ABBVIE BIOCHEMICAL AND MEDICAL DEVICES FACILITY – ASSESSMENT OF COMPLIANCE WITH BAT CONCLUSION DOCUMENT ON BEST AVAILABLE TECHNIQUES IN COMMON WASTE WATER AND WASTE GAS TREATMENT/MANAGEMENT SYSTEMS IN THE CHEMICAL SECTOR, JUNE 2016

The full and complete BAT Conclusion Document is available at the EIPPC Bureau website: http://eippcb.jrc.ec.europa.eu/reference/

Conclusions on BAT	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
1. Environmental management systems		
BAT 1. In order to improve the overall environmental performance, BAT is to implement and adhere to an environmental management system (EMS) that incorporates all of the following features: (i) commitment of the management, including senior management; (ii) an environmental policy that includes the continuous improvement of the installation by the management; (iii) planning and establishing the necessary procedures, objectives and targets, in conjunction with financial planning and investment; (iv) implementation of procedures paying particular attention to: (a) structure and responsibility; (b) recruitment, training, awareness and competence; (c) communication; (d) employee involvement; (e) documentation; (f) effective process control; (g) maintenance programmes;	Applicable – The facility has an existing Environmental Management System (EMS) that will be upgraded to incorporate the new bio-chemical suite. The EMS is accredited to ISO 14001 standard. The EMS incorporates the requirements as outlined in BAT and is available for review by the Environmental Protection Agency (EPA) as required. AbbVie also maintain an EHS & Energy Sustainability Long Range Plan which sets out targets for energy efficiency and persons responsible for monitoring and measuring those targets and documenting successes. This document includes short term and long-term targets.	In place – revised EMS document to be produced following approval of Industrial Emissions (IE) licence.

(h) emergency preparedness and response; (i) safeguarding compliance with environmental legislation; (v) checking performance and taking corrective action, paying particular attention to: (a) monitoring and measurement (see also the Reference Report on Monitoring of emissions to Air and Water from IED installations — ROM); (b) corrective and preventive action; (c) maintenance of records; (d) independent (where practicable) internal or external auditing in order to determine whether or not the EMS conforms to planned arrangements and has been properly implemented and maintained; (vi) review of the EMS and its continuing suitability, adequacy and effectiveness by senior management; (vii) following the development of cleaner technologies; (viii) consideration for the environmental impacts from the eventual decommissioning of the plant at the design stage of a new plant, and throughout its operating life; (ix) application of sectoral benchmarking on a regular basis; (x) waste management plan (see BAT 13). Specifically, for chemical sector activities, BAT is to incorporate the following features in the EMS: (xi) on multi-operator installations/sites, establishment of a convention that sets out the roles, responsibilities and coordination of operating procedures of each plant operator in order to enhance the cooperation between the various operators; (xii) establishment of inventories of waste water and waste gas streams (see BAT 2). In some cases, the following features are part of the EMS: (xiii) odour management plan (see BAT 20); (xiv) noise management plan (see BAT 22).	AbbVie has also established Environmental Health & Safety (EHS) management requirements that conform to the ISO 50001, ISO 55001 and OHSAS18001 management system standards.	

BAT 2. In order to facilitate the reduction of emissions to water and air and the reduction of water usage, BAT is to establish and to maintain an inventory of waste water and waste gas streams, as part of the environmental management system (see BAT 1), that incorporates all of the following features: (i) information about the chemical production processes, including: (a) chemical reaction equations, also showing side products; (b) simplified process flow sheets that show the origin of the emissions; (c) descriptions of process-integrated techniques and waste water/waste gas treatment at source including their performances; (ii) information, as comprehensive as is reasonably possible, about the characteristics of the waste water streams, such as: (a) average values and variability of flow, pH, temperature, and conductivity; (b) average concentration and load values of relevant pollutants/parameters and their variability (e.g. COD/TOC, nitrogen species, phosphorus, metals, salts, specific organic compounds); (c) data on bio eliminability (e.g. BOD, BOD/COD ratio, Zahn-Wellens test, biological inhibition potential (e.g. nitrification)); (iii) information, as comprehensive as is reasonably possible, about the characteristics of the waste gas streams, such as: (a) average values and variability of flow and temperature; (b) average concentration and load values of relevant pollutants/parameters and their variability (e.g. VOC, CO, NOX, SOX, chlorine, hydrogen chloride); (c) flammability, lower and higher explosive limits, reactivity; (d) presence of other substances that may affect the waste gas treatment system or plant safety (e.g. oxygen, nitrogen, water vapour, dust).	Applicable – The management of wastewater will be subject to extensive monitoring and will be controlled through the implementation of the EMS and through a variety of environmental design considerations and operational measures. Low strength wastewater will be collected via a separate wastewater collection system to high high strength wastewater. High high strength wastewater from areas containing cytotoxic materials will be collected in a closed collection system and diverted to a sunken bulk storage tank which will be emptied via road tanker for offsite disposal (incineration). Low strength wastewater from secondary equipment wash and misc. process use and non-drug contact wastewater will be pumped to a separate sunken bulk storage tank and will undergo pH and temperature adjustment as required before being pumped to the municipal sewer outlet. Low strength water can also contain boiler blow-down and cooling tower water.	In place – revised EMS document to be produced following approval of IE licence. Wastewater discharges to sewer not yet operational (required for licenced activity only). To be implemented post grant of licence.

	Continuous sampling and grab sampling will be completed for wastewater composition in accordance with the IE licence requirements. Information from sample analysis to be retained as part of on-site inventory. Other foul water sources are domestic foul only. No waste gas emissions – boilers only.	
2. Monitoring		
BAT 3. For relevant emissions to water as identified by the inventory of waste water streams (see BAT 2), BAT is to monitor key process parameters (including continuous monitoring of waste water flow, pH and temperature) at key locations (e.g. influent to pre-treatment and influent to final treatment).	Applicable – Emissions of industrial effluent to the public sewer will be monitored at the licenced emission point in accordance with the requirements of IE licence for the facility. Continuous monitoring of pH, temperature and flow proposed. Other parameters to be sampled by composite sampler and reported monthly for daily, weekly and monthly averages. Information from sample analysis to be retained as part of on-site inventory.	Wastewater discharges to sewer not yet operational (required for licenced activity only).
BAT 4. BAT is to monitor emissions to water in accordance with EN standards with at least the minimum frequency given in the table on pages 29-30 of the BAT Conclusions document. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.	Not Applicable – There are no wastewater emissions to surface water. Emissions of wastewater will be to the public sewer which will be treated offsite. Monitoring of the low strength	Wastewater discharges to sewer not yet operational (required for licenced activity only). To be implemented post grant of licence.

	wastewater emissions from the facility will be at the licenced monitoring points (SE1a, SE1b) in accordance with the requirements of IE licence for the facility. Monitoring and analysis will be in accordance with the relevant EN standards indicated on the table. For Chemical Oxygen Demand (COD), Total Phosphorous, chlorides, sulphates, Oils, Fats and Greases, detergents the relevant ISO or national standard will be applied as agreed with the EPA.	
BAT 5. BAT is to periodically monitor diffuse VOC emissions to air from relevant sources by using an appropriate combination of the techniques I-III or, where large amounts of VOC are handled, all of the techniques I-III. I. sniffing methods (e.g. with portable instruments according to EN 15446) associated with correlation curves for key equipment; II. optical gas imaging methods; III. calculation of emissions based on emissions factors, periodically validated (e.g. once every two years) by measurements. Where large amounts of VOCs are handled, the screening and quantification of emissions from the installation by periodic campaigns with optical absorption-based techniques, such as Differential absorption light detection and ranging (DIAL) or Solar occultation flux (SOF), is a useful complementary technique to the techniques I to III. Description See Section 6.2.	Not Applicable – potential diffuse Volatile Organic Compounds (VOCs) sources are carefully controlled and as such there will be limited diffuse VOC sources (I.e. Isopropyl Alcohol (IPA) from pre-wetted wipes and spray bottles, solvents from printing). Monitoring of VOC emissions will not be required as there are no proposed emissions to air from the processes.	N/A

BAT 6. BAT is to periodically monitor odour emissions from relevant sources in accordance with EN standards. *Description: Emissions can be monitored by dynamic olfactometry according to EN 13725. Emission monitoring may be complemented by measurement/estimation of odour exposure or estimation of odour impact.*	Not applicable – No odours are expected from the plant. Vaporised hydrogen peroxide (used for decontamination) will be emitted to air via a catalytic converted unit which neutralises any waste gas including odours. No monitoring is required however certification of the unit's compliance will be provided to the EPA as required.	N/A
3. Emissions to Water		
3.1. Water usage and waste water generation		
BAT 7. In order to reduce the usage of water and the generation of waste water, BAT is to reduce the volume and/or pollutant load of waste water streams, to enhance the reuse of waste water within the production process and to recover and reuse raw materials.	Applicable - Process is constrained by Good Management Practice (GMP) regulations and as such there is limited opportunity for recovery and recycling of waste streams. Clean in Place (CIP) rinses will be once through only due to the exposure to cytotoxic material. Water used for cleaning is set based on validated cleaning cycles and therefore no potential for reductions in water use. Water reduction targets are in place for the remainder of the site in accordance with the company's environmental policies. No trade wastewater produced from existing medical devices facility.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.

	Boiler and cooling tower water recirculated and blow down discharged to sewer only as necessary.	
3.2. Waste water collection and segregation		
BAT 8. In order to prevent the contamination of uncontaminated water and to reduce emissions to water, BAT is to segregate uncontaminated waste water streams from waste water streams that require treatment.	Applicable – Stormwater drains and wastewater drains are segregated. Uncontaminated rainwater is collected and discharged to the land drain adjacent to the site rather than to foul sewer. Wastewater will be segregated into low strength and high high strength wastewater streams with only low strength wastewater to be discharged to sewer.	Bio-chemical facility construction in progress – BAT to be in place upon commencement.
BAT 9. In order to prevent uncontrolled emissions to water, BAT is to provide an appropriate buffer storage capacity for waste water incurred during other than normal operating conditions based on a risk assessment (taking into account e.g. the nature of the pollutant, the effects on further treatment, and the receiving environment), and to take appropriate further measures (e.g. control, treat, reuse).	Applicable – Low strength wastewater will be diverted to a bunded 10m^3 sunken sump tank where it will be pumped to a bunded 30m^3 GRP sunken bulk tank to smooth out peaks and troughs in the effluent. The bund will be chemical resistant coating lined concrete and is equipped with level detection i.e. in the unlikely event of a spillage, the wastewater will be pumped to the appropriate storage tank and tested. The wastewater stream will undergo pH and temperature adjustment as required before being pumped to the municipal	Bio-chemical facility construction in progress – BAT to be in place upon commencement.

	sewer outlet. It will be measured for flow/temperature/pH at point of discharge. The wastewater will then be combines with the foul sewer.	
3.3. Waste water treatment		
BAT 10. In order to reduce emissions to water, BAT is to use an integrated waste water management and treatment strategy that includes an appropriate combination of the techniques in the priority order given on the table on pages 31-32. Description: The integrated waste water management and treatment strategy is based on the inventory of waste water streams (see BAT 2).	Applicable – Process-integrated techniques and wastewater pre-treatment (pH and temperature adjustment) have been utilised. Final wastewater treatment is via local Sligo Wastewater Treatment Plant (WWTP). Contaminant recovery not possible (cytotoxic material). Wastewater will be collected via separated wastewater collection systems (high high strength and low strength). Wastewater from areas containing cytotoxic materials will be collected in a closed collection system and the commissioned Process Automatic System and site SOPs will prevent cross contamination of low strength waste with high high strength waste. The process areas only contain high high strength drains. Wastewater that has not been contaminated by cytotoxic materials will be diverted to the low strength wastewater system for pH and	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.

	temperature adjustment and controlled disposal to sewer.	
BAT-associated emission levels (BAT-AELs): see Section 3.4.		
BAT 11. In order to reduce emissions to water, BAT is to pre-treat waste water that contains pollutants that cannot be dealt with adequately during final waste water treatment by using appropriate techniques. Description: Waste water pre-treatment is carried out as part of an integrated waste water management and treatment strategy (see BAT 10) and is generally necessary to: • protect the final waste water treatment plant (e.g. protection of a biological treatment plant against inhibitory or toxic compounds); • remove compounds that are insufficiently abated during final treatment (e.g. toxic compounds, poorly/nonbiodegradable organic compounds, organic compounds that are present in high concentrations, or metals during biological treatment); • remove compounds that are otherwise stripped to air from the collection system or during final treatment (e.g. volatile halogenated organic compounds, benzene); • remove compounds that have other negative effects (e.g. corrosion of equipment; unwanted reaction with other substances; contamination of waste water sludge). In general, pre-treatment is carried out as close as possible to the source in order to avoid dilution, in particular for metals. Sometimes, waste water streams with appropriate characteristics can be segregated and collected in order to undergo a dedicated combined pre-treatment.	Applicable – Wastewater that has been in contact with cytotoxic material will not be treated onsite and will not be discharged to sewer. This waste stream will require removal offsite for incineration. Low strength wastewater contains very low levels of contaminants and will not require pre-treatment onsite before discharging to sewer. Attenuation and pH and temperature adjustment will be provided prior to discharge to sewer. Certain lab chemicals and liquid wastes are also not suitable for discharge to the sewer and will be collected in suitable plastic drums, labelled as hazardous waste, and transferred to a designated waste chemical storage area. This will be managed by the facility's SOPs. Diesel and other fuel will be excluded from effluent by site management and control. There are 3 no. stormwater discharge points to the south and east of the site and 4 no. hydrocarbon interceptors within the drainage network and these are cleaned out as needed.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.

BAT 12. In order to reduce emissions to water, BAT is to use an appropriate combination of final waste water treatment techniques. Description: Final waste water treatment is carried out as part of an integrated waste water management and treatment strategy (see BAT 10). Appropriate final waste water treatment techniques, depending on the pollutant, are outlined on page 33.	Applicable – waste water will contain very low levels of contaminants and will not require preliminary or primary treatment (pH and temperature adjustment only) to ensure discharges from site meet the required quality standards thereby ensuring no damage to the downstream treatment facility. No anticipated issues with Total Nitrogen, Total P, Biochemical Oxygen Demand (BOD), COD, sulphates, chlorides, suspended solids, etc. Further details on the final wastewater treatment is provided in Attachment 7.3.2. Equivalent Levels of Protection.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.
Section 3.4. BAT-associated emission levels for emissions to water		
The BAT-associated emission levels (BAT-AELs), for emissions to water given in Table 1, Table 2 and Table 3 apply to direct emissions to a receiving water body from: (i) the activities specified in Section 4 of Annex I to Directive 2010/75/EU; (ii) independently operated waste water treatment plants specified in Section 6.11 of Annex I to Directive 2010/75/EU provided that the main pollutant load originates from activities specified in Section 4 of Annex I to Directive 2010/75/EU; (iii) the combined treatment of waste water from different origins provided that the main pollutant load originates from activities specified in Section 4 of Annex I to Directive 2010/75/EU. The BAT-AELs apply at the point where the emission leaves the installation.	Not Applicable – No direct discharge to receiving waters. All discharges to public foul sewer. Attachment 7.3.2. Equivalent Levels of Protection provides an overview of the proposed Emission Limit Values (ELVs) for the facility and outlines how equivalent levels of protection will be met by the offsite wastewater treatment to ensure compliance with BAT ELVs. Non-wastewater streams (i.e.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.

The associated monitoring is in BAT 4.	uncontaminated stormwater) will be collected in a site stormwater drain network and discharged via hydrocarbon interceptors to the surface water drain adjacent to the site.	
4. Waste		
BAT 13. In order to prevent or, where this is not practicable, to reduce the quantity of waste being sent for disposal, BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered.	Applicable – There is a waste management plan and EMS in place for the existing facility. This will be updated to reflect the site changes associated with the new bio-chemical suite. The EMS includes a requirement for the site to manage wastes in accordance with Waste Hierarchy. All waste management to be carried out in accordance with the IE licence and relevant legislation, is overseen by the EHS and Supply Chain. The EHS Department regularly audit the onsite waste storage facilities and infrastructure and provide advice on waste segregation requirements. EHS support Operations and Supply Chain in preparing and updating documented procedures for waste management, managing the waste contractors, auditing and maintaining a full paper trail of waste documentation for all waste movements from the site.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.
BAT 14.	Not Applicable – No waste water sludge	N/A

In order to reduce the volume of waste water sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of the techniques given in the table on page 36.	generated.	
5. Emissions to air		
5.1. Waste gas collection		
BAT 15. In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is to enclose the emission sources and to treat the emissions, where possible.	Applicable – hydrogen peroxide to be used for sterilisation in the new bio-chemical suite. Waste VHP gases collected in dedicated extract and treated using catalytic converter. No waste gases from the existing facility.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.
5.2. Waste gas treatment		
BAT 16. In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques. Description: The integrated waste gas management and treatment strategy is based on the inventory of waste gas streams (see BAT 2) giving priority to process-integrated techniques.	Applicable – hydrogen peroxide to be used for Isolator sterilisation in the new bio-chemical suite. Waste Vaporised Hydrogen Peroxide (VHP) gases collected in dedicated extract and treated using 2 no. catalytic converters in series on the exhaust line. The use of VHP is within a single fill/finish suite onsite and therefore is not relevant to the entire process as a whole. Integrated techniques to not apply.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.
5.3. Flaring		
BAT 17. In order to prevent emissions to air from flares, BAT is to use flaring only for safety reasons or non-routine operational conditions (e.g. start-ups, shutdowns) by using one or both of the techniques given in the table on page 37.	Not Applicable – no flaring	N/A

BAT 18. In order to reduce emissions to air from flares when flaring is unavoidable, BAT is to use one or both of the techniques given in the table on page 37.	Not Applicable– no flaring	N/A
5.4. Diffuse VOC emissions		
BAT 19. In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given below: Plant Design a) Limit the number of potential emission sources b) Maximise process-inherent containment features c) Select high-integrity equipment d) Facilitate maintenance activities by ensuring access to potentially leaky equipment Plant Commissioning e) Ensure well-defined and comprehensive procedures for plant/ equipment construction and assembly. This includes using the designed gasket stress for flanged joint assembly f) Ensure robust plant/equipment commissioning and handover procedures in line with the design requirements Plant Operation g) Ensure good maintenance and timely replacement of equipment h) Use a risk-based leak detection and repair (LDAR) programme i) As far as it is reasonable, prevent diffuse VOC emissions, collect them at source, and treat them The associated monitoring is in BAT 5.	Applicable – As part of the design of the facility the project engineers have identified a number of measures designed to limit emission sources, improve integrity of process equipment and connections etc. Commissioning will be completed by vendors as part of the project – this will be overseen by suitably qualified engineers to ensure the required performance criteria are achieved. IPA, used as 70% IPA in pre-wetted wipes and both 99.7% and 70% IPA in bottles, will be used for cleaning and sterilising production surfaces after use. IPA will be stored internally in sealed wipes packaging and sealed bottles in the Warehouse until used. Di-methyl alcohol (DMA) and di-methyl sulfoxide (DMSO) will be used for dilution of the toxin for Monoclonal Antibody (MAB) conjugation in small quantities (6-12L). 100% DMA will be delivered to site in sealed 5L, 15L or 25L bottles and will be stored within the designated flammables area of the Warehouse. DMA will be transferred	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.

	directly to the conjugation suite where it will be pumped using a peristaltic pump and single use tubing. There are no anticipated fugitive emissions from this process. Glacial acetic acid required in small quantities as part of the buffer solution formulation will be stored in sealed containers (1L bottles) in the Warehouse prior to use. These will be dispensed directly into the buffer solution within an air-controlled environment. Within the existing processes, the anticipated solvent usage will include solvents used in printing onto medical devices. Solvents used in printing are stored in sealed containers in locked cabinets until use. The volumes used are not significant and there are no significant fugitive emissions requiring abatement.	
BAT 20. BAT 20. In order to prevent or, where that is not practicable, to reduce odour emissions, BAT is to set up, implement and regularly review an odour management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements: (i) a protocol containing appropriate actions and timelines; (ii) a protocol for conducting odour monitoring; (iii) a protocol for response to identified odour incidents;	Not applicable – No odours are expected from the plant.	N/A

(iv) an odour prevention and reduction programme designed to identify the source(s); to measure/estimate odour exposure; to characterise the contributions of the sources; and to implement prevention and/or reduction measures. The associated monitoring is in BAT 6.		
BAT 21. In order to prevent or, where that is not practicable, to reduce odour emissions from waste water collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques given in the table on page 39.	Not applicable – No odours are expected from the plant.	N/A
5.6. Noise emissions		
BAT 22. In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to set up and implement a noise management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements: (i) a protocol containing appropriate actions and timelines; (ii) a protocol for conducting noise monitoring; (iii) a protocol for response to identified noise incidents; (iv) a noise prevention and reduction programme designed to identify the source(s), to measure/estimate noise exposure, to characterise the contributions of the sources and to implement prevention and/or reduction measures.	Applicable- A noise management plan including noise monitoring will be outlined in the facility's EMS. The impact assessment undertaken as part of the Environmental Impact Assessment Report (EIAR) found that predicted noise levels associated with the day to day operations of the site will be compliant with the proposed criteria applicable to a site of this nature. Due consideration as part of the detailed design process will ensure that the new development will operate within the noise limits stipulated in the site IE licence issued by the EPA.	Bio-chemical facility construction in progress – BAT to be in place upon commencement in 2018.
BAT 23. In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to use one or a combination of the techniques given in the table on page 40.	Applicable - Noise from external plant items will be minimised through installation of low noise generating equipment. Through equipment	Bio-chemical facility construction in progress – BAT to be in place upon commencement

	specification, all new internal plant will be below 85dB. No new external plan (other than the generator, which is for emergency situations only). Noise model shows that operational noise will be within the relevant day time and night time limits at the noise receptors.	in 2018.