Environment Agency permitting decisions

Bespoke permit

We have decided to grant the permit for HES North Tyne operated by Healthcare Environmental Services Limited.

The permit number is EPR/LP3936AB/A001

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

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

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

Description of the main features of the Installation

This site will accept both hazardous and non hazardous waste.

- Hazardous clinical waste will be accepted and shredded prior to treatment in two rotoclave type autoclaves. This treatment will sanitise the waste.
- Other hazardous wastes will be accepted for temporary storage before further treatment off site which will be regulated through this permit but is actually a waste operation rather than an installation.
- The facility will also undertake a sharps bin washing process. Sharps bins will be accepted and mechanically opened in an enclosed area. The sharps will then be collected and stored in a larger bin. The sharps bins will be cleaned and sterilised in a cleaning system before being returned for reuse. The bulk storage of sharps is an installation activity, as this is the repackaging of hazardous waste.
- Non hazardous wastes from healthcare sources will be accepted and stored prior to off site disposal or recovery. This is a waste operation.

Structure of this document

- Key issues
- Annex 1 the decision checklist
- Annex 2 the consultation and web responses

Key issues of the decision

Microbial emissions

The potential sources of microbial emissions are the acceptance of waste, handling of waste, shredding of waste and treatment of waste in the autoclave, and if the treatment process is not effective, the handling and storage of waste that has been autoclaved.

Emission Prevention

Waste handling and spillages
The waste is received in its original packaging, which means there should be limited escape routes for microbes during waste acceptance, unless there is a spill. The operator has highlighted that they are reducing the likelihood of this happening by receiving waste in leak proof and United Nations (UN) approved packages. Waste packages will be stored in lidded wheeled bins. If spillages did occur they would be cleaned up immediately using available spill kits.

Shredder
The shredder will be located in an enclosed area. Prior to shredding the waste is transferred cart to cart to allow for a full inspection of the incoming waste in accordance with our guidance on waste acceptance. Following inspection the cart is placed in the cart lift which tips the waste into the shredder feed hopper which will be kept under negative pressure. The shredder uses a Local Exhaust Ventilation (LEV) system. The LEV system vents via a high efficiency particulate air (HEPA) filter. The operator will check the filters daily. If the filters are identified to be not working then immediate action will be taken to get them working again and no waste will be processed until they are fixed. If the LEV system fails, the operator will cease shredding untreated waste immediately. A lined waste bin is placed under the shredder to collect the shredded waste, this area is also under negative pressure. The operator will check the carts frequently to check that they are not overfilled. The bin is then transferred (with its lid closed) to a temporary storage area before being loaded onto the autoclave platform.

Repackaging of sharps
The sharps bin washing system will invert the sharps bin in an enclosed unit. The sharps will be transferred to a larger bin within the enclosed unit. The sharps bins will be sterilised in a bin washing plant.

Autoclave
The operator will undertake validation and regular efficacy monitoring to ensure the autoclave is treating the waste to a sufficient standard. They will also undertake fugitive emission monitoring to demonstrate that the autoclave is not releasing bioaerosols (as discussed below). The autoclave is a sealed system and will not have any routine point source emissions to air. Following validation, the autoclave programmable logic controller (PLC) will be set at the

validated parameters to ensure the required parameters are reached. The autoclave uses a condenser to condense steam prior to discharge to foul sewer for further treatment. The autoclaves do have emergency release valves which would vent in an emergency to prevent an explosion. The likelihood of this occurring will be reduced by the maintenance programme in place.

All hard surfaces will be washed down and disinfected at the end of each shift.

Microbial Emissions Monitoring

Validation

The operator has detailed that validation testing will be undertaken to demonstrate that the autoclave treatment will destroy microbial materials to the standard set out in our guidance- State and Territorial Association on Alternate Treatment Technologies (STAATT) level III standard.

They have stated in the application that they will submit a proposal for the validation testing for agreement to the Environment Agency in advance. They have suggested that we include a pre-operational condition in the permit requiring a validation report to be submitted. They have confirmed that the validation testing will be done in accordance with our guidance. We have included a pre-operational condition requiring the operator to undertake the validation testing. This condition will prevent the treatment of waste until we agree that the validation report was conducted to the appropriate standard, and demonstrates that the required treatment efficacy has been achieved. We have also included a requirement in schedule 3 of the permit requiring the operator to undertake process monitoring to ensure the appropriate efficacy level is maintained.

The operator has stated in the application that they will undertake validation testing every four years. This has also been incorporated into the monitoring requirements of the permit.

Routine Efficacy Monitoring

Each autoclave unit will be subject to separate efficacy monitoring.

The operator has detailed that they will undertake routine efficacy monitoring in accordance with Annex 2 of our guidance not 5.07 Clinical Waste. This testing will demonstrate that the treatment process is working effectively to the correct standard.

The operator will use four spore strips (one used as a control) which they will place in the waste via a carrier which is attached to an easily identifiable object. This will be distributed through the waste load. Following treatment in the autoclave they will be placed in sealed plastic bags and sent to a lab for testing. A thermal indicator will also be used to demonstrate that the required temperature had been reached.

Annex 2 of our guidance specifies the performance parameters for routine efficacy monitoring, should the results of efficacy testing indicate a failure then a full investigation must be carried out followed by revalidation of the autoclave unit. The unit must not be used to process waste until it has been revalidated. Once revalidated the unit will revert to weekly monitoring.

The operator will be undertaking weekly efficacy testing for the first six months, then monthly thereafter. The operator has said that they will produce summary reports on the efficacy of treatment annually and submit these to the Environment Agency annually.

Fugitive Bioaerosol emission monitoring

The monitoring will involve the preparation of a spore suspension of bacillus atrophaeus at a known population value. They have committed to meeting our requirement of ensuring the population of spores is at least 1x 10^6 spores per gram of waste treated. The spore concentration will be calculated based on the typical amount in the waste loads that will be treated. The spore suspension will be placed in sealed plastic containers and on sterile dressings within sealed plastic bags. The spore samples will then be placed within the bulk mass of waste before being shredded and processed through the autoclave.

The operator has detailed that they will select the air sampling points to reflect the main potential sources of fugitive emissions. At duly making the operator indicated that air sampling will be undertaken at the shredder extraction discharge, adjacent to the autoclaves, adjacent to the waste conveyer between the shredder and autoclaves, next to the binwash and at the site boundary. Air samples will be taken using a centrifugal air sampler which uses an agar media. Control samples will be taken before the suspensions are added to the system, and then samples will be taken while the waste is processed and approximately two hours after the treatment cycle is complete. The agar plates will then be sent to a laboratory to be incubated for 48 hours and then the colonies of bacillus atrophaeus will be counted.

The operator will undertake the monitoring of bioaerosols on site surfaces using agar settle plates. The plates will be put around the plant in a grid like pattern. The plates will be exposed for 3 hours after the spore suspensions were added to the process. The plates will then be sent to a laboratory for incubation for 48 hours before the colonies are counted.

Bin washing

For the binwash, a 100ml sample of the spore suspension will be placed at the bottom of a clinical waste cart prior to washing. The spore population will be based on the required level in our guidance (at least 1x 10^6 spores per gram of waste typically present) assuming that 5g of waste is retained in the bin following emptying. The bin will then be processed as normal. Air and surface sampling will be taken at the same time. Samples will be taken from the wastewater immediately after the cycle has finished, and ten and twenty

minutes later. The samples will be sent to a laboratory for incubation before colony counting.

Monitoring of microbial emissions to sewer

The steam from the autoclave is condensed via an air to air condenser. This condensate is discharged to sewer, meaning that this is a potential pathway for biological material to enter the environment. Our guidance document on Clinical Waste 5.07 indicates that releases of microbial emissions to sewer are less likely to present a risk, but requires operators to monitor releases to identify failures in process integrity. The operator has committed to undertake monitoring of emissions to sewer in line with our guidance.

The monitoring of waste water prior to discharge to sewer will first take place as part of the validation testing, and annually thereafter as part of the fugitive bioaerosol monitoring. Following the treatment of waste in the autoclave containing the bioaerosol suspension, two samples of waste water from the condenser will be collected from the pipe where it discharges to sewer. The samples of wastewater will be sent for incubation on agar plates.

Conclusion

We have assessed the measures that the operator will take to minimise the risk of microbial emissions and consider that these represent the Best Available Techniques (BAT) outlined in our guidance document 5.07 on Clinical Waste. We consider that by using these methods the operator will minimise the risk to the environment. We have also assessed the operator's proposals for validation, routine efficacy and Bioaerosol monitoring and consider these represent BAT and will indicate if the process is achieving the required destruction rate, and if the containment measures proposed are effective. In line with our guidance, we have included a pre-operational condition requiring the operator to submit a validation report demonstrating that the required destruction rate has been achieved, as well as their final proposals for efficacy and fugitive bioaerosol monitoring. We have also included monitoring and emission limit values (ELVs) that reflect the requirements and benchmark levels in our guidance document 5.07. The monitoring and ELVs will ensure that microbial emissions are controlled over the life of the site.

Odour

The operator has submitted an odour management plan as part of their application which includes an inventory of potential odour releases. We have assessed the odour management plan against our guidance note H4. The key measures the operator is proposing to control or minimise odour emissions are as follows:

- Clinical waste is stored in lidded wheeled bins
- Loading bay doors are closed apart from during deliveries
- Minimising the length of time the waste is stored on site- the waste is generally processed within 48 hours
- The shredder uses a Local Exhaust Ventilation (LEV) system which has carbon filters to control odours. These will be checked daily to ensure they are working effectively. There is a maintenance programme in place for the upkeep of the LEV filters
- Any odorous materials are prioritised for treatment or transfer
- Spillages will be cleared up immediately
- Storage areas are checked every shift
- If the shredder LEV system breaks down no waste will be processed.

The autoclave does not have an emission to air, the steam is condensed before being discharged to sewer.

There are emergency vents in place on the autoclave, which in the event of over pressurisation could lead to an emergency venting of steam. This steam could potentially carry odour. The risk of this occurring will be mitigated by the maintenance programme in place.

The operator will maintain an inventory of odorous materials received as part of their waste reception logging documentation.

The carbon filters will be checked daily and if they are not working effectively then the operator has committed to undertake immediate action to restore them as soon as possible. The LEV system will be tested annually.

A daily sniff test will be undertaken and the result recorded in the site diary. If an odour is detected, the operator will conduct a sniff test upwind to identify if the odour is coming from the site. If the site is the cause of the odour the operator proposes to prioritise the odorous material for treatment or arrange its removal as soon as practicable.

The operator has confirmed that if a complaint is received they will instigate a sniff test to ascertain if the site is the source of the odour. If the site is the source of the odour the operator will identify the odorous material, and treat the waste immediately if possible, if this isn't possible they will arrange for the waste to be removed. As temporary mitigation they will ensure the doors are closed and cover the waste if appropriate. Following a confirmed odour complaint an investigation will be undertaken to identify why the incident occurred, and site procedures may be revised to reduce the likelihood of further odorous complaints.

We, the Environment Agency, have reviewed and approved the Odour Management Plan and consider it complies with the requirements of our H4 Odour management guidance note. We agree with the scope and suitability of key measures but this should not be taken as confirmation that the details of equipment specification design, operation and maintenance are suitable and sufficient. That remains the responsibility of the operator. We have incorporated the odour management plan and the risk assessment as an operating technique.

Drainage

The applicant has submitted a site drainage plan to support their application which demonstrates that the areas within the building will drain to foul sewer. The yard area will drain to surface water drains before joining an attenuation pond which eventually joins the Longbenton Letch watercourse approximately 90m north of the installation. The site is predominately surfaced with concrete (see section on site condition report for further details).

The operator will be undertaking bin washing activities which they have confirmed will be undertaken in accordance with a trade effluent discharge. They will only use biodegradable detergents. The operator has confirmed that they will not be discharging any hazardous pollutants to sewer.

Internal risks
The site will store a range of liquid and solid pollutants which could potentially enter the sewer system. The key aspects which need to be controlled will be the binwashing, waste handling and storage, and chemical storage.

The site binwasher and sharps container washing systems are fully enclosed systems which will contain liquids and contaminants before discharge to foul sewer. They will be located within the building, on an impermeable surface with a sealed drainage system connected to the foul sewer.

Hazardous and non hazardous wastes will be accepted on site for storage and bulking up prior to transfer off site, as well as the waste accepted for autoclave treatment. The waste will be stored within its original packaging prior to transfer to pallets, storage in wheeled lidded bins or treatment. The operator has confirmed that waste will be stored in enclosed trailers prior to

transfer off site. Amongst other waste codes, the site will be storing Waste Electrical and Electronic Equipment (WEEE). The operator has confirmed that this waste will be stored within a bund on an impermeable surface.

The operator will be storing a range of chemical raw materials, such as chemicals required for maintenance of machinery, detergents and disinfectants for use in bin washing and boiler feed chemicals. The operator has stated that they will store all chemicals within secondary containment that meets the standards required by our guidance. They will be storing chemicals based on their hazard types to prevent unwanted reactions if spills were to occur. The chemicals will be stored within bunds, predominately bunds which are contained beneath a grid base. The bund material will be made of appropriate materials which will not degrade if spillages occur. Bund capacity will be 110% of the total volume of the chemicals stored within them. Chemical storage areas will be checked once per 12 hour shift.

The operator has confirmed that a planned preventative maintenance programme is in place for site equipment and infrastructure. The operator has stated that spill kits will be available in the building and externally which will be used to clear up spills immediately.

External risks

Autoclaved waste will be compacted into skips. The compactor and one skip is located outside of the building on the south western side. The compactor is fed via a covered conveyer from the building. There will also be up to 5 enclosed skips located in the yard area which will store waste that has been treated by the autoclave. The compactor and waste storage skips will be located on an area of the site that drains to surface water. However, the skips will be sealed to minimise the risk of leaks. The operator has confirmed that the waste storage areas will be checked once per shift. The operator has confirmed that they will enact the site spill procedure if a leak is detected.

The operator will store diesel outside in a 10,000 litre bunded tank for refuelling fork lift trucks. This will be protected from vehicle collision by barriers. They have also included in their application that a spill kit will be located next to this tank.

The operator has confirmed that there are inspection and maintenance procedures in place to check for leaks from tanks or any cracks in the impermeable surface.

Conclusion

A key control mechanism the operator is relying on to prevent off site pollution is discharging effluent to foul sewer. The operator has not provided any details on the integrity of their on-site drains leading to the foul sewer. We have included an improvement condition requiring the operator to undertake a survey to assess the condition of their drains, and if improvement works are deemed necessary, to provide a timescale for these improvements for

agreement with the Environment Agency. This should ensure that pollutants will not escape the site into the soil and groundwater.

We consider that the arrangements described in the application are adequate to prevent waste or chemicals escaping the site and polluting soil, groundwater or surface water.

Firewater

The operator has said that in the event of a fire, any firewater produced will drain into the off site foul sewer system. They will fit drain stoppers or pneumatic bladders on the surface water drainage system to prevent run off to surface water. Once the incident has been addressed, the firewater in the surface water drain will pumped to foul sewer. They will also use flexible spillage containment bunding to either retain firewater in the building, in the case of a fire inside the building, and to prevent firewater in the yard reaching surface water drains.

Noise

The site is located within an industrial estate, with the nearest residential receptors being located approximately 208m to the north west of the site. The operator has undertaken an assessment of the main noise sources on site and has identified that noise may be emitted from the shredder, conveyers, boiler, forklift trucks, air cooled condensers, vehicle movements and vehicle reversing alarms. The operator has highlighted that this equipment has been designed to produce low levels of noise. The equipment will be maintained in line with the manufacturer's recommendations to minimise the noise created by wear and abrasion. They have committed to minimising the time intermittent noise sources such as reversing alarms are operational. The majority of nose producing equipment will be located within a building which is likely to contribute further to the attenuation of noise from the facility.

The operator confirmed that occasionally they will shred metal sharps. The noise potential from shredding metal is higher than shredding other types of waste. However the operator has highlighted that the shredder will be enclosed as well as within the building, giving additional protection.

The operator has committed to undertaking a noise monitoring survey once the plant is operational. If the noise monitoring survey indicates that there is a need for further action, the operator has committed to developing a noise management plan and undertaking remedial actions.

We have made a risk based decision not to request noise monitoring prior to the permit being issued. We consider that the site is unlikely to cause noise complaints for the following reasons:

- The shredder will not routinely shred sharps.
- The equipment is designed to minimise produce low levels of noise.
- The site is in an existing industrial estate which will emit similar noises.

- The site is over 200m from sensitive residential receptors.

However, as a precaution we have included an improvement condition requiring the operator to undertake the noise survey they suggested within three months of the completion of commissioning. The improvement condition (reference IC1) requires the operator to undertake a monitoring survey and assessment in line with British Standard BS 4142:2014. There is also a standard condition in the permit which requires the operator not to cause pollution outside the site, which means that if noise issues do arise, we can request a noise management plan.

Emissions from the boiler

The operator will be using a 5MW thermal input natural gas boiler. According to our H1 Annex F guidance on Air Emissions, we would not necessarily expect operators to assess in detail emissions to air from such small boilers. We consider that boilers of this size are unlikely to have a negative impact on the environment.

Best Available Techniques (BAT) Assessment

The relevant BAT guidance document is Sector Guidance Note (SGN) EPR 5.07 Clinical Waste. We have compared the key measures proposed by the operator against indicative BAT in table 1.

Table 1 Comparison of Indicative BAT with key measures proposed by the operator	
Indicative BAT	*Key measures proposed*
Waste Pre-acceptance procedures- As part of our application forms, the operator is requested to confirm their pre acceptance procedures are in line with section 2.2 of the SGN. The Operator has confirmed they will comply with this section of the SGN.	
Ensure that advice you give to waste producers on segregation and packaging is in accordance with the Safe Management of Healthcare Waste (HTM 07 01). Consider subsequent changes in legislation and guidance. Additional, non-conflicting, colour codes may be used where HTM 07 01 specifies no colour.	In the pre-acceptance procedure submitted they have confirmed that any advice given by staff will comply with the HTM 07 01 guidance.
Obtain the following information in writing when you receive the waste disposal enquiry: • *the details of the waste producer (e.g. medical practice) , including address and contact details;* • *the specific process from which the waste derives – veterinary, primary care, dental, acute, laboratory, and so on;* • *an indication of the waste streams produced, their quantity, physical form, composition, properties, classification and description (more detailed checks will be conducted as part of the site audit).*	The operator has confirmed that as part of their pre-acceptance procedures they will gather this information using an online tool.
Obtain a representative audit analysis of the waste undertaken at the medical practice that produced the waste. This guidance places no restrictions on who may undertake this audit, however it assumes that in most cases this will be the waste producer.	A pre-acceptance online questionnaire will be completed by the waste producer. The operating techniques detail that as part of this questionnaire, they will seek written evidence that an adequate waste audit has been carried out at the producers premises to demonstrate that waste has been segregated in line with the Safe Management of Healthcare Waste (HTM 07 01) government guidance.

Table 1 Comparison of Indicative BAT with key measures proposed by the operator	
Indicative BAT	*Key measures proposed*
The audit data must be obtained and assessed before delivery of the first batch of waste from each medical practice and then at the following minimum frequencies: • *every 12 months for each medical practice that produces five tonnes or more of clinical waste in any calendar year (see point 9 below);* • *every two years for each veterinary practice, dental practice, and laboratory that produces less than five tonnes of clinical waste in any calendar year,* • *every five years for other healthcare producers of clinical waste* *The information is no longer valid for pre-acceptance once the time intervals above have passed since the date the producer audit was completed. In addition, repeat the audits if the producer makes significant changes to their waste segregation.*	The pre-acceptance procedure details that the pre-acceptance audit will be received and assessed before any waste is collected and treated. The operator has confirmed that the frequency of audits will vary dependent on the volume of waste and the source of the waste, with reference to SGN 5.07. They have confirmed that they will request a new pre-acceptance audit from a customer if they make significant changes to their waste segregation practices.
Suitably trained and competent staff must assess the producer waste audit report. These staff must have a clear understanding of clinical waste, its composition, classification, packaging and transport, the wastes associated with specific healthcare activities, any conditions within the permit that relate to these, and the requirements for the completion of waste consignment and transfer notes. Keep a record of this assessment, its conclusions, and any actions taken (for example advising the producer that they must implement an offensive hygiene waste stream) with the audit.	The operator has detailed in their pre-acceptance procedures that the compliance manager and general manager are trained to assess the returned pre-acceptance audit forms and provide advice and guidance to the producer if they identify incomplete and inadequate areas of the audit form. The operator will keep a record of the assessment and actions taken.

Waste Acceptance Procedures- As with the waste pre-acceptance measures, the operator has confirmed via our application forms that their waste acceptance measures are in line with the SGN.	
On arrival: • *weigh each consignment of clinical waste unless alternative reliable volumetric systems are available;* • *do not accept waste unless there is sufficient authorised storage capacity and adequate manning;* • *check and if appropriate approve all documents, resolving discrepancies before accepting the waste.*	Their operating techniques describe how the waste is weighed. They also discuss how they discuss the expected loads at the beginning of each day to ensure the site has capacity to accept these wastes. They have noted that a suitably qualified staff member will check all incoming paper work and in the event of a discrepancy, take actions to resolve the discrepancy, including potentially sending the delivery vehicle back to the producer or to an alternative facility.
Where possible undertake confirmatory checks before offloading. Visual or electronic inspection of the waste within the 'carts' must in any event be carried out prior to disposal or recovery. Where waste is delivered in wheeled carts, or other bulk containers, it is likely that the waste at the bottom of the carts is not wholly visible and additional procedures are needed to check that waste.	Waste accepted on site will be subject to a visual check. The operator has confirmed that they will be tipping one cart into another so that all the waste within the cart can be inspected.
Where no non-conforming wastes are identified in the wheeled carts from an individual producer, or transfer station if that is where waste is loaded into the carts, for either a period of three months or six collections then the visual inspection frequencies for that producer can be reduced to spot checks of one cart in ten. If a spot check identifies a non-conforming waste, preventative measures must be taken to prevent a recurrence, and all loads from that source must be checked for the period of time set out above.	The operator has stated that they will undertake spot checks in line with section 2.2 of the SGN. They have confirmed that they will check every cart until they can be confident that no non confirming wastes are being received. They will then reduce spot check frequency.
Emissions Monitoring	
Prevent bioaerosol emissions from point sources where practicable, by the appropriate use of high efficiency particulate air (HEPA) filters.	The shredder uses a Local Exhaust Ventilation (LEV) system to shred under negative pressure. The LEV system uses HEPA filters.

Any plant that macerates/shreds clinical waste that has not already been rendered safe shall also be designed and built specifically to ensure microbiological aerosol containment. For example, include operation under negative pressure, with air drawn away from the hopper entrance and passed through HEPA filters. Hoppers must have doors on the opening to retain aerosols. The doors must be closed whilst the shredder is operating.	The shredder uses an LEV system to accept waste and shred under negative pressure. The LEV system uses HEPA filters.
Efficacy Monitoring- Annex 2	
The methods used for routine monitoring shall be the same as that used for site commissioning validation, unless an alternative method was demonstrated by parallel testing during commissioning to produce the same results.	The operator has confirmed they will be using spore strips of baccilus atrophaeus.
For thermal processes, thermal indicator strips or multipoint data loggers must always be used in parallel where possible.	The operator has confirmed that they will include a thermal indicator strip during efficacy monitoring.

Emissions monitoring- Annex 3 *Prepare and dispense (in a laboratory environment), a dry or liquid suspension of bacillus spores in a number of sealed, small volume plastic containers. Dispersed these throughout the waste load and processed.*	The operator has confirmed that they will prepare the suspension of bacillus spores in a number of sealed small volume plastic containers which will be dispersed throughout the waste load which will be processed.
Take samples: • *prior to the processing of the seeded waste (controls);* • *at intervals during the processing of the seeded waste (the intervals shall relate to process stages and timing of potential emissions);* • *periodically thereafter for at least 2 hours after the cycle is complete;*	The operator has confirmed they will take samples before the waste is processed, and periodically until at least two hours after the treatment cycle is complete.
Conduct air monitoring around identified point source emissions from the process, as well as at the site boundaries, and at any other relevant locations within the site – for example open vehicle access doors to building within which the plant is located.	The operator has confirmed that air monitoring will be undertaken at the key points of the facility as identified in Annex 3 of SGN 5.07.
To support the air monitoring outlined above, it is recommended that settle plates are employed in large numbers to form a grid-like pattern around the device/site.	The operator has detailed that they will undertake surface monitoring using settle plates.

Routine efficacy monitoring will be undertaken weekly for the first 6 months and monthly thereafter, in accordance with SGN 5.07. Three spore strips will be used, as required by Annex 2 of SGN 5.07. Fugitive bioaerosol emissions monitoring will be undertaken annually. We have included a note in the permit requiring the operator to undertake fugitive bioaerosol monitoring during commissioning. This is in line with SGN 5.07.

The operator has applied to accept and store 11 waste codes that do not appear in the list of acceptable waste codes in SGN 5.07. These waste codes are not clinical waste, but rather are other waste streams that arise at sites that also produce clinical waste. These wastes can be accepted at the facility, but the relevant SGN is 5.06 ‘Guidance for the Recovery and Disposal of hazardous and non hazardous waste’. The requirements of 5.06 are slightly different to that of 5.07, to reflect the differing types of waste handled. We have assessed the operator’s storage arrangements against BAT in 5.06. Wastes will be stored within leak proof UN approved containers on impermeable surfaces within the site building. The operator has confirmed that liquid wastes and WEEE wastes will be stored within bunded areas. The operator will be ensuring incompatible waste streams will not be stored

together. All waste for transfer will be kept within their own primary packaging. Waste storage areas will be checked once per shift. The operator will be using a tagging system on each cart to denote waste types. The operator will be using barcode identifier and radio frequency intermitting device readers to label and track all waste consignments. The operator has submitted a site layout plan, but this does not show the layout of the waste storage areas for wastes. The operator has said that the final layout will not be determined until the site is operational. The operator has stated that they will send an updated plan to the Environment Agency once the operations have commenced. As the operator is committed to storing waste in the building, within it's original containers and segregating incompatible waste, we are satisfied that we do not need to see the updated site plan before the permit is issued.

Volatile Organic Compounds (VOCs)

The operator identified in their environmental risk assessment that there is a risk of emitting volatile organic compounds if they have processed chemically contaminated waste and then the door seal leaked or they needed to vent in an emergency. The operator has confirmed in writing that they will not process chemically contaminated waste in the autoclave. They will be undertaking waste pre-acceptance and acceptance checks (as detailed in the BAT assessment section) to ensure that only the appropriate waste is processed. They will also be undertaking a preventative maintenance regime on the autoclaves so that the risk of leaks or emergency venting occurring is minimised. Every 12 hours the door seals will be checked as part of the site operating procedures. Based on these factors, we consider the risk of VOC emissions occurring to be low.

Site Condition Report

The site is located on an industrial estate, and uses an existing building which was most recently a dairy distribution depot. The ground surface within the building is made up of concrete. The external ground surface is made of reinforced concrete hardstanding which covers the majority of the site, though in the north and east section of the site the space between the building and the site boundary is landscaped with gravel and concrete paving slabs. The break between paving slabs is filled by wooden baffles. The concrete hardstanding has shallow trench drains which drain to foul sewer. Apart from at the installation entrance, kerbing is in place at the south western corner of the building and eastern installation boundary to reduce the potential for liquid spillages to reach permeable ground.

The site is located on made ground which according to a desk study of the history of the site, is likely to comprise of materials from colliery spoil and coal burning wastes. The site history indicates that the site was previously a slag heap. The surrounding area historically hosted a number of coal pits, collieries and quarries and a tile works.

The geology of the site is natural superficial deposits of Glacial Till over the Pennine Middle Coal Measures. The Coal Measures are designated as a secondary aquifer. The site condition report indicates that the Glacial Till is designated an unproductive aquifer, however the site may be underlain by perched groundwater.

The nearest watercourse is 60m to the north of the site which joins the Longbenton Letch.

The site condition report refers to improvement works being required to the drains and site surfacing. The operator has since then confirmed that these actions have been undertaken.

The operator has not taken baseline samples of soil and groundwater. This is in spite of them identifying in their site condition report that because of the previous use of the site as a slag heap or tip mean that contaminants such as metals and total petroleum hydrocarbons may be present. They have justified this as they consider the site is unlikely to have an impact on the soil and groundwater as they consider the site infrastructure will prevent any potential pollutants reaching the soil or groundwater. We have highlighted to the operator relevant sections of our H5 guidance so they are aware that if contamination is found when the permit is surrendered, they may have to remediate the land. Apart from this issue, we consider the site condition report to adequately characterise the site when accompanied by the rest of the supporting information received during determination.

Annex 1: decision checklist

This document should be read in conjunction with the Duly Making checklist, the application and supporting information and permit/ notice.

Aspect considered	Justification / Detail	Criteria met Yes
Consultation		
Scope of consultation	The consultation requirements were identified and implemented. The decision was taken in accordance with Regulatory Guidance Note (RGN) 6 High Profile Sites, our Public Participation Statement and our Working Together Agreements.	✓
Responses to consultation and web publicising	The web publicising and consultation responses (Annex 2) were taken into account in the decision. The decision was taken in accordance with our guidance.	✓
Operator		
Control of the facility	We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with EPR RGN 1 Understanding the meaning of operator.	✓
European Directives		
Applicable directives	All applicable European directives have been considered in the determination of the application. The site report says that the site is not an Industrial Emissions Directive installation- this is incorrect, the site is subject to the directive.	✓
The site		
Extent of the site of the facility	The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility. A plan is included in the permit and the operator is required to carry on the permitted activities within the site boundary.	✓
Site condition report	The operator has provided a description of the condition of the site.	✓

Aspect considered	Justification / Detail	Criteria met Yes
	We consider this description is satisfactory. The decision was taken in accordance with our guidance on site condition reports and baseline reporting under IED– guidance and templates (H5). See key issues for full details.	
Biodiversity, Heritage, Landscape and Nature Conservation	The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat. The site is within 10km of a Special Area of Conservation, a Special Protection Area and a Ramsar site. The site is also within 2km of a local nature reserve, and six local wildlife sites. A full assessment of the application and its potential to affect the designated sites has been carried out as part of the permitting process. We consider that the application will not affect the sites. We consider that the application includes adequate measures for controlling the risk from the site emissions so the designated sites will not be impacted. We have not formally consulted on the application. The decision was taken in accordance with our guidance. An appendix 11 has been completed and sent to Natural England for their information.	✓
Environmental Risk Assessment and operating techniques		
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The operator's risk assessment is satisfactory. The assessment shows that, applying the conservative criteria in our guidance on Environmental Risk Assessment or similar methodology supplied by the operator and reviewed by ourselves, all emissions may be categorised as environmentally insignificant.	✓

Aspect considered	Justification / Detail	Criteria met Yes
	We are satisfied that the measures the operator is proposing will ensure the environment is protected. See key issues for more details.	
Operating techniques	We have reviewed the techniques used by the operator and compared these with the relevant guidance notes. The proposed techniques/ emission levels for priorities for control are in line with the benchmark levels contained in the TGN and we consider them to represent appropriate techniques for the facility. The permit conditions ensure compliance with relevant BAT Reference Documents (BREFs) and BAT Conclusions. See key issues for more details.	✓
The permit conditions		
Waste types	We have specified the permitted waste types, descriptions and quantities, which can be accepted at the regulated facility. We are satisfied that the operator can accept these wastes for the following reasons: Annex 5 of our guidance note 5.07 details waste codes which are acceptable for autoclave treatment. We have checked the waste codes the operator has applied to treat in the autoclave against our guidance and consider them appropriate. Some of the waste codes they have applied to store are not listed in the 5.07 guidance, but we have assessed the storage arrangements against the BAT listed in guidance document 5.06 so we are satisfied these can be accepted. See BAT key issues section for more details. The operator has applied to include a 99 code, 09 01 99 which they describe as lead foils which are produced in X-ray departments within healthcare premises. We have included this code in the permit with this specific description.	✓

Aspect considered	Justification / Detail	Criteria met Yes
	We have included a description with wastes codes 18 01 06, 18 01 07, 18 02 05 and 18 02 06, which excludes the acceptance of X-Ray photochemicals under these waste codes. This is in line with our guidance, as well as in the application from the operator. We made these decisions with respect to waste types in accordance with Annex 5 of SGN 5.07 'Clinical Waste' and SGN 5.06 'Guidance for the Recovery and Disposal of hazardous and non hazardous waste'.	
Pre-operational conditions	Based on the information in the application, we consider that we need to impose pre-operational conditions. We have included a pre-operational condition requiring the operator to submit a site commissioning validation report. The wording is standard wording taken from SGN 5.07. The site commissioning report must contain confirmation of the treatment efficacy testing and results, the proposals for ongoing routine efficacy monitoring, confirmation of the emissions from the site and proposals for ongoing emissions monitoring at the site. See key issues section on validation testing for more details.	✓
Improvement conditions	Based on the information on the application, we consider that we need to impose improvement conditions. We have imposed improvement conditions to ensure that: ➢ the appropriate measures are in place to prevent fugitive emissions. ➢ the appropriate measures are in place to prevent annoyance from noise and vibration. See key issues section for further details.	✓
Incorporating the application	We have specified that the applicant must operate the permit in accordance with descriptions in the application, including all additional information received as part of the determination process. These descriptions are specified in the Operating Techniques table in the permit.	✓

Aspect considered	Justification / Detail	Criteria met Yes
	We have incorporated the application and supporting information received as part of permit determination as it details how the operator will manage the site in a way that minimises and prevents pollution. We have incorporated the odour management plan as this is how the operator proposes to manage the odour risk from the facility.	
Emission limits	We have decided that emission limits should be set for the parameters listed in the permit. Microbial emissions have been identified as being emitted in significant quantities and ELVs and equivalent parameters or technical measures based on BAT have been set for those substances. If the process and containment measures are not effective, there is the possibility for microbial emissions to escape the site. The monitoring will demonstrate the containment is effective, and the emission limits included will ensure the levels are within sector benchmark levels. We have included emission limit values for emission of bacillus spores for the fugitive bioaerosol monitoring of air and surfaces and discharges to wastewater. The limits included in the permit reflect the benchmarks in our guidance note 'EPR 5.07 Clinical Waste'.	✓
Monitoring	We have decided that monitoring should be carried out for the parameters listed in the permit, using the methods detailed and to the frequencies specified. These monitoring requirements have been imposed in order to demonstrate the treatment and containment measures are both working effectively to minimise the risk of microbial emissions. We have required the operator to undertake point source and fugitive bioaerosol monitoring of air and waste water using the methods they have proposed in their application. We have also included process monitoring to ensure they demonstrate the required treatment efficacy is achieved.	✓

Aspect considered	Justification / Detail	Criteria met Yes
	We made these decisions in accordance with our guidance note 'EPR 5.07 Clinical Waste'. Based on the information in the application we are satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate.	
Reporting	We have specified reporting in the permit. The reporting requirements and frequencies mirror the monitoring requirements. We made these decisions in accordance with guidance note 'EPR 5.07 Clinical Waste'.	✓
Operator Competence		
Environment management system	There is no known reason to consider that the operator will not have the management systems to enable it to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.	✓
Technical competence	Technical competency is required for activities permitted. The operator is a member of an agreed scheme. The operator has supplied certificates held by the technically competent manager. We consider they hold an appropriate level of qualification for this facility type.	✓
Relevant convictions	The National Enforcement Database has been checked to ensure that all relevant convictions have been declared. No relevant convictions were found. The operator satisfies the criteria in RGN 5 on Operator Competence.	✓

Aspect considered	Justification / Detail	Criteria met
		Yes
Financial provision	There is no known reason to consider that the operator will not be financially able to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.	✓

Annex 2: Consultation and web publicising responses

Summary of responses to consultation and web publication and the way in which we have taken these into account in the determination process.

Response received from
Public Health England
Brief summary of issues raised
Based on the information in the application, they have no significant concerns regarding the risk to the health of the local population. This response assumes the operator will take all appropriate measures to prevent or control pollution in accordance with relevant sector guidance and industry best practice.
Summary of actions taken or show how this has been covered
The operator has committed to following our guidance as part of the application. The permit conditions will require the operator to prevent or control pollution.

The application was advertised on our website from 10 July to 7 August 2015 for public comments, but no comments were received.