



# IEL Review Attachment-4-7-2- BREF-OFC (Organic Fine Chemicals Assessment)

Amgen Technology (Ireland) Ltd  
Syringe Capacity Scale-up  
IE0313150-22-RP-0016, Issue: A



# Document Sign Off

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Amgen Technology (Ireland) Ltd  
Syringe Capacity Scale-up  
IE0313150-22-RP-0016, Issue A

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### Qualifying Statement (disclaimer)

This document has been prepared by PM Group based on information supplied by third parties. Please note that where we refer to information in reports from others, it must be recognised that PM Group has no responsibility for the accuracy of the information contained therein.

## 1 Introduction

Amgen Technology Ireland UC, hereinafter referred to as Amgen, has initiated a review of Industrial Emissions (IE) Licence P0019-02 for its installation located at Pottery Road, Dun Laoghaire, Co Dublin. In accordance with the requirements of the EPA's "*Licence Application Form Guidance: Industrial Emissions (IE), Integrated Pollution Control (IPC) and Waste (Version 2.1 – June 2021)*", the purpose of this report is to fulfil the requirements of Section 4, Subsection 4.7 of the IE Licence Review Application Form (Application No. LA011061), which requires an assessment of activities at the facility against applicable published Best Available Techniques Conclusions (BATC) and BAT Reference (BREF) documents available on the European IPPC Bureau website<sup>1</sup>. Definitions of BATC and BREF according to Directive 2010/75/EU are presented in Appendix A for reference.

The European IPPC Bureau published the BAT (Best Available Techniques) Reference Document (BREF) entitled "*Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals*" (abbreviated to BREF OFC) in August 2006. The BREF OFC reflects an information exchange carried out under Article 16(2) of Council Directive 96/61/EC<sup>2</sup> (known as the IPPC Directive) from 2003 to 2005 and includes the manufacture of pharmaceutical products using chemical or biological processes. The BREF OFC provides reference information for the permitting authority to take into account when determining permit conditions.

The purpose of this report is to demonstrate that site activities comply with the requirements of BAT conclusions presented in Chapter 5 of the BREF OFC and that appropriate measures are implemented to prevent pollution with a detailed assessment of each individual BAT presented in Appendix B.

The Amgen facility have been designed to operate utilising the best available technology in compliance with all applicable regulations. Biotechnology represents a more favourable production process compared with traditional organic chemistry routes by virtue of low hazardous waste generation, comparatively clean waste water stream generation (with significantly less organic and nutrient loads than conventional bulk manufacturing due to absence of solvents and other hazardous chemicals in manufacturing process), low atmospheric emissions (little or no Volatile Organic Compound (VOCs) emissions) and low site fire or emergency risk (absence of bulk chemical storage on site).

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<sup>1</sup> <https://eippcb.jrc.ec.europa.eu/reference>

<sup>2</sup> No longer in force; Repealed by Industrial Emissions Directive 2010/75/EU.

# Appendix A

## Glossary

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According to Industrial Emissions Directive (IED) 2010/75/EU<sup>3</sup>:

*'best available techniques' means the most effective and advanced stage in the development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing the basis for emission limit values and other permit conditions designed to prevent and, where that is not practicable, to reduce emissions and the impact on the environment as a whole:*

*(a) 'techniques' includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned;*

*(b) 'available techniques' means those developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the costs and advantages, whether or not the techniques are used or produced inside the Member State in question, as long as they are reasonably accessible to the operator;*

*(c) 'best' means most effective in achieving a high general level of protection of the environment as a whole;*

*'BAT reference document' means a document, resulting from the exchange of information organised pursuant to Article 13, drawn up for defined activities and describing, in particular, applied techniques, present emissions and consumption levels, techniques considered for the determination of best available techniques as well as BAT conclusions and any emerging techniques, giving special consideration to the criteria listed in Annex III.*

*'BAT conclusions' means a document containing the parts of a BAT reference document laying down the conclusions on best available techniques, their description, information to assess their applicability, the emission levels associated with the best available techniques, associated monitoring, associated consumption levels and, where appropriate, relevant site remediation measures.*

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<sup>3</sup> Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast)

# Appendix B

## Detailed BREF OFC Assessment

## Best Available Techniques (BAT) Conclusions from Chapter 5 of BAT Reference (BREF) Document on Organic Fine Chemicals, August 2006 (Extracts)

The full and completed BREF Document on Organic Fine Chemicals, August 2006, is available at the EIPPC Bureau website:

<http://eippcb.jrc.ec.europa.eu/reference/>

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.1.1</b>	<b>BAT for Prevention of environmental impact</b>		
	<b>5.1.1.1</b>	<b>Integration of environmental, health and safety considerations into process development</b>		
1	5.1.1.1	BAT is to provide an auditable trail for the integration of environmental, health and safety considerations into process development (see Section 4.1.2).	<p><b>Applicable</b> Amgen syringe and vial products take all measures to protect the environment and health and safety by preparing detailed SOPs to be followed during all stages of the production process. Amgen syringe production procedures are validated by the EMEA and the FDA.</p> <p>New processes are brought to site through the 'Change Control' procedure. EHS considerations for the site have been incorporated in the process design. The environmental, health and safety (EHS) impact is assessed using "EHS by dEHSign" to conduct consistent, high quality EHS design reviews of projects managed through the Capital Investment Lifecycle Management (ILM) process.</p> <p>SOP-421149 "Control of New Substances" dictates how substances at the Amgen site are assessed prior to their arrival on site for their environment impacts and impact on staff from injury or illness due to exposure to hazardous substances whether solid, liquid or gas.</p>	In place
2	5.1.1.1	BAT is to develop new processes as follows (see Section 4.1.1):	<b>Applicable</b>	In place



BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		<p>a) to improve process design to maximise the incorporation of all the input materials used into the final product (see, e.g. Sections 4.1.4.3 and 4.1.4.8).</p> <p>b) to use substances that possess little or no toxicity to human health and the environment. Substances should be chosen in order to minimise the potential for accidents, releases, explosions and fires (e.g for solvent selection, see Section 4.1.3).</p> <p>c) to avoid the use of auxiliary substances (e.g. solvents, separation agents, etc. see e.g. Section 4.1.4.2)</p> <p>d) to minimise energy requirements in recognition of the associated environmental and economic impacts. Reactions at ambient temperatures and pressures should be preferred.</p> <p>e) to use renewable feedstock rather than depleting, wherever technically and economically practicable</p> <p>f) to avoid unnecessary derivatisation (e.g. blocking or protection groups)</p> <p>g) to apply catalytic reagents, which are typically superior to stoichiometric reagents (see, e.g. Sections 4.1.4.4 and 4.1.4.5)</p>	<p>New processes are brought to site through the 'Change Control' procedure. EHS considerations for the site have been incorporated in the process design. The environmental, health and safety (EHS) impact is assessed using "EHS by dEHSign" to conduct consistent, high quality EHS design reviews of projects managed through the Capital Investment Lifecycle Management (ILM) process.</p> <p>SOP-421149 "Control of New Substances" dictates how substances at the Amgen site are assessed prior to their arrival on site for their environment impacts and impact on staff from injury or illness due to exposure to hazardous substances whether solid, liquid or gas.</p> <p>Biotechnology offers a more advantageous method of production when contrasted with conventional organic chemistry pathways due to its reduced creation of hazardous waste, generation of relatively cleaner wastewater streams, diminished atmospheric emissions, and a decreased risk of site fires or emergencies. Amgen's site does not produce any drug substance onsite instead only formulates it, fills material into vials &amp; syringes, and then packages it.</p>	
	5.1.1.2	<b>Process safety and prevention of runaway reactions</b>		

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.1.1.2.1</b>	<b>Safety assessment</b>		
3	5.1.1.2.1	<p>BAT is to carry out a structured safety assessment for normal operation and to take into account effects due to deviations of the chemical process and deviations in the operation of the plant (see Section 4.1.6).</p> <p>In order to ensure that a process can be controlled adequately, BAT is to apply one or a combination of the following techniques (without ranking, see Section 4.1.6.1):</p> <ul style="list-style-type: none"> <li>a) organisational measures</li> <li>b) concepts involving control engineering techniques</li> <li>c) reaction stoppers (e.g. neutralisation, quenching)</li> <li>d) emergency cooling</li> <li>e) pressure resistant construction</li> <li>f) pressure relief.</li> </ul>	<p><b>Applicable</b></p> <p>As part of the Amgen EMS system, operators have control and can stop production process as required in the event of a fault developing to ensure safety of all employees, plant and the environment.</p> <p>There is no chemical process undertaken at Amgen.</p> <p>Biotechnology offers a more advantageous method of production when contrasted with conventional organic chemistry pathways due to its reduced creation of hazardous waste, generation of relatively cleaner wastewater streams, diminished atmospheric emissions, and a decreased risk of site fires or emergencies. Amgen’s site does not produce any drug substance onsite instead only formulates it, fills material into vials &amp; syringes and then packages it.</p> <p>New processes are brought to site through the ‘Change Control’ procedure. EHS considerations for the site have been incorporated in the process design. The environmental, health and safety (EHS) impact is assessed using “EHS by dEHSign” to conduct consistent, high quality EHS design reviews of projects managed through the Capital Investment Lifecycle Management (ILM) process.</p> <p>The design of each process at the existing Amgen campus and the design of the site expansion have and will undergo Process Hazard Analysis (PHA) reviews e.g. Hazard and Operability and EHS design reviews, ATEX reviews to ensure that the relevant control measures (including organisation measures, engineering techniques, reaction stoppers, emergency cooling, and pressure relief) are in place to avoid any hazards and plant operability issues which may or may</p>	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			<p>not lead to environmental impact. The requirement for some or all of the measures listed in this BAT Statement will be determined during these reviews.</p> <p>All vessels include pressure relief devices.</p> <p>Emergency cooling is not required at Amgen because no chemical reactions take place during production.</p>	
	<b>5.1.1.2.2</b>	<b>Handling and storage of hazardous substances</b>		
4	5.1.1.2.2	BAT is to establish and implement procedures and technical measures to limit risks from the handling and storage of hazardous substances (for an example, see Section 4.2.30).	<p><b>Applicable</b></p> <p>SOP-421149 “Control of New Substances” dictates how substances at the Amgen site are assessed prior to their arrival on site for their environment impacts and impact on staff from injury or illness due to exposure to hazardous substances whether solid, liquid or gas.</p> <p>New processes are brought to site through the ‘Change Control’ procedure. EHS considerations for the site have been incorporated in the process design. The environmental, health and safety (EHS) impact is assessed using “EHS by dEHSign” to conduct consistent, high quality EHS design reviews of projects managed through the Capital Investment Lifecycle Management (ILM) process.</p>	In place
5	5.1.1.2.2	BAT is to provide sufficient and adequate training for operators who handle hazardous substances (for an	<p><b>Applicable</b></p> <p>Handling and storage is carried out in accordance with the</p>	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		example, see Section 4.2.29).	<p>site's current Industrial Emissions Licence conditions and 'IPC Guidance Note on Storage and Transfer of Materials for Scheduled Activities, 2004' published by the EPA: -The loading and unloading of materials are carried out in designated areas protected against spillage and leachate runoff;</p> <ul style="list-style-type: none"> <li>- Chemical and waste storage areas are bunded and leak detection systems are in place;</li> <li>-The integrity and water-tightness of all tanks, bunding structures, containers and underground pipelines is carried out at least once every three years in accordance with IE Licence requirements and remedial action identified during survey is carried out in a timely manner;</li> <li>- A preventative maintenance programme is in place to ensure the timely repair/ replacement of equipment.</li> <li>- Spill response materials (containment booms and/or absorbent material) are maintained at strategic locations that are prominently identified around the site.</li> <li>- SOP-421149 "Control of New Substances" dictates how substances at the Amgen site are assessed prior to their arrival on site for their environment impacts and impact on staff from injury or illness due to exposure to hazardous substances whether solid, liquid or gas.</li> <li>- New processes are brought to site through the 'Change Control' procedure.</li> <li>- EHS considerations for the site have been incorporated in process design.</li> <li>- The environmental, health and safety (EHS) impact is assessed using "EHS by dEHSign" to conduct consistent, high quality EHS design reviews of projects managed through the</li> </ul>	

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			Capital Investment Lifecycle Management (ILM) process.	
	<b>5.1.2</b>	<b>Minimisation of environmental impact</b>		
	<b>5.1.2.1</b>	<b>Plant Design</b>		
6	5.1.2.1	<p>BAT is to design new plants in such a way that emissions are minimised by applying techniques including the following (see Sections 4.2.1, 4.2.3, 4.2.14, 4.2.15, 4.2.21):</p> <ul style="list-style-type: none"> <li>a) using closed and sealed equipment</li> <li>b) closing the production building and ventilating it mechanically</li> <li>c) using inert gas blanketing for process equipment where VOCs are handled</li> <li>d) connecting reactors to one or more condensers for solvent recovery</li> <li>e) connecting condensers to the recovery/abatement system</li> <li>f) using gravity flow instead of pumps (pumps can be an important source of fugitive emissions)</li> <li>g) enabling the segregation and selective treatment of waste water streams</li> <li>h) enabling a high degree of automation by application of a modern process control system in order to ensure a stable and efficient operation.</li> </ul>	<p><b>Applicable</b></p> <p>Amgen has a single entry/exit point for all materials, personnel and waste flows allowing for strict control. Segregation of hazardous waste is and will be carried out at source with wastes sent for recovery or recycling under licensed contract. Extract air vents are and will be located throughout the facility which will emit spent fresh air which has been utilised in building(s) HVAC system. The majority of material storage is and will be internal and material transfer is and will be carried out within enclosed areas, with only limited organic solvents present in process. Where possible gravity flow is and will be used in the drainage systems. Biowaste is and will be segregated at source and heat inactivated prior to joining the non bio process aqueous waste for treatment in effluent system.</p>	In place
	<b>5.1.2.2</b>	<b>Ground protection and water retention options</b>		
7	5.1.2.2.1	BAT is to design, build, operate and maintain	<b>Applicable</b>	In place

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		<p>facilities, where substances (usually liquids) which represent a potential risk of contamination of ground and groundwater are handled, in such a way that spill potential is minimised. Facilities have to be sealed, stable and sufficiently resistant against possible mechanical, thermal or chemical stress (see Section 4.2.27).</p>	<p>All storage facilities are specified in order to be compatible to what is being stored. All process vessels are with the required level alarms and switches in order to prevent overfills and unnecessary emissions. All process parameters are controlled by the PCS (Process Control System). Staff are trained and follow SOPs. The process undergoes HAZOPs to ensure that the necessary controls are in place in the case of deviations from the operating norms. The facility has been designed in order to allow for ease of and safe access for maintenance.</p> <p>All oil, fuel and chemicals are stored in bunded facilities and protected from impact that may result in ground contamination. Chemical storage is limited to bunded tank farms, drums stores and designated process areas. Handling and transfer of fuel and chemicals are carefully controlled. The volume of chemicals stored and the containment measures present minimises the risk of release of solid/liquid material spillages to the water environment in line with best practice, incorporated as part of detailed design of the facility. The environmental risk to ground and groundwater is low due to the water-based technologies currently on site. Notwithstanding, spill preventions measures are in place at the facility to prevent contamination of ground and groundwater: - The loading and unloading of materials are carried out in designated areas protected against spillage and leachate runoff; -</p> <p>Chemical and waste storage areas are bunded and leak detection systems are in place in line with EPA guidance Best Available Technique Conclusion requirements. Tanks located in the WWTP are also bunded, as required; -</p> <p>A drainage system that segregates storm water from waste water is maintained on site with double-walled piping maintained on the process drainage system;</p>	

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			<p>- The integrity and water-tightness of all tanks, bunding structures, containers and underground pipelines is carried out at least once every three years in accordance with IE Licence requirements and remedial action identified during survey is carried out in a timely manner;</p> <p>- A preventative maintenance programme is in place to ensure leakage is prevented.</p>	
8	5.1.2.2.2	BAT is to enable leakages to be quickly and reliably recognised (see Section 4.2.27).	<p><b>Applicable</b></p> <p>Site storage tanks and pipelines are on planned routine inspection programme (Risk Based Inspection programme) in accordance with IE Licence Requirements.</p> <p>A preventive maintenance (PM) system is in place through which routine maintenance checks are carried out and results recorded for e.g. pipelines are visually inspected. All tanks are pressure tested and/or internally inspected every three years. All bund area integrity are certified every three years. An Engineering Operations Maintenance protocol is in place for calibration and preventive maintenance of safety critical instrumentation and equipment.</p> <p>There is an Emergency Response Team (ERT) that are trained to respond to all foreseeable emergency events on site including but not limited to oil spills, chemical spills, internal and external, biological spills in production areas, small fire events, evacuations, response to life safety system alarms. As exists currently operations will be 24 hours a day, 7 days a week, with ERT cover at night and weekends that will be able to respond to emergency events outside of "normal working hours"</p> <p>Amgen's maintenance schedule provides for regular</p>	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
			inspection of all bunded facilities and for the periodic testing of bund containment.	
9	5.1.2.2.3	BAT is to provide sufficient retention volumes to safely retain spills and leaking substances in order to enable treatment or disposal (see Section 4.2.27).	<p><b>Applicable</b></p> <p>The internal process drainage system is capable of safely retaining any spill and leakages. This process system is connected to the waste water balancing system tanks with a total volume of 420 m<sup>3</sup> that can also act as retention if required.</p> <p>Spill kits and gully pot blockers are also available on site in order to contain any potential spill or leakages.</p> <p>Additional buffer tanks are also in place to hold any non-conforming waste water which is tucked off site by licenced contractors for additional treatment and not discharged to Dun Laoghaire Rathdown, Shanganagh WWTP.</p> <p>Wastewater must conform to licenced parameters prior to discharge to Dun Laoghaire Rathdown, Shanganagh WWTP. Should the wastewater fall outside of the trigger levels of PH 6.5 to 8.5, it is balanced prior to discharge.</p> <p>In line with '<i>IPC Guidance Note on Storage and Transfer of Materials for Scheduled Activities, 2004</i>' published by the EPA, the capacity of all bunded area is at least 110% of the volume of the largest vessel/tank or 25% of the total volume stored in the area, whichever is greater.</p>	In place
10	5.1.2.2.4	BAT is to provide sufficient retention volume to safely retain fire fighting water and contaminated surface water (see Section 4.2.28).	<p><b>Applicable</b></p> <p>In July 2020 Amgen had a fire water retention study carried</p>	In place



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			<p>out by AWN Consulting who confirmed that based on the risk assessment for each area in accordance with EPA's guidance, all of the areas of the Amgen plant were assessed and deemed to <i>be RO- Not at Risk</i> with exception of areas 12, 14 and 20. The study confirmed that sufficient fire water retention is in place to contain both firefighting media and product making allowance for potential rainfall contribution at each of these areas.</p>	
11	5.1.2.2.5	<p>BAT is to apply all the following techniques (see also Section 4.2.27):</p> <ul style="list-style-type: none"> <li>a) carrying out loading and unloading only in designated areas protected against leakage run-off</li> <li>b) storing and collecting materials awaiting disposal in designated areas protected against leakage run-off</li> <li>c) fitting all pump sumps or other treatment plant chambers from which spillage might occur with high liquid level alarms or regularly supervising pump sumps by personnel instead</li> <li>d) establishing programmes for testing and inspecting tanks and pipelines including flanges and valves</li> <li>e) providing spill control equipment, such as containment booms and suitable absorbent material</li> <li>f) testing and demonstrating the integrity of bunds</li> <li>g) equipping tanks with overfill prevention.</li> </ul>	<p><b>Applicable</b></p> <ul style="list-style-type: none"> <li>(a) All loading and unloading is carried out in areas that are connected to the site drainage system. Because the diversion valve on the storm water system is closed during loading and unloading, storm water runoff during loading and unloading is diverted to the firewater retention tanks and is removed off site by licenced contractors, Therefore any leakage or runoff is contained collected and stored for removal by tanker.</li> <li>(b) All wastes is held in designated areas which is connected to the site drainage system. Therefore any leakage run-off is collected and stored in the firewater retention tanks for removal off site by licenced contractor.</li> <li>(c) The facility and the process is governed by SOPs and by the PCS, which controls all process parameters. Tanks are fitted with high level alarms to prevent overflowing.</li> <li>(d) Visual check are carried out periodically on-site. Testing and inspection of tanks and pipelines is carried out in accordance with the IEL.</li> <li>(e) Spill kits are provided throughout the site.</li> <li>(f) Any bunds installed are initially tested for use and tested thereafter in accordance with the requirements of the IEL.</li> <li>(g) All tanks are fitted with overfill protection</li> </ul>	In place

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			The Amgen SOPs for maintenance and inspection contain all of the required BATs and all findings are recorded and actioned and closed out as required.	
	<b>5.1.2.3</b>	<b>Minimisation of VOC emissions</b>		
	<b>5.1.2.3.1</b>	<b>Enclosure of sources</b>		
12	5.1.2.3.1	BAT is to contain and enclose sources and to close any openings in order to minimise uncontrolled emissions (see Section 4.2.14).	<b>Applicable</b> Only use bench scale VOC's in labs and for surface cleaning/sterilisation	In place
	<b>5.1.2.3.2</b>	<b>Drying in closed circuits</b>		
13	5.1.2.3.2	BAT is to carry out drying by using closed circuits, including condensers for solvent recovery (see Section 4.2.14).	<b>Not applicable</b> No solvents used in process	Not applicable
	<b>5.1.2.3.3</b>	<b>Equipment cleaning using solvents</b>		
14	5.1.2.3.3	BAT is to keep equipment closed for rinsing and cleaning with solvents (see Section 4.2.14).	<b>Applicable</b> For all significant processing equipment that isn't designed for single use undergoes cleaning through an automated system known as Clean In Place (CIP). The equipment is subjected to rinsing with purified water, and any remaining contaminants are eliminated by employing recirculating cleaning solutions. This cleaning process is enclosed and contained.	In place
	<b>5.1.2.3.4</b>	<b>Recirculation of process vents</b>		
15	5.1.2.3.4	BAT is to use recirculation of process vapours where	<b>Not applicable</b>	Not applicable

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		purity requirements allow this (see Section 4.2.14).	Not applicable – water-based process. Small volume Solvents only used in labs and for surface sterilisation. Due to the nature of the process, significant quantities of process vapours are not generated on site.	
	<b>5.1.2.4</b>	<b>Minimisation of exhaust gas volume flows and loads</b>		
	<b>5.1.2.4.1</b>	<b>Closures of openings</b>		
16	5.1.2.4.1	BAT is to close any unnecessary openings in order to prevent air being sucked to the gas collection system via the process equipment (see Sections 4.2.14 and 4.3.5.17).	<b>Not applicable</b> Not Applicable – no exhaust gas collection. All gas vents from process areas (non-exhaust gases) have a non-return valves to prevent ingress or filter.	Not applicable
	<b>5.1.2.4.2</b>	<b>Testing the airtightness of process equipment</b>		
17	5.1.2.4.2	BAT is to ensure the airtightness of process equipment, especially of vessels (see Section 4.2.16).	<b>Not Applicable –</b> No exhaust gases produced from production. All process vessels are designed to be air tight for GMP purposes and are pressure tested.	Not applicable
	<b>5.1.2.4.3</b>	<b>Inertisation</b>		
18	5.1.2.4.3	BAT is to apply shock inertisation instead of continuous inertisation (see Section 4.2.17).	<b>Not applicable</b> Inertisation is not required.	Not applicable
	<b>5.1.2.4.4</b>	<b>Minimisation of exhaust gas volume flows from distillations</b>		

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
19	5.1.2.4.4	BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser (see Section 4.2.20).	<b>Not applicable</b> No distillation in the process.	Not applicable
	<b>5.1.2.4.5</b>	<b>Liquid additions into vessels</b>		
20	5.1.2.4.5	<p>BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg, unless reaction chemistry and/or safety considerations make it impractical (see Sections 4.2.15, 4.2.18). In such cases, the addition of liquid as top feed with a pipe directed to the wall reduces splashing and hence, the organic load in the displaced gas.</p> <p>If both solids and an organic liquid are added to a vessel, BAT is to use solids as a blanket in circumstances where the density difference promotes the reduction of the organic load in the displaced gas, unless reaction chemistry and/or safety considerations make it impractical (see Section 4.2.18).</p>	<b>Applicable</b> Liquids are added to process vessels using a peristaltic pump and disposable tubing	In place
	<b>5.1.2.4.6</b>	<b>Minimisation of peak emission concentrations</b>		
21	5.1.2.4.6	<p>BAT is to minimise the accumulation of peak loads and flows and related emission concentration peaks by, e.g.</p> <p>a) optimisation of the production matrix (see Section 4.3.5.17)</p> <p>b) application of smoothing filters (see Section 4.3.5.16 and also Section 4.3.5.13).</p>	<b>Not Applicable</b>	Not applicable
	<b>5.1.2.5</b>	<b>Minimisation of volume and load of waste water streams</b>		
	<b>5.1.2.5.1</b>	<b>Mother liquors with high salt content</b>		

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
22	5.1.2.5.1	BAT is to avoid mother liquors with high salt content or to enable the work-up of mother liquors by the application of alternative separation techniques (see Section 4.2.24), e.g. a) membrane processes, b) solvent-based processes, c) reactive extraction, d) or to omit intermediate isolation.	<b>Not applicable</b>	Not applicable
	<b>5.1.2.5.2</b>	<b>Countercurrent product washing</b>		
23	5.1.2.5.2	BAT is to apply countercurrent product washing where the production scale justifies the introduction of the technique (see Section 4.2.22).	<b>Not applicable</b> Product washing is not required.	Not applicable
	<b>5.1.2.5.3</b>	<b>Water-free vacuum generation</b>		
24	5.1.2.5.3	BAT is to apply water-free vacuum generation (see Sections 4.2.5, 4.2.6 and 4.2.7).	<b>Not applicable</b> Vacuum generation is not applied at the site.	Not applicable
	<b>5.1.2.5.4</b>	<b>Determination of the completion of reactions</b>		
25	5.1.2.5.4	For batch processes, BAT is to establish clear procedures for the determination of the desired end point of the reaction (for an example, see Section 4.2.23).	<b>Applicable</b> SOPs are in place which outline the desired end point of the formulation reaction. The PCS controls the recipe and all other process parameters. The same will apply to the production lines in the east expansion	In place
	<b>5.1.2.5.5</b>	<b>Indirect cooling</b>		
26	5.1.2.5.5	BAT is to apply indirect cooling (see Section 4.2.9)	<b>Not applicable</b>	Not applicable

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.1.2.5.6</b>	<b>Cleaning</b>		
27	5.1.2.5.6	BAT is to apply a pre-rinsing step prior to rinsing/cleaning of equipment to minimise organic loads in wash-waters (see Section 4.2.12).	<b>Applicable</b> All of the major processing equipment that is not single use are cleaned via an automated system (Clean In Place or 'CIP'). The equipment is rinsed with HWFI and residual debris or contaminants are removed by use of recirculating cleaning solutions.	In place
	<b>5.1.2.6</b>	<b>Minimisation of energy consumption</b>		
28	5.1.2.6	BAT is to assess the options and to optimise the energy consumption (for examples, see Sections 4.2.11 and 4.2.20).	<b>Applicable</b> Amgen monitors energy consumption and has in place energy saving procedures in place.	In place
	<b>5.2</b>	<b>Management and treatment of waste streams</b>		
	<b>5.2.1</b>	<b>Mass balances and process waste stream analysis</b>		
	<b>5.2.1.1.1</b>	<b>Mass Balances</b>		
29	5.2.1.1.1	BAT is to establish mass balances for VOCs (including CHCs), TOC or COD, AOX or EOX and heavy metals on a yearly basis (see Sections 4.3.1.4, 4.3.1.5 and 4.3.1.6)	<b>Not applicable</b> Due to the nature of waste streams generated on site mass balances for heavy metals, AOX and EOX are not applicable. COD is monitored in accordance with the site's IE licence P0019-02. COD of wastewater passing through SE1 is monitored for COD. The Process is designed to not generate wastewater with high organic loads.	

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.2.1.1.2</b>	<b>Waste Stream Analysis</b>		
30	5.2.1.1.2	BAT is to carry out a detailed waste stream analysis in order to identify the origin of the waste stream and a basic data set to enable management and suitable treatment of exhaust gases, waste water streams and solid residues (see Section 4.3.1.1).	<p><b>Applicable</b></p> <p>An inventory of waste water streams is maintained on site. The nature of the process leads to insignificant gaseous emissions. The standard operating procedure 'Waste Management Procedure' is used at the Amgen facility and details the methodology to be followed for the identification and characterisation, handling, storage and ultimate recovery, treatment or disposal of both solid and liquid waste materials at off-site licenced waste facilities. A Total Waste Management (TWM) contractor is responsible for waste management of hazardous and non-hazardous waste generated which includes a dedicated TWM team.</p>	In place
	<b>5.2.1.1.3</b>	<b>Assessment of waste water streams</b>		
31	5.2.1.1.3	BAT is to assess at least the parameters given in Table 5.1 for waste water streams, unless the parameter can be seen as irrelevant from a scientific point of view (see Section 4.3.1.2).	<p><b>Applicable</b></p> <p>Amgen monitors its process/wastewater daily, weekly quarterly and annually as required by Schedule C.3.2 of the current licence P0019-02.</p>	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation																							
		<table border="1"> <thead> <tr> <th>Parameter</th> <th></th> </tr> </thead> <tbody> <tr><td>Volume per batch</td><td rowspan="4">Standard</td></tr> <tr><td>Batches per year</td></tr> <tr><td>Volume per day</td></tr> <tr><td>Volume per year</td></tr> <tr><td>COD or TOC</td><td rowspan="12">Where it is expected</td></tr> <tr><td>BOD<sub>5</sub></td></tr> <tr><td>pH</td></tr> <tr><td>Bioimmobility</td></tr> <tr><td>Biological inhibition, including nitrification</td></tr> <tr><td>AOX</td></tr> <tr><td>CHCs</td></tr> <tr><td>Solvents</td></tr> <tr><td>Heavy metals</td></tr> <tr><td>Total N</td></tr> <tr><td>Total P</td></tr> <tr><td>Chloride</td></tr> <tr><td>Bromide</td></tr> <tr><td>SO<sub>4</sub><sup>2-</sup></td></tr> <tr><td>Residual toxicity</td></tr> </tbody> </table> <p>Table 5.1: Parameters for the assessment of waste water streams</p>	Parameter		Volume per batch	Standard	Batches per year	Volume per day	Volume per year	COD or TOC	Where it is expected	BOD <sub>5</sub>	pH	Bioimmobility	Biological inhibition, including nitrification	AOX	CHCs	Solvents	Heavy metals	Total N	Total P	Chloride	Bromide	SO <sub>4</sub> <sup>2-</sup>	Residual toxicity		
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	<b>5.2.1.1.4</b>	<b>Monitoring of emissions to air</b>																									
32	5.2.1.1.4	<p>For emissions to air, BAT is to monitor the emission profile which reflects the operational mode of the production process (see Section 4.3.1.8).</p> <p>In the case of a non-oxidative abatement/recovery system, BAT is to apply a continuous monitoring system (e.g. FID), where exhaust gases from various processes are treated in a central recovery/abatement system (see Section 4.3.1.8).</p> <p>BAT is to individually monitor substances with ecotoxicological potential if such substances are released (see Section 4.3.1.8).</p>	<p><b>Not applicable</b></p> <p>Not required due to the nature of waste gas stream generated at the facility. The two main emission points listed in Schedule B in IE Licence P0019-02 are from steam generating boilers, therefore, monitoring to reflect the operational mode of production is not applicable (maximum concentration of emitted parameters does not necessarily correlate with maximum steam demand as boilers will be more efficient at greater steam demand). In line with Schedule B of Licence No. P0019-02, boiler emissions to air are monitored bi-annually for nitrogen oxides</p>	Not applicable																							



BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.2.1.1.5</b>	<b>Assessment of individual volume flows</b>		
33	5.2.1.1.5	BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems (see Section 4.3.1.7).	<b>Not applicable</b> Not required due to nature of waste gas stream generated at the facility .No exhaust gas produced during process	Not applicable
	<b>5.2.2</b>	<b>Re-use of solvents</b>		
34	5.2.2	BAT is to re-use solvents as far as purity requirements (e.g. requirements according to cGMP) allow, by: a) using the solvent from previous batches of a production campaign for future batches as far as purity requirements allow (see Section 4.3.4) b) collecting spent solvents for on-site or off-site purification and re-use (for an example, see Section 4.3.3) c) collecting spent solvents for on-site or off-site utilisation of the calorific value (see Section 4.3.5.7).	<b>Not applicable</b> Solvents are not used in the production process and therefore not applicable	Not applicable
	<b>5.2.3</b>	<b>Treatment of exhaust gases</b>		
	<b>5.2.3.1</b>	<b>Selection of VOC recovery/abatement techniques and achievable emission levels</b>		
35	<b>5.2.3.1.1</b>	BAT is to select VOC recovery and abatement techniques according to the flow scheme in Figure 5.1	There are only minor emissions of VOCs from Laboratories. There are no process emissions of VOCs.	Not Applicable
	<b>5.2.3.1.2</b>	<b>Non-oxidative VOC recovery and abatement techniques</b>		
36	5.2.3.1.2	BAT is to reduce emissions to the levels given in Table 5.2 where nonoxidative VOC recovery or	<b>Not Applicable</b>	Not applicable

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		abatement techniques are applied (see Sections 4.3.5.6, 4.3.5.11, 4.3.5.14, 4.3.5.17, 4.3.5.18).	Not required due to nature of waste gas stream generated at the facility. No VOC emission other than minor emissions from laboratory analysis.	
	<b>5.2.3.1.3</b>	<b>VOC abatement by thermal oxidation/incineration and catalytic oxidation</b>		
37	5.2.3.1.3	BAT is to reduce VOC emissions to the levels given in Table 5.3 where thermal oxidation/incineration or catalytic oxidation are applied (see Sections 4.3.5.7, 4.3.5.8, 4.3.5.18).	<b>Not applicable</b> Not required due to nature of waste gas stream generated at the facility.	Not applicable
	<b>5.2.3.2</b>	<b>Recovery/abatement of NO<sub>x</sub></b>		
	<b>5.2.3.2.1</b>	<b>NO<sub>x</sub> from thermal oxidation/incineration or catalytic oxidation</b>		
38	5.2.3.2.1	For thermal oxidation/incineration or catalytic oxidation, BAT is to achieve the NO <sub>x</sub> emission levels given in Table 5.5 and, where necessary, to apply a DeNO <sub>x</sub> system (e.g. SCR or SNCR) or two stage combustion to achieve such levels (see Sections 4.3.5.7 and 4.3.5.19).	<b>Not applicable</b> There is no thermal treatment of waste gas at the facility.	Not applicable
	<b>5.2.3.2.2</b>	<b>NO<sub>x</sub> from chemical processes</b>		
39	5.2.3.2.2	For exhaust gases from chemical production processes, BAT is to achieve the NO <sub>x</sub> emission levels given in Table 5.5 and, where necessary to apply treatment techniques such as scrubbing or scrubber cascades with scrubber media such as H <sub>2</sub> O and/or H <sub>2</sub> O <sub>2</sub> to achieve such levels (see Section 4.3.5.1)	<b>Not applicable</b> No chemical production undertaken on site.	Not applicable
	<b>5.2.3.3</b>	<b>Recovery/abatement of HCl, Cl<sub>2</sub> and HBr/Br<sub>2</sub></b>		
40	5.2.3.3	BAT is to achieve HCl emission levels of 0.2 – 7.5 mg/m <sup>3</sup> or 0.001 – 0.08 kg/hour and, where necessary, to apply of one or more scrubbers using	<b>Not applicable</b> No HCL, Cl <sub>2</sub> or HBr/Br <sub>2</sub> used on site in any form	Not applicable

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		scrubbing media such as H <sub>2</sub> O or NaOH in order to achieve such levels (see Section 4.3.5.3)		
41	5.2.3.3	BAT is to achieve Cl <sub>2</sub> emission levels of 0.1 – 1 mg/m <sup>3</sup> and, where necessary, to apply techniques such as absorption of the excess chlorine (see Section 4.3.5.5) and/or scrubbing with scrubbing media such as NaHSO <sub>3</sub> in order to achieve such levels (see Section 4.3.5.2).	<b>Not applicable</b> No Chlorine emission from the site	Not applicable
42	5.2.3.3	BAT is to achieve HBr emission levels <1 mg/m <sup>3</sup> and, where necessary, to apply scrubbing with scrubbing media such as H <sub>2</sub> O or NaOH in order to achieve such levels (see Sections 1.1.1, 4.3.5.4).	<b>Not applicable</b> No HBr used on site	Not applicable
	<b>5.2.3.4</b>	<b>NH<sub>3</sub> emission levels</b>		
	<b>5.2.3.4.1</b>	<b>Removal of NH<sub>3</sub> from exhaust gases</b>		
43	5.2.3.4.1	BAT is to achieve NH <sub>3</sub> emission levels of 0.1 – 10 mg/m <sup>3</sup> or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H <sub>2</sub> O or acid in order to achieve such levels (see Section 4.3.5.20).	<b>Not applicable</b> Not required due to nature of waste gas streams generated at the facility.	Not applicable
	<b>5.2.3.4.2</b>	<b>NH<sub>3</sub> slip from DeNO<sub>x</sub></b>		
44	5.2.3.4.2	BAT is to achieve NH <sub>3</sub> slip levels from SCR or SNCR of <2 mg/m <sup>3</sup> or <0.02 kg/hour (see Section 4.3.5.7).	<b>Not applicable</b> SCR or SNCR is not required at the facility.	Not applicable
	<b>5.2.3.5</b>	<b>Removal of SO<sub>x</sub> from exhaust gases</b>		
45	5.2.3.5	BAT is to achieve SO <sub>x</sub> emission levels of 1 – 15 mg/m <sup>3</sup> or 0.001 – 0.1 kg/hour and, where necessary, to apply scrubbing with scrubbing media such as H <sub>2</sub> O or NaOH in order to achieve such levels (see	<b>Not applicable</b> No SO <sub>x</sub> emissions from site. Natural gas used as fuel and back up gas oil contains less than 10ppm sulphur	Not applicable

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		Section 4.3.5.21).		
	<b>5.2.3.6</b>	<b>Removal of particulates from exhaust gases</b>		
46	5.2.3.6	BAT is to achieve particulate emission levels of 0.05 – 5 mg/m <sup>3</sup> or 0.001 – 0.1 kg/hour and, where necessary, to apply techniques such as bag filters, fabric filters, cyclones, scrubbing, or wet electrostatic precipitation (WESP) in order to achieve such levels (see Section 4.3.5.22).	<b>Not applicable</b> No significant particulate emissions from boiler stacks and no other source of particulate emission on site	Not Applicable
	<b>5.2.3.7</b>	<b>Removal of free cyanides from exhaust gases</b>		
47	5.2.3.7	BAT is to remove free cyanides from exhaust gases, and to achieve a waste gas emission level of 1 mg/m <sup>3</sup> or 3 g/hour as HCN (see Section 4.3.6.2).	<b>Not applicable</b> No cyanides used or produced on site	Not applicable
	<b>5.2.4</b>	<b>Management and treatment of waste water streams</b>		
	<b>5.2.4.1</b>	<b>Typical waste water streams for segregation, pretreatment or disposal</b>		
	<b>5.2.4.1.1</b>	<b>Mother liquors from halogenation and sulphochlorination</b>		
48	5.2.4.1.1	BAT is to segregate and pretreat or dispose of mother liquors from halogenations and sulphochlorinations (see Sections 4.3.2.5, 4.3.2.10).	<b>Not applicable</b> Not required due to nature of the process at the facility.	Not applicable
	<b>5.2.4.1.2</b>	<b>Waste water streams containing biologically active substances</b>		
49	5.2.4.1.2	BAT is to pre-treat waste water streams containing biologically active substances at levels which could pose a risk either to a subsequent waste water treatment or to the receiving environment after discharge (see Sections 4.3.2.6, 4.3.7.5, 4.3.7.9, 4.3.8.13 and 4.3.8.18).	<b>Applicable</b> Genetically Modified Microorganism (GMM) activities used on site are classified as Class 1 and Class 2. These are use in a laboratory environment only and not in the production process.  Biowaste is segregated at source and then autoclaved waste streams to kill biologically active cells prior to removal from site for disposal.	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
	<b>5.2.4.1.3</b>	<b>Spent acids from sulphonations or nitrations</b>		
50	5.2.4.1.3	BAT is to segregate and collect separately spent acids, e.g. from sulphonations or nitrations for on-site or off-site recovery or to apply BAT given in 5.2.4.2 (see Sections 4.3.2.6, 4.3.2.8).	<b>Not applicable</b> Not applicable due to nature of the process at the facility.	Not applicable
	<b>5.2.4.2</b>	<b>Treatment of waste water streams with relevant refractory organic load</b>		
	<b>5.2.4.2.1</b>	<b>Relevant refractory organic loading</b>		
51	5.2.4.2.1	For the purposes of pretreatment, BAT is to classify organic loading as follows:  Refractory organic loading is not relevant if the waste water stream shows a bioeliminability of greater than about 80 – 90 % (see Sections 4.3.7.6, 4.3.7.7, 4.3.7.8). In cases with lower bioeliminability, the refractory organic loading is not relevant if it is lower than the range of about 7.5 – 40 kg TOC per batch or per day (see Sections 4.3.7.10, 4.3.7.12 and 4.3.7.13)	<b>Not applicable</b> Not applicable – no significant refractory organic loads	Not applicable
	<b>5.2.4.2.2</b>	<b>Segregation and pretreatment</b>		
52	5.2.4.2.2	BAT is to segregate and pretreat waste water streams containing relevant refractory organic loadings according to the criteria given in Section 5.2.4.2.1.	<b>Not applicable</b> Not applicable – no significant refractory organic loads	Not applicable
	<b>5.2.4.2.3</b>	<b>Overall COD elimination</b>		

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
53	5.2.4.2.3	For the segregated waste water streams carrying a relevant refractory organic load according to Section 5.2.4.2.1, BAT is to achieve overall COD elimination rates for the combination of pretreatment and biological treatment of >95 % (see Section 4.3.8.9).	<b>Not applicable</b> Not applicable – no significant refractory organic loads	Not applicable
	<b>5.2.4.3</b>	<b>Removal of solvents from waste water streams</b>		
54	5.2.4.3	BAT is to recover solvents from waste water streams for on-site or off-site reuse, using techniques such as stripping, distillation/rectification, extraction or combinations of such techniques, where the costs for biological treatment and purchase of fresh solvents are higher than the costs for recovery and purification (see Section 4.3.7.18).	<b>Not applicable</b> Due to the nature of waste water streams, recovery of solvents for reuse is not applicable. No CHC's used as part of process	Not applicable
55	5.2.4.3	BAT is to recover solvents from waste water streams in order to use the calorific value if the energy balance shows that overall natural fuel can be substituted (see Section 4.3.5.7).	<b>Not applicable</b> Due to the nature of waste water streams, recovery of solvents in order to use the calorific value is not applicable.	Not applicable
	<b>5.2.4.4</b>	<b>Removal of halogenated compounds from waste water streams</b>		
	<b>5.2.4.4.1</b>	<b>Removal of purgeable chlorinated hydrocarbons</b>		
56	5.2.4.4.1	BAT is to remove purgeable CHCs from waste water streams, e.g. by stripping, rectification or extraction and to achieve sum concentrations <1 mg/l in the outlet from pretreatment or to achieve sum concentrations of <0.1 mg/l in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Sections 4.3.7.18, 4.3.7.19, 4.3.7.20).	<b>Not applicable</b> Chlorinated hydrocarbons not present in waste water streams.	Not applicable
	<b>5.2.4.4.2</b>	<b>Pretreatment of waste water streams containing AOX</b>		

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
57	5.2.4.4.2	BAT is to pretreat waste water streams with significant AOX loads and to achieve the AOX levels given in Table 5.6 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.14).	<b>Not applicable</b> Halogenated organic compounds not present in wastewater streams.	Not applicable
	<b>5.2.4.5</b>	<b>Pretreatment of waste water streams containing heavy metals</b>		
58	5.2.4.5	BAT is to pretreat waste water streams containing significant levels of heavy metals or heavy metal compounds from processes where they are used deliberately and to achieve the heavy metal concentrations given in Table 5.7 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.22).	<b>Not applicable</b> No heavy metal used or arises from the process. Not applicable as waste water generated on site is adequately treated by the WWTP at Shanganagh.	Not applicable
	<b>5.2.4.6</b>	<b>Destruction of free cyanides</b>		
59	5.2.4.6	BAT is to recondition waste water streams containing free cyanides in order to substitute raw materials where technically possible (see Section 4.3.6.2).  BAT is to:  a) pretreat waste water streams containing significant loads of cyanides and to achieve a cyanide level of 1 mg/l or lower in the treated waste water stream (see Section 4.3.6.2) or to  b) enable safe degradation in a biological WWTP (see Section 4.3.6.2 under Applicability).	<b>Not applicable</b> Free cyanides not present in wastewater streams.	Not applicable
	<b>5.2.4.7</b>	<b>Biological waste water treatment</b>		
60	5.2.4.7	After the application of BAT given in Sections 5.2.4.1, 5.2.4.2, 5.2.4.3, 5.2.4.4 and 5.2.4.5 (management and treatment of waste water streams), BAT is to	<b>Applicable</b> The site has 2no 220m <sup>3</sup> neutralisation tanks used to treat	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		treat effluents containing a relevant organic load, such as waste water streams from production processes, rinsing and cleaning water, in a biological WWTP (see Sections 4.3.8.6 and 4.3.8.10).	wastewater from site operations. Post neutralisation and other pre-treatment effluent is discharged under consent to Shanganagh WWTP. In accordance Schedule B.2 of IE Licence P0019-02 flow rate, temperature and pH of treated effluent are monitored continuously. Composite samples of treated effluent are submitted to an external accredited laboratory for analysis for biological oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids, oils, fats & greases, toxicity, Zinc and VOCs & SVOCs.	
	<b>5.2.4.7.1</b>	<b>On-site and joint treatment</b>		
61	5.2.4.7.1	BAT is to ensure that the elimination in a joint waste water treatment is overall not poorer than in the case of on-site treatment. This is realised by regular degradability/bioeliminability testing (see Section 4.3.8.5).	<b>Not applicable</b> Effluent discharged under license to Shanganagh-Bray WWTP for biological treatment.	Not applicable
	<b>5.2.4.7.2</b>	<b>Elimination rates and emission levels</b>		
62	5.2.4.7.2	BAT is to take full advantage of the biological degradation potential of the total effluent and to achieve BOD elimination rates above 99 % and yearly average BOD emission levels of 1 – 18 mg/l. The levels relate to the effluent after biological treatment without dilution, e.g. by mixing with cooling water (see Section 4.3.8.11).  BAT is to achieve the emission levels given in Table 5.8.	<b>Applicable</b> Biological waste water treatment carried out in Shanganagh-Bray WWTP	In place
	<b>5.2.4.8</b>	<b>Monitoring of the total effluent</b>		
63	5.2.4.8	BAT is to regularly monitor the total effluent to and from the biological WWTP measuring at least the	In accordance Schedule B.2 of IE Licence P0019-02 flow rate, temperature and pH of treated effluent are monitored	In place



BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		parameters given in Table 5.1 (see Section 4.3.8.21).	continuously. Composite samples of treated effluent are submitted to an external accredited laboratory for analysis for biological oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids, oils, fats & greases, toxicity, Zinc and VOCs & SVOCs.	
	<b>5.2.4.8.1</b>	<b>Biomonitoring</b>		
64	5.2.4.8.1	BAT is to carry out regular biomonitoring of the total effluent after the biological WWTP where substances with ecotoxicological potential are handled or produced with or without intention (for examples, see Sections 4.3.8.18 and 4.3.8.19).	<b>Not applicable</b> Substances with ecotoxicological potential are not handled or produced with or without intention.	Not applicable
	<b>5.2.4.8.2</b>	<b>Online toxicity monitoring</b>		
65	5.2.4.8.2	BAT is to apply online toxicity monitoring in combination with online TOC measurement if residual acute toxicity is identified as a concern, for examples see Sections 4.3.8.7 and 4.3.8.20.	<b>Not applicable</b> Residual acute toxicity is not identified as a concern.	Not applicable
	<b>5.3</b>	<b>Environmental management</b>		
66	5.3	BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates, as appropriate to individual circumstances, the following features: (see Chapter 4) <ul style="list-style-type: none"> <li>• definition of an environmental policy for the installation by top management (commitment of the top management is regarded as a precondition for a successful application of other features of the EMS)</li> <li>• planning and establishing the necessary procedures</li> </ul>	An Environmental Management System (EMS) has been developed and is in operation at Amgen Technology (Ireland) UC in accordance with IE Licence requirements. The EMS is accredited to EcoMerit. The company also has an Environmental Policy and Environmental Management Programme in place within the organisation which is committed to adopt the best available technology and processes to attain a high standard of environmental control throughout the site operations.	In place

BAT No.	BAT Ref. Section	BAT Statement	Applicability Assessment (describe how the technique applies or not to your installation)	State whether it is in place or state schedule for implementation
		<ul style="list-style-type: none"> <li>• implementation of the procedures, paying particular attention to               <ul style="list-style-type: none"> <li>– structure and responsibility</li> <li>– training, awareness and competence</li> <li>– communication</li> <li>– employee involvement</li> <li>– documentation</li> <li>– efficient process control</li> <li>– maintenance programme</li> <li>– emergency preparedness and response</li> <li>– safeguarding compliance with environmental legislation.</li> </ul> </li> <li>• checking performance and taking corrective action, paying particular attention to               <ul style="list-style-type: none"> <li>– monitoring and measurement (see also the Reference document on Monitoring of Emissions)</li> <li>– corrective and preventive action</li> <li>– maintenance of records</li> <li>– independent (where practicable) internal auditing in order to determine whether or not the environmental management system conforms to planned arrangements and has been properly implemented and maintained.</li> </ul> </li> <li>• review by top management.</li> </ul>		