlined in section. Rows with no green text are screened out at this stage.

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
1	Proton pump inhibitors	Omeprazole, lansoprazole	No	Yes
2	Statins	Simvastatin, atorvastatin, pravastatin	No	Yes
3	Paracetamol	Paracetamol	Yes	Yes
4	Beta-blockers	Bisoprolol, atenolol, propranolol	Yes	Yes
5	Calcium and vitamin D	Calcium and vitamin D	No	Yes
6	Calcium-channel blockers	Amlodipine, felodipine, diltiazem, nifedipine, lercanidipine	No	Yes
7	H_1 receptor antagonists	Cyclizine, cetirizine, loratadine, fexofenadine, chlorphenamine	No	Yes
8	Aspirin	Aspirin	No	Yes
9	Opioids: weak/moderate	Tramadol, codeine, dihydrocodeine	Yes	Yes
10	Opioids: strong	Morphine	Yes	Yes
11	$Beta_2$ agonists	Salbutamol, salmeterol	No	Yes
12	Angiotensin-converting enzyme inhibitors	Ramipril, lisinopril, perindopril	No	Yes
13	Diuretics, loop	Furosemide, bumetanide	Yes	Yes
14	Vitamin K antagonists	Warfarin	No	Yes

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
15	Vitamins	Folic acid, thiamine hydrochloride, vitamin B group	No	Yes
16	Non-steroidal anti-inflammatory drugs	Naproxen, ibuprofen	No	Yes
17	Penicillins, broad spectrum	Amoxicillin, co-amoxiclav	Yes	Yes
18	Laxatives - osmotic	Macrogol, lactulose	No	Yes
19	Anti-depressants, selective serotonin re-uptake inhibitors	Citalopram, sertraline, fluoxetine	No	Yes
20	Corticosteroids, systemic	prednisolone	Yes	Yes
21	Laxatives – stimulant	Senna, docusate sodium	No	Yes
22	Corticosteroids, inhaled	Prednisolone	No	Yes
23	Thyroid hormones	Levothyroxine	No	Yes
24	Benzodiazepines	Diazepam, temazepam	Yes	Yes
25	Alpha-adrenoceptor blocking drugs	Doxazosin, tamsulosin	No	Yes
26	Biguanides	Metformin	No	Yes
27	Insulin	Insulin	Yes	Yes
28	Angiotensin-II receptor antagonists	losartan, candesartan, irbesartan	No	Yes
29	Corticosteroids, topical	hydrocortisone	No	Yes
30	Gabapentin and pregabalin	Gabapentin and pregabalin	No	Yes

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
31	Anti-depressants, tricyclic and related drugs	Amitriptyline	No	Yes
32	Anti-platelet drugs	Clopidogrel	No	Yes
33	Anti-fungal drugs	Clotrimazole, ketoconazole	No	Yes
34	Histamine (H_2)-receptor antagonists	Ranitidine	No	Yes
35	Diuretics, thiazide and thiazide-like	Bendroflumethiazide, indapamide	No	Yes
36	Emollients	Emollients	No	Yes
37	Nitrates	Isosorbide mononitrate, glyceryl trinitrate	No	Yes
38	Trimethoprim	Trimethoprim	No	Yes
39	Iron	Ferrous fumarate, ferrous sulphate	No	Yes
40	Biphosphonates	Alendronic acid	No	Yes
41	Penicillins, penicillinase resistant	Flucloxacillin	Yes	Yes
42	Sulfonylureas	gliclazide	No	Yes
43	Macrolides	clarithromycin	Yes	Yes
44	Gout and hyperuricaemia	allopurinol	No	Yes
45	Alginates and antacids	Alginates and antacids	No	Yes
46	Anti-depressant drugs, other	venlafaxine, mirtazapine	No	Yes
47	Z drugs	zopiclone	No	Yes

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
48	Ocular lubricants (artificial tears)	hypromellose	No	Yes
49	Anti-emetics, dopamine (D2)-receptor antagonists	metoclopramide, domperidone	Yes	Yes
50	Anti-muscarinics, cardiovascular and gastrointestinal uses	atropine, hyoscine butylbromide	Yes	Yes
51	Anti-psychotics: 2nd generation	quetiapine, olanzapine, risperidone	Yes	Yes
52	Anti-muscarinics, bronchodilators	tiotropium, ipratropium bromide	No	Yes
53	Cardiac glycosides	digoxin	Yes	Yes
54	Methotrexate	Methotrexate	Yes	No
55	Anti-muscarinics, genitourinary uses	solifenacin, tolterodine, oxybutynin	No	Yes
56	Anti-proliferative immunosuppressants	azathioprine	Yes	No
57	Tetracyclines	doxycycline	No	Yes
58	Aldosterone antagonists	spironolactone	No	Yes
59	Metronidazole	Metronidazole	Yes	Yes
60	Dipeptidyl peptidase-4 inhibitors	sitagliptin, linagliptin	No	Yes
61	Anti-motility drugs	loperamide	No	Yes
62	Quinine sulphate	Quinine sulphate	Yes	Yes
63	Dopaminergic drugs used in parkinsonism	co-careldopa (carbidopa/levodopa)	No	Yes
64	Lamotrigine	Lamotrigine	No	Yes

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
65	Direct oral anticoagulants	rivaroxaban, apixaban, dabigatran	No	Yes
66	Anti-psychotics: 1st generation	haloperidol	Yes	Yes
67	Mucolytics	carbocisteine	No	Yes
68	Levetiracetam	Levetiracetam	Yes	Yes
69	Prostaglandin analogues	latanoprost	No	Yes
70	Penicillin	benzylpenicillin, phenoxymethylpenicillin	Yes	Yes
71	Valproate	Valproate	Yes	Yes
72	5α-reductase inhibitors	finasteride	No	No
73	Chloramphenicol	Chloramphenicol	Yes	No
74	Aminosalicylates	mesalazine	No	Yes
75	Nitrofurantoin	Nitrofurantoin	No	Yes
76	Carbamazepine	Carbamazepine	No	Yes
77	Antivirals	aciclovir	Yes	Yes
78	Cephalosporins	ceftriaxone, cefalexin	Yes	Yes
79	Local anaesthetics	lidocaine	Yes	Yes
80	Amiodarone	Amiodarone	Yes	Yes
81	Drugs used in substance dependence	nicotine, methadone	No	Yes
82	Oestrogens and progestogens	combined ethinylestradiol, desogestrel, estradiol	No	No
83	Phosphodiesterase (type 5) inhibitors	sildenafil	Yes	Yes

Rank	Drug, Class or BNF Grouping	Most commonly prescribed examples	Can be administered by injection	Non-hazardous (not cytotoxic / cytostatic)
84	Acetylcholinesterase inhibitors	donepezil	No	Yes
85	Serotonin (5HT1)-receptor agonists	sumatriptan	Yes	Yes
86	Leukotriene receptor antagonists	montelukast	No	Yes
87	Drugs for breast cancer	tamoxifen	No	No
88	Heparins	enoxaparin, heparin	Yes	Yes
89	Serotonin ($5HT_3$)-receptor antagonists	ondansetron	Yes	Yes
90	Oxygen	Oxygen	No	Yes
91	Quinolones	ciprofloxacin, moxifloxacin	Yes	Yes
92	Penicillins, anti-pseudomonal	piperacillin sodium/tazobactam sodium	Yes	Yes
93	Vancomycin	Vancomycin	Yes	Yes
94	Aminoglycosides	gentamicin	Yes	Yes
95	Activated charcoal	Activated charcoal	No	Yes
96	Adrenaline (epinephrine)	Adrenaline (epinephrine)	Yes	Yes
97	Adenosine	Adenosine	Yes	Yes
98	Acetylcysteine	Acetylcysteine	Yes	Yes
99	Fibrinolytics, e.g. alteplase	Fibrinolytics, e.g. alteplase	Yes	Yes
100	Naloxone	Naloxone	Yes	Yes

Table 16 - 100 most commonly prescribed drugs / drug groups

16. Appendix 2 – Assessment of Target API Chemical and Physical Properties

The following table (*Table 17*) shows the shortlist of 36 APIs likely to be present in the sharps waste stream, and provides and evaluation of their administration methods and chemical and physical properties.

Ref.	Drug / API	Injected Form	Molecular Weight	State (20-25 deg C)	Melting Point (c)	Boiling Point (c)	Decomposition Temp
1	Paracetamol	Intravenous infusion	151	Solid	166	250	200-320
2	Atenolol	Intravenous injection	266	Solid	147-160	>458	>203
3	Tramadol	Intramuscular, intravenous or subcutaneous injection / Intravenous infusion	263	Solid	180	407	275-290
4	Morphine	Intramuscular, intravenous or subcutaneous injection / Intravenous infusion	285	Solid	255	190	?
5	Furosemide	Intramuscular or intravenous injection / Intravenous infusion	331	Solid	206-295	582	206
6	Amoxicillin	Intramuscular or intravenous injection / Intravenous infusion	365	Solid	194	>333	>150
7	prednisolone	Intramuscular injection	360	Solid	235	>391	>230
8	Diazepam	Intramuscular or intravenous injection / Intravenous infusion	285	Solid	125-132	497	?
9	Insulin	Intramuscular, intravenous or subcutaneous injection / Intravenous infusion	Variable chain length	Solid	?	?	Unstable at room temp
10	Flucloxacillin	Intramuscular or intravenous injection / Intravenous infusion	454	Solid	>178	>333	?
11	metoclopramide	Intramuscular, intravenous or subcutaneous injection / Subcutaneous infusion	300	Solid	147	418	?
12	atropine	Intramuscular, intravenous or subcutaneous injection	289	Solid	114	>385	>40
13	Olanzapine	Intramuscular injection	312	Solid	195	>337	?

Ref.	Drug / API	Injected Form	Molecular Weight	State (20-25 deg C)	Melting Point (c)	Boiling Point (c)	Decomposition Temp
14	Digoxin	Intravenous infusion	781	Solid	249	932	249
15	Metronidazole	Intravenous infusion	171	Solid	159-163	405	?
16	haloperidol	Intramuscular injection / subcutaneous infusion	376	Solid	148-152	?	?
17	Levetiracetam	Intravenous infusion	170	Solid	115-119	?	?
18	benzylpenicillin	Intramuscular or intravenous injection / Intravenous infusion	334	Solid	214-217	>307	?
19	Valproate	Intravenous injection / Intravenous infusion	144	Liquid (Acid) / Solid (Salt)	<125	220	?
20	aciclovir	Intravenous infusion	225	Solid	256	437	?
21	ceftriaxone	Intramuscular or intravenous injection / Intravenous infusion	555	Solid	>155	613	?
22	lidocaine	Intravenous injection	234	Solid	68	159-181	>120
23	Amiodarone	Intravenous injection / Intravenous infusion	645	Solid	156	>469	?
24	sildenafil	Intravenous injection	475	Solid	187-190	>328	?
25	Sumatriptan	Subcutaneous injection	295	Solid	169-171	>295	?
26	enoxaparin	Subcutaneous or intravenous injection	>1135 (chain length varies)	Solid	?	?	Unstable at room temp
27	ondansetron	Intramuscular or intravenous injection / Intravenous infusion	293	Solid	231-232	>335	?
28	ciprofloxacin	Intravenous infusion	331	Solid	255-257	?	255-257
29	piperacillin sodium	Intravenous infusion	518	Solid	>186	>318	?
30	Vancomycin	Intravenous infusion	1449	Solid	>360	?	?
31	gentamicin	Intramuscular or intravenous or intrathecal injection / Intravenous infusion	478	Solid	102-108	?	105
32	Adrenaline (epinephrine)	Intramuscular or intravenous or intracavernosal injection / Intravenous infusion	183	Solid	211-212	215	?
33	Adenosine	Intravenous injection / Intravenous infusion	267	Solid	235-246	?	?
34	Acetylcysteine	Intravenous infusion	163	Solid	110	>259	?
35	alteplase	Intravenous injection / Intravenous infusion	Variable chain length	Solid	?	?	Unstable in solution

Ref.	Drug / API	Injected Form	Molecular Weight	State (20-25 deg C)	Melting Point (c)	Boiling Point (c)	Decomposition Temp
36	Naloxone	Intramuscular or intravenous injection / Intravenous infusion	327	Solid	178-205	>402	?

Table 17 - API's likely to be present in the sharps waste stream

17. Appendix 3 – References Used

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18. Appendix 4 – API Contamination Controls - Testing

Overview

Testing was completed at Stericycle Telford to demonstrate the effectiveness of switching processing modes from medicinally contaminated to infectious only and the associated clean-down regime in ensuring that pharmaceutically contaminated effluent is not discharged to sewer. The testing used a challenge API load which was added to the process in a quantifiable amount and periodic samples of the discharge effluent were taken to measure the concentration of API at different time periods after the challenge load was added. A challenge load of paracetamol was selected for the reasons outlined below. The primary aim is to determine the required clean down period where effluent would require control.

The testing aimed to demonstrate the following:

1. Determine the baseline contamination concentration within infectious only waste
2. Quantify the medicinal concentration in the effluent when processing a quantifiable challenge load
3. Determine the concentration in the effluent at different periods to quantify an appropriate clean down time for API controls to remain in place.

The challenge load was added to non-medicinally contaminated waste input to ensure there is was no interference with the challenge load concentration.

Sampling Regime

The process flow for how the sampling and testing was completed is as follows:

Phase 1 - Baseline 1.

1. The plant operated in Mode 1 (non-medicinal processing) however the effluent capture was manually initiated to divert the effluent into the IBC.
2. Processing of non-medicinal waste continued for at least one hour generating non-medicinally contaminated effluent.
3. A 5-liter sample was extracted from the IBC (sample 1).

Phase 2 – Challenge Load

4. The plant simulated being switched to Mode 2 by adding a challenge load pharmaceutical. The IBC capturing effluent was switched out for an empty unit.
5. A challenge load of a widely used and available pharmaceutical was added to the waste loaded into the heat disinfection unit. The proposed challenge load was 100,000mg of paracetamol.
6. The plant simulated being switched back to mode 1 (non-medicinal processing) by continuing to process non-medicinal waste.
7. Effluent continued to be captured

Phase 3 – Post clean down

8. The IBC capturing effluent was switched out for an empty unit at 60 minutes, 120 minutes, 180 minutes and 240 minutes. A sample was collected from each (sample 3-6).
9. End of sampling/testing exercise.

Analysis

The samples obtained above were sent to an approved laboratory. Each sample will be tested using Liquid Chromatography-Mass Spectrometry (LC-MS) analysis to determine the concentration of medicinal content

(paracetamol) within the effluent at each sampling point. This provided quantitative data to demonstrate the effectiveness of the containment strategy and clean down process.

Challenge load justification

A challenge load of Paracetamol was used because it is the most likely pharmaceutical to be present within the medicinally contaminated waste stream (see Appendix 2 – Assessment of Target API Chemical and Physical Properties).

The challenge load of 100,000mg has been constructed on the following logic:

- Our producers consign 180103/180109 to Stericycle on a 95/5% concentration ratio
- The most commonly used sharps unit in the NHS is 13l
- The usable capacity of a 13l container is 10.4l
- A 770l bin has capacity for 40 13l units
- The average weight of a 180103/180109 bin is 60kg (net)
- Each 13l container weighs 709g therefore 28.4kg is packaging and 31.6kg is waste
- 5% of the waste is medicinal, thus 1.58kg in total
- Paracetamol solution for infusion is concentrated at 1000mg per 100ml.
- Assuming 1.58kg equates to 1.58l (at the same density), the total paracetamol present is likely to be 15,800mg.
- Challenge load proposed is 633% of the above.
- The limit of detection for the analytical methodology is in the Parts per Billion (PPB) range and the expected concentration of the effluent produced by the challenge load is in the Parts per Million (PPM) range.

Testing and Result Summary

Pharmaceutical emissions monitoring took place on the 15th December 2021 and the 19th January 2022. Waste was spiked with a 100,000mg dose of paracetamol suspension and effluent was captured from the process at various points in time to demonstrate the effectiveness of the proposed clean down procedure. The results shown that paracetamol concentrations in the process effluent returned to baseline levels between 180 and 240 minutes from the point of spiking. As such, Stericycle will implement a clean down process in excess of 240 minutes.

Result Interpretation

Test 1 was undertaken on the 15th December 2021 and 3 effluent samples were taken to establish the baseline paracetamol concentration, the concentration during the 'spiked period' and the concentration after 120 minutes. The results shown baseline paracetamol concentrations of 1600ng/l with a peak of 4100-4300ng/l and a concentration of 2800-3000ng/l after 120 minutes. These results show the correct 'curve' in terms of concentrations peaking and decreasing over time towards the baseline however a 120 minutes clean down was not sufficient to return concentrations to baseline. As such, Stericycle scheduled a second test which was undertaken on the 19th January 2022 and 5 effluent samples were taken to repeat the original test and extend it to establish concentrations after 180 and 240 minutes. The results shown baseline concentrations to be similar to that of test 1 at 1700ng/l. The breakdown of the 'contaminated period' shows that paracetamol concentrations peaked in the second hour following the spiking of the challenge load and these results mirrored overall concentrations during the first test. Concentrations neared baseline conditions at 2000ng/l after a 180-minutes however they levelled past the baseline at 1400ng/l after a 240-minutes. The raw data is shown in the

Table 18 - Test Results – Raw Data below. Test 2 has been plotted onto a chart (*Figure 15*) showing the contaminated 'curve'. This shows a clear baseline and peak in paracetamol concentrations at 120 minutes after spiking of the challenge load. The data clearly shows that a clean down period of between 180-240 minutes is effective in returning paracetamol concentrations in the effluent down to baseline levels. As such, Stericycle consider a clean down process in excess of 240-minute appropriate.

The consistent and reproducible results across the 2 tests are shown in an addition chart (*Figure 16*) demonstrates a high confidence level in the process flow of the paracetamol through the heat treatment process and confirms that a negligible proportion of the pharmaceutical load transfers into the effluent and that the vast majority is retained in the process residues (flock).

Raw Data & Charts

Test Ref:	Test 1	Test 1	Test 2
Test Date:	15/12/2021	15/12/2021	19/01/2022
Sample Set	First Sample Set	Second Sample Set	Sample Set
Analysis Report Date:	22/12/2021	10/01/2022	24/01/2022
Sample Time	Paracetamol Concentration (ng/l)		
Baseline Sample	1600	n/a	1700
Contaminated (60 min after spiked)	4100	4300	4100
Contaminated (120 min after spiked)	n/a	n/a	4800
Post clean down (120 min after spiked)	3000	2800	n/a
Post clean down (180 min after spiked)	n/a	n/a	2000
Post clean down (240 min after spiked)	n/a	n/a	1400

Table 18 - Test Results – Raw Data

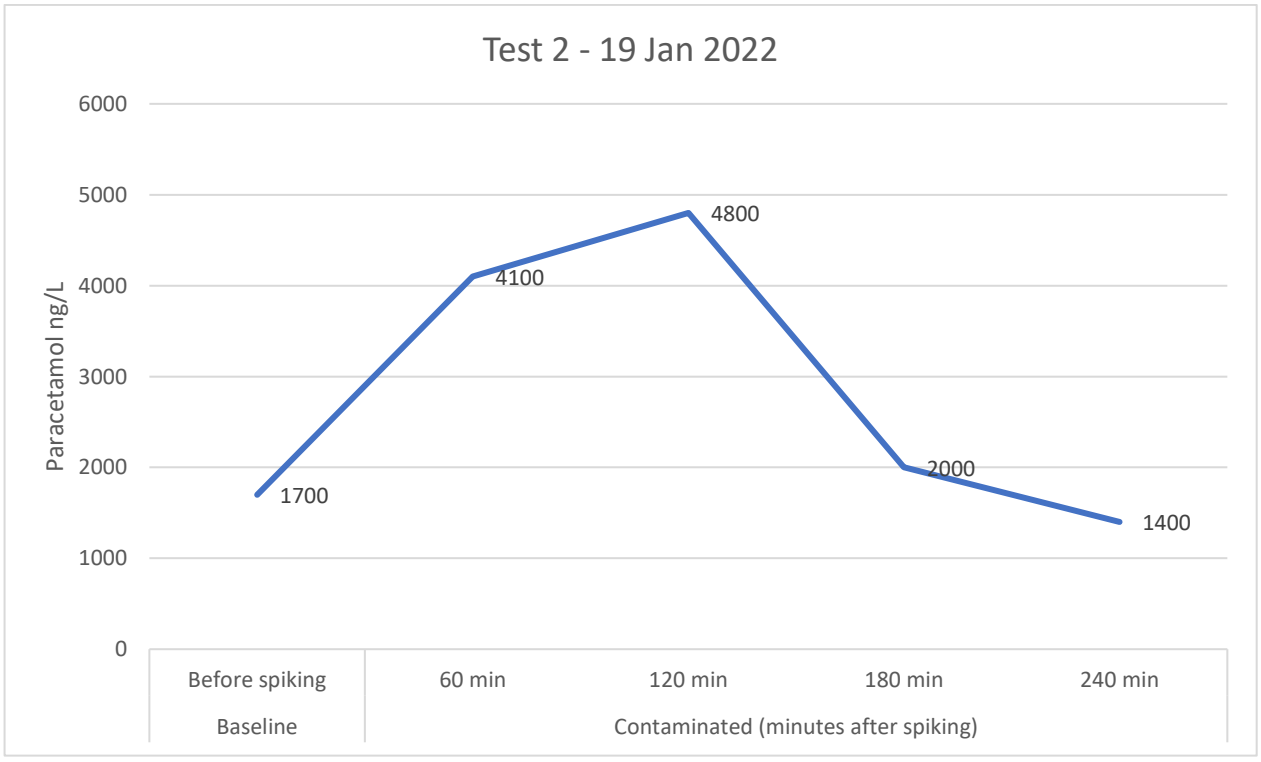

Figure 15 - Test 2 Results

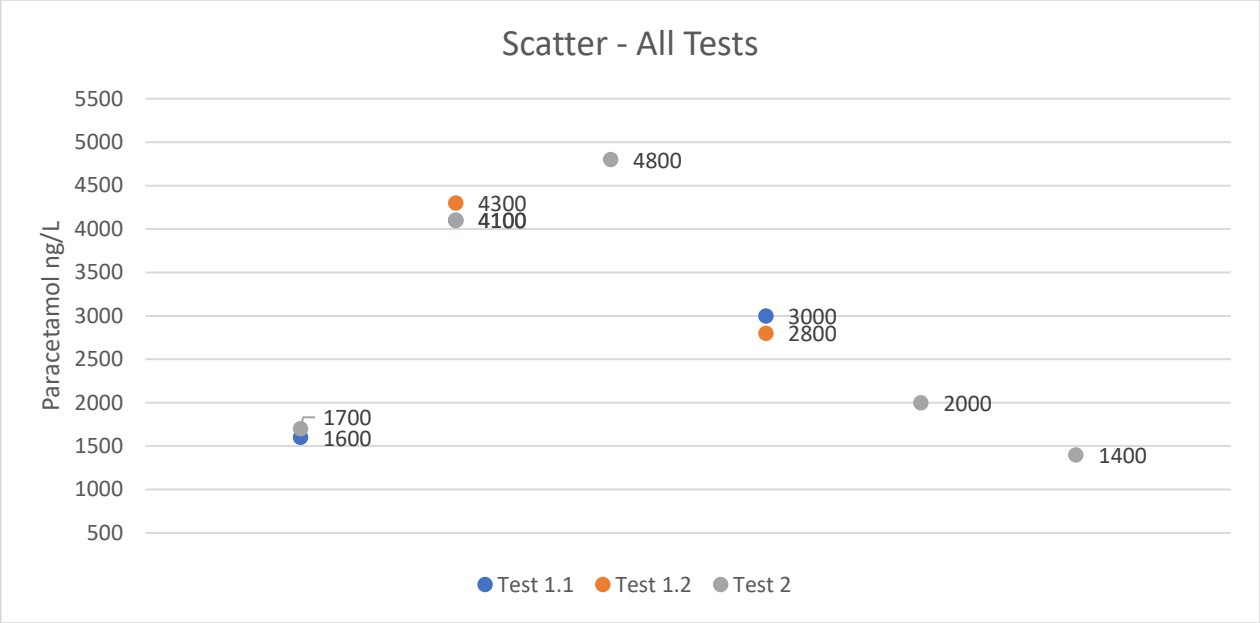

Figure 16 - All Test Results – Scatter

19. Appendix 5 - Environmental Risk Assessment

See Separate Attachment - Doc Ref 08_Knowsley ERA Aug 22 (Appendix 5 Doc Ref 6)

20. Appendix 6 – Air Quality Assessment

See Separate Attachment - Doc Ref 06a_Appendix 6_AQA