Attachment 1.2 Non-Technical Summary

1.0 INTRODUCTION

AbbVie Ireland NL B.V. (AbbVie) is applying to the Environmental Protection Agency (EPA) for an Industrial Emissions (IE) Licence for their existing facility in Ballytivnan, Co. Sligo. The site location is shown in Drawing 001. The requirement for a licence stems from the proposed addition of a bio-chemical pharmaceutical suite to the existing medical devices facility.

2.0 GENERAL INFORMATION

2.1 Planning Permission

Planning permission for the new bio-chemical pharmaceutical suite and additional site alterations (Planning Reference PL 18/185) was granted by Sligo County Council (SCC) on 7th August 2018.

The application was accompanied by an Environmental Impact Assessment Report (EIAR) together with a Natura Impact Screening Statement which were approved as part of the permission. As these were submitted prior to detailed design, additional and revised detail relating to the project since the time of the EIAR submission to SCC is therefore provided in this IE licence application.

2.2 Site Notice and Notifications of Application Intent

A site notice advising of the licence application was erected outside the AbbVie site on 29th August 2019, at the same location which the notice for planning permission was erected. This location is shown on Drawing 010. The notice will remain in place for one month after the date of submission to the EPA.

Notification of the Licence review application was also placed in the Irish Examiner on 30th of August 2018.

A letter was also sent to the planning authority, SCC, notifying them of the application on 30th of August 2018.

2.3 Activities to be Licenced

The licensable activity, under the First Schedule of the EPA Act 1992 is,
Class 5.16**:**
Production of Pharmaceutical Products including intermediates.

Production, for the purposes of the activities mentioned in paragraph 5.12 to 5.17, means the production on an industrial scale by chemical or biological processing of substances or groups of substances mentioned in any of those paragraphs. The regulations do not define what is meant by ‘industrial scale’ however the proposed facility will be an industrial use.

There are no restrictions on capacity outlined in the planning permission(s) for the facility.

2.4 Seveso III Regulations

Based on the information available for products used on site and corresponding usage and storage volumes, the EC (Control of Major Accidents Hazards involving Dangerous Substances) Regulations 2015 (S.I. No. 209 of 2015) do not apply to this site.

2.5 Medium Combustion Plant Regulations

Medium combustion plant directive (EU) 2015/2193 requirements including the relevant monitoring and emission limit values will be regulated by the IE Licence.

3.0 DESCRIPTION OF SITE AND ACTIVITIES

3.1 Description of the Facility

A site layout drawing of the site is provided (Drawing No. 002), showing the location of all activities and identifying the main buildings and facilities.

3.2 Hours of Operation

The Medical device section of the facility is an existing production site. The new bio-chemical suite intends to commence production in 2019 and will operate up to 7 days per week, 24 hours per day.

3.3 Environmental Management System (EMS) and Energy Management

An EMS will be in place at the facility to manage and control potential impacts of the facility on the environment. Environmental objectives and targets will be included in the EMS and there will be specific roles and responsibilities established within the facility to manage, control and operate the EMS. Procedures will be in place to ensure the targets are met and ongoing improvement is achieved.

AbbVie has established Environmental Health & Safety (EHS) management requirements that conform to the ISO14001, ISO 50001, ISO 55001 and OHSAS18001 management system standards.

In addition to the environmental and energy objectives and targets to be achieved by the proposed facility in line with AbbVie's own corporate standards, the new suite has been designed to achieve a very high standard of energy efficiency and sustainability. AbbVie is seeking to maximise opportunities for the use of renewable clean energy and resources e.g. AbbVie currently has a planning application with Sligo County Council (ref 18344) seeking permission to establish a 1700m^2 150kWp Photovoltaic cell installation. AbbVie will, where practicable, focus on the design of buildings that have a positive impact on the health of their occupants while saving valuable resources during both construction and operational stages.

It should be noted that the proposed bio-chemical suite will be a modern production facility regulated by the Health Products Regulatory Agency (HPRA) as well as the EPA and a number of other regulatory bodies. As with any HPRA-approved site/process, there are very specific restrictions in terms of the conditions under which the process is completed. cGMP (Current Good Manufacturing Practice quality system) is a system for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards. For the bio-chemical facility this means temperature, ventilation, lighting levels etc. are subject to relatively tight

restrictions, however there will be a variety of instances where energy saving measures have been implemented within the aforementioned limits.

AbbVie will incorporate the new facility in its existing ISO 50001 energy management system. It is anticipated that the operation of the facility, following completion of construction, will be subject to regular energy efficiency auditing and further energy reduction measures.

3.4 Structure and Personnel

The structure of upper management for the facility is detailed on the organizational chart below.

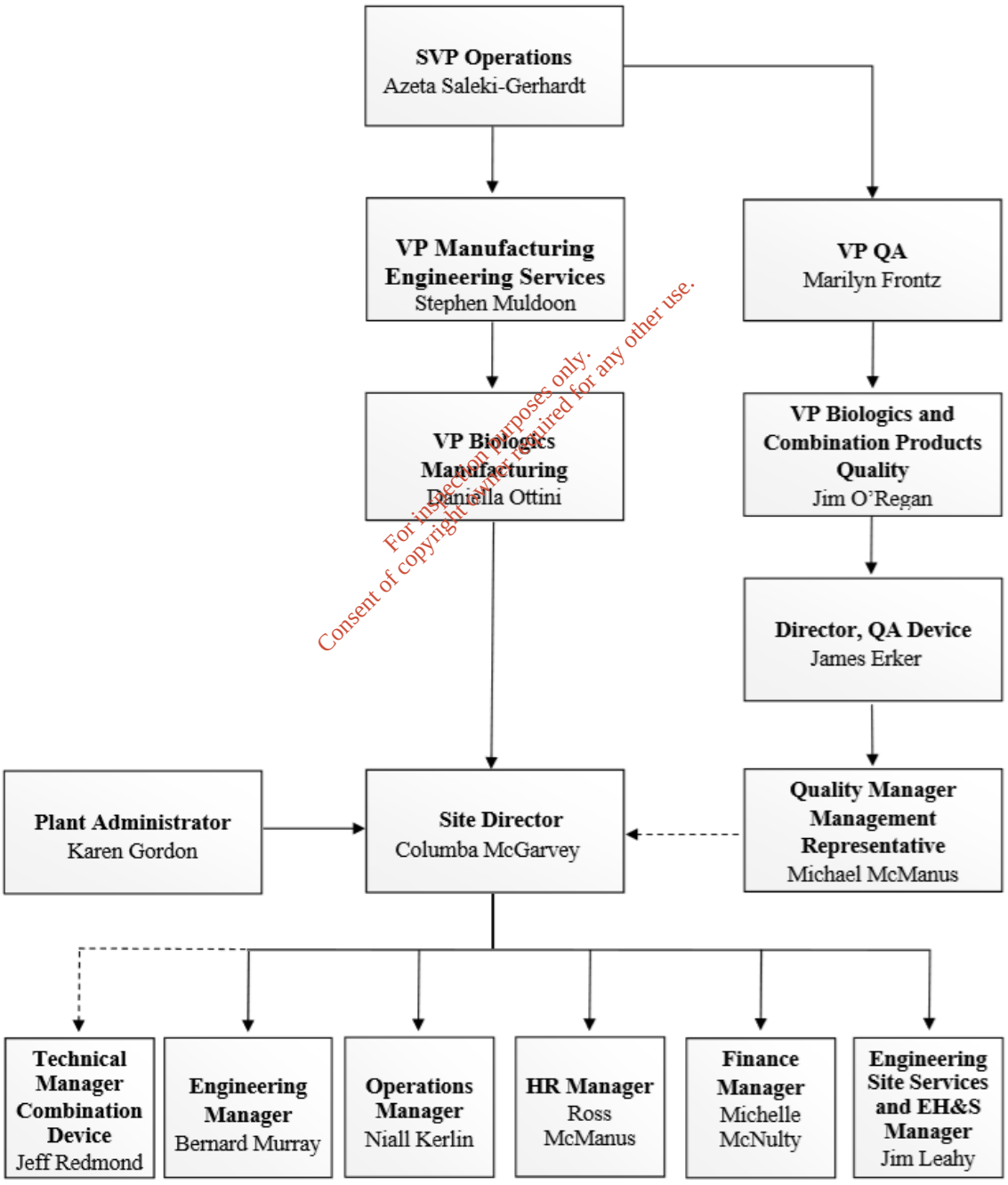

Figure 1. *AbbVie Ballytivnan High Level Organisational Chart*

The existing organisational chart for EHS and Engineering is provided in Figure 2 whilst the proposed organisation structure under the introduction of the bio-chemical suite ('biologics') is provided in Figure 3.

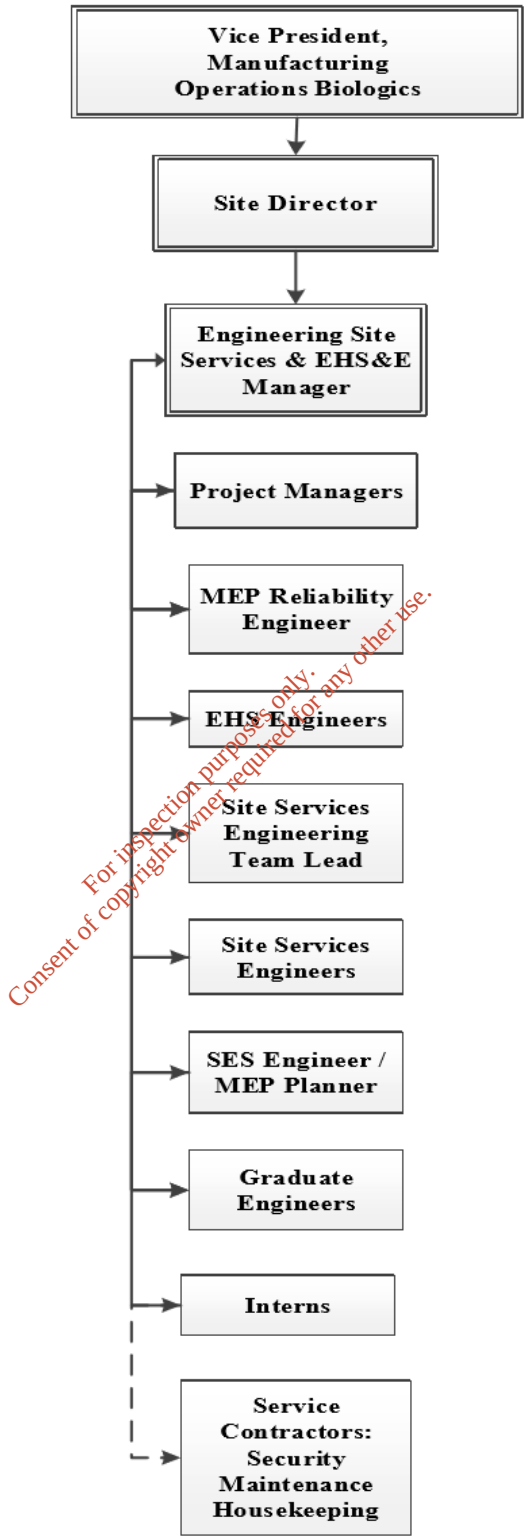

Figure 2. *AbbVie Ballytivnan EHS and Engineering Organisational Chart*

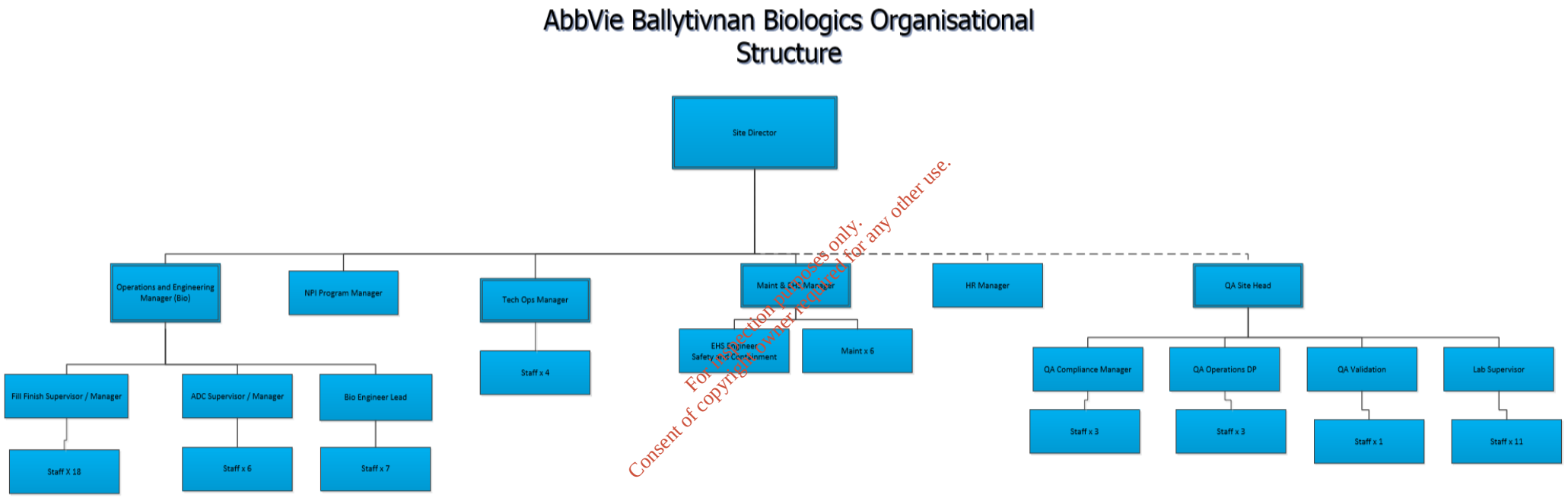

Figure 3. *AbbVie Ballytivnan Biologics Organisational Chart*

Whilst the entire leadership team has specific responsibilities for environmental and health & safety matters, the primary responsibility for the facilities maintenance and compliance with its IE licence rests with the facility Engineering Services & EHS Manager who reports directly to the Site Director. The Engineering Services & EHS Manager is supported by the EHS Engineer.

Approximately 120 personnel currently working at the site will be moved and deployed to a different manufacturing facility in the Sligo area and the circa 179 existing persons manufacturing medical devices will remain onsite. The new development will employ approximately 100 personnel and will operate on a shift basis, similar to existing shift patterns.

3.5 Plant Description

The site layout drawing (Drawing no. 002) shows the general layout of the buildings and car parking areas at the facility. This consists of the following buildings:

- Existing Manufacturing Facility;
- Proposed Integrated Biochemical Manufacturing Facility;
- Existing Warehouse, Utility, Administration and Canteen Buildings.

The site will also include:

- Waste storage area;
- Existing external lockable self-bunded chemstores (solvent store and hydrocarbon store);
- Liquid nitrogen bulk tank;
- LPG bulk tank;
- Cooling towers;
- High high strength wastewater storage sunken bulk tank and sump tank;
- Low strength wastewater sunken bulk tank and sump tank;
- Emergency generator;
- Security buildings;
- Car parking.

The proposed bio-chemical suite will be located in a shell space in Building 03 on the Sligo Ballytivnan site, along with required support facilities, equipment and utilities. The following Block Flow Diagram outlines the core processing functionality and the process related support functions.

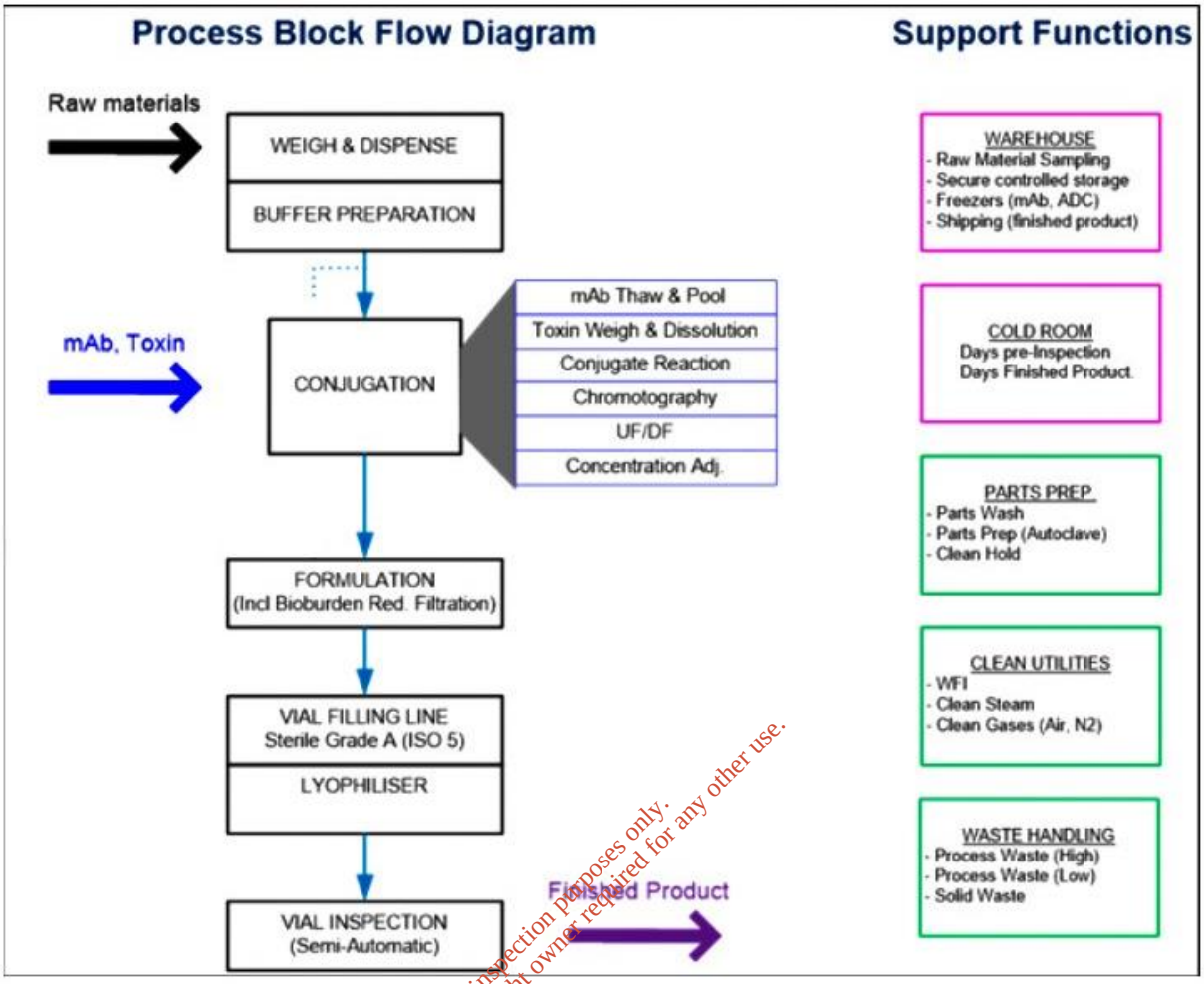

Figure 4 *Process Block Flow Diagram for Bio-Chemical Pharmaceutical Production*

3.5.1 Unit operations

3.5.1.1 New Operations

The proposed bio-chemical suite is anticipated to be used for the production of 2 no. drug preparations. Additional drug production lines may be incorporated into the facility processes at a later stage.

The 2 no. drug production lines operate slightly differently; however, the basic process operations can be described as follows:

1. Raw Materials

All raw materials will be brought in through the Warehouse, where there is provision for sampling within a controlled environment, and the materials will be stored until required. The Warehouse will also be used to receive and store process consumables, such as filter cartridges and single use equipment.

2. Weigh & Dispense for Buffer Preparation

Weighing & Dispensing will occur in a small dedicated room adjacent to the Buffer Preparation room. A walk-in downflow booth will be provided for dust minimisation, together with the appropriate bench scales and floor scales. Raw materials (powder and liquid) will be supplied in small quantities (typically bags up to 10 kg) that will

mitigate the requirement for material handling aids. Small quantities of raw materials (partial bags) will be stored within the raw material storage cabinets provided in the Weigh & Dispense room.

3. Buffer Preparation

Buffer preparation will occur in a controlled room adjacent to the conjugation room. This room will have separate access for personnel and materials from the general circulation corridor. There will be no handling of Active Pharmaceutical Ingredients (API) or potent material in the Buffer Prep room. The equipment will be dedicated to this room and will not move to other High Containment rooms (with the exception of totes).

Excipients will be supplied via the adjacent Weigh & Dispense Room in bags and containers.

Two ambient water for Injection (WFI) points of use will be provided in the room, one adjacent to the area for solution make-up, and the second for direct filling of WFI into single use (SU) bags. WFI will be filtered to 500L or 1000L SU bags (within totes) for pumping via a peristaltic pump through the wall to the Conjugation suite.

Buffers will be made up in large quantities (up to 500L) within Single Use Mixers (SUMs). The SUM can be located within a downflow cabinet for powder dispensing for dust minimisation during the powder addition step.

The complete Buffer will be filtered using a single use 0.2 µm filter into a SU bag (within tote) for storage at ambient temperature in the room, as shown below.

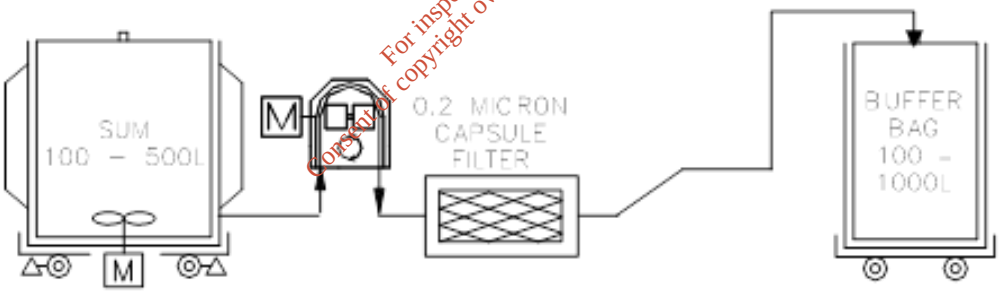

Figure 5 *Buffer filtration*

When the buffer is required for a process step in the Conjugation Room, the tubing from the SU buffer bags will be bundled and passed through to the Conjugation room using a clean-room wall Hose Transfer Pass-Through device. After use, these hoses will be pulled through to the Conjugation Room for disposal. All hoses will be uniquely identified to prevent mix-up.

For small scale make-ups (<50L) the buffers will be made-up using bottles or carboys within a downflow cabinet (or on a bench) using a magnetic lab mixer and filtered into SU bags or bottles for transfer through the material pass-through (cabinet cleanroom type) into the Conjugation suite. The material pass-through is uni-directional.

Other buffers (<50L) will also be made up in this area and will be transferred (via 0.2-micron filter) to a SU Bag, either small bags (<20L) or alternatively a 100L SU Bag (within tote). These will then be transferred to the Formulation Room in a tote/trolley via the MAL and the corridor.

All process contact components used in Buffer Prep are single use (bags, filters, tubing etc.). There will be no requirement for Clean-in-Place (CIP). The externals of equipment (SUMs, totes) will be cleaned by manual wipe down.

4. MAB (Monoclonal Antibody) Thawing & Pooling

MAB product will be delivered to the Conjugation room in a frozen state from the Warehouse, via the material airlock, and the frozen MAB containers will be thawed. After thawing the MAB product is ready to be pooled into a SUM and diluted with WFI or buffers. The MAB will then be dispensed from a GMP Isolator into a single use mixer

5. Weigh, Dispense and Dissolution of Toxin

Weighing and dispensing of the Toxin (drug linker) will be in a negatively pressurised containment isolator to provide containment controls for the safe handling of potent materials. Solvents for dissolution of the drug linker (DMSO or DMA) will be pumped directly into the dispensing chamber of the isolator as required.

7. Conjugation Reaction

Conjugation of the MAB and the toxin will occur within the conjugate reactors. The reactors will be designed as stainless steel, portable vessels with an agitator, a contained sampling device and an integrated cooling/heating jacket. The cooling/ heating requirements of the process will be controlled by a stand-alone Temperature-Control-Unit (TCU).

Once the toxin and MAB have been transferred to the Reactor, the Buffers, reducing agent, and quenching agent will be added to the reactor. Buffers will be transferred in SU Bags via the Material Pass-Through (cabinet type) from Buffer Preparation.

Upon completion of the conjugate process the in-process material will be transferred to the first purification step (ultra-filtration or chromatography) as required for the specific drug product.

8. Chromatography

Only one of the products requires a Chromatography manufacturing step. The chromatography process consists of a fluid handling skid and pre-packed disposable chromatography column. The use of disposable chromatography columns will be employed to provide a closed system process and eliminate the need for cleaning and column repacking. Buffers will be pumped into the Conjugation Room from the Buffer Prep Room. Upon completion of the chromatography process, the in-process material will be transferred to a SUM.

9. Ultra-Filtration / Depth-Filtration

The Ultra-Filtration / Depth-Filtration (UF/DF) process consists of a UF/DF skid and single-use filtration elements. The use of single-use filter elements will be employed to provide a closed and contained system process. Buffers will be pumped into the conjugation room from the buffer prep room.

Upon completion of the UF/DF process the concentrated in-process material will be collected in a SUM.

10. Formulation

The pooled product will then be formulated or diluted with buffer before transfer to the filling suite.

11. Filling

The formulated product will be delivered from the formulation room to the filling suite. A final filtration step will be undertaken in the filling isolator prior to the product being filled into vials.

The Filing Line is a single use product pathway. It is also fully integrated within the Lyophiliser.

Isolators are capable of wipe down and wetting (manual spray lances) for decontamination cleaning. All waste water generated will be directed to the high high strength waste collection system

The vial Filling Line is primarily intended for lyophilised fill with the sequence:

- Fill,
- Stopper,
- Load to Lyophiliser (Lyo),
- Freeze Dry,
- Lyo Unload,
- Cap,
- Tray-off.

Finished vials will be transferred to a Cold Room in preparation for semi-automatic inspection.

12. Lyophiliser (Freeze Dryer)

Filled vials will be transferred to the Lyo via the Lyo automated load/unload system, which is fully contained within an isolator. The Lyo is used to freeze-dry the final product.

13. Automation

All key process operations will be automated and operated by the process staff from within the process areas. The automation will allow the critical process parameters to be monitored and logged.

The automation will include control of raw materials through monitoring of dispensing operations and dispensed material use in the process.

Critical process utilities will be controlled and / or monitored to ensure product quality is not compromised and system alarms are dealt with in a timely manner.

3.5.1.2 Existing Operations

The existing site operations involves Moulding, Pad printing and Sub-assembly of plastic components for use in combination devices supporting AbbVie medical products.

1. Products

AbbVie Ballytivnan currently produces drug delivery devices, including an auto injector pen that is used by patients around the world who use the company's treatment indicated for a range of immune-related illnesses including rheumatoid arthritis and Crohn's disease.

2. Raw Materials

Resin, Ink, Springs, Trays and Corrugates are delivered to the site with digital records kept on all deliveries. Samples are collected and tested.

3. Moulding

The site manufactures combination devices. Components are moulded using the resin. In process samples are taken for inspection. Moulded parts are left to cure. Once cured, samples are measured in Metrology in-house.

4. Printing

Some components require printing. Numbers are printed on one variant of the pen. In Process samples are taken and inspected.

5. Assembly

Two halves are then assembled in the automation part of the facility. Post assembly functional testing is carried out in Metrology. Some of these components are injection moulded onsite and others are purchased and delivered to the site. Once manually assembled they are sent off site for sterilization and then returned for final packaging.

6. Metrology

The site functionally and dimensionally tests all components before they are shipped to a distribution centre in the Netherlands.

4.0 MATERIALS USE AND QUANTITIES

A full list of chemicals and their hazard statements is included in Attachment 4-6-2 in Section 4 of this IE licence application.

The majority of the hazardous chemicals that are or will be stored on site are stored in small quantities in sealed drums and bottles. These will be stored in designated areas within the Warehouse or in the existing self-bunded external chemstores.

Diesel will be stored within a 10,000 litre (L) double skinned belly tank integrated with the back-up generator. LPG is stored in a bulk 30m^3 tank. Liquid nitrogen will be stored in a 10m^3 bulk tank in the yard. The vaporized nitrogen will provide nitrogen to the lyophiliser and isolators. The nitrogen pad will be free of sumps, open drains or other areas where cold nitrogen gas could accumulate in the event of a release.

The high high strength wastewater tank will be bunded, sunken, and will have a capacity of 60,000L. The tank will be located beside the main building. The sunken low strength wastewater bulk tank will also be stored in the same location. This tank will have a capacity of 30,000L and will be within the same bund as the high high strength wastewater tank.

All wastewater sump and bulk storage tanks have chemical resistant lined bunds equipped with level detection. In the event of a spill, the spillage will be diverted to the appropriate storage tank and tested. The locations of the sumps and tanks are shown on Drawing 007.

Existing separate designated external chemstores are in place at the current facility, 1 no. for the storage of solvents and 1 no. for the storage of hydrocarbons. These are lockable with restricted access and are self-bunded. There are also 8 no. existing large plastics storage silos located to the south of the existing site.

Raw materials and supplies will be delivered to site by contractors/vendors. Access to the site is via the security centre at the west of the site, the goods will then be escorted to the delivery unloading platform located at the rear of the Warehouse. Goods will be unloaded by trained operators and stored in the Warehouse until use.

All bunds will be capable of containing 110% of the volume of the largest drum/tank within the bund or 25 % of the total volume of the substance stored therein (whichever is the larger) and will be designed in accordance with the EPA's guidelines for the storage and transfer of materials for scheduled activities (EPA, 2004). All bunds will be integrity tested every three years in accordance with the requirements of the IE licence, once issued.

Isopropyl Alcohol (IPA) used as 70% IPA on wet wipes (new bio-chemical facility) and 70% and 99.7% IPA in bottles (medical devices facility) will be used for decontaminating work surfaces in the production areas in accordance with good cGMP practices.

Di-methyl alcohol (DMA) and di-methyl sulfoxide (DMSO) will be used in small quantities (6-12 litres) for dilution of the toxins for the MAB conjugation.100% DMA/DMSO will be delivered to site in sealed 5L, 15L or 25L bottles and will be stored within the designated flammables area of the Warehouse.

Glacial acetic acid will be required in small quantities as part of the buffer solution formulation and will be stored in sealed containers (1L bottles) in the Warehouse prior to use.

Within the existing processes, solvents such as inks and thinners are used as part of the printing process and are stored in sealed containers in locked cabinets until use.

5.0 WASTE

Waste management is covered under Section 8 of this application. All waste documentation will be retained on site in accordance with legislative requirements and will be carried out in accordance with the Environmental Management System for the facility, which is designed to meet ISO 14001:2015 standards.

Transport of all waste leaving the site will be by appropriately permitted hauliers only and all waste to be taken to suitably registered, permitted or licenced facilities. Records and copies of relevant documentation of all waste leaving the site will be maintained on file.

Hazardous Waste

Lab chemicals and liquid wastes (other than high high strength wastewater) not suitable for discharge to the sewer will be collected in suitable containers, properly

labelled then transferred to a bunded area in a suitable onsite location prior to collection by a licenced waste disposal contractor.

Solid waste from single use equipment will be double bagged and transported to the waste storage area in the Warehouse where it will be placed into a combi-drum for transfer offsite by a specialist waste contractor.

Empty containers (Ink Videojet production cartridge's, IPA bottles, Pad Printer ink containers) are collected in a lined labelled hazardous waste bin in the Production area. Printer Ink Cartridges are removed to the designated storage location in the external waste disposal area and stored in a UN approved hermitically sealed 200L drum.

Health Care Centre Clinical/Bio Waste and uncontaminated sharps will be placed in yellow puncture-resistant sealable UN approved plastic containers. The plastic containers will then be stored in the designated UN approved 200L drum to await shipment. All other clinical wastes will be placed in UN approved plastic hazardous bags and transferred to the designated waste disposal area awaiting shipment.

All vessels containing hazardous wastes including bio-wastes, spent oils or other regulated substances will be clearly marked to show the contents, and periodically inspected to ensure integrity. Containers will be stored in such a manner as to prevent leaks and spills and in such a way that any accidental leaks or spills would be fully contained and would not pose a risk to soil, ground water or surface water.

Waste paints (solvent and oil-based paints) and thinners will be collected in the designated storage location in the external flammable stores area and placed in a UN approved hermitically sealed 200L drum. (UN1263)

Spent fluorescent tubes, broken Waste Electrical and Electronic Equipment (WEEE) and all batteries will be placed in the designated box in the waste storage area. It is anticipated that the annual tonnage of hazardous waste, including high high strength wastewater, will be approximately 3,125 tonnes.

Non-Hazardous Waste

Non-hazardous waste will be segregated for recycling and recycling stations will be located throughout the proposed facility, as per the existing facility. These will be stored in dedicated waste storage areas prior to collection by a specialist waste contractor.

General waste is collected each day and stored in the designated storage location in the waste storage area. The nominated waste company collects the general waste weekly. Food waste is disposed of in the designated compost waste bins in the canteen. The compost waste bin is serviced on a regular basis by an approved waste vendor.

Plastic from moulding and subassembly waste plastic (e.g. polypropylene/acetal) segregated at source in the moulding department is taken to the waste storage area on each shift and placed in the appropriate bin or bag according to the material.

All liquid dye is collected in the marked 5L containers and transferred to the 200L drums. Empty glass bottles are placed in a labelled plastic drum located in the waste storage area. All other liquid potential waste generated from test methods is collected in a marked 60L container.

Office printer cartridges are removed to the designated storage location in the hazardous waste solvent store and stored in UN approved hermitically sealed 200L drums.
When a consignment of waste has accumulated, the relevant personnel organizes disposal in accordance with the site SOPs.

It is anticipated that the annual tonnage of non-hazardous waste will be approximately 204 tonnes.

6.0 EMISSIONS AND MONITORING

6.1 Emissions to Air

Boiler emissions
There are 3 no. existing low pressure hot water boilers which operate on Liquid Petroleum Gas (LPG). All three of these boilers connect to a common flue with one emission point and all three boilers are minor emission points i.e. have a rating of under 1MW (540kW) each.

There will be 7 no. new boilers as part of the proposed development. Five of these will be hot water boilers (4 no. low pressure hot water and 1 no. domestic hot water) and will be minor emissions i.e. have a rating of under 1MW (540kW). The remaining two will be steam boilers (1 no. duty and 1 no. stand-by) which will be major emissions i.e. have a rating of over 1MW i.e. 1.6MW.

The two major emission steam boilers will have a stack height of 17.4m above ground level. The steam boilers will operate in a standby/duty mode, with only one boiler in operation at any one time.

A platform for EPA sampling and associated power points etc. will be provided for the 2 no. steam boilers as per EPA guidance on sampling. In accordance with the Medium Combustion Plant Regulations 2017, monitoring of NOx will be undertaken every 3 years.

Minor emissions
Minor emissions from the facility will include solvent store and pad printing extracts from the existing facility, the new and existing low pressure hot water boilers and domestic hot water boilers, tank and process vents, autoclave vents, and the vaporized hydrogen peroxide (VHP) vents (from sterilization). All minor emissions can operate up to 80% of the time or 7000 hours per year.

Air Handling Units (AHU) units in non-process areas (e.g. canteen, non- airlock corridors, office spaces, Warehouse, laboratory, etc) have not been included as minor emission points in the licence.

Potential Emissions
Potential emissions include pressure relief valves and 1 new emergency generator. The emergency generator will be tested on a monthly basis.

Fugitive Emissions

Fugitive emissions are defined as low level diffuse emissions, mainly of volatile organic compounds, that occur when either gaseous or liquid process fluids escape from plant equipment. There are no such emissions anticipated from the new facility.

Volatile solvents are used at the existing facility for printing and will be used at the proposed facility for surface cleaning (IPA) and solution preparation (DMA, DMSO and Acetic Acid). Solvents will be delivered in sealed bottles or drums and will remain sealed until required for use.

In the case of solution preparation solvents, these will be dispensed directly from the container to the point of use in an air-controlled environment. There will be no fugitive emissions from this process.

IPA and solvents used in printing will evaporate from the surface onto which they are applied into the internal room air. However, the volume of solvent lost to internal room air will not be significant.

6.2 Emissions to Sewer

Wastewater from the facility will comprise low strength wastewater including reject water from water purification systems, boilers and cooling towers blowdown, and wastewater from non-product contact equipment, as well as domestic effluent from welfare facilities such as toilets, showers and canteen facilities.

All low strength wastewater arising from the new bio-chemical suite, that will ultimately be discharged into the municipal sewerage system, will pass through a monitoring station (SE-1a). The average low strength wastewater volume for off-site disposal is expected to be in the region of 180m^3/day.

Existing foul effluent will tie into the wastewaters downstream of the monitoring station. This has recently been discussed and agreed with Irish Water as satisfying their initial requirements.

All wastewater will be discharged via Sewer Emission Point SE-1 to the local foul network and then to SCC Waste Water Treatment Plant (WWTP).

6.3 Emissions to Surface Water

Stormwater from the site arises from buildings run-off, car-parks, roadways, service yards and other developed areas of the site. There are 3 no. discharge locations which drain to the east and south of the site i.e. SW1, SW2, and SW3. These discharge points have manholes for visual inspection and drain via hydrocarbon petrol interceptors, as per the existing facility, before combining in the outfall of the plant to the Shannon Eighter watercourse.

As the area proposed for development is already mostly hard standing there will be no significant change in run-off from the site.

In accordance with Best Available Technology (BAT), clean stormwater is kept separate from wastewater and there is no inherent risk of cross-contamination. Stormwater run-off is from buildings and car parks only and therefore there is no requirement to undertake regular sampling of the stormwater prior to discharge. Weekly visual inspections will be undertaken for the stormwater discharge points in accordance with the facility's Licence.

6.4 Noise Emissions

The primary sources of outward noise in the operational context are deemed long term and will involve:

- Building Services and Factory Process Plant and
- Additional vehicular traffic on public roads.

The main operational noise sources associated with building services and factory process plant will include cooling towers, boiler stacks, AHU's, condenser units and various rooftop mounted fan and exhaust units. It is expected that all the plant items will operate continuously and up to 24/7.

Noise monitoring was undertaken at locations across the site as outlined in Attachment 7.1.3.2 of the licence application. Fixed noise monitoring locations are not proposed in this IE licence application and it is advised that monitoring locations be selected to best represent the noise sensitive receptors (NSRs).

6.5 Groundwater Monitoring

Operation of the plant will be according to BAT principles and in compliance with the licence for the site to ensure that inputs to, and any subsequent contamination of, soil and water environments does not occur during normal and/ or emergency conditions (material spillage or fire event situations).

There are no existing or proposed emissions points to ground from the facility.

There are 3 no. existing groundwater monitoring wells i.e. MW1, MW2 and MW3. There are no current indications of water table pollution arising either upstream of or on the site however it is proposed to undertake bi-annual groundwater monitoring as per other similar AbbVie sites.

It is proposed that monitoring results are compared with current regulatory limits and guidelines, including the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and the EPA (2003) Interim guidelines.

7.0 MITIGATION MEASURES/ABATEMENT

AbbVie will implement appropriate mitigation measures in order to protect the surrounding site environment and to follow regulations and limits set by legislation.

7.1 Atmospheric Emissions

Existing air quality is generally well within the National and European Union (EU) air quality standards therefore no abatement system is required for the new main air emissions. For the proposed development, no specific abatement is required as the operational phase is predicted to have an imperceptible impact on ambient air quality and climate.

New minor emissions from preparatory and production vessels, emissions from fume hoods, autoclave vents, lyo vents, production room vents, and low pressure hot water boilers are not considered to be significant and appropriate abatement (i.e. HEPA filters and 2 um filters as appropriate) will be employed to remove trace contaminants. Dual catalytic converters in series will be in place on the Isolator lines to convert H_2O2 to H_20 and O_2.

Existing minor emissions from the pad printer and the solvent store contain small amounts of VOCs; however, the quantities of emissions are not considered significant and abatement systems are not required.

7.2 Emissions to Sewer

A new wastewater collection sump and bulk tank system will provide for pH and temperature adjustment for the low strength wastewater should there be a need for this before discharge at sewer discharge point SE-1. Monitoring will also be undertaken as required by the IE licence.

7.3 Emissions to Surface Water

The current abatement technique for the stormwater network of the facility comprises all 3 no. stormwater emission points discharging via 4 no. existing hydrocarbon petrol interceptors. The stormwater then combines in the outfall of the plant to the Shannon Eighter watercourse. A Class 1 full retention interceptor will be installed on the stormwater drainage line draining the area around the bulk diesel storage tank as is required.

The potential effects on the local water environment are considered to be low for this proposed development so no abatement is required. However, the facility will continue to adhere to an environmental management plan (EMP) which will be in place to ensure compliance together with stringent EPA licencing requirements. This will include full containment of potential pollutant sources, site-specific emergency response measures and management of stormwater run-off from the site.

Monitoring will also be undertaken as required by the future licence requirements.

7.4 Noise Emissions

The impact assessment has found that predicted noise levels associated with the day to day operations of the new facility (i.e. building services and factory process plant) will be well within the proposed criteria applicable to a site of this nature, so no additional abatement will be required. Notwithstanding this, 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. Proposed AHUs will be internal and therefore do not require additional abatement.

Any change in noise levels associated with vehicles at road junctions in the vicinity of the proposed development is expected to be imperceptible so no abatement will be required.

8.0 COMPLIANCE

8.1 Air Emission Limits

Attachment 7.4.1 outlines the nature of the proposed major emissions including the relevant parameters. The only major emission points are the 2 no. boiler stacks.

As the facility falls within the scope of the Medium Combustion Plant Directive the emission limit values from Schedule 2 of the Directive apply. Schedule 2 specifies that new combustion points using gaseous fuels other than natural gas must comply with the Emission Limit Value (ELV) of <200 mg/Nm^3 for NOx.

The major emissions boilers have a designed NOx emission value of 200 mg/Nm³ which complies with the ELV for boilers fuelled by gaseous fuels other than natural gas (i.e. LPG) in operation after December 2018. As the total thermal input of the boilers is between 1-20MW, monitoring of the emissions will be undertaken every three years in accordance with Schedule 3 of the Directive.

The emergency diesel generator will also be monitored in accordance with the directive. In accordance with Regulation 13 of the Directive, the hours of use for the generators will be under the threshold limit and as such the emission limit values do not apply. Periodic monitoring will be undertaken in accordance with the regulations.

8.2 Sewer Emission Limits

Attachment 7.3.1 outlines the nature of the proposed discharge including the relevant parameters. These values have been discussed with Irish Water and are adequate to ensure no detrimental impact on the Sligo WWTP. Monitoring of these parameters will be undertaken as outlined in the attachment.

The relevant sectorial BAT instruments include the EU Decision BAT Conclusions for common wastewater and waste gas treatment / management systems in the chemical sector (2016) and the EU Reference Document on BAT for the Manufacture of Organic Fine Chemicals (2006). Both documents provide ELV's for discharges from a biological waste water treatment plant to a waterbody. As the wastewater from the facility will be treated offsite in an Irish Water Wastewater Treatment Plant (i.e. Sligo WWTP), these limit values have been addressed in Attachment 7.3.2 Equivalent Level of Protection.

8.3 Stormwater Emissions

In accordance with BAT, clean stormwater is kept separate from wastewater and there is no inherent risk of cross-contamination. Stormwater run-off is from buildings and car parks only and therefore there is no requirement to undertake regular sampling of the stormwater prior to discharge. Weekly visual inspections will be undertaken for stormwater discharge points in accordance with the facility's IE Licence.

Due to the nature of the run-off (stormwater from buildings and roads only) and the inclusion of hydrocarbon interceptors, the proposed discharge is unlikely to contain more than trace hydrocarbons and metals. It is not anticipated that the surface water quality will exceed the Environmental Quality Standards as set out in SI 272 of 2009 and SI 386 of 2015 (Surface Water Regulations).

8.4 Noise Emissions

From the detailed design of the facility, an assessment of all plant items was undertaken as part of the noise model (see Attachment 7.1.3.2). The details and location of all noise emission points and associated noise source data were provided by Jacobs Engineering. A detailed computer-based noise model has been prepared using proprietary noise modelling software package, *iNoise V2017 Enterprise*. Noise prediction calculations have carried out in accordance with ISO 9613-2:1996 *Acoustics -- Attenuation of sound during propagation outdoors -- Part 2: General method of calculation*.

Reference has been made to the EPA publication Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (NG4) 2016, as the proposed facility will be licenced by the EPA. This guidance is used to

set operational noise limits from activities under the control of the EPA (manufacturing, industrial, waste management etc.). These limits can be seen in Table 1.

As a worst case it was assumed that the plant (except emergency items) will be operating continuously during daytime, evening and night periods. From the modelled values, the predicted noise levels at all Noise Sensitive Locations (NSL) will be below the day, evening and night-time noise criteria that are applicable to the site operations (see Table 1).

Day (07:00 to 19:00hrs)	Evening (19:00 to 23:00hrs)	Night (23:00 to 07:00hrs)
55dB $L_{Ar\ (15mins)}$	50dB $L_{Ar\ (15mins)}$	45dB $L_{Aeq\ (15mins)}$

Table 1 *Proposed Operational Noise Criteria*

In the event of a failure in electricity supply from the national grid, a standby generator will operate in order to maintain the site key operations. Otherwise, testing of emergency plant is likely to be scheduled on an agreed frequency and would typically involve operation of plant consecutively over a short time during a scheduled daytime period. The predicted emergency noise levels at the nearest modelled locations were within the relevant emergency operations limits.

From this assessment, it is anticipated that all operational and emergency noise levels will be within both the relevant emergency operations limits, as well as the normal operational limits.

It is anticipated that annual noise monitoring of the site will be undertaken for the facility at monitoring locations selected to best represent the nearest noise sensitive receptors (NSRs).

8.5 Groundwater Protection

The results of the recent groundwater sampling rounds at the AbbVie facility are presented in Section 8 *Stage 7 – Site investigation, Baseline Soil & Water Quality Assessment* of the Baseline Report (Attachment 4.8.3). The results are compared with Drinking Water Parametric Values (PVs) provided in the European Union (Drinking Water) Regulations 2014 (S.I. No. 122 of 2014), as well as the relevant Groundwater Threshold Values (GTVs) for Ireland as outlined in the Environmental Objectives (Groundwater) (Amendment) Regulations 2016 (S.I. No. 366 of 2016).

Overall, the groundwater quality is good with no major noticeable contamination across the AbbVie site apart from minor exceedances of some inorganics. Volatile Organic Compounds (VOCs), Semi Volatile Organic Compounds (SVOCs), Polycyclic Aromatic Hydrocarbons (PAHs) and most inorganic parameters were not detected above statutory or guideline levels during groundwater monitoring.

There will be no direct discharges of contaminated water to groundwater or soil environment during the operation of the facility, and an environmental management plan (EMP) will be in place to ensure compliance with licencing requirements. This will include full and adequate containment and management of potential contaminants. Site-specific emergency response measures will be in place and all relevant personnel will be trained accordingly.

In order to minimise any impact on the underlying sunken strata from material spillages, chemical storage tanks will be fully bunded in designated areas with an

impervious loading area. Bunding will be to a volume in compliance with EPA standards.

Drainage from the diesel storage area will be to a Class 1 full retention interceptor which will be inspected and properly managed. All tanks, bunding and transfer pipelines will be tested regularly to confirm integrity as per the site EMP and licencing requirements.

As such, it is considered that other than those parameters that are natural elevated in the local groundwater body, there will be no impact on the quality of the groundwater status of the Drumcliff Strandhill GWB from the site operations.

Based on the existing monitoring results it is anticipated that the site operations will not result in exceedances in the GTVs. The facility is therefore considered to be compliant with the EU Council Directive on groundwater protection (2006/118/EC).

9.0 BEST AVAILABLE TECHNIQUES

The following documents are considered potentially relevant in terms of BAT conclusions, BREF and BAT guidance:

- EU Conclusions on Best Available Techniques in Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector, June 2016;
- BREF document on Best Available Techniques for the Manufacture of Organic Fine Chemicals, August 2006;
- BREF document on Best Available Techniques for Energy Efficiency, February 2009;
- BREF document on Best Available Techniques for Emissions from Storage, July 2006.

Please refer to Attachments 4-7-1 to 4-7-3 for detailed assessments of compliance with BAT for each of the above listed BREF and BAT guidance documents. It is concluded from this assessment that the facility when completed will comply with the required best available techniques.

10.0 POLLUTION PREVENTATIVE MEASURES AND MEASURES TO MINIMISE

10.1 Minimisation of Emissions to Air

Measures are in place in accordance with BAT for the Manufacture of Organic Fine Chemicals and BAT for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector.

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, DMA, DMSO and other volatile organic solvents used in production, as well as printing solvents used in the medical devices facility, will be stored internally in sealed bottles (and sealed wipes packaging) until used.

10.2 Minimisation of Emissions to Water

Measures are in place in accordance with BAT for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector. Stormwater drains and wastewater drains are segregated. Uncontaminated rainwater is collected and discharged to the municipal storm water sewer rather than to foul sewer.

Wastewater will be discharged after flow balancing, temperature control, and pH neutralisation to ensure no impacts on the sewer network. The main issue at the Sligo WWTP as identified in the 2017 AER for the facility is Total Phosphorus which is consistent with most facilities across Ireland. The Total Phosphorous concentration of the wastewater discharge from the AbbVie facility is anticipated to be 68 mg/L which, once diluted with the rest of the hydraulic load of the Sligo WWTP (at a dilution factor of 0.0096), will contribute 0.019 mg /L to the total influent to the facility. Irish Water have advised that the receiving wastewater system will have the capacity to accept the proposed discharge.

10.3 Minimisation of Noise Emissions

Control of noise has been considered as part of the design of the new facility. Where practical, external plant layout has utilised barrier screening of on-site buildings, low noise generating plant items such as attenuated cooling towers have been selected and noisy plant items have been located within buildings. Proposed AHUs will be internal and therefore do not require additional abatement.

Noise levels at the existing facility have also been reduced through the removal of operational noise sources from Abbott owned equipment. In particular, the sterilisation equipment which had been previously identified as an undesirable noise source. The Abbott owned equipment was removed between January 2018 and May 2018.

10.4 Solid Waste Minimisation

AbbVie is committed to minimising the environmental impact of its operations and the proposed waste management process for the facility is considered an essential and integral component in the efficient operation of the facility. AbbVie will seek to meet the intent of the waste management hierarchy.

An EMS will be developed for the facility as required under the IE Licence. The purpose of the EMS is to identify the environmental objectives and targets and action plans which have been created by the Health, Safety and Environmental Manager. It is AbbVie policy that this will contain waste-reduction goals and employees who can significantly affect the achievement of these goals will be notified.

AbbVie's EHS and Energy Sustainability Long Range Plan 2017-2020 sets out waste disposal reduction targets to reduce the total amount of hazardous waste and non-hazardous waste generated, as well as tactics for achieving these targets matched with a relevant person responsible for that tactic. AbbVie currently operates a Zero Waste to Landfill site and it committed to maintaining this performance. The facility also tracks waste-reduction progress.

The entire production process has been designed with waste reduction in mind. The raw materials used in the bio-chemical pharmaceutical products to be produced at the site are extremely valuable therefore the minimisation of waste is crucial to the commercial success of the site.

AbbVie will evaluate its chemical and raw materials list (see Attachment 4.6.2) at least annually to determine whether chemicals are unnecessary or unused and efforts will be made to minimize use of such chemicals in the future.

11.0 RISK MANAGEMENT AND LIABILITY

11.1 Risk Management

In terms of risk management, the facility will operate to a wide variety of Standard Operating Procedures (SOPs). These include SOPs on spill prevention and control, incident investigation & reporting, hazard identification and risk assessment, and transfer and storage of materials and wastes. An on-site Emergency Response Plan (ERP) is in place at the facility and will be updated to include the new suite.

11.2 Out-of-hours and Abnormal Circumstances

An on-site emergency preparedness plan will be generated and maintained, which details the required response of AbbVie Emergency Response personnel in the event of an incident on site. The emergency preparedness plan (ERP) will include arrangements for contacting the emergency services and those people in the surrounding environment that might be affected. The plan also includes for out of hours response.

It should be noted that the proposed facility will operate 24/7, 365 days a year. There is, therefore, no additional specific procedure required for emergencies outside normal working hours.

11.3 Site Closure and Liability

A Closure, Restoration and Aftercare Management Plan (CRAMP) and Environmental Liabilities Risk Assessment (ELRA) will be submitted as required following commencement of the operation. These documents will be prepared in accordance with the Environmental Protection Agency's Guidance on Assessing and Costing Environmental Liabilities (2014). These documents also outline the key staff members associated with site closure and their associated responsibilities, stages of clean-up to be undertaken and the necessary validation and documentation to be completed post implementation of the closure plan.

A Closure Plan (Attachment 9-2-3) has been submitted with the application that outlines the stages for a closure scenario at the facility to avoid any risk of environmental pollution and to return the site to a satisfactory state in accordance with the Baseline Report provided (Attachment 4-8-3).

12.0 EXISTING ENVIRONMENT

The nearest watercourse is the Willsborough Stream, which is located close to the north western boundary of the AbbVie site. The largely culverted Shannon Eighter Stream is >50m to the south of the site. From a review of the EPA on-line Database Envision, the most up-to-date status (River Waterbody WFD Status 2010-2012) of the Willsborough Stream is 'Good'. The Willsborough Stream is also classified as being 'Not at risk of not achieving good status'. EPA monitoring concludes that based on 2015 analysis of both upstream and downstream monitoring locations, the Willsborough Stream has a surface water quality of 'Good Status'.

A Stage 1 Flood Risk Assessment was undertaken as part of the Environmental Impact Assessment submitted with the planning application. This assessment has been carried out and is submitted as part of this planning application. The purpose of the assessment was to identify whether there may be any flooding or surface water management issues related to the proposed development site that may warrant further investigation. The results of that assessment were that there is no significant risk of flooding at the site.

The emissions to sewer from the current facility is primarily sanitary, domestic foul and canteen wastewater (32.6m^3/day). The proposed development will include the addition of low strength wastewater to the emissions to sewer. Low Strength wastewater is specific wastewater including flashpot condensate, utilities blowdowns, and washwater from non-toxin / product contact equipment. The addition of this low strength wastewater will result in a maximum daily volume of 180m^3/day to be discharged to the foul sewer and then to Sligo WWTP.

The proposed development will also include the addition of high high strength wastewater which is liquid waste from high containment areas or liquid waste which has been identified that may contain some toxin or other harmful substances. This will be stored separately in the high high strength wastewater tank and will be tankered offsite for incineration.

Air quality monitoring programs have been undertaken in recent years by the EPA and Local Authorities. The most recent annual report on air quality "Air Quality Annual Monitoring Report 2015", details the range and scope of monitoring undertaken throughout Ireland (EIS, 2017). Air quality monitoring in 'Zone C', the most relevant zone to Ballytivnan, over the last 5 years suggests an upper average of no more than 13 µg/m^3 as a background concentration. A conservative estimate of the current background NO_2 concentration in the region of the AbbVie facility is 13 µg/m^3.

Reference to the GSI (2018) on-line mapping indicates the predominant subsoil type in the general area at the AbbVie site is Made Ground and limestone tills. The EPA/Teagasc Soils Map identified podzolics, gleys and alluvium as the distinct soil types that exist in the general area.

Results of baseline soil testing carried out in July 2018 can be seen in Section 8.2 *Baseline Soil Analysis* of the Soil & Water Baseline Report. Overall, this indicated that the soil is relatively clean and there is no known contamination present on site.

The GSI (2018) currently classifies the bedrock aquifer underlying the site as a (Ll) Locally Important Aquifer - The GSI well search for the area surrounding the site does not identify any groundwater abstraction wells within 1.5 km of the subject site.

The Groundwater Body (GWB) regionally underlying the site is the Drumcliff Strandhill GWB (EU Groundwater Body Code: IE_WE_0044). Currently, the EPA (2018) on-line mapping classifies the GWB as "under review" meaning it may or may not achieve good status.

13.0 PREDICTED IMPACTS

13.1 Air Quality

Air dispersion modelling was carried out using the United States Environmental Protection Agency's regulatory model AERMOD (Version 16216r) and the report is

provided as Appendix A to this report. The purpose of this modelling study is to determine whether the emissions from the site will lead to ambient concentrations that are in compliance with the relevant ambient air quality standards for Nitrogen Oxides (as NO_2). The results indicate that the ambient ground level concentrations of nitrogen oxides (as NO_2) are below the annual and 1-hour ambient air quality standards. Emissions from the facility lead to an ambient NO_2 concentration (including background) which is 24% of the maximum 1-hour limit and 38% of the annual limit at the worst-case off-site location for the worst-case years modelled (2014 and 2015).

New process emissions will comprise minor emissions from preparatory and production vessels, production rooms, lyo vents, emissions from fume hoods, and low pressure hot water boilers etc. These emissions are not considered to be significant and abatement in the form of HEPA filters or 2um filters will be employed where required to prevent any minor discharges of contaminants to air. The VHP vents will also be equipped with 2 catalytic converters in series to convert H_2O_2 to H_2O and O_2 before venting.

Existing process emissions include extracts from the pad printer and the solvent store. These contain small amounts of VOCs; however, the quantities of emissions are not considered significant and abatement systems are not required.

1 no. diesel generator will provide emergency power to critical and essential manufacturing and utility equipment and systems. Emissions of NO_x and particulate matter from the emergency generators will be inconsequential as the generators are small in size and will be used only for maintenance and testing every month.

13.2 Surface Water

The proposed development will not have a significant impact on the quality of the receiving surface water bodies as further discussed in Attachment 7.1.3.3 Receiving Environment Report. There is a very low risk of Principle Pollution Substances being discharged from the facility via the stormwater network due to the stringent controls and procedures in place to prevent and minimize spills.

The existing drainage systems along with those proposed ensures appropriate drainage for the site. There is inconsequential increase in hardstanding area, therefore no resultant measurable increase in surface run-off. In keeping with the Stage 1 assessment, the review of available information has identified no flood hazards for the proposed works at the proposed development site therefore; in accordance with The Planning System and Flood Risk Management Guidelines for Planning Authorities, there is no requirement to proceed to the Stage 2 or 3 assessments.

13.3 Sewer

Operation of the plant will be according to BAT principles and in compliance with the licence conditions to ensure that inputs to, and subsequent contamination of, soil and water environments does not occur during normal and / or emergency conditions (material spillage or fire event situations).

Wastewater will be discharged after flow balancing and pH neutralisation to ensure no impacts on the sewer network. Irish Water has advised that the receiving wastewater system will have the capacity to accept the proposed discharge.

S.I. No. 283/2013 - Environmental Protection Agency (Integrated Pollution Control) (Licensing) Regulations 2013, lists a number of Principle Pollution Substance including:

- Substances which contribute to eutrophication (in particular, nitrates and phosphates).
- Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as BOD, COD, etc.).

As such, these parameters will be monitored in accordance with the licence conditions. Mitigation measures were included in the design of the facility to limit the contributions of these parameters as discussed in the BAT Conclusions document for wastewater and waste gas (Attachment 4.7.1).

Other Principle Pollution Substances such as heavy metals are not relevant for this facility as there will be no direct contributions of metals to the wastewater streams. Trace quantities from cleaning of metal equipment may be present in the wastewater only.

Wastewater to be discharged is relatively low strength and has similar characteristics to domestic wastewater. The loading associated with the proposed discharge, as a percentage of Sligo WWTP is insignificant when compared with the overall plant loading.

13.4 Noise

To assess the potential noise impact of the proposed plant items an industrial noise prediction model incorporating the new plant items associated with the proposed development has been prepared. Noise levels have been predicted at the three nearest NSLs, the locations of which are shown in the modelling report.

An environmental noise survey was conducted to quantify the existing noise environment in the vicinity of nearest NSLs. The survey was conducted in accordance with the EPA's NG4 Guidance. The existing AbbVie facility was operational during the noise survey. Plant noise emissions that were measured during the survey were then used to determine the expected cumulative noise emissions at the nearest noise sensitive locations for both the existing and new mechanical plant items. It is understood that some of the noise sources operational at the existing facility at the time of the surveys are due to be decommissioned as part of the proposed development.

There are several items of noise generating equipment proposed for the new development. It was assumed for the assessment that all plant items will operate 24 hours a day as a worst case. The assessment considered all the major and minor noise sources of plant items that had been identified as having the potential to emit noise beyond the site boundary. The details and location of all noise emission points and associated noise source data were provided by Jacobs Engineering.

Appropriate operational noise criteria were derived for the site following review of noise survey data and receiving environment, in accordance with the relevant NG4 Guidance. The applicable noise criteria identified were in line with the typical limit values for noise from licenced sites.

To assess the impact of noise from new mechanical plant at nearby NSL's, a detailed computer-based noise model has been prepared using proprietary noise modelling software package, *iNoise V2018 Enterprise*. Noise prediction calculations have

carried out in accordance with ISO 9613-2:1996 *Acoustics -- Attenuation of sound during propagation outdoors -- Part 2: General method of calculation*. The predicted noise levels at all NSL's for new mechanical plant and the levels of existing plant noise from the facility are considerably the day, evening and night-time noise criteria for site operations.

It should be noted that noise impact assessment has been completed using information obtained from the design team for significant items of plant which are currently being procured from vendors. It is anticipated that where there is any substantial variation in the noise emission level of plant when installed on site (i.e. that has not been accounted for in the data used for this assessment), additional noise control measures such as, acoustic barriers or attenuator systems will be employed where necessary, to ensure that the operation of the facility will comply with the required noise criteria set out in this report or defined in the Licence issued to the operator.

13.5 Ground water

There will be no direct discharges of contaminated water to groundwater or soil environment during operation. As such, the only impact that could occur is due to accidental emissions such as localised accidental leakages from cars/vehicles in the car park areas/ on site or accidental leakage from the bunded diesel storage tanks and/ or chemical releases during refuelling or transport.

During operation, an EMP will be in place to ensure compliance with licencing requirements. This will include full and adequate containment and management of potential contaminants. Site-specific emergency response measures will be in place and all relevant personnel will be trained accordingly.

It is considered that other than those parameters that are naturally elevated in the local groundwater body, there will be no impact on the quality of the groundwater. As such, it is anticipated that there will be no additional exceedances of the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and the EPA (2003) Interim guidelines.

As there will be no increase in hardstanding, the proposed development will not have a significant impact on the recharge of the groundwater body. The aquifer is classified as Moderately Productive only in Local Zones, with the site naturally underlain by natural gravelly and sandy firm Clays ranging in thickness from 5 m to 10 mbgl.

Groundwater monitoring will be undertaken at the following points: MW1, MW2 and MW3. It is proposed that monitoring results are compared with current regulatory limits and guidelines, including the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and the EPA (2003) Interim guidelines.

13.6 Cross-boundary Impacts

There are no anticipated impacts over long distances or outside the territory of Ireland as a result of the proposed changes onsite.

All proposed air emissions and monitoring will be compliant with ambient air quality standards and will not have a transboundary impact.

All proposed sewer emissions and monitoring will not result in transboundary impacts on the downstream wastewater treatment plant.

All other changes are minor and will have negligible impacts on the environment as a whole.

14.0 ALTERNATIVES

In terms of alternative methods for the manufacture of bio-chemical pharmaceutical products, there are two options available. The first uses fixed stainless-steel vessels whilst the second option is an emerging trend using single use bag technology.

Fixed vessels will be used for the conjugation vessels only. The use of stainless steel vessels means the equipment will continue to be used for the production batches. The production equipment therefore requires cleaning after each batch is manufactured. For small batch processes this option tends to be expensive and therefore is only proposed to be used for conjugation due to the larger volume of material used during this stage.

Single use technology reduces the need for cleaning. It is also more flexible and allows the process to be reconfigured to allow for the introduction of new products or technologies. AbbVie plan to use single use technology for buffer and media preparation, production, and chromatography columns.

The process is constrained by Good Management Practice (GMP) regulations and as such there is limited opportunity for alternative processes. However, the facility has been designed to confirm with best industrial practice for a high-containment facility.

15.0 CONCLUSIONS

This non-technical summary includes a brief overview of the IE licence application, detailing each of the sections contained within the application that are relevant and applicable to the AbbVie site.

The conclusions from the EIAR submitted with planning, and included in Attachment 6.3.6 of this application, are presented in Table 2 below.

It should be noted that in order to obtain comprehensive detailed description of the facility and the activities that will be carried out there, the full application should be viewed.

Environmental Factor	Likely Effects Identified	Brief Description of Effect	Mitigation Measures proposed to Control Effects
Air	Generation of air pollutants such as NO_2 from boiler emissions and additional traffic	Boiler related air emissions may generate quantities of air pollutants such as NO_2. However, the NO_2 modelling results from the proposed boiler emissions at the worst-case off-site receptor indicate that the ambient ground level concentrations are significantly below the relevant air quality standards for NO_2. Additional traffic generated due to the opening of the proposed development may also lead to the release of air pollutants. However, the increase in traffic associated with the proposed development during the operational phase is not of the required magnitude to cause any significant impacts at nearby sensitive receptors according to TII and UK guidance.	The modelling assessment has found that ambient NO_2 concentrations as a result of the Proposed Development and the Cumulative Assessment are in compliance with the relevant ambient air quality limit values at all locations at or beyond the site boundary. The impacts to air quality from operation of the proposed development are therefore deemed long-term, negative and not significant. No additional mitigation measures are required.
Noise and Vibration	Long-term sources of outward noise: • Building Services and Factory Process Plant; and; • Additional vehicular traffic on public roads.	The main operational noise sources associated with building services and factory process plant will include cooling towers, boiler stacks, air handling units (AHU's), condenser units and various rooftop mounted fan and exhaust units. It is expected that all the plant items will operate continuously 24/7. The additional traffic introduced onto the local road network due to this development will result in an increase of traffic volumes of far less than 25% at all locations and is deemed to be an imperceptible change.	Most of the noise generating plant items will be located within fully enclosed plant rooms or ventilated plant enclosures louvered with attenuation. All air handling units, will be hard ducted to louvres or will have noise attenuation in series, therefore noise breakout will be minimal. In addition, all plant will be selected such that there are no tonal or impulsive emissions. The impact assessment has found that predicted noise levels associated with the day to day operations of the site will be well within the proposed criteria applicable to a site of this nature. Any change in noise levels associated with vehicles at road junctions in the vicinity of the proposed development is expected to be imperceptible. No mitigation measures required.

Soils	No likely impact on local geology or groundwater	There is no likely impact on any geological heritage, mineral locations, sensitive groundwater receptors or groundwater supplies in the vicinity of the proposed development site. There will be no direct discharges to groundwater or soil environment during the operational phase. As such, local impact could only occur due to accidental leakages from cars/vehicles in the car park areas or accidental leakage from chemical storage areas (mostly IBCs and drums), bulk diesel fuel tanks or transfer lines which are unlikely as will be double contained and regularly tested and maintained as required by licencing. There will be no groundwater abstraction or licenced discharge to ground during operation of the proposed development.	The operation of an Environmental Management Plan (EMP) and operation within the requirements of an EPA licence will minimise the likelihood of any spill or leaks at the site. Compliance with standard monitoring and maintenance procedures in an EPA licence will provide adequate protection for the land soil and groundwater beneath the facility. The increase in risk to soil and groundwater environment is low as apart from fuel storage and any bulk storage will either be in double skinned or bunded tanks.
Water	No likely impact on local hydrogeology	There will be no direct discharges of contaminated water to surface water or to the two local drainage ditches located within the site boundary during the operational phase. As such impact could only occur due to accidental leakages. Most chemicals are stored on-site in small quantities of drums and IBCs and will be stored in the on-site warehouse. Bulk chemical storage will be in either double skinned tanks or bunded tanks. A dedicated sprinkler/misting system will be installed in the proposed development, complete with a dedicated collection system for any ensuing fire water. As a result of the no increase in hardstanding, there will be no measurable increase surface run-off.	As current, an environmental management plan (EMP) will be in place to ensure compliance together with stringent EPA licencing requirements. This will include full containment of potential pollutant sources, site-specific emergency response measures and management of surface water run-off and wastewater discharge from the site.

		Wastewater is of low strength and will be discharged to a local waste water treatment facility or treated on site.	
Waste	Imperceptible impact on environment from new waste streams	The proposed development will give rise to a variety of waste streams when the project is completed and manufacturing processes are fully operational. The process in the new pharmaceutical manufacturing operation is expected to generate two categories of waste - hazardous and non-hazardous waste. Hazardous process waste will consist of both a liquid and solid waste stream. Liquid waste will consist of washwater. Solid hazardous waste will consist of waste streams that will include storage bags, drum liners, tubes and hoses, filter cartridges and support implements such as spatulas, probes and funnels. Typical non-process hazardous waste generated in this type of setting usually consists of lead batteries, WEEE and fluorescent light tubes. The predicted impacts on the environment from waste generation during the operational phase are expected to be neutral, long term and imperceptible.	The management of waste generated from the new development will be carried out in accordance with waste management procedures at the facility which will be developed to ensure all waste will be appropriately managed. The legal requirements for storage and recording of waste generated at the facility will be managed in accordance with the site's future IED Licence. Adherence to these existing procedures and future licence requirements once the new facility is operational will ensure there are no significant impacts from waste generated at the facility.
Biodiversity	Negligible impacts given the low ecological value of the existing habitats.	The CEMP details measures to prevent accidental spill offs. Interactions with surface water are therefore thought to be minimal as there are no existing water courses across the site or in the	Following the best practice management measures detailed in the project description and within the CEMP, no specific mitigation measures are required to moderate the potential impact on biodiversity.

		immediate vicinity. The AA Screening Report states that there are no significant adverse effects foreseen to be likely to affect the ecological integrity of any European Sites. There are no NHA's within the zone of influence of the project. The closest pNHA is the Cummeen Strand/Drumcliff Bay (Sligo Bay) which is also an SAC. The site is 0.7 km away from the proposed development and it is hydrologically connected to the site however the proposed works will have no direct interaction with the pNHA and the detailed hydrological assessment carried out as part of the EIAR shows that the proposed works will have a Long term imperceptible significance with a neutral impact on water quality during the operational phase. There are no pathways for effects to any other pNHA or NHA sites.	

Table 2 *Likely Significant Effects of Proposed Development from EIAR May 2018*