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FIREWATER RISK ASSESSMENT 2020

REGENERON IRELAND

IE LICENCE P0991-01

Technical Report Prepared For

Regeneron Ireland

Technical Report Prepared By

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EXECUTIVE SUMMARY

AWN Consulting were requested by Regeneron Ireland to carry out a firewater risk assessment at their bio-pharmaceutical manufacturing facility in Raheen Business Park, Ballycummin, Raheen, Co. Limerick. The assessment has been carried out in accordance with methodology prepared by the Environmental Protection Agency (EPA) in the recently published *Guidance on Retention Requirements for Firewater Run-off* (EPA, 2019).

The facility at Raheen is for the bulk production of bio-pharmaceutical medical products for patients worldwide, together with associated business support functions. This includes central production cleanrooms, warehousing, clean water and steam utilities including boilers, heating ventilation and air conditioning systems, and electrical switch rooms. A Quality Control Laboratory for quality control test procedures related to the manufacturing process is also included within the site.

The Regeneron site is located within the National River Basin District in Hydrometric Area No. 24 (Shannon Estuary South) of the Irish River Network. The First Cycle Shannon River Management Plan (2009-2015) has been superseded by the Second Cycle River Basin Management Plan (2018-2021).

As part of the following assessment, the site has been segregated into 19 no. areas based on separation distances between buildings and / or the presence of concrete 2hr fire rated walls between the areas. These areas are as follows:

1. Main production building and south utilities yard (substation, pump house, water tanks)
2. Warehouse and Central Utilities Area
3. Headblock, Headblock boiler room and chillers, Admin building and QC Building
4. Existing Waste Management Yard
5. North Utilities Yard - East (substation/electrical room, gas storage and ethanol storage)
6. North Utilities Yard - West (chemstores, acid and caustic tanks)
7. Emergency generators with diesel storage (south utilities yard)
8. Wastewater Management System
9. Waste Management Building (NEW)
10. Autoclave Area (NEW)
11. East Expansion and Yard (NEW)
12. Multi Storey Car Park (NEW)
13. Administration and Lab Building (ALB) and Yard (NEW)
14. 20kV Substation (South Utilities Yard)

Areas not containing significant quantities of substances classified as hazardous to the environment were not considered to pose a risk to the environment through the generation of firewater and firewater may be disposed of via the stormwater drainage network. Based on the risk assessment undertaken for each area in accordance with the EPA's guidance, all of the areas assessed were deemed to be ***R0 – Not at Risk*** except for Areas 6 and 7.

The only bulk storage of hazardous to the environment chemicals is diesel storage in the South Utilities yard (Area 7) and the Nalco 93099 storage in the North Utilities Yard (Area 6) both of which received a rating of ***R1 – at Risk*** on this basis.

Area 7 consists of 2 no. 55,000 litre bunded diesel fuel oil tanks containing up to 88,000 litres of diesel at any one time (80% capacity) in the worst-case scenario. As the total volume of diesel (H411 chemical) exceeds 10 tonnes, firewater calculations for the diesel tanks were included in this assessment.

The diesel tanks are contained within a designated concrete bund which is sufficient to contain the diesel in the event of a major spill or tank rupture. Should a fire occur at the diesel tanks, the resulting hydrocarbons, the foam / powder suppressants, as well as 24hours worth of rainfall would be fully contained within the existing bund. As such, additional firewater retention is not required.

Nalco 93033, a biocide with an H400/H410 hazard rating, is also used for the treatment of cooling tower water across the site. The onsite storage is spread across the site in small quantities in different areas: the North Utilities Yard (Area 6), the Wastewater Management System (Area 8), and the East Expansion Yard (Area 11), and the ALB Yard (Area 13). As shown in the risk assessment in Section 7 of this document, the amount of Nalco 93033 stored exceeds the threshold for Area 6 only.

The allocation of the site into the separate areas was done in accordance with the EPA's guidance based on the presence of firewalls and/or separation distances. Therefore, it is concluded that it is unlikely that a fire would spread from one area to another nor that the entire Nalco 93033 storage would be lost to firewater during a fire event.

In Area 6 the Nalco chemstores and the caustic tank were considered in the calculation as they drain to the same location, and all other tanks are contained within their own bunds. The Nalco chemstores are located adjacent to the cooling towers and the acid and caustic tanks and there is a drain alongside the chemstores that drains to the 45.9m^3 caustic (Sodium Hydroxide) bund which is then pumped to the 16m^3 utility sump. Should a fire occur in this area it is anticipated that firewater from the Nalco stores and the caustic tank will be contained in the caustic tank bund and the utilities sump. As a worst case, they could also be pumped out to the Wastewater Management System to be treated and discharged to sewer in accordance with the facility's IE licence.

As such, additional firewater retention is not required at the Regeneron site in Limerick.

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1.0 INTRODUCTION

AWN Consulting were requested by Regeneron Ireland to carry out a firewater risk assessment at their bio-pharmaceutical manufacturing facility in Raheen Business Park, Ballycummin, Raheen, Co. Limerick. The assessment has been carried out in accordance with methodology prepared by the Environmental Protection Agency (EPA)[1] and the United Kingdom Health & Safety Executive (HSE)[2].

The facility in Raheen is for the bulk production of bio-pharmaceutical medical products for patients worldwide, together with associated business support functions. This includes central production cleanrooms, warehousing, clean water and steam utilities including boilers, heating ventilation and air conditioning systems, and electrical switch rooms. A Quality Control Laboratory for quality control test procedures related to the manufacturing process is also included within the built site.

The facility received an IE licence (P0991-01) in 2014 under Class 5.16 of the First Schedule of the Environmental Protection Agency Act 1992, as amended, for 'the production of pharmaceutical products including intermediates. The activity does not come under the Control of Major Accident Hazards involving Dangerous Substances Regulations (S.I. No. 209 of 2015).

In April 2018 Regeneron Ireland UC were granted planning permission for an extension to the east of the existing manufacturing building to allow for additional production areas (Planning ref. 17/1170). Regeneron also applied to Limerick City & County Council (LCCC) in November 2018 for planning permission (Planning ref. 18/1098) for an Administration and Laboratory Building (ALB), a multi storey carpark, and an extension of the existing carpark to the west of the current main manufacturing installation. For completeness, these new developments have also been considered in this assessment.

2.0 DESCRIPTION OF OPERATIONAL ACTIVITY

2.1 Site Location

The Regeneron Ireland site is located within an established industrial park in Raheen, Limerick approximately 5 km south east of Limerick City centre. The site has a number of access roads to the west, south-west and south-east. A number of industrial buildings are situated to the south, north and east with some agricultural and green-field sites to the west. The site location is shown in Figure 2.1.

Figure 2.1 Site Location and Hydrological Environment

2.2 Site Operations

The Regeneron Ireland facility in Raheen manufactures a variety of therapeutic proteins using biotechnology derived processes which are produced in a bulk or formulated state and are filled for shipping. The product candidates have the potential to help patients living with conditions ranging from rheumatoid arthritis and asthma to cancer and hypercholesterolemia.

The primary process areas can be separated into Upstream and Downstream production. Upstream production consists of cell culture using bioreactors and harvest to produce a clarified cell 'broth'. Downstream production takes the cell broth and captures the crude protein which undergoes purification and product formulation followed by filling.

Figure 2.2 outlines the processes involved in primary production with upstream and downstream stages identified.

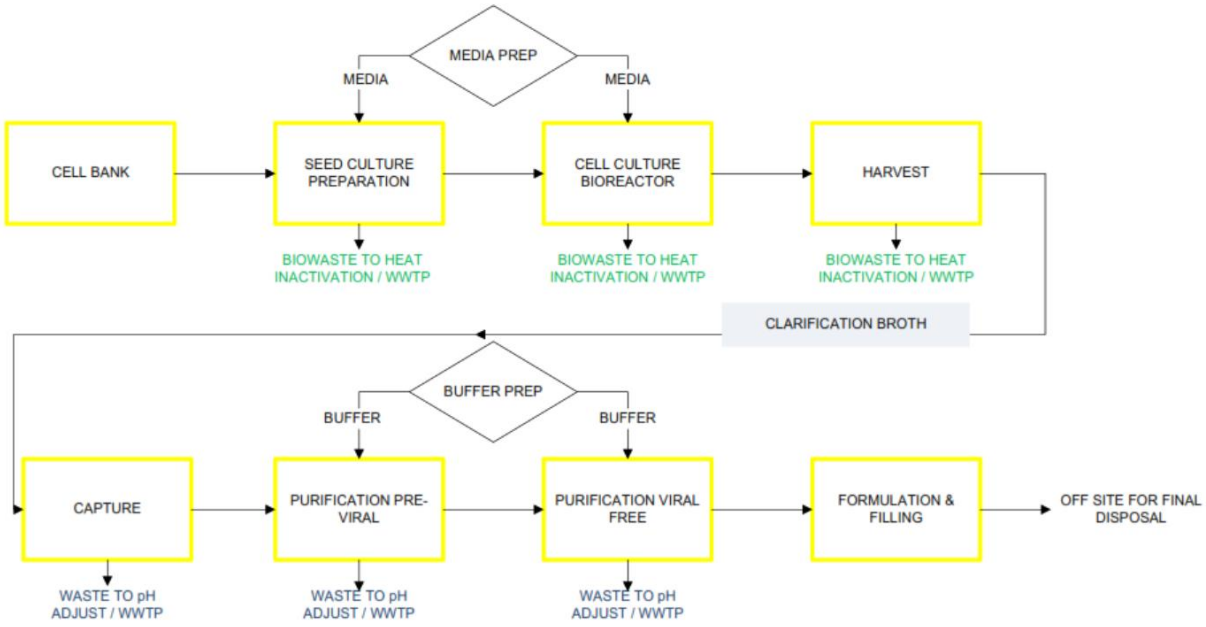


Figure 2.2 *Process Flow Diagram for Regeneron Ireland Primary Processes*

2.3 Site Layout

The Regeneron Ireland facility is a multi-train, biopharmaceutical manufacturing facility and includes quality control laboratory and business support functions. The existing site layout is shown in Figure 2.3 below and includes the following areas:

- Core production building (consisting of 4 no. bulk biologics production trains, warehouse space and support utilities);
- Internal Warehouse
- Clean Utilities Area;
- Quality Control (QC) laboratory;
- Administration Head block;
- Boiler room;
- Chillers room;
- Waste Management Yard;
- Wastewater Management System;
- South Utilities Yard;
- North Utilities Yard;
- Contractors compounds;
- Car parking areas; and
- Security gatehouse.

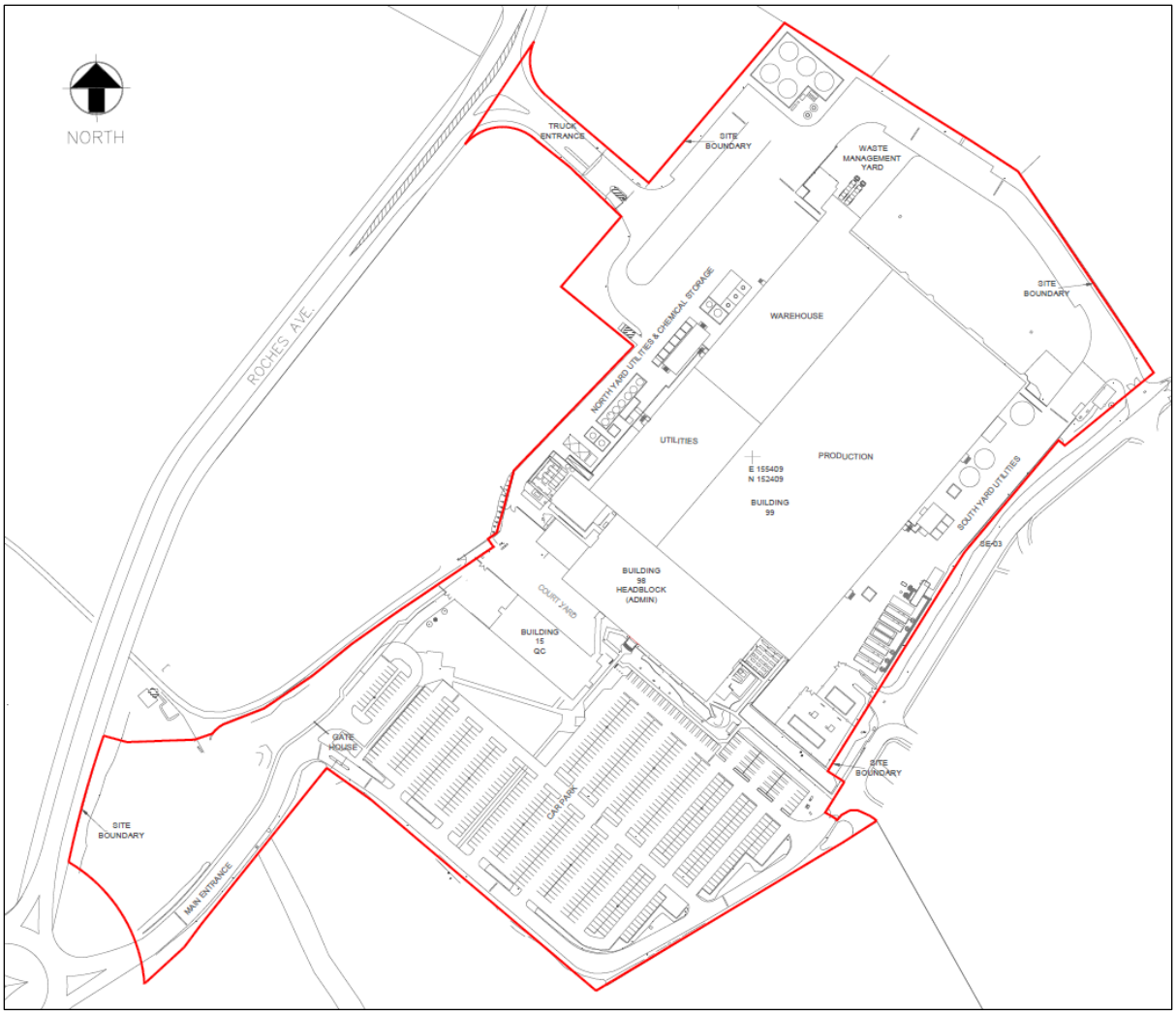


Figure 2.3 Existing Site Layout at Regeneron Ireland

The new developments to the site are shown in Drawing 1 and include:

- single storey manufacturing extension designed for the phased construction of 3 to 4 no. manufacturing suites according to future needs and a new plant room area - built but not fitted out;
- new waste management area - built but not fitted out;
- external modular bunded chemical storage units - not yet in place;
- Administration and Laboratory Building (ALB) – under construction;
- Multi Story Car Park (MSCP) – under construction;
- Additional mobile diesel fired generator and 2000L diesel tank (in place)
- Changes to the site's stormwater drainage and attenuation – in progress;
- Additional open car park areas – in progress.

Production Building

The main production building comprises 4 no. production trains which are organised to allow process operations to flow from east to west, with upstream (cell culture and harvest) and downstream (purification and formulation) suites separated into their own production blocks.

In the upstream block the seed labs are located at the far east of the production area followed by the seed bioreactor rooms, then the production rooms, then media prep, then the harvest suites, and finally the support functions (i.e. equipment wash and utilities closets).

In the downstream block the support equipment-wash and the utilities are at the east end of the block followed by buffer prep, then the individual initial purification operation rooms, then the final purification suites, and finally the formulation/bulk filling suite at the western end.

Warehouse

The Warehouse is internal to the main building and is used for storage of raw materials and final products and is equipped with a number of 2-8°C cold storage rooms and -30°C freezer rooms. Small amounts of flammable liquids and materials are also stored in this area and are segregated according to safety regulations and insurance requirements.

The Warehouse currently houses the decontamination autoclave used for inactivating solid production wastes and the bio-waste heat inactivation skids and tanks for aqueous production wastes. As part of the east expansion development, the autoclaves will be moved to a new designated autoclave area adjacent to the Warehouse (not yet completed as of Nov 2020).

Internal Utilities Area

This area consists of 5 no. natural gas fired boilers used for process plant steam generation. During normal operations these boilers operate on a 3 duty / 2 standby basis. The east expansion will include an additional 2 no. natural gas fired boilers for process plant steam to be used in the new manufacturing trains.

This area also includes other primary production utilities such as WFI storage tanks, stills and skids, RO skids, LPHW skid, air compressors and chillers.

Headblock Utilities Room

There are also 2 no. existing natural gas fired boilers used to generate low pressure hot water (LPHW) for the HVAC system. These include 2 no. steam to water heat exchangers used to generate hot water for distribution to heating coils. These are located in a designated area adjacent to the boiler room.

Chillers Room

There are 5 no chillers which provide chilled water for cooling the ambient WFI loop, cooling the media after HTST operation, material cool down in tanks, tank cool down following Steaming in Place (SIP), WFI still cooling, clean steam generator cooling, Ultra Filtration / Diafiltration (i.e. purification) skid cooling, centrifuge cooling, and bio-reactor cooling (to maintain set-point bioreactor operating temperature).

There are also 3 no. air cooled chillers in the North Yard as outlined below.

Quality Control Laboratory

The Quality Control (QC) lab is a separate building used for quality control testing procedures related to the manufacturing process. These tests include product release testing, raw materials testing, in-process control testing, and environmental monitoring and microbial testing.

The QC building is a three storey building, the first and second comprise laboratory areas and the top floor is dedicated to HVAC and Utilities.

The QC lab includes 2 no. natural gas fired boilers for steam (0.62 MW boiler) and hot water (0.54 MW boiler) generation.

All aqueous biological waste generated in the QC is chemically inactivated in the laboratory. All solid biological wastes are autoclaved to render them deactivated as per the GMO consent and associated regulations (Class 1 wastes may also be sent offsite for deactivation if required). Adjacent to the QC lab is a lab wastewater sump (tank and lift station) for diversion of lab wastewater to the Utility Sump and on to the Wastewater Management System.

The QC building also has a separate yard that contains a 1000L Liquid Nitrogen tank.

Offices and Support Facilities

The offices are housed in the headblock building and comprise administration/finance, production planning/purchasing, human resources, manufacturing, quality assurance, engineering/facilities and EHS.

The main support facilities on site are the cafeteria (in the headblock), waste management, cleaning, occupational health, and the security hut at the entrance to the installation.

Electrical Room

This in located in the north yard and contains switchboards and other controls required for the running of the site. There are 6 no. transformers to the front of the electrical room building.

Waste Management Yard

There was an existing enlarged Waste Management Yard to the north of the site adjacent to the truck entrance. This area included:

- 2 no. compactors (general and recyclable);
- 3 no. bunded chemstores for wastes (lab smalls);
- Enclosed area for packaging and sorting of waste;
- Several skips for assorted wastes.

Utilities Yards and External Storage Areas

The south utilities yard consists of the following storage units and utilities:

- 38kV substation;
- 5 no. emergency generators including diesel storage (2 x 55,000 litre tanks);
- Process water tanks;

- Bunded bio-waste and process waste sumps (tank and lift station for diversion of process area wastewater to WWTP);
- 750 m^3 firewater storage tank;
- Pump house including diesel (2 x Diesel Tanks),
- Salt storage, and a softened backwash water tank;
- Portacabins (to be retained) x2.

The northern yard is slightly larger and includes the following storage units and utilities:

- Bunded Acid 33% (25m^3) and Caustic 40% (25m^3) storage;
- Cooling towers including 3 no. bunded cooling tower chemstores;
- Gas storage (oxygen, liquid nitrogen, and carbon dioxide);
- 3 no. water chillers;
- Bunded 20% Ethanol storage tank (25m^3);
- Bunded base chemstore;
- Lubricant store;
- Bunded utilities wastewater sump (tank and lift station for diversion of utilities wastewater to WWTP);
- Electrical room;
- AGI Skid;
- 6 no. transformers;
- 1 no portacabin (to be retained);
- Temporary Waste Compound (to be removed).

The bulk caustic and acid chemicals are used to make up the Clean in Place (CIP) caustic wash solution (0.2N caustic) and acid rinse solution (0.5% phosphoric acid) and are 10N caustic and 33% phosphoric acid respectively.

Wastewater Management System

The production area is equipped with a double contained process drainage network with leak detection which diverts all process wastewater to the wastewater treatment system in the Wastewater Management System. The Wastewater Management System is located in the northern corner of the site and comprises flow balancing, temperature control and pH correction for all process wastewater and utilities wastewater from the site.

This area includes bulk storage of wastewater treatment chemicals including double skinned 20m^3 Caustic and 20m^3 Acid tanks, a double skinned 10m^3 Chemiox (odour abatement) tank as well as a chemstore for cooling tower treatment chemicals and a chemstore for antifoam.

The additional mobile generator and 2000L diesel tank are also located in this area.

Cooling Towers

There are 7 no. cooling towers in the North Yard of the existing installation as well as an additional 2 no. cooling towers located at the Wastewater Management System. A chemical addition system to treat the tower water is provided for corrosion prevention, microbial control, and to increase the solubility of mineral salt. The cooling tower water is used for cooling of the 4 no. Compressors, and 5 no. Chillers. The designated Wastewater Management System cooling towers are used to cool the wastewater streams.

As part of the east expansion there will be an additional 4 no. cooling towers provided.

NEW East Extension Building

The east extension, granted planning permission under ref. 17/1170, is a single storey multi-purpose building designed for the phased construction of 3 to 4 no. manufacturing suites according to future needs. This has now been built but not fitted out as of November 2020.

The east expansion will also include a plant room, waste handling facility, plant and equipment mezzanines. The plant room will house 1 no. LPHW boiler, 2 no. large steam boilers, chillers, clean steam generators, compressors, purified water generation and water for injection, as well as process cooling systems. External items of equipment also include electricity transformers, cooling towers, and modular bunded chemical storage units.

There will be 4 no. cooling towers and associated water treatment chemical storage for the extension (not yet completed as of November 2020).

NEW Autoclave Area

There will be a new designated autoclaves area located adjacent to the east expansion. This area will include the decontamination autoclaves used for inactivating solid production wastes (not yet completed as of November 2020).

NEW Administration and Laboratory Building (ALB)

A planning application has been approved by LCCC (ref. 18/1098) for a new three storey laboratory and administration building and construction is currently underway. The building will be used to house laboratories for operational research and in process testing and optimization. The final products from these trials could potentially be produced by any of the lines at Limerick or elsewhere in the Regeneron network. This building is currently under construction as of May 2020.

The ALB will consist of the following facilities:

- Dedicated laboratories (PS Culture Lab, a PS Media and Buffer Lab, a PS Large Scale Bio Process Lab, and a Micro Investigation Lab);
- Office and social facilities including office seating for up to 600 Regeneron personnel;
- Boiler/Plant room;
- Waste staging area including 2 no. waste compactors and a baler.
- Warehouse and Yard facilities

The yard area will comprise of Liquid Nitrogen storage (max 4000L Liquid N_2 tank), tanker loading bays, process waste sump, air cooled chillers, cooling water treatment chemicals within designated self-bunded chemstores, and dosing pumps, possible caged bottle gas storage, and a natural gas let-down station.

The ALB will be stand alone and self-contained from a utilities perspective with the exception of gases O_2, CO_2, N_2 and Compressed Air. Process water is supplied from the site Process Water system and process wastewater will be collected locally and pumped to the main site process wastewater collection sump and on to the Wastewater Management System. Bio-hazardous liquid wastes will be chemically deactivated locally before combining with the process wastewater. Electrical Power will be provided by tying into the site MV ring main system with 2 local transformers providing the LV supply to the building.

Shared utilities will come from the existing manufacturing building via a new pipe bridge onsite. This does not contain flammable materials and will not form a fire pathway between the two buildings.

The new ALB will have 2 no. low pressure hot water (LPHW) boilers (0.5 MW), a steam generator (0.6 MW) and 2 no. water heaters (0.12 MW).

NEW Multi Story Car Park (MSCP)

As part of planning application ref. 18/1098 there is also a new multi-storey car park with capacity for 800 cars over 4 levels. The multi-storey car park will be located along the south western edge of the site. The top deck will include a roof and the ramps are designed to a shallow gradient to provide for a pleasant driver experience and to eliminate operational issues associated with excessively steep ramps. This building is now complete and in use.

TEMPORARY Contractor Compounds

At the existing installation the contractors' compound is to the east of the main building. This area contains a temporary office, workshops and storage areas.

As part of the east expansion development there is a new contractor's compound in the north east corner of the site. This will consist of an electrical compound, clean room, workshop, wheel wash, canteen and other support facilities.

The area does not form part of the licenced activity and it is anticipated that it will be removed following construction of the east expansion and ALB.

2.3 Utilities and Services

Surface Water Drainage

The existing on-site stormwater drainage network covers the entire built area of the site and collects rainwater runoff from yard areas, site roads, car park areas, and building roofs. Stormwater collected in the drainage network drains to a point in the north west corner of the site and discharges via a Class 1 by-pass petrol interceptor (c. 37,000L) into the main Raheen Business Park stormwater sewer at licensed emission point SE-2 (to be renamed SW-1). The drainage line is also equipped with an automatic pH-controlled penstock which will shut off the flow of stormwater if the pH exceeds the agreed trigger levels or in the event of sprinkler activation. It can also be closed manually locally at the unit. The drainage network around the south yard also includes 2 no. Class 1 full retention interceptors (10,000L each) as this area contains bulk diesel storage.

The storm water discharge from the Raheen Business Park stormwater sewer exits the estate and follows the route of a culvert and pipe to Loughmore Common Canal, which enters the Barnakyle River, which in turn flows into the Maigue River, which ultimately discharges to the River Shannon Estuary.

As part of the recent works, stormwater from the new ALB and parts of the new car parking area will be routed to a new underground attenuation tank located to the north west of the installation, with adequate attenuation capacity of 1240m^3. The outfall from the new attenuation tank will be equipped with an additional pH-controlled penstock for best practice and a hydro brake to control the discharge rate to 4 l/s. Stormwater from this drainage line will then discharge into the existing site drainage network via a new Class 1 by-pass petrol interceptor (190L) including a new silt trap (1200L).

Drainage from the MSCP and surrounding car parks, however, will drain to an engineered percolation area at new emission point SW-2. Drainage from the MSCP will be diverted to a 470m^3 attenuation tank. Following the attenuation tank, the stormwater will subsequently drain via a hydro brake and a Class 1 by-pass interceptor (825L) including a sediment trap (5500L) to the single lined percolation area which also serves as a filter for sediment. The hydro brake will control the discharge rate to 4 l/s.

Drawing 2 provides a drainage layout for the revised site.

Wastewater Drainage

Wastewater from the new developments will emanate from sources similar to the current installation, these are;

- Biological waste from upstream process areas requiring heat inactivation;
- Other process wastewaters from cell free unit operations, production support areas, and chemically inactivated bio-waste & utility waste from the labs in the QC and ALB;
- Utilities wastewater including cooling tower blow down, boiler blow down, softener back washers and WFI sanitisation water, chilled water;
- Domestic/foul effluent.

Process wastewater and bio-waste (following inactivation) is diverted via separate drainage lines to a 420m^3 reception tank in the Wastewater Management System prior to being pumped into 1 of 2 equalisation tanks (410 m^3 each) as required. This is then sent through a cooling tower and a pH correction skid prior to being pumped into the outfall monitoring tank (2.6m^3). ALB waters will also go into the existing Process Waste sump and fed forward to the main Wastewater Management System.

Utilities wastewater goes to the Wastewater Management System via the utilities wastewater sump where it is held in a 410m^3 equalisation tank prior to cooling, pH correction, and discharge to the outfall monitoring tank. Wastewater Management System cooling tower blow down does not require an equalisation tank but is held in the outfall monitoring tank following cooling and pH adjustment as well.

The wastewater stream is measured for flow rate/temperature/pH at point of discharge. Wastewater from the onsite wastewater treatment plant is discharged to the Irish Water sewer along the north western boundary via licensed discharge point SE-1, and there are no proposed changes to this arrangement under the licence review.

The facility is currently licensed to dispose of up to 3,500m^3 of wastewater per day.

All process drainage is double contained. Integrity testing of all underground pipelines is carried out every three years in accordance with the existing IE licence.

Foul Water Drainage

Foul water comprises domestic effluent from welfare facilities such as toilets, showers, and canteen facilities. There is an existing drainage network across the site with foul effluent discharging directly to the local municipal sewer without further onsite treatment. Foul water from the new developments will discharge through services currently utilised by the larger Regeneron installation and will be extended to facilitate the new developments. The existing discharge point (SE-3) is at the eastern boundary of the site and is separate from the process wastewater discharge at SE-1. The foul water drainage works are in place but are not yet active.

Potable Water and Firefighting Water Supply

The water supply for the site comes from the public water supply. The pre-existing water supply infrastructure is provided by the Raheen Industrial Estate.

Fire-fighting water is supplied to the site from the water mains and is stored in a 750 m^3 storage reservoir located in the south yard.

Adjacent to the fire-fighting water reservoir is a dedicated pump house containing 2 no. diesel fired pumps for supply of firewater across the installation. Firewater is gravity fed from the tanks to the pumps. In the event of a fire, water can be supplied at a rate of 568m^3/hour. The pumps are tested by Regeneron staff on a weekly basis and undergo routine maintenance by the external service provider.

Electrical Supply and Distribution

Electrical energy is used to power the installation and is supplied from a 38kV ESB Substation Building which is located along the southern boundary of the site.

5 no. emergency diesel generators in the south utilities yard are available to supply emergency power to critical and essential manufacturing and utility equipment and systems. All generators have a 15 m exhaust stack.

Natural Gas

Natural gas enters the site via an AGI skid in the north yard from where low-pressure gas is distributed across the site.

Building Automation System (BAS)

The installation operates a BAS automation system for control, monitoring, data collection and alarm/reporting of the HVAC air handling systems and mechanical utility systems site wide. Specifically, this includes the Process Chilled Glycol, HVAC Chilled Water, Cooling Tower System, Compressed Air, Utility Steam (boilers) and Condensate, Process Water (softened), City water, Fuel Oil and Natural Gas utility systems. Monitoring or supervisory control of boilers, compressed air units, the HVAC hot water package, and the server room air conditioning units is undertaken by the BAS.

Rooms requiring environmental control is managed by the BAS and identified monitoring signals from pressure transmitters and humidity/temperature instruments will provide readings to the BAS. The BAS also provides automation features for specific equipment in the major process areas located in the production areas including Media and Buffer Preparation, Upstream Processing (Cell Culture), Downstream Processing (Purification), Clean Utilities and Equipment Preparation, Process Utility storage and distribution, and controlled equipment in the production and utilities areas (i.e. bioreactors, mixers, chromatography, filtration, and associated instrumentation).

The BAS is capable of being configured to categorize alarm levels. The alarm levels allow for alarm optimization by differentiating alert alarms from action alarms. The alarm levels also facilitate alarm masking and alarm shelving to avoid nuisance alarms and alarm floods. BAS alarms are displayed and acknowledged on the BAS workstations.

2.4 Materials and Waste Storage

2.4.1 Raw Materials Management

The following outlines the storage of key raw materials across the site.

Solvents

Isopropyl Alcohol (IPA) is predominantly used as 70% IPA wet wipes, 70% IPA in bottles, and 70% IPA in spray canisters, used for decontaminating work surfaces in the QC lab and ALB labs (pre-wetted wipes and IPA in bottles) and the production areas (IPA from canisters sprayed onto cloths) in accordance with Good Management Practice (GMP). The pre-wetted wipes and 70% IPA spray canisters are stored in sealed packets and sealed canisters in the Warehouse and in smaller cabinets in the production areas and laboratories.

Ethanol (70%) and Ethanol (20%) is used for the sanitization step of the chromatography operation and for the storage of chromatography columns. At present, only 20% ethanol is used. In the future, small volumes (c. 400L) of 100% ethanol will also be diluted to make up 70% ethanol used for a column flush.

The 20% Ethanol is delivered to the bulk ethanol tank as 20% ethanol from IBCs and is delivered through a closed pressurised loop to the chromatography suite for column regeneration (cleaning) and storage of the columns.

The 70% Ethanol will arrive onsite as 100% ethanol in 2 no. 200L drums or 1 no. 1000L IBC (maximum) and will be diluted to 70% in the chromatography suite before being delivered through a closed pressurised loop to the columns for column regeneration (cleaning). The spent 70% ethanol will be disposed of into an IBC; and the unused 100% ethanol will be retained in the drum or IBC, resealed, and removed to a designated chemstore in the Waste Management Yard to be removed from the site as waste.

Glacial acetic acid is required in small quantities in production and in the ALB laboratories as part of the buffer solution formulation will be stored in sealed 4 - 10L containers in the Warehouse prior to use. These will be dispensed directly into the buffer solution prep units within an air-controlled environment.

2-Propanol (100% IPA) will also be used in the ALB laboratories for buffer or media solution formation. 100% IPA will be stored in sealed 1L bottles in flammable storage units within the ALB labs.

CIP Chemicals

Bulk CIP chemicals (phosphoric acid and sodium hydroxide) are stored in 25m^3 bunded bulk tanks in the north utilities yard and are pumped directly into day tanks on the skids and washers in the production area.

Lab Chemicals

Lab chemicals and supplies are stored within the QC lab. These are delivered to the site via the loading bay, recorded on the system, and transferred to the QC labs (and in future to the ALB lab) via pallet trucks and / or bunded carts. Following transfer to the labs the chemicals are transported by lab cart to the designated storage areas. Both the QC lab and the ALB labs contain adequate storage for daily/weekly usage requirements.

Flammables

The Warehouse is used to store small quantities of flammable chemicals and materials including;

- Aerosols (IPA spray) in caged storage;
- Flammable chrome media on pallets
- Flammable resins in a flammables cabinet
- Flammable corrosives

Flammables are segregated in accordance with the relevant legislation including the Safety, Health and Welfare at Work (Chemical Agents) regulations, SI 619 of 2001, as well as Health and Safety Executive (United Kingdom) guidance including HSG71 Chemical Warehousing: The Storage of Packaged Dangerous Substances and HSG51 The Storage of Flammable Liquids in Containers.

Powders

Media powders for use in the production areas are stored in the Warehouse in sealed bags and are transferred to the weigh and dispense area on carts. Bags of powders remain closed sealed and are opened within the weigh & dispense suite where they are dispensed into smaller dedicated containers sized for manual addition to the process.

Single Use Components

Single use components are stored in bulk within the Warehouse and are transferred to the production areas as required. A designated storeroom within the production area will also be provided for frequently used items.

Other single use items such as gowning materials and space cleaning consumables are stored in a separate designated store within the production area.

Refrigerants

Refrigerants are stored across the site within the chiller systems. These are stored in closed loop systems and are topped up as required. Annual service of all refrigeration systems is undertaken by Approved Contractors. Refrigerant is only removed as part of remedial work in the event of a leak or replacement of some components. The following outlines how each is used.

- *R404a – Headblock chiller, Headblock splits, canteen freezers and chillers, Warehouse temporary cool rooms,*
- *R134a – Process chillers, kitchen, and canteen chillers*
- *R410A – Data Centre A/C units, Load centre A/C units, QC A/C units, Security A/C, Headblock splits*
- *FM200 – DOC Control Tanks*
- *R407F – Warehouse refrigeration, QC refrigeration*

Fuel Storage

Diesel is stored in a number of locations around the site including:

- 2 no. bunded bulk (55,000L) tanks in the south utilities yard for use by the emergency generators;
- 2 no. double skinned 300 Gallon diesel tanks at the sprinkler pump house;
- 1 no. 2000L double skinned diesel tank for the mobile generator stored in the Wastewater Management System area.

Whilst the bulk tanks can hold up to 110,000L of diesel, only approximately 50,000L is stored on site in the bulk tanks at any one time. The tanks are stored within a shared bund within a volume of c.121m^3 (i.e. 110% capacity of the tanks held within)

Water Treatment Chemicals

Water treatment chemicals (Nalco) are stored in the following areas:

- The Wastewater Management System chemstore for use in the wastewater cooling towers;
- The North Utilities Yard Main Chemstore;
- The North Utilities Yard chlorine dosing Chemstore;
- The water treatment chemstore in the new ALB yard;
- The cooling tower chemstore for the east expansion cooling towers; and,
- The cooling tower chemstore for the east expansion boilers.

Nalco chemicals are delivered to the site in 200L drums by the supplier. The supplier recharges the onsite tanks and removes the empty 200L drums from the site. Chemicals used in smaller quantities are delivered to the site in 25L bottles and stored in the relevant chemstores.

The chemicals are charged directly into the boilers and / or cooling tower makeup within sealed, double skinned pipelines.

Wastewater Management System Chemicals

Acid (sulphuric) and caustic (sodium hydroxide) for pH adjustment of the industrial wastewaters are stored in double skinned bulk tanks (20m^3) within the Wastewater Management System. These are charged directly into the pH correction tank within a contained area and flange guards, which are inspected weekly, are in place on the pipelines.

There is also a double skinned 10m^3 Chemiox tank (odour abatement) as well as a chemstore for cooling tower treatment chemicals and a chemstore for antifoam. These are inspected weekly.

Bulk Gas Storage

Process gases (Liquid N, N_2, CO_2 and O_2) are stored in bulk liquid gas storage tanks in the north utilities yard and are piped directly to the production areas as required. These include the following:

- Liquid Nitrogen – 30,205L
- Nitrogen – 3,160L
- Carbon Dioxide – 11,535L
- Oxygen – 11,535L

There is also a 1000L Liquid N_2 tank in the QC yard adjacent to the QC Building.

A new max. 4000L Liquid N_2 tank is also proposed for the ALB yard. CO_2 and O_2 will be delivered from the main tanks in the north utilities yard. This is not yet in place as of May 2020.

2.4.2 Process Intermediates

During the cell culture process there are multiple process intermediates that are produced. These intermediates are stored in closed bioprocess vessels (bags) in the classified suites, or in freezers. Intermediates may be frozen in the production building or they may be removed from the production building through material airlocks and transferred to the warehouse via the staging area for long-term frozen storage.

When a drug substance is generated it is filled, capped in bulk bottles, and removed from the production building through material airlocks. It will then be transferred via the staging area to the warehouse for freezing and long-term storage.

2.4.3 Waste Management

Solid Wastes

Bio-hazardous solid waste from the production areas and labs will include spent single use bags, filters, tubes, etc., which require decontamination in the decon autoclave prior to being removed offsite for treatment in a waste to energy facility. Single use components are bagged within the manufacturing area and QC Labs and placed in bags or totes for transfer from the suites through material airlocks (MALs) or labs and taken to the dedicated decon autoclave for deactivation. After deactivation the waste is taken to the Waste Management Yard to be removed off site for final treatment. Biohazardous waste not deactivated on site is disposed to dedicated bins clearly labeled as bio-hazardous waste and sent off site through a dedicated vendor as per the sites GMO consent.

Other hazardous (i.e. not bio-hazardous) solid wastes will also be generated in the production areas and lab areas. These include spent wipes and other consumables containing IPA, contaminated PPE, spent single use bags and filters (from downstream processes not containing bio-hazardous materials), etc. These are bagged within the manufacturing area and QC Labs and placed in bags or totes for transfer from the suites through material airlocks (MALs) or from the labs and taken to Waste Management Yard for removal offsite for treatment in a waste to energy facility.

Non-hazardous solid wastes including unused bags, filters, etc. as well as packing elements are segregated and stored within the Waste Management Yard prior to being removed offsite for recycling where possible, or disposal at a waste to energy facility.

Transport of all waste leaving the site is by appropriately permitted hauliers only, and all waste is taken to suitably registered, permitted or licensed facilities; and records and copies of relevant documentation of all waste leaving the site is maintained on file.

Liquid Wastes

Process wastewater which may have come into contact with biological materials and/or off-spec bioreactor batches is managed using a heat inactivation system prior to being discharged to the Wastewater Management System. Process wastewater which has not come in contact with biological material is collected in the various sumps and conveyed to the Wastewater Management System. Lab liquid waste that may have come into contact with biological materials is chemically deactivated within the specific labs and discharged to process drains which is conveyed to the Wastewater Management System. Certain lab chemicals and liquid wastes not suitable for discharge to the sewer are collected in suitable plastic drums, labelled as hazardous waste, and transferred to the designated chemstores in the Waste Management Yard.

2.5 Bunds and Pipelines

All tanks, bunded storage and pipelines have been designed for the specific purpose and contents. As required the structures are rendered impervious to the materials stored therein. All bunds are 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 and will designed in accordance with the Environmental Protection Agency's guidelines for the storage and transfer of materials for scheduled activities (EPA, 2004).

The only underground pipelines are the treated process wastewater, foul sewer, and surface water lines. All process drainage is double contained. The foul and stormwater characteristics are as such that double containment is not necessary as per the EPA 2004 guidance on the storage and transfer of materials.

The majority of the bulk tanks are stored in bunds meeting the requirements of Agency guidelines on the "Storage and Transfer of Materials for Scheduled Activities". Integrity testing is completed in accordance with BS8007 "Code of Practice for design of concrete structures for retaining aqueous liquids" i.e. bunds are demonstrated to be capable of holding 110% of the capacity of the largest tank or drum within the bunded area or 25% of the total volume of substances stored within the bund (whichever the larger).

The following is a summary of the existing reinforced concrete bunds (internal and external) at the installation:

- Wastewater Treatment Bund
- WWTP Chemical Loading sump
- Biowaste sump bund
- Process waste sump bund
- Utilities waste sump bund
- Ethanol storage tank bund
- Phosphoric acid for CIP storage tank bund
- Caustic for CIP storage tank bund
- Generator Tank Farm bund
- QC Lab Waste Lift Station sump bund

There are also a number of bunded Chemstores and plastic mobile pallet bunds for loading areas, waste drums, and other general use. Additional bunds required for the ALB and the east expansion will be added to the bund register. All concrete bunds have local sumps which will be used to pump out uncontaminated rainwater to the Wastewater Management System. Collected rainfall is tested by site maintenance staff and, if clean and free from contaminants, it will be pumped out using a mobile pump.

Tanks that do not require bunds, such as the firewater pump house diesel tanks, are double skinned and located adjacent to a hydrocarbon interceptor.

Integrity testing of all concrete bunds and pipelines is carried out every three years in accordance with the existing IE licence.

3.0 RECEIVING ENVIRONMENT

3.1 Surface Water (Hydrology)

The Regeneron site is located within the National River Basin District in Hydrometric Area No. 24 Shannon Estuary South of the Irish River Network. The First Cycle Shannon River Management Plan (2009-2015) has been superseded by Second Cycle River Basin Management Plan (2018-2021). The Shannon River Management Plan shows that the area of the facility is within the Maigue catchment and the Ballynaclough sub catchment.

Arterial drainage is in a western direction from the Raheen Business Park. Storm water drainage from the business park site passes through a petrol interceptor before joining a public culvert/pipe storm water route to Loughmore Common Canal, which enters the Barnakyle River (Water body code IE_SH_24_1704) which subsequently flows into the Maigue River and then discharges to the River Shannon.

The River Shannon is located approximately 4.0 km northwest of the installation with the Lower River Shannon Tributary approximately 3 km to the northeast of the installation. The Limerick City & Environs Municipal WWTP located in Bunlicky, which receives and treat wastewater from the Regeneron site, discharges treated effluent within the tidal reach of the River Shannon at the eastern limit of Limerick City. This stretch of the river is within both the Lower River Shannon cSAC and the River Shannon and River Fergus Estuaries SPA. The EPA online mapping data (*Envision*) indicates that for the period 2010 to 2015 the water quality in this transitional estuarine reach of the River Shannon into which the WWTP discharges is of "moderate" status[1].

The closest surface water feature to the facility is the Barnakyle River, which skirts the southern end of Raheen Business Park. The Barnakyle River is a tributary of the River Maigue which flows into the River Shannon approximately 10km west of Limerick City. Available data for 2013 from the EPA on-line mapping database *Envision* indicates that water quality in the river Barnakyle is Poor[1].

EPA's *Envision* Database was also consulted to determine if any designated salmonid waters (S.I. 293/1988-European Communities (Quality of Salmonid Waters) Regulations, 1988) existed close to the site or are located so that they may be adversely impacted by the operation of the facility. The Barnakyle River was not included in the register of salmonid waters included in those regulations[1].

A Stage 1 flood risk assessment was undertaken as part of the most recent planning application for the east extension (Planning Ref. 171170). This report concluded that there have been no flood events recorded at the site. The OPW Provisional Flood Risk Assessment (PFRA) maps for the area were also researched and did not indicate risks of fluvial or pluvial flooding at the site[2].

3.2 Geology and Hydrogeology

According to the Geological Survey of Ireland (GSI) website and the Teagasc soil maps, the generalised bedrock beneath the site is classified as basalt and other volcanic rocks. However, during the site investigation undertaken at the site between 3rd and 6th of September 2013[3] the presence of fine to medium grained limestone beneath the site at depth from 0.8m to 4.1m bgl. The limestone is described as

[1] EPA (2018) Envision on-line mapping, Available on-line at: http://gis.epa.ie/Envision/
[2] Office of Public Works (OPW) Provisional Flood Risk Assessment (PFRA) maps, available at: http://www.cfram.ie/pfra/interactive-mapping/. Accessed 2018.
[3] PM Group (2014), Baseline Report for Regeneron Ireland (April 2014).

Carboniferous limestone of the Waulsortian Formation. The Waulsortian Formation consists of large areas of unbedded limestone which is prone to karstification.

The natural subsoil type located at the facility is predominantly glacial tills (carboniferous limestone till) according to the GSI website. The site investigations undertaken for the original baseline, completed in 2013[1], as well as the additional studies undertaken in 2017[4] and the investigations undertaken by AWN in August 2018[5], confirm that the site consists of tills derived from the underlying limestone as well as made ground.

The aquifer underlying the site is classified by the GSI as a (Ll) Locally Important Bedrock Aquifer, which is moderately productive, only in local zones. LI classified aquifers characteristically have well yields in the order of 100m^3 per day however according to the GSI well data base well yields are poor in the area around the site (GSI, 2018[2]). This would indicate a low transmissivity (T) of the underlying bedrock formation.

The GSI (2018[6]) Interim Vulnerability Map presently classifies the aquifer in the area of the subject site as predominantly *High* (H) which indicates an overburden depth of 3-5m with low permeability soil present. The bedrock boreholes installed onsite during the 2013, 2017 and 2018 investigations showed that the depth to bedrock varies across the site but is between approximately 0.5 – 8.3 mbgl confirming that the aquifer vulnerability ranges from *high* to *extreme*.

Groundwater flow is interpreted to be in the direction of the Barnakyle River approximately 200m west of the site i.e. flow is likely to be mainly from north and north east to the south and southwest, as outlined in the 2017 EIS.

The GSI (2018[2]) database identifies no groundwater source protection zones (SPZ) in the immediate vicinity of the subject site. The nearest source protection zones are located at ~10km south (near Fedamore).

The Groundwater Body (GWB) underlying the site, the Limerick Southwest GWB, is currently classified as having 'Poor Status' EPA (2018[7]). However, the most recent round of groundwater sampling undertaken at the site, in accordance with the requirements of Regeneron's IE Licence, showed no exceedances above the available groundwater threshold values (GTV's) for a number of indicator parameters in the samples tested from all 4 monitoring wells. These include PCB's, pesticides, VOCs, sodium, total PAH's and glycols. The chemicals of concern stored in bulk onsite are ethanol, phosphoric acid and sodium hydroxide. The slight exceedances of the GTVs seen for some parameters do not indicate any connection to onsite activities.

3.3 Human Receptors

The subject site is within an established industrial area with other manufacturing facilities within close proximity of the site. Greenfield areas are located to the south and west of the site, and the Roche Castle (a protected structure) and grounds are located to the north.

The closest residential area is c. 400m to the east of the site along the Ballycummin Road. Limerick city centre is located c. 5km to the north west of the site.

[4] PM Group (2017), Technical and Environmental Due Diligence Report for Regeneron Site (June 2017)
[5] AWN (2018), Soil and Groundwater Baseline, Ref. PC/18/10093R01a (November 2018).
[6] GSI (2018) Online Mapping System http://gsi.ie/Mapping.htm
[7] EPA (2018) Envision on-line mapping, Available on-line at: http://gis.epa.ie/Envision/

The nearest schools (c. 1.4km) are Redhill School to the south west and St Gabriel's School to the north east. In addition to these there is Limerick City Educate together c. 2km to the north west of the site and Crescent College Comprehensive c. 1.6Km to the north east of the site.

The University Hospital of Limerick is located c. 1.4km to the north of the site, in close proximity to St Gabriel's School.

3.4 Ecological Receptors

Table 3.1 summarises the designated Nature 2000 sites within 15km of the site (the Zone of Influence) or 20km of a hydrological link. No other Natura 2000 Sites with hydrological linkages of 20 km or less were found beyond those already identified within the 15 km Zone of Influence (ZOI).

Site Name	Code	SAC	SPA	NHA	pNHA	Distance [km]
Loughmore Common Turlough	000438				✓	0.64
Lower River Shannon	002165	✓				2.50
River Shannon and River Fergus Estuaries	004077		✓			2.50
Inner Shannon Estuary - South Shore	000435				✓	2.71
Fergus Estuary And Inner Shannon, North Shore	002048				✓	3.93
Knockalisheen Marsh	002001				✓	7.35
Tory Hill	000439	✓			✓	8.20
Adare Woodlands	000429				✓	9.41
Garrannon Wood	001012				✓	9.73
Skoolhill	001996				✓	9.78
Dromore & Bleach Loughs	001030				✓	9.83
Cloonlara House	000028				✓	11.25
Askerton Fen Complex SAC	002279	✓				11.85
Castleconnell (Domestic Dwelling, Occupied)	000433				✓	12.33
Curraghchase Wood	000174	✓			✓	13.39
Lough Gur	000437				✓	14.19

Table 3.1 *Nature 2000 Sites within the ZOI*[8]

The AA Screening Report provided with the planning application for the east extension sets out the likelihood and significance of any potential impacts on European designated sites. 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 Loughmore Common Turlough pNHA is within 1 km of the Regeneron site however, the main threats to the site are drainage, agricultural reclamation, pollution and afforestation. None of the proposed characteristics of the project will impose additional threats to this site as best practice guidelines outlined in the construction environmental management plan will be followed to ensure minimal interaction with the hydrodynamic properties of the surrounding area.

There are no open watercourses onsite. Drainage is northwards to the Shannon Estuary, 3 km from the study site via the Barnakyle River and the River Maigue. The site has limited biological and hydrological connectivity to these designated sites.

[8] Environmental Impact Services (2017), Environmental Impact Assessment Report for Proposed Extension of Bulk biologics Facility at Regeneron Ireland U.C., Raheen Business Park, County Limerick, December 2017

3.5 Source – Pathway – Receptor Linkages

Overall, it is considered that there is limited risk of a significant pollutant linkages to existing at the facility due to the following.

- The operational areas of the site are fully hard paved to prevent linkages to the soil and groundwater environments;
- All site operations involving biological materials are carried out internal to the buildings in high containment suites;
- All external chemical/diesel storage is bunded to EPA standard and is surrounded by hard stand;
- All other chemical storage is internal to the buildings within lockable, self-bunded stores;
- Any accidental hydrocarbon emissions such as localised accidental leakages from cars/vehicles in the car park area would drain to the onsite stormwater network and would be captured in the hydrocarbon interceptor;
- Any spill of chemicals / diesel during transfer or delivery would be immediately addressed using onsite spill kits and all deliveries are supervised.

3.6 Ecological Receptor Criteria

Based on the outline above, the site does not fall within the criterial for firewater retention based on source-pathway-receptor linkages to important pathways.

4.0 IDENTIFICATION OF HAZARDOUS SUBSTANCES

The Firewater Risk Assessment process as defined by EPA guidance focuses on substances that pose a risk to the environment by way of environmental toxicity.

4.1 Inventory of raw materials and wastes

A list of the relevant raw materials, including their hazard statements, is included in Table 4.2. These chemicals are lab chemicals, production chemicals (stored and used internally), or bulk chemicals stored in the Utilities yards. Chemicals classified as being hazardous to the aquatic environment have been included.

Other production chemicals used on site are listed in Attachment 4.6.2 of the IE licence application. These chemicals are not listed in Table 4.2 as they have been classified as WGK 1 (other than a very small amount (0.001 tonnes) of Trypan Blue which is WGK3 and stored in the labs) and are not hazardous to water.

Drawing 3 shows the layout of the chemicals including the location of the lab chemicals and the bulk tanks.

Table 4.1 below provides a description of the relevant Classification, Labelling and Packaging (CLP) Regulations (EC no. 1272/2008) hazard statements that apply to the chemicals in Table 4.2.

Hazard Statements	Description
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long-lasting effects
H411	Toxic to aquatic life with long-lasting effects
H412	Harmful to aquatic life with long-lasting effects
H413	May cause long-lasting harmful effects to aquatic life
H420	Harms public health and the environment by destroying ozone in the upper atmosphere
H433	Harmful to terrestrial vertebrates

Table 4.1 Relevant Hazard Statements

Material/ Substance	Storage Container	Area Stored	Amount Stored	Hazard Statements
Diesel Fuel	Bulk tanks (bunded) and double skinned tanks	South Utilities Yard Wastewater Management System (Future only)	77.15 tonnes @ a density of 0.832 kg/L (92,730 litres)	H226, H315, **H411**
Chelate Formulation C10	1L bottles	Production Areas and Warehouse	0.2 tonnes	H317, H318, **H412**
Chelate Formulation C13	1L bottles	Production Areas and Warehouse	0.3 tonnes	H318, **H412**
Sporicidal Active Chlorine	1L bottles	Production Areas and Warehouse	0.2 tonnes	H290, H**412**
Sodium Hypochlorite (Bleach)	<2.5L bottles	Lab Areas	N/A	H270, H272, H314, H314, **H400**
Ammonium Hydroxide	<1L bottles	Lab Areas	N/A	H314, **H400**
Nalco 93033 - Cooling water treatment	750L Tank + 2 x 430L tanks + 200L drums	North Utilities Yard (chemstore) - 750L Tank + 430L Tank Wastewater Management System (chemstore) – 430L Tank East Expansion yard (chemstore) – 1-2 drums	2.2 tonnes @ a density of 1.11 kg/L (2,010 litres)	H290, H314, **H400, H410**
Nalco 3DT426 - Cooling water treatment	2 x 430L tanks	Wastewater Management System (chemstore) – 430L Tank North Utilities Yard (chemstore) – 430L Tank	0.86 tonnes @ a density of 1 kg/L (860 litres)	H314, H335, **H411**
Nalco 77352 - BIOCIDE	60 L tanks	ALB yard (chemstore) – 60 L tank x 2 North Utilities Yard (chemstore) – 60 L tanks	0.18 tonnes @ a density of 1 kg/L (180 litres)	H302, H332, H314, H318, H334, H317, H335, **H410**
Nalco TRAC 109 - Anti Corrison/Anti Scale Chiller Treatment	430L tank and 4 x 25L drums	North Utilities Yard (chemstore)	0.53 tonnes @ a density of 1 kg/L (530 litres)	H314, H318, H335, **H411**

Table 4.2 *Environmentally Hazardous substances stored on-site (environmental hazards in **bold**)*

4.2 Classification of Chemicals

The EPA's 2019 guidelines require an assessment of the quantities of substances that process CLP hazard statements within the range of H400 to H499 (Environmental Hazards). Table 4.3 specifies the storage thresholds for specific hazard statements which lead to the potential for firewater retention.

Hazard Statement	Storage Quantity (tonnes)
H400 H410	1
H401 H411	10
H402 H412	100
H413	1000

Table 4.3 *Storage Thresholds of Substances with Environmental Hazard Statements*

Table 4.4 shows the total amounts stored per hazard category.

Hazard Statement	Storage Quantity (tonnes)
H400 H410	**2.38**
H401 H411	**78.54**
H402 H412	0.7
H413	-

Table 4.4 *Storage Amounts with Environmental Hazard Statements*

The overall storage of Diesel and Nalco 93033 at the Regeneron facility falls within the thresholds for potentially requiring firewater retention. However, as both Nalco 93033 and diesel are stored in multiple locations the volume of diesel in each area is broken down in Tables 4.5 and 4.6.

Area	Storage Container	Max Storage Quantity (tonnes)
Emergency generator (South utilities Yard)	2 x 55,000L tanks	88,000L (73.22 tonnes)**
Pump house	2 x 300 Imperial Gallon tanks	2,730 L (2.26 tonnes)
Mobile generator (at Wastewater Management Area)	1 x 2,000L tank	2,000L (1.66 tonnes)

Table 4.5 *Storage of Diesel*

***The generator diesel tanks are typically filled to c.50% (or 25,000L each) in accordance with Regeneron's refueling policy. However, as a worst-case conservative estimate up to 88,000L has been included in the calculation assuming the tanks are filled to 80%.*

Regeneron typically utilise 30,000L per annum and have approx. 50,000L stored on site in the bulk tanks at any one time. The max 'potential' storage is higher due to the size of the tanks but will not be stored in practice.

Nalco tanks are also filled to c. 80% but have been included at the full volume of the tanks in table 4.6.

Area	Storage Container	Max Storage Quantity of NALCO 93033
North Utilities Yard (adjacent to cooling towers in a chemstore)	750L Tank + 430L Tank	1,180L (1.3 tonnes)
Wastewater Management System (chemstore)	430L tank	430L (0.48 tonnes)
East Expansion yard (chemstore)	200L drums (up to 2 drums)	400L (0.44 tonnes)

Table 4.6 *Storage of Nalco 93033*

4.3 Containment Systems

Apart from diesel fuel, all other hazardous to the environment chemicals are stored within drums or smaller containers within the building or the self-bunded chemstores.

All tanks and pipelines are subject to a preventative maintenance programme and regular inspection, and all concrete bunds are subject to integrity testing every 3 years in accordance with the requirements of the IE licence.

Diesel Containment

The bulk tanks are stored in the generator tank farm area which is bunded to a capacity of 121m^3 (i.e. 110% of the capacity of the tanks held within). The bund where diesel is stored has passed the most recent integrity test on 24th October 2017 with the next test scheduled in 2020. The surrounding area and in particular the loading area are concrete hardstand to avoid any direct discharge to ground, and there is 1 no. 10,000L Class 1 full retention interceptor installed on the drainage line from this area. The smaller diesel tanks at the sprinkler pump house are double skinned, on a concrete hardstand area and the drainage line from this area is through the 10,000L Class 1 full retention interceptor.

The mobile generator in the Wastewater Management System area is double skinned and any leak in the tank would be fully contained. This will be stored on hardstand yard areas to avoid any direct discharge to ground. Whilst the tank is not bunded, any spillage of diesel during use would either be cleaned up using spills kits or as a worst case be directed to the stormwater drainage network which includes a c. 37,000L Class 1 by-pass petrol interceptor.

Nalco 93033 Containment

Nalco 93033 is mainly stored in tanks within the self-bunded chemstores. The east expansion has not yet been fitted out but the future chemstore in the east expansion yard will contain up to 2 no. 200L drums.

The areas surrounding these chemstores and in particular the loading area are continuous concrete hard standing to avoid any direct discharge to ground.

Drainage from the area around the North Utilities Yard chemstore also goes to the Utilities Sump (16m^3) rather than to the stormwater drainage network and is subsequently discharged to sewer via the Wastewater Management System.

5.0 SEPARATION INTO RISK ASSESSMENT AREAS

The following areas are separated by 2-hour fire walls:

- Between the Headblock/admin building and the main Production building;
- Between the Production Area and the internal utilities and warehouse area.

In addition to 2-hour firewalls, 1-hour fire separations are provided within the main production building to sub-divide the building into several areas. These separations are a full storey in height. The following areas are separated by 1-hour fire walls:

- Between the internal Central Utilities Area and the Warehouse;
- Around the south side of the electrical room (Sub-station 4&5);
- Around the north side of Substation 6 (South Utilities Yard);
- Between the sprinkler pump house and the production building;
- Around the equipment store (including the solvent storage and waste store) within the Warehouse area;
- Around the stair wells in the head block.

Once the site has been developed to include the ALB, East Expansion and other associated site changes the following will also be separated by 2 hour rated fire walls:

- Between the main production building and the East Expansion;
- Between the new designated autoclave area and both the East Expansion and the main production building;
- The new Waste Management Building and the East Expansion.

There will also be overhead pipe racks between the East Expansion to the Wastewater Management System, and the ALB Building and the headblock. These will not contain flammable materials and will not cause the spread of fire from one area to the next.

The cooling towers are non-flammable and will not cause the spread of fire from the west of the North Utilities Yard (including the acid and caustic tanks and water treatment chemicals chemstore) and the east of the North Utilities Yard (including the substation and the ethanol and gas storage).

The acid/caustic tank and Nalco chemstore in the North Utilities Yard is separated from other areas by both separation distances and drainage. This area drains to the Utility Sump rather than to the site wide stormwater drainage network.

The diesel fired emergency generators in the South Utilities Yard are separated from other permanent structures by both separation distances and drainage. The diesel stored is contained within its own bund; stormwater to this area will be captured in the bund rather than in the site wide stormwater drainage network.

Other fixtures in the South Utilities Yard are either temporary / to be removed (i.e. induction centre) or non-flammable (i.e. process water tanks) which will not cause the fire to spread. There is a 1-hour fire wall around the induction centre, which combined with the distance of c.10m between the building and the generators is sufficient to prevent the spread of a fire.

There is a 20kV substation in the south utilities yard has a blast wall to the back of the building and does not contain any combustible material. The 38KV building is not owned by Regeneron (owned and operated by ESB) and is a neighbour to the Regeneron site.

Based on the above, the potential for fire spread can be segregated into the following areas.

1. Main production building and south utilities yard (substation, pump house, water tanks).
   - *Separated from Warehouse/Central Utilities Area, East Expansion, and Headblock by 2 hour fire walls;*
   - *Located >15m from emergency generators.*

2. Warehouse and Central Utilities Area
   - *Separated from Main Production Area and Headblock building by 2 hour fire walls.*

3. Headblock, headblock boiler room and chillers, admin building and QC building
   - *Separated from Main Production Area and Warehouse/Central Utilities Area by 2 hour fire walls;*
   - *Chillers are external;*
   - *The boiler house is separated Utilities Area by a 2 hour fire wall.*

4. Existing Waste Management Yard
   - *Located c.15m from the North Utilities Yard.*

5. North Utilities Yard - East (substation/electrical room, gas storage and ethanol storage)
   - *North Yard-East is located >15m from the acid & caustic tanks and chemstore.*
   - *The substation has a 1 hour firewall on south side.*

6. North Utilities Yard - West (Nalco chemstores, acid and caustic tanks)
   - *Located >15m from headblock boiler room and chillers;*
   - *Located >15m from substation 4&5 and the ethanol and gas storage area.*
   - *Separated from the manufacturing building and the remainder of the North Yard in terms of drainage (drains to the Utility Sump rather than to the stormwater network).*
   - *Chemstores are c.9m from the Headblock boiler house and are non-flammable structures.*

7. Emergency generators with diesel storage (South Utilities Yard)
   - *Separated from the main production area and from other south yard Permanent fixtures by >15m.*
   - *Separated in terms of drainage.*

8. Wastewater Management System
   - *Located >15m from all other areas.*

9. Waste Management Building (NEW)
   - *Separated from East Expansion by 2-hour firewall.*

10. Autoclave Area (NEW)
    - *Separated from both the East Expansion and the main manufacturing building by 2-hour firewalls.*

11. East Expansion and Yard (NEW)
    - *Separated from both the autoclave area and the main manufacturing building by 2-hour firewalls.*

12. Multi Storey Car Park (NEW)
    - *Separated from all other areas by >15m.*

13. Administration and Lab Building and Yard (NEW)
    - *Separated from the main manufacturing building by >15m.*

14. 20kV Substation
    - *Separated from the main manufacturing building by >15m.*
    - *Separated from the ALB by >15m.*
    - *Separated from the generators by >15m.*

6.0 FIRE CONTROL SYSTEMS

The principals of the fire-control measures are based on the following points,

- Fire prevention
- Fire detection
- Fire containment
- Fire suppression

6.1 Fire Prevention and Mitigation

6.1.1 Fire Compartmentalization

As outlined, the facility utilizes 2-hour firewalls and 1-hour fire separations. Other fire restriction measures including fire resistant doors and shutters are also provided where required.

6.1.2 Explosion Prevention

The site has a live EPD (Explosion protection document) which includes a description of the facility, process, hazardous area classifications, procedures and controls. The document is considered 'live' and will be updated when there is a change in process / new process.

6.1.3 Standard Operation Procedures and Policies

There are a number of Regeneron controlled standard operating procedures (SOPs) in place at the site which cover emergency response, chemical handing, and handling of flammable materials which are communicated to all staff during induction. Additional training of staff is undertaken periodically in accordance with Regeneron's training system.

The Emergency Response Team (ERP) undertake additional training including basic fire response, first aid, incident management, and chemical spill management in accordance with their specified role.

There is a no smoking policy onsite and smoking is restricted to a dedicated smoking hut on the site boundary, within the contractor's compound.

A permit to work system is in place and hot work permits are required by contractors and Regeneron personnel undertaking work that is potentially hazardous. As hot works pose a potential ignition source the permit to work system is designed to prevent a potential fire scenario.

6.2 Fire Detection Systems

The existing facility is equipped with automated fire detection systems (both heat and smoke detectors on site dependent on area requirements) which are connected to a main fire panel in the security office which is manned at all times. In the event that a fire is detected, the fire panel will display the location of the detected fire; and in the case of a detected fire within the main production building, then the specific production line will also be indicated. Once detected the location of the potential fire will go into an alarm state and, in the event of a production area fire, production will cease, and process kit will be left 'as-is'. Gas supply systems to the production areas will also cease.

The fire detection and alarm system are connected to the sprinkler and gas suppression systems and these will be triggered in the event of a fire.

The automated fire detection system will be expanded to include the east extension and ALB as they are developed (in progress).

The fire detection and alarm system are subject to routine checks by Regeneron personnel and is inspected and tested by the external service provider on a regular basis.

6.3 Fight Fighting and Emergency Response

6.3.1 Emergency Response Plan and Fire Brigade Response

As outlined above, the facility has an established Emergency Response Plan (ERP) which covers all possible emergency scenarios including fires, chemical spills, explosions, etc. The ERP outlines the relevant responsible personnel, the response procedure, the emergency contacts, and the training required to provide the ERT with adequate skills. The ERP is reviewed regularly by the EHS manager and is updated as required.

The closest fire station is at Mulgave Street in Limerick City, c. 7km from the Regeneron site. The ERT have liaised with Limerick Fire Brigade on the potential fire scenarios and the fire brigade has been on site. In a response to a fire it is understood that the fire brigade could be onsite within 10 minutes of the alarm being raised.

6.3.2 Fire-fighting water and Fire hydrants

Fire-fighting water is supplied to the site from the water mains and is stored in a 750m^3 storage reservoir located in the south yard. The reservoir is split into parts to allow one part to be cleaned whilst the other remains in service.

Adjacent to the fire-fighting water reservoir is a dedicated pump house containing 2 no. diesel fired pumps for supply of firewater across the facility. Firewater is gravity fed from the tank to the pumps. In the event of a fire, water can be supplied at a rate of 2500L/minute. The pumps are tested by Regeneron staff on a weekly basis and undergo routine maintenance by the external service provider.

There are fire hydrants across the site for the supply of fire-fighting water. All hydrant outlets are to the Limerick City and County Council standard for fire hose couplings.

The location of the fire hydrants follows the following standard:

- 90m spacing in yard areas;
- 45m spacing in high hazard areas, such as fuel storage areas;
- 12m spacing for buildings and equipment.

6.3.3 Internal Sprinkler System

Fire water for the sprinkler system is supplied from the firefighting water tank in the south yard (750m^3). The west pipe sprinkler system is installed across all production and utilities areas and is designed to an application rate of 8.1mm/minute. The sprinkler system has been designed in accordance with the National Fire Protection Association (NFPA) standards.

The wet pipe sprinkler system is zoned in accordance with the fire separations and includes the following areas:

- Zone 1: Boiler house
- Zone 2: Central utilities area
- Zone 3: Warehouse
- Zone 4: PA 8&9 Downstream
- Zone 5: PA 8&9 Upstream
- Zone 6: PA 10&11 Downstream
- Zone 7: PA 10&11 Upstream
- Zone 8: Head Block Building
- Zone 9: QC Building

Drawing 4 provides a site drawing of the ring main and a list of Hydrants, Post Indicator Valves (PIV) and Direction Indicator Values (DIV) for the main production building.

6.3.4 Gas Suppression system

Table 6.1 provides a list of the gas suppression systems linked to the Fire Alarm.

Area	Type	Quantity	Bottle size
Data Centre A	FM200	3 Bottles Total	221kg
Data Centre B	FM200	3 Bottles Total	260kg
Doc Control	FM200	5 Bottles	446kg
Facilities Doc Control	FM200	1 Bottle	70 kg
502 Data Centre	FM200	5 Bottles	67.5Litres Each
Load Centre 4/5	Argonite	39 Bottles	80 Litres Each
Load Centre 6	Argonite	21 Bottles	80 Litres Each
Generator Compound	Argonite	5 Bottles	80 Litres Each
Kitchen	Ansul R102	3 bottles	6L

Table 6.1 *Gas Suppression Systems*

6.3.5 Fire Extinguishers

Hand-held fire extinguishers are also located around the site including CO2, foam, water and powder type extinguishers. CO2 extinguishers are provided in IT rooms, electrical rooms and wiring closets. In GMP areas, ‘clean agent’ extinguishers are provided in stainless steel cabinets, whilst in non-GMP areas, multi-purpose ABC type extinguishers are provided.

Relevant personnel are trained in the use of these extinguishers. Annual inspection of the extinguishers is undertaken by the external service provider.

7.0 FIRE RISK ASSESSMENT

7.1 Classification of Environmental Risk Assessment

A risk assessment is a tool used to measure the potential significance of a fire event and the potential environmental impact of such an event, in each of the determined site assessment areas. It aims to give a quantitative measure of the total environmental risk posed through the use of a decision matrix which compares the level of fire significance with the environmental hazard potential.

The resulting classification gives an indication of the requirement for firewater retention in each of the site assessment areas.

Significance of the Fire Event

Significance of the fire event is a measure of the potential scale of a fire scenario occurring at the facility. To facilitate this, it is necessary to assess the possible sources and responses to a fire scenario and to produce a measurable outcome.

To undertake this calculation of it is necessary to determine the following factors:

- Quantities and types of flammable and combustible materials
- The fire detection systems in place
- The fire suppression systems in place

The amount and type of flammable and combustible materials will determine the risk of a fire in the area and the extent of the fire spread. The risk is lowest when there are low volumes of flammable and combustible materials and highest when there are significant volumes of flammable and combustible materials.

The fire detection methods will determine the likelihood and / or speed of detection of the fire incident. The risk will be lowest if the facility incorporates an automatic fire detection system and/or the area in question is highly occupied.

The effectiveness of the fire response system such as automatic sprinklers, fire tenders, etc., will determine whether the fire can be suppressed in a timely manner. The areas with an automatic system can be classified as low risk while other areas given sufficient fire extinguishers and fire response procedures can be classified as medium.

Table 6.1 highlights the classification of the significance of the fire event used.

Significance (S)	Description
S 1	Low Significance
S 2	Medium Significance
S 3	High Significance

Table 6.1 *Classification of the Significance of the Fire*

Environmental Hazard Potential

The environmental severity is an assessment of the total potential for environmental damage. This is not a measure of risk or probability of the chemical components reaching the environment or receiving body but the potential damaging effects. The environmental severity depends on the characteristics of the materials located within the facility that could cause environmental damage, in this case to the Barnakyle River.

The defining factor outlined in the EPA guideline is the quantities and types of 'Hazardous to the Aquatic Environment' Materials (H400, H401, H402, H410, H411, H412, H413) as well as the WGK Classification.

Table 6.2 highlights the classification of environmental severity used.

Hazard Potential (H)	Description
H0	No Hazard Potential
H1	Hazard Potential

Table 6.2 *Classification of Environmental Severity*

Overall Firewater Run-off Risk

The above classifications are used to determine the firewater run-off risk (R) as per the matrix below:

	H0	H1
S1	R0	R1
S2	R0	R1
S3	R1	R1

Table 6.3 *Classification of Environmental Severity*

Based on the firewater retention risk rating (R), the guidance provides an indication as to whether firewater retention is required (see Table 6.4)

Risk	Minimum Firewater Retention Measures Required
R0	No dedicated firewater retention required
R1	Firewater run-off must be retained within the operational site. The retention can be provided by means of the site's drainage system and other suitable infrastructure which is not exclusively foreseen for firewater retention (e.g. storm water ponds / tanks in wastewater treatment plants). All elements of the site infrastructure to be used for firewater retention (including shutoff valves) must be regularly inspected to ensure functionality and impermeability. The retention facility must remain impermeable for the duration of the incident up to the removal of the firewater run-off. The documented available retention capacity in the existing site infrastructure must be monitored and maintained. Automatic shut-off valves must be maintained and tested. Diversion of firewater to retention facilities must be automatic on activation of the site fire alarm. Onsite bunds cannot be used to provide firewater retention unless the content of a bund is directly involved in the fire event.

Table 6.4 *Requirement for Firewater Retention*

7.2 Environmental Risk Assessment of the Site

Area 1 Main production building and south utilities yard (substation, pump house, water tanks)

Significance of the Fire Event

The main production building comprises four production trains. Each production train consist multiple bioreactors of various sizes, support vessels and Clean in Place (CIP) skids. The building due to its construction is not considered combustible. There are some flammable materials used in this area, the majority of which is from the ethanol which is used in a 20% ethanol/sodium hydroxide mixture (H225, highly flammable). A conservative estimate of 0.5 tonnes per production train has been included.

IPA in 70% IPA (H225, highly flammable) in spray canisters will be used in the production areas and stored in local storage unit. Smaller volumes of H226, flammable, chemicals and powders are also used <2 tonnes). A conservative estimate of 5 tonnes of plastics / other packing and 20 tonnes of raw materials have also been included in the calculation for completeness.

There are no ignition sources in this area and the risk of faults leading to an ignition source is deemed unlikely. The production area is equipped with fire detection and alarms. The fire detection and alarm system are connected to the sprinkler and gas suppression systems and these will be triggered in the event of a fire. 1-hour firewalls also separate each of the control areas.

The South Utilities Yard consists of a fire water storage tank, process water storage tanks and pump house. The contents of which includes a brine tank, 2 no. booster pump skids, water softener skid, 2 no. sprinkler pumps, 2 no. diesel storage tanks and 2 no. jockey pumps. The pump house does contain up to 2.26 tonnes of diesel in the 2 no. double skinned tanks; however, this area is equipped with an automatic sprinkler installation.

There is a potential for an ignition/heat source in the South Utilities Yard due to the presence of the electric pumps and the substation. Good fire detection and suppression systems are available. Firefighting equipment in the area includes hose reels and portable fire extinguishers.

The pump house does contain up to 2.26 tonnes of diesel in the 2 no. double skinned tanks; however, this area is equipped with an automatic sprinkler installation.

As such, the fire significance (S) rating is ***S1 – Low.***

Environmental Hazard Potential

This area contains small volumes of hazardous to the environment chemicals as specified in Table 4.2 (assumed 20% for production areas). Area 1 also contains live GMO within the upstream production trains. All process tanks also have level alarms and are inspected regularly so the chance of a leak being undetected is low. These are Class 1 GMOs only and are not considered to be hazardous to the environment. Other materials stored in this area have a WGK 1 rating and a conservative estimate has been included in the calculations.

Diesel is classified as H411, toxic to aquatic life with long-lasting effects. The sprinkler pump house contains up to 2.26 tonnes (2,730 L) of diesel however these tanks are double skinned and the south yard in this area is equipped with 1 no. 10m^3 Class 1 full

retention interceptor. The main drainage line is also equipped with an additional 37m^3 Class 1 by-pass interceptor.

In the event of tank failure, the contents of the process water tank and brine tank do not present a risk in terms of fire water contamination and in fact have the potential to dilute fire water in the area.

The surface water drainage system can be isolated through the shut off valve in the event of fire-water run-off being generated. This ensures that there are limited pathways to environmental receptors from the site in the event of a fire.

The hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

To obtain the overall firewater run-off risk value it is necessary to use a decision matrix to produce a measurable result. As described in Section 7.1 the overall Environmental risk is calculated by multiplying the matrix factors obtained for the Fire Event Significance and Environmental Hazard Potential.

Based on the EPA's classification for the overall firewater run-off risk (R), Area 1 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S1
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.5 *Determination of Overall Firewater Run-off Risk – Area 1*

Area 2 Warehouse and Central Utilities Area

Significance of the Fire Event

The Warehouse area contains multiple types of substances; buffer solutions, acids, bases, and organic compounds. As outlined in Section 2.4 of this report, this includes a store for flammable chemicals and materials. The flammable store is an ATEX rated area and is strictly controlled. Based on the chemical list provided with the IE licence application, this could include up to 10 tonnes of H225, very flammable chemicals, and 10 tonnes of H226, flammable chemicals. This is a conservative maximum.

A conservative estimate of 20 tonnes of plastics / other packing and 40 tonnes of raw materials / media powders (excluding non-flammable liquids) have also been included in the calculation for completeness.

The Central Utilities Area contains the large steam boilers. Natural gas is used to fire the boilers; however, each boiler is equipped with a gas detector which would shut off the gas supply if the concentration of flammable gases reaches half of the Lower Explosive Limit (LEL).

The Warehouse and Central Utilities Areas are equipped with fire detection and alarm systems which are connected to the sprinkler and gas suppression systems and these will be triggered in the event of a fire.

In conclusions there are flammable materials stored in this area, however, there are good fire detection and suppression measures in place namely sprinkler systems and fire extinguishers, and therefore the fire significance (S) rating is ***S1 - Low.***

Environmental Hazard Potential

This area contains small volumes of hazardous to the environment chemicals as specified in Table 4.2. The total volume of these chemicals is less than the threshold of 1 tonne for H400+ chemicals. Other materials stored in the Warehouse have a WGK 1 rating and a conservative estimate has been included in the calculations.

There are no chemicals stored in the Central Utilities Area**.** Small quantities of water treatment chemicals including biocides will be present within boilers themselves however these will not be significant quantities and will be significantly diluted.

There is limited in situ containment for fire water run-off from the Warehouse and Central Utilities Area and as such fire water could flow into the storm water drains outside the warehouse. However, the stormwater network is equipped with a shut off valve that can be closed manually.

As such, the resulting hazard potential is ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 2 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S1
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.6 *Determination of Overall Firewater Run-off Risk – Area 2*

Area 3 Headblock, Headblock boiler room and chillers, Admin building and QC Building

Significance of the Fire Event

This QC Building contains small amounts of laboratory chemicals, some of which are flammable. Furnishings within the laboratory are not considered combustible. A conservative estimate of 20 tonnes of combustibles has been included in the calculation for completeness.

There is a small 1000L Liquid Nitrogen tank in the yard adjacent to the QC Building. This is a compressed gas but not a flammable gas and therefore has been included under the list of combustible process materials.

There would be potential for sources of ignition from an electrical fire. The QC building is equipped with an automatic sprinkler protection system. Fire hose reels are installed in areas such as stairwells and corridors. Fire extinguishers are installed in technical rooms and at all exit doors. These extinguishers contain carbon dioxide, ABC powder, or AFFF (aqueous film forming foam)

The comms room also contains an approved gaseous based fire protection system.

The headblock boiler room contains the LPHW boilers. Natural gas is used to fire the boilers; however, each boiler is equipped with a gas detector which would shut off the gas supply if the concentration of flammable gases reaches half of the LEL. The chillers house refrigerant is not flammable.

The Headblock boiler room and chiller room are equipped with fire detection and alarm systems. Fire extinguishers are available in the event of a localised fire.

There are potential ignition/heat sources in the canteen area. The administration building contains significant volumes of combustible materials (including the building itself). The area is equipped with fire detection and alarm systems and fire extinguishers are available.

As such, the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

The volume of hazardous to the environment chemicals stored in the QC lab, as identified in Table 4.2, are insignificant when referring to EPA Firewater Retention Guidance document. Whilst GMO will be processed in this area this will be Class 1 GMO with small amounts of Class 2 GMO is 1 no. laboratory. Conservative estimates of WGK rated materials have been included for completeness.

The office and canteen areas do not contain any hazardous materials and as such any release of firewater to the stormwater drainage network would not be regarded as hazardous to the environment.

Small quantities of water treatment systems will be present within the boilers. Water treatment chemicals include biocides. The majority of the water treatment chemicals for the boilers are stored in the chemstore at the Cooling Towers in the north yard. The chiller refrigerants are not hazardous to the aquatic environment.

Therefore, the resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 3 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.8 *Determination of Overall Firewater Run-off Risk – Area 3*

Area 4 Existing Waste Management Yard

This area contains 2 no. compactors (general and recyclable), 3 no. bunded chemstores for wastes (lab smalls), an enclosed area for packaging and sorting of waste, and several skips for assorted wastes. This includes bio-hazardous wastes that have been disactivated in the Waste Management Area. The area also includes the current contractors support facilities and the gas compound.

Other hazardous (i.e. not bio-hazardous) solid wastes including spent wipes and other consumables containing IPA, contaminated PPE, spent single use bags and filters (from downstream processes not containing bio-hazardous materials), etc., will be stored here.

Certain lab chemicals and liquid wastes not suitable for discharge to the sewer will be collected in suitable plastic drums, labelled as hazardous waste, and transferred to the designated chemstores in the Waste Management Yard.

Significance of the Fire Event

The majority of the waste is assumed not to be flammable but may be combustible.

The temporary waste management yard may contain spent 70% ethanol in drums or IBCs (H225 highly flammable). The total volume of ethanol is anticipated to be up to 1 IBC or $1m^3$ at any time. Spent IPA wipes and other consumables are H225 highly flammable. Up to 20 tonnes will be stored in this area at any one time. Other smaller flammable lab chemicals may also be stored here in the self-bunded chemstores.

The area will also include the gas compound which is a source of ignition. This is under the control of Bord Gais rather than Regeneron however the area is zoned for fire safety and no flammable products or structures are located within close proximity to the compound as per relevant safety regulations.

The area is equipped with a L1 fire detection and alarm system as well as fire extinguishers for fire suppression.

Due to the volume of combustible and flammable materials the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

This area is not used to store large volumes of hazardous liquid wastes. Small volumes of lab chemicals will be present in the self-bunded chemstores however the volumes are not significant. A conservative estimate of 2 tonnes of H401/411 chemicals and 0.5 tonnes of H400/410 chemicals have been included in the calculation. The resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 4 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.15 *Determination of Overall Firewater Run-off Risk – Area 4*

Area 5 North Utilities Yard (East)

This Area includes the large substation/electrical room, bulk gas storage and ethanol storage. The ethanol tank is bunded and would be self-contained in the event of a fire.

Significance of the Fire Event

The bulk ethanol tank contains 25m^3 of 20% ethanol. Ethanol is classified as H225, flammable. During the delivery of ethanol there is potential for flammable vapours to be present.

There are a number of bulk gas storage tanks in this area. These include Liquid N, N_2, CO_2 and O_2. These gases are not flammable gases but are compressed gases that may explode in a fire. As the EPA Guidance only stipulates H220 and H221 gases they have not been included in the tally of flammable gases in the WRA Tool for this area. However, they have been included in the list combustible process materials.

There is a low potential for ignition/heat source to be present during delivery of chemicals to this area as there is an earthing connection interlock with the tanker. Additional controls are in place in the north yard to prevent ignition sources including a permit to work scheme, speed controls, and a no smoking policy. The area around the ethanol tank is classified as an ATEX zone in the Regeneron EPD (Explosives Protection Document).

There are good fire detection and firefighting systems in place for the ethanol storage. There are fire hydrants in the area for firefighting.

As such, the fire significance (S) rating is ***S2 - Medium.***

Environmental Hazard Potential

There is a bulk Ethanol tank in this area which is classified as WGK1. There are no H400+ chemicals stored in this area.

The stormwater drainage network is also equipped with a shut off valve that can be manual shut in the event of a fire event.

The resulting hazard potential is ***H0 – No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 5 is classified as not at risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.11 *Determination of Overall Firewater Run-off Risk – Area 5*

Area 6 North Utilities Yard (West)

This Area includes the CIP chemical tanks and water treatment chemical chemstores. The CIP chemical tanks and ethanol tank are bunded and, as outlined below, would be self-contained in the event of a fire. The chemstore is also self-bunded and would contain the contents of a ruptured drum or container.

Significance of the Fire Event

The chemicals stored in this area are not flammable in nature.

There is a low potential for ignition/heat source to be present during delivery of chemicals to this area as there is an earthing connection interlock with the tanker. Additional controls are in place in the north yard to prevent ignition sources including a permit to work scheme, speed controls, and a no smoking policy.

There are fire hydrants in the area for firefighting.

As such, the fire significance (S) rating is ***S1-Low.***

Environmental Hazard Potential

The north utilities yard contains acid and caustic bulk tanks (CIP chemicals) within designated bunds which would be sufficient to contain the contents of the tank and any firefighting water in the very unlikely event that the tanks ruptured during a fire. The CIP tanks are classified as WGK1.

The main chemstore contains a 430L tank of Nalco 93033, a 430L tank of Nalco 3DT426, a 430L tank of Nalco TRAC 109, a 60L tank of 77352, and Nalco Tri Act 2813 (100L tank). Nalco Tri Act 2813 is not an H400+ chemical.

The new WFI Chlorine dosing chemstore contains a 750L tank of Nalco 93033 only.

The new drum chemstore contains 1-4 drums of Nalco TRAC 109 and 1-3 drums of other Nalco products (Nalco 1318, 2584, 77211, 22310) and up to 4 drums of Nalco 77393. A maximum of 20 no. 200L drums (4,000L) has been accounted for.

The total quantity of H400/410 chemicals stored in this area therefore exceeds the threshold of 1 tonne equivalent and as such firewater retention is required on this basis.

The chemstores are self-bunded to contain the contents of any drums or containers that may rupture in a fire. Drainage from the area around the North Utilities yard chemstores also goes to the Utilities Sump rather than to the stormwater drainage network and is subsequently discharged to sewer via the Wastewater Management System.

Based on the volume of Nalco 93033 stored the resulting hazard potential is ***H1 - Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 6 is classified as at risk and firewater retention is therefore required.

Category	Rating
Significance of Fire Event (S)	S1
Environmental Hazard Potential (H)	H1
Overall Firewater Run-off Risk (R)	**R1**

Table 6.11 *Determination of Overall Firewater Run-off Risk – Area 6*

Area 7 Emergency generators with diesel storage (South Utilities Yard)

Significance of the Fire Event

There are 2 no. 55,000 L bunded diesel tanks. The tanks are typically filled to c.50% (or 25,000L each) in accordance with Regeneron's refueling policy. However, as a worst-case conservative estimate up to 88,000L has been included in the calculation assuming the tanks are filled to 80%. As such, the area contains c. 73 tonnes of H226 (Flammable) chemicals.

There is the potential for heat/ignition sources in this area due to the presence of generators. Good fire detection and suppression systems are available. Firefighting equipment in the area includes hose reels and portable fire extinguishers.

Based to the volume of flammable material, the presence of fire detection and suppression systems (non-automatic), the fire significance (S) rating is ***S3-High.***

Environmental Hazard Potential

Diesel is classified as H411, toxic to aquatic life with long-lasting effects. The 2 no. 55,000 L tanks are within a designated bund as outlined in Section 4 of this report. As above, a worst-case conservative estimate up to 88,000L has been included in the calculation assuming the tanks are filled to 80%.

The south yard in this area is equipped with 1 no. 10m^3 Class 1 full retention interceptor. The main drainage line is also equipped with an additional 37m^3 Class 1 by-pass interceptor.

The resulting hazard potential is therefore ***H1 - Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 7 is classified as at risk and firewater retention is therefore required.

Category	Rating
Significance of Fire Event (S)	S3
Environmental Hazard Potential (H)	H1
Overall Firewater Run-off Risk (R)	**R1**

Table 6.12 *Determination of Overall Firewater Run-off Risk – Area 7*

As this area contains bulk diesel storage firewater considerations have been outlined in Section 8.0 of this report.

Area 8 Wastewater Management System

The Wastewater Management System provides temperature, flow and pH balancing for the industrial wastewater streams. The area contains double skinned 20m^3 Caustic and 20m^3 Acid tanks, a double skinned 10m^3 Chemiox (odour abatement) tank as well as a chemstore for cooling tower treatment chemicals, a chemstore for antifoam, and a double skinned 2000L diesel tank.

There is also a delivery bay and a 0.93m^3 containment sump.

Significance of the Fire Event

Diesel is classified as H226, flammable however this will be stored in small quantities only. Sodium hydroxide and sulphuric acid are not classified as flammable or combustible.

Cooling tower treatment chemicals are stored in the external chemstore which contains relatively small quantities of various materials, some of which are flammable in nature.

Due to the nature of the area there are no ignition/heat sources and as such there is a low risk of a fire occurring.

There is no fire detection and alarm system in this area. The area is equipped with 3 x fire hoses and portable fire extinguishers.

The Wastewater Management System is in close proximity to the new Contractors Compound however only the materials and waste storage area will be within the 15m range of fire spread. As there are no known ignition sources in the materials and waste storage area of the new contractor's compound, the risk of a fire occurring in that area and spreading to the Wastewater Management System is also low.

As such, due to the materials present and the low risk of a fire occurring the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

The new portable generator with diesel tank will be double skinned to contain leaks. In the event of a rupture, the stormwater drainage network is also equipped with hydrocarbon interceptors. This will be stored in a hard stand area.

The cooling water chemicals chemstore will contain biocides and other hazardous to the environmental chemicals however these are in small quantities only. This includes up 430 litres of Nalco 93033 which is classified as H400/H410 and up to 430 litres of Nalco 9DT426, classified as H411.

The total combined quantity of H400/410 and equivalent chemicals stored in this area does not exceed the threshold of 1 tonne equivalent and as such firewater retention is not required on this basis.

Additional Nalco chemicals classified as WGK1 are also stored in the cooling water chemicals chemstore. These do not pose a risk to water quality.

The Caustic, Acid, Chemiox and antifoam are non-hazardous to water as per the respective Material and Safety Data Sheets for these chemicals.

Any fire water that would be applied in this area may make its way into the site surface water system; however, the stormwater drainage network is also equipped with a shut off valve which can be manual switched off to contain any major spillage in the event it occurs. This ensures that there are limited pathways to the offsite environmental receptors.

Given the nature of the material present and the presence of the shut-off valve the consequence of a contaminated fire water discharge to the environment the resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 8 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.14 *Determination of Overall Firewater Run-off Risk – Area 8*

Area 9 Waste Management Building (NEW)

This area will contain the re-located waste management facilities. This area will be built as part of the East Expansion.

Significance of the Fire Event

The majority of the waste is assumed not to be flammable but may be combustible. This includes bio-hazardous wastes that have been disactivated in the autoclave.

The waste management building may contain spent 70% ethanol in drums or IBCs (H225 highly flammable). The total volume of ethanol is anticipated to be up to 1 IBC or $1m^3$ at any time.

Spent IPA wipes and other consumables are H225 highly flammable. Up to 20 tonnes will be stored in this area at any one time.

Other smaller flammable lab chemicals may also be stored here in the self-bunded chemstores.

The area will be equipped with a L1 fire detection and alarm system as well as automated fire suppression.

Due to the volume of combustible and flammable materials the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

This area is not used to store large volumes of hazardous liquid wastes. Small volumes of lab chemicals will be present in the self-bunded chemstores however the volumes are not significant. A conservative estimate of 2 tonnes of H401/411 chemicals and 0.5 tonnes of H400/410 chemicals have been included in the calculation. The resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 9 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.15 *Determination of Overall Firewater Run-off Risk – Area 9*

Area 10 - Autoclave Area (NEW)

The new designated autoclave area will be located adjacent to the east expansion. This area will include the decontamination autoclaves used for inactivating solid production wastes.

Significance of the Fire Event

The waste being treated is anticipated to be combustible but not flammable. The volume of material sent for autoclaving is c. 34 tonnes per year. However, autoclaving of waste is not undertaken every day and as such a conservative estimate of 1 tonne on any given day has been included in the calculations.

There is potential for ignition sources from the heating system of the autoclaves.

The area will be equipped with a L1 fire detection and alarm system which is connected to the sprinkler system and these will be triggered in the event of a fire.
As such, the fire significance (S) rating is ***S1 – Low.***

Environmental Hazard Potential

This waste is anticipated to not be hazardous to the environment either before or after treatment. The resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 10 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S1
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.16 *Determination of Overall Firewater Run-off Risk – Area 10*

Area 11 East Expansion and Yard (NEW)

The East Expansion will be a single storey multi-purpose building designed for the phased construction of 3 to 4 no. manufacturing suites according to future needs.

This building will include a plant room, waste handling facility, plant, and equipment mezzanines. The plant room will house 1 no. LPHW boiler, 2 no. large steam boilers, chillers, clean steam generators, compressors, purified water generation and water for injection, as well as process cooling systems.

The yard adjacent to the east expansion will contain electricity transformers, cooling towers, and modular bunded chemical storage units once completed.

Significance of the Fire Event

As with the main production building the east expansion due to its construction is not considered combustible.

There will be some flammable materials used in this area, the majority of which is from the ethanol which is used in a 20% ethanol/sodium hydroxide mixture. IPA in 70% IPA (H225, highly flammable) in spray canisters will be used in the production areas and stored in local storage units. Conservative estimates for plastics and process materials have also been included in the calculation.

The boilers in this area use natural gas which is classified as flammable. There are gas detectors on each of these boilers that will shut off in the event of the gas level reaching half of the LEL.

The transformers could provide a source of ignition. The transformers are equipped with fire detection and alarms.

As with the main production area, the east expansion will be equipped with fire detection and alarm systems which are connected to the sprinkler and gas suppression systems and these will be triggered in the event of a fire. The east expansion will be separated from the main production building by a 2-hour fire wall. 1-hour firewalls will also separate each of the control areas.

The yard adjacent to the east expansion will contain electricity transformers, cooling towers, and modular bunded chemical storage units once completed. Cooling tower treatment chemicals are stored in the external chemstore which contains retains relatively small quantities of various materials, some of which are flammable in nature. Firefighting equipment including hose reels and portable fire extinguishers will be readily available.

As such, the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

As with the main production building, this area will contain small volumes of hazardous to the environment chemicals (assumed 20% for production areas).

A conservative estimate has been included in the calculation sheet for other process materials and boiler chemicals with a WGK1 rating.

This area also contains live GMO within the upstream production trains. All process tanks also have level alarms and are inspected regularly so the chance of a leak being

undetected is low. Whilst GMO will be processed in this area this will be Class 1 GMO only.

The Chemstore in this area will contains up to 430L of Nalco 93033 which is classified as H400/H410. This is lower than the threshold of 1 tonne for this classification and does not trigger the requirement for firewater retention for this zone. Additional Nalco chemicals classified as WGK1 are also stored in this area. These do not pose a risk to water quality. The chemstore is self-bunded to contain the contents of any drums or containers that may rupture in a fire.

The cooling towers will contain cooling water with small quantities of water treatment chemicals, including biocide, however the volumes will not be significant.

The stormwater drainage network is also equipped with a shut off valve that can be manual shut in the event of a fire event.

In the event of a fire there is limited potential for contaminants to reach the environmental receptors. The resulting hazard potential is ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 11 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.17 *Determination of Overall Firewater Run-off Risk – Area 11*

Area 12 Multi Storey Car Park (NEW)

The new multi-storey car park will have capacity for 800 cars over 4 level and will be located along the south western edge of the site.

Significance of the Fire Event

The only flammable materials present in this area will be due to fuel leaks from vehicles.

The building will we equipped with fire detection and alarm systems as well as fire extinguishers. There will be a dry riser system in the building for the fire tender to connect hose.

The building itself is a concrete structure and is not highly combustible.

Therefore, the fire significance (S) rating is ***S2-Medium.***

Environmental Hazard Potential

Similarly fuel or oil from vehicles could pose a hazard to the environment however as these amounts are anticipated to be low the resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 12 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.19 *Determination of Overall Firewater Run-off Risk – Area 12*

Area 13 Administration and Lab Building (ALB) and yard (NEW)

This building will be a three storey laboratory and administration building. This area will contain live GMOs within the highly contained laboratories. The ALB will also contain office and social facilities, a boiler and plant room, and storage rooms. The automated storage solution and material handling systems (Kardex) will need to be segregated from the rest of the building through a 1-hour firewall.

The ALB yard area will comprise of liquid Nitrogen storage (max 4000L Liquid N_2 tank), tanker loading bays, process waste sump, air cooled chillers, cooling water treatment chemicals within designated self-bunded chemstores, and dosing pumps, possible caged bottle gas storage, and a natural gas let-down station. The waste staging area including 2 no. trash compactors and a baler will also be in this area.

Significance of the Fire Event

This area contains small amount of laboratory chemicals, some of which are flammable. Furnishings within the laboratory are not considered combustible.

There would be potential for sources of ignition from an electrical fire or from the boilers. The boilers in this area use natural gas which is classified as flammable. There are gas detectors on each of these boilers that will shut off in the event of the gas level reaching half of the LEL.

The building is surrounded by a 1-hour firewall. As the building contains offices and canteen areas these will be combustible building materials.

A sprinkler system shall provide fire protection to the building in accordance with the Insurer's requirements. The system shall be supplied from a tie into the existing fire ring main. Sprinkler system design shall be in accordance with NFPA 13 and FM guidelines. Pre-action sprinkler systems will be included in the design to protect walk-in cold rooms.

The yard area contains a max 4000L Liquid N_2 tank. The other gases will be hard piped from the main production building; however, a bottle gas connection skid will be included in the yard for the infrequent occurrence of an outage at the main production building. Caged gases would include O_2, CO_2, N_2 and Compressed Air.

These gases are not flammable gases but are compressed gases that may explode in a fire. As the EPA Guidance only stipulates H220 and H221 gases they have not been included in the tally of flammable gases in the WRA Tool for this area. However, they have been included in the list of combustible process materials.

Water treatment chemicals will be stored in the external chemstore which will contain relatively small quantities of various materials, some of which are flammable in nature. The chillers house refrigerant is not flammable.

A conservative estimate of 20 tonnes of combustible material has been included for completeness however the actual amount is likely to be much less.

There is a low potential for ignition/heat source to be present during delivery of chemicals to this area as there will be an earthing connection interlock with the tanker. Other sources of ignition could include the pumps and machinery used in the area.

Additional controls will be in place to prevent ignition sources including a permit to work scheme, speed controls, and a no smoking policy.

Firefighting equipment including hose reels and portable fire extinguishers will be readily available.

As the fire detection and suppression systems are not automatic, the fire significance (S) rating is ***S2 – Medium.***

Environmental Hazard Potential

There may be small amounts of materials that are hazardous to the environment only. Whilst GMO will be processed in this area this will be Class 1 GMO only.

The boilers will contain small quantities of boiler treatment chemicals. A conservative estimate only has been included in the calculation sheet under WGK1 chemicals.

The Chemstore in this area contains up to 60L of Nalco 77352 which is classified as H410. This is lower than the threshold of 1 tonne for this classification and does not trigger the requirement for firewater retention for this zone. Additional Nalco chemicals classified as WGK1 are also stored in this area. These do not pose a risk to water quality.

The cooling towers will contain cooling water with small quantities of water treatment chemicals, including biocide, however the volumes will not be significant. The chiller refrigerants are not hazardous to the environment in water.

Therefore, the resulting hazard potential is ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 13 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.20 Determination *of Overall Firewater Run-off Risk – Area 13*

Area 14 20kV Substation (South Utilities Yard)

This area is the small substation behind the production building.

Significance of the Fire Event

The substation presents an ignition source. However, the building itself is not combustible. There is no requirement for fire suppression.

Therefore, the fire significance (S) rating is ***S2-Medium.***

Environmental Hazard Potential

There may be small amounts of oil present. The resulting hazard potential is therefore ***H0 - No Hazard Potential.***

Overall Firewater Run-off Risk

Based on the EPA's classification for the overall firewater run-off risk (R), Area 14 is classified as no risk and firewater retention is therefore not required.

Category	Rating
Significance of Fire Event (S)	S2
Environmental Hazard Potential (H)	H0
Overall Firewater Run-off Risk (R)	**R0**

Table 6.19 *Determination of Overall Firewater Run-off Risk – Area 14*

8.0 REQUIRED RETENTION VOLUME FOR FIREWATER

In accordance with the EPA guidance, this assessment has looked at the potential generation of firewater containing substances dangerous to the environment.

Areas not containing significant quantities of these substances were not considered to pose a risk to the environment through the generation of firewater and firewater may be disposed of via the stormwater drainage network.

Sufficient controls are in place to contain leaks and spills of hazardous to the environment chemicals as outlined in Section 3 of this report.

As the total volume of diesel (H411 chemical) exceeds 10 tonnes and the total volume of Nalco 93033 (H410 chemical) exceeds 1 tonne, firewater calculations have been completed.

Diesel and Nalco 93033 are stored in a number of locations around the site and only exceed the relevant thresholds in the North Utilities Yard – West (Area 6) and the Emergency Generators (Area 7). Based on the individual risk assessments for each area, these areas require firewater retention.

The storage of diesel, Nalco 93033 and other H400+ chemicals in the Wastewater Management System area (Area 8), the future East Expansion Yard (Area 11), the future ALB Yard (Area 13) and at the sprinkler pump house (Area 1) is low enough that these areas does not pose a risk to the water environment in the event of a fire, as per the EPA's 2019 Guidance.

As outlined above, the bulk diesel tanks adjacent to the Emergency Generators in the South Utilities Yard are within a designated bund which is sufficient to contain the diesel in the event of a major spill or tank rupture. This separates them from other areas of the South Utilities Yard in terms of drainage. The firewater calculations therefore do not take into account the other areas in the South Utilities Yard as only the bulk storage of diesel poses a risk to the environment.

In the North Utilities Yard, the Nalco chemstores are located adjacent to the cooling towers and the acid and caustic tanks. There is a drain alongside the chemstores that drains to the 45.9m^3 caustic (Sodium Hydroxide) bund which is then is pumped to the 16m^3 utility sump. The area around the chemstores also receives a very small amount of stormwater; however, the majority of the stormwater drains away from this area and into the drainage points within the North Utilities Yard itself.

The caustic and basic tanks are held within their own bunds and are separate from the chemstores in terms of drainage. As the only hazardous to the environment chemicals are the Nalco products only the chemstores, the area around the chemstores (c. 50m^2), the caustic tank and its bund (42m^2) have been considered in the following calculations.

8.1 Calculations for Area 6

The firewater calculations below have been based on ***Method 2 – Tank Farm / Process Plant*** retention calculation.

The three chemstores in the North Utilities Yard – West hold up to 6,200 litres of liquids in at any one time. The caustic and it's 25,000 litres are stored within its own bund (7m x 6m x 1.15m).

The 2 no. hydrants located in the north utilities yard would be used to fight the fire. These hydrants are supplied from the 750m^3 firewater tank. The flow rate is 2500L/min.

Neither the chemstores, the caustic tank, nor the products stored within them are flammable. However, as a worst case it has been assumed that firefighting water and/or cooling water for the bulk tanks will be applied over a 1-hour period. The area is also small and will not require application from 2 hydrants. As such, it assumed a maximum of 2 tenders (2 x 1.8m^3) and 1 hydrant (2500L x 60mins) will be applied.

The following assumptions were made in calculating fire water retention volume:

- Up to 93.6m^3 of firefighting water will be applied to the area from one of the hydrants and the 2 tenders.
- The total volume of liquids is 31.2m^3 litres. VT is therefore the full inventory of all tanks and chemstores in Area 6; there is no other equipment in Area 6.
- 55.1 mm of rainfall is the 10-year 24 Hour Return rainfall event used for the firewater calculation as per the EPA (2019) guidance - Met Eireann rainfall return shown in Appendix 1.
- The total area of the caustic bund and the area around the chemstores is 92m^2.

It should be noted that Area 6 does not drain to the site wide stormwater drainage network and therefore only the area applicable to the drainage has been used for calculating the rainfall contribution. Rain falling on the remainder of the site will not be collected in the Utilities Sump. Page 19 of the EPA Guidance states that consideration can be given to the specific drainage arrangements of the site.

Under this scenario the firewater calculations would be as follows:

- Contribution from chemstores and caustic tanks (V_T) 31.2 m^3
- Firefighting and/or cooling water likely to be used (W_E) 153.6m^3
- Rainfall contribution (R_W) = 0.0551m x 92m^2 (bund area) 5.07m^3

The total required retention volume ($V_T + W_E$) **189.9m^3**

The available capacity in the bund and the utility sump combined is 61.9m^3. The firewater retention requirement is therefore **128m^3.**

It is noted that this hasn't accounted for the base of the chemstores which will provide additional retention for the Nalco chemicals. It is also considered highly unlikely that the Nalco chemstores will set on fire given they are not combustible and do not contain flammable chemicals.

In addition, the utility sump can be pumped out to the Wastewater Management System. As the only contaminants in the firewater will be Nalco/water treatment chemicals and CIP chemicals, both of which will be diluted, it is expected that these can be transferred to the Wastewater Management System and diluted further before being discharged to sewer in accordance with the facility's IE licence.

Note: Whilst the guidance stipulates a 6-hour fire, attended by four fire tenders and the use of two hydrants, Area 6 is not used to store combustible or flammable materials. This area will therefore not burn for 6 hours. Such a volume of water would be significantly in excess of the required water volume for this area. However, there is a 420m^3 reception tank in the Wastewater Management System and 2 equalisation tanks (410m^3 each). These will be sufficient to contain the hypothetical 6 hour firewater volume from the EPA guidance as well as the volume of materials stored (V_t) and the rainfall contribution (R_w).

8.2 Calculations for Area 7

The firewater calculations below have been based on ***Method 2 – Tank Farm / Process Plant*** retention calculation.

The diesel tank being fully contained within its bund with no possible ignition sources would not be directly involved in a fire event. Under the worst-case scenario, the tank may rupture during the fire event and the diesel will be fully contained within the enclosed bund.

The nature of the fire event has also been considered when calculating the firewater potential as water will not be required to fight all fire types. Fires involving hydrocarbons will be fought using foam rather than firewater from the tenders. Each water tender carries c. 50L of foam, which at an assumed expansion rate of 200:1 is 10,000L. It is assumed this will be supplied from 2 fire tenders, rather than 4, as this fire will be restricted to a small area (generators only).

Cooling of the diesel tanks using water from the local hydrants following a fire would not be required as the fire load for such an area is not significant enough to cause overheating of the tanks.

The following assumptions were made in calculating fire water retention volume:

- The fire tenders will use foam rather than water to fight a hydrocarbon fire. A conservative estimate of 20m^3 has therefore been included.
- The total volume of diesel in the tanks at any one time has been estimated at 88,000L based on filling to 80%; however, it is noted that the tanks are usually only filled to 50%.
- 55.1 mm of rainfall is the 10-year 24 Hour Return rainfall event used for the firewater calculation as per the EPA (2019) guidance - Met Eireann rainfall return shown in Appendix 1.

It should be noted that in the event of a fire, firewater contaminated with diesel will be stored in the bund along with any rainwater. Rainwater falling on the other parts of the site will not enter the bund. Page 19 of the EPA Guidance states that consideration can be given to the specific drainage arrangements of the site.

Under this scenario the firewater calculations would be as follows:

- Contribution from the diesel tanks – worst case scenario (V_T) 88 m^3
- Foam likely to be used (W_E) 20m^3
- Rainfall contribution (R_W) = 0.0551m x 35m^2 (bund area) 1.9m^3

The total required retention volume (V_T + W_E) **<u>109.9m^3</u>**

9.0 FIREWATER RETENTION OPTIONS

9.1 Firewater Retention for Area 6

There is a 420m^3 reception tank in the Wastewater Management System prior to being pumped into 1 of 2 equalisation tanks (410m^3 each) as required. These will be sufficient to contain the firewater produced.

9.2 Firewater Retention for Area 7

The bulk fuel tanks have bunds with a total capacity of 121m^3. As such, in the unlikely event that the diesel tanks rupture during a fire, the foam suppressant, cooling water, diesel, and rainwater can be retained within the bund and additional firewater retention is not required.

It should also be noted that drainage from the area around the generators is diverted via 2 no. Class 1 full retention interceptors (10,000L each). In the unlikely event of firewater overflow from the bund, the diesel would be captured in the interceptor(s) preventing the loss of diesel to the stormwater network. As the firefighting foam and rainwater are not environmentally hazardous, diesel is the only substance of concern and as such will be contained.

10.0 CONCLUSIONS & RECOMMENDATIONS

The preceding risk assessment was completed in accordance with the recently published *EPA Guidance on Retention Requirements for Firewater Run-off* (EPA, 2019).

The purpose of this risk assessment was to determine whether firewater retention was required to prevent the loss of substances hazardous to the environment to the surface, soil and groundwater environments.

Area 7 consists of 2 no. 55,000 L bunded diesel fuel oil tanks containing up to 88,000L of diesel at any one time (i.e. 80% capacity). Should a fire occur at the diesel tanks, the resulting hydrocarbons and foam / powder suppressants as well as 24hours worth of rainfall would be fully contained within the existing bund.

Section 4 of this report identified that in addition to the diesel stored onsite there is also c. 2.2 tonnes of Nalco 93033 stored across the site. However, this substance is stored in small (>1 tonne) volumes across four separate areas: the North Utilities Yard (Area 6), the Wastewater Management System (Area 8), the East Expansion Yard (Area 11) and the Administration and Laboratory Building yard (Area 13). These areas were determined in accordance with the EPA's guidance on site segregation, as outlined in Section 7 of this report, to be sufficiently separated (by either firewalls or distance) to deter the spread of fire from one area to the next. On this basis it is unlikely that that the entire 2.2 tonnes of Nalco 93033 would be lost to firewater during a fire event and.

The only Nalco storage area that therefore requires an assessment of firewater retention was Area 6. The Nalco chemstores and the caustic tank were considered in the calculation as they drain to the same location. Should a fire occur in the North Yard it is anticipated that firewater from the Nalco stores and the caustic tank will be contained in the caustic tank bund and the utilities sump. As a worst case, they could also be pumped out to the Wastewater Management System to be treated and discharged to sewer in accordance with the facility's IE licence.

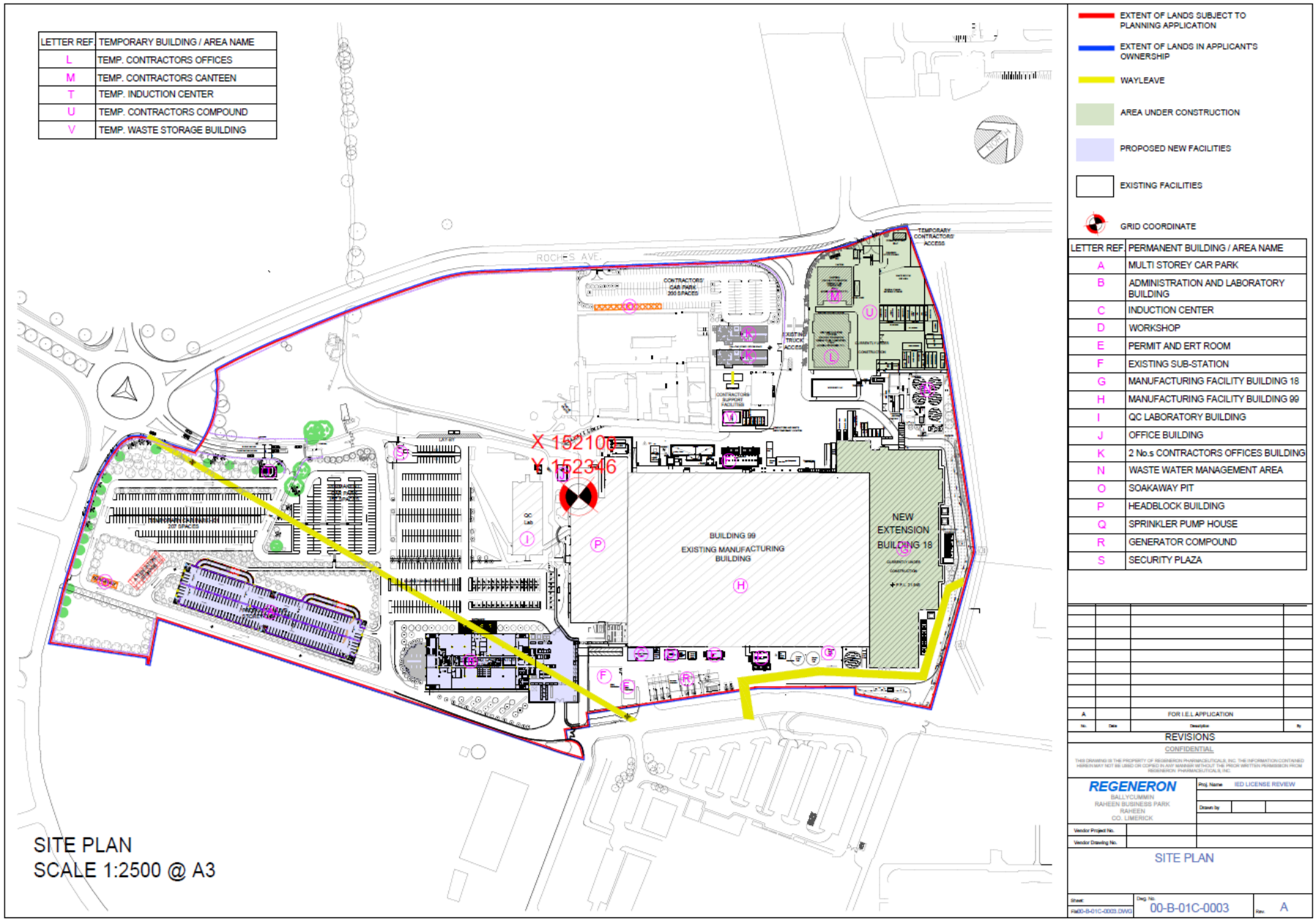
References

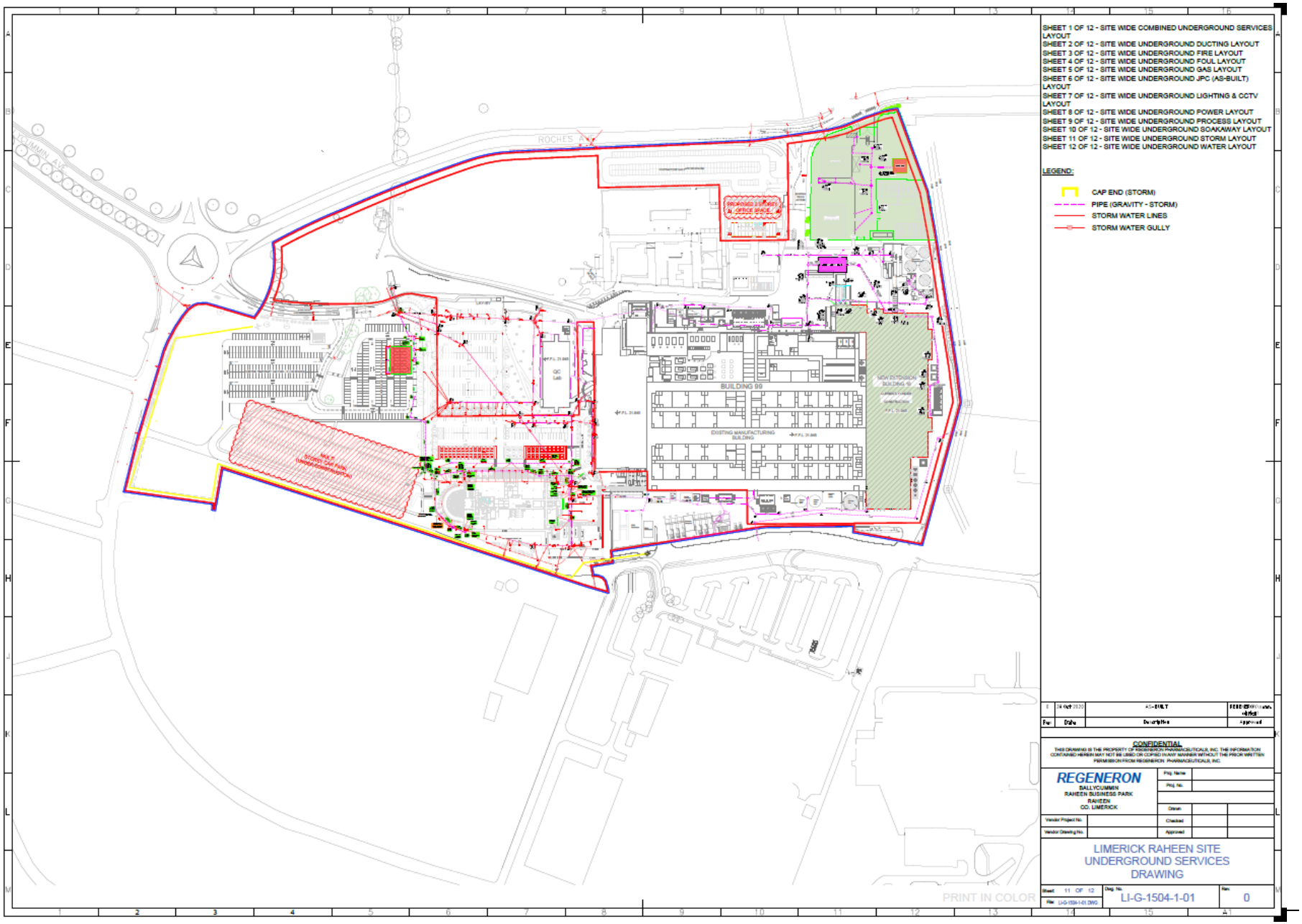
Environmental Protection Agency (EPA), (2019), *EPA Guidance on Retention Requirements for Firewater Run-off,* EPA.

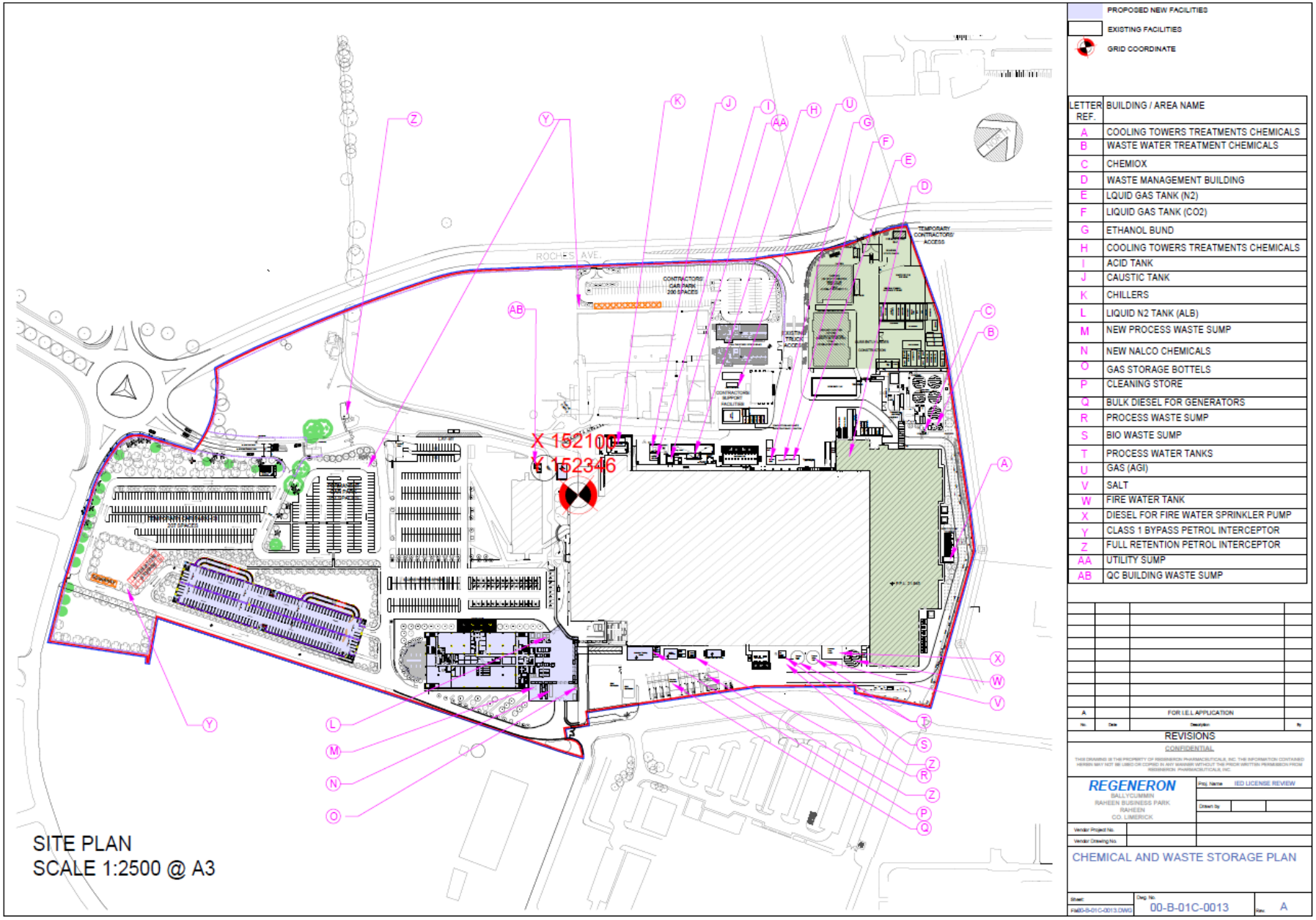
Health and Safety Executive (HSE), (1995), *The control of firewater from Control of Industrial Major Accident Hazards (CIMAH) sites to prevent environmental damage,* Document No. EH70, HSE.

PM Group (2015), Fire Water Risk Assessment & Retention Study, Regeneron Ireland Firewater Risk Assessment, Document no. IE0311659-22-RP-0001, Issue: A.

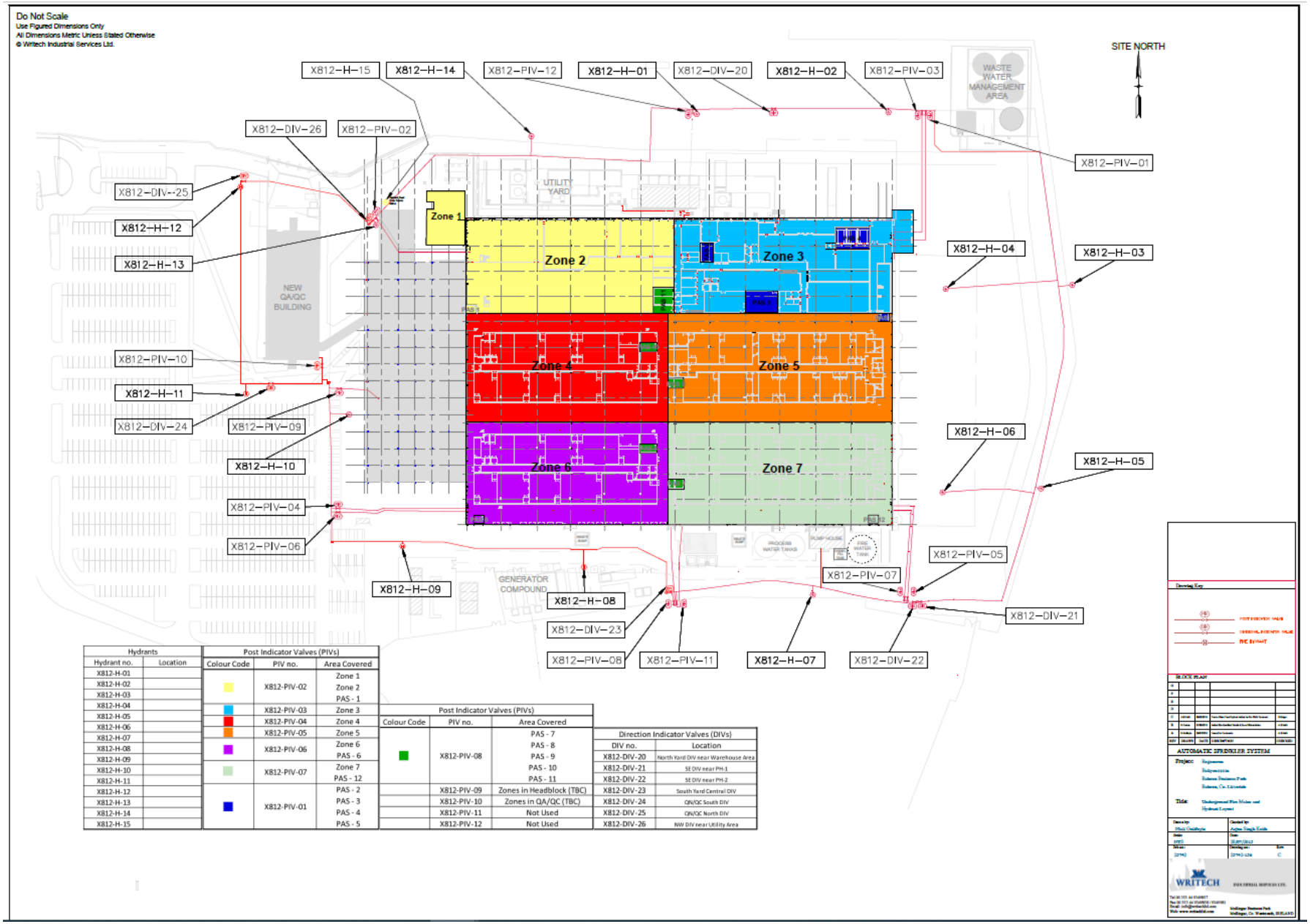
Drawings 1 to 4


LETTER REF | TEMPORARY BUILDING / AREA NAME
L | TEMP. CONTRACTORS OFFICES
M | TEMP. CONTRACTORS CANTEEN
T | TEMP. INDUCTION CENTER
U | TEMP. CONTRACTORS COMPOUND
V | TEMP. WASTE STORAGE BUILDING
ROCHES AVE.
X 152108
Y 152346
BUILDING 99
EXISTING MANUFACTURING
BUILDING
NEW
EXTENSION
BUILDING 18
SITE PLAN
SCALE 1:2500 @ A3
EXTENT OF LANDS SUBJECT TO PLANNING APPLICATION
EXTENT OF LANDS IN APPLICANT'S OWNERSHIP
WAYLEAVE
AREA UNDER CONSTRUCTION
PROPOSED NEW FACILITIES
EXISTING FACILITIES
GRID COORDINATE
LETTER REF | PERMANENT BUILDING / AREA NAME
A | MULTI STOREY CAR PARK
B | ADMINISTRATION AND LABORATORY BUILDING
C | INDUCTION CENTER
D | WORKSHOP
E | PERMIT AND ERT ROOM
F | EXISTING SUB-STATION
G | MANUFACTURING FACILITY BUILDING 18
H | MANUFACTURING FACILITY BUILDING 99
I | QC LABORATORY BUILDING
J | OFFICE BUILDING
K | 2 No.s CONTRACTORS OFFICES BUILDING
N | WASTE WATER MANAGEMENT AREA
O | SOAKAWAY PIT
P | HEADBLOCK BUILDING
Q | SPRINKLER PUMP HOUSE
R | GENERATOR COMPOUND
S | SECURITY PLAZA
A | FOR I.E.L. APPLICATION
REVISIONS
CONFIDENTIAL
REGENERON
BALLYCUMMIN
RAHEEN BUSINESS PARK
RAHEEN
CO. LIMERICK
SITE PLAN
00-B-01C-0003
A


SHEET 1 OF 12 - SITE WIDE COMBINED UNDERGROUND SERVICES LAYOUT
SHEET 2 OF 12 - SITE WIDE UNDERGROUND DUCTING LAYOUT
SHEET 3 OF 12 - SITE WIDE UNDERGROUND FIRE LAYOUT
SHEET 4 OF 12 - SITE WIDE UNDERGROUND FOUL LAYOUT
SHEET 5 OF 12 - SITE WIDE UNDERGROUND GAS LAYOUT
SHEET 6 OF 12 - SITE WIDE UNDERGROUND JPC (AS-BUILT) LAYOUT
SHEET 7 OF 12 - SITE WIDE UNDERGROUND LIGHTING & CCTV LAYOUT
SHEET 8 OF 12 - SITE WIDE UNDERGROUND POWER LAYOUT
SHEET 9 OF 12 - SITE WIDE UNDERGROUND PROCESS LAYOUT
SHEET 10 OF 12 - SITE WIDE UNDERGROUND SOAKAWAY LAYOUT
SHEET 11 OF 12 - SITE WIDE UNDERGROUND STORM LAYOUT
SHEET 12 OF 12 - SITE WIDE UNDERGROUND WATER LAYOUT
LEGEND:
CAP END (STORM)
PIPE (GRAVITY - STORM)
STORM WATER LINES
STORM WATER GULLY
CONFIDENTIAL
REGENERON
BALLYCUMMEN
RAHEEN BUSINESS PARK
RAHEEN
CO. LIMERICK
LIMERICK RAHEEN SITE
UNDERGROUND SERVICES
DRAWING
LI-G-1504-1-01
0
PRINT IN COLOR



LETTER REF.	BUILDING / AREA NAME
A	COOLING TOWERS TREATMENTS CHEMICALS
B	WASTE WATER TREATMENT CHEMICALS
C	CHEMIOX
D	WASTE MANAGEMENT BUILDING
E	LQUID GAS TANK (N2)
F	LIQUID GAS TANK (CO2)
G	ETHANOL BUND
H	COOLING TOWERS TREATMENTS CHEMICALS
I	ACID TANK
J	CAUSTIC TANK
K	CHILLERS
L	LIQUID N2 TANK (ALB)
M	NEW PROCESS WASTE SUMP
N	NEW NALCO CHEMICALS
O	GAS STORAGE BOTTELS
P	CLEANING STORE
Q	BULK DIESEL FOR GENERATORS
R	PROCESS WASTE SUMP
S	BIO WASTE SUMP
T	PROCESS WATER TANKS
U	GAS (AGI)
V	SALT
W	FIRE WATER TANK
X	DIESEL FOR FIRE WATER SPRINKLER PUMP
Y	CLASS 1 BYPASS PETROL INTERCEPTOR
Z	FULL RETENTION PETROL INTERCEPTOR
AA	UTILITY SUMP
AB	QC BUILDING WASTE SUMP



Hydrants	
Hydrant no.	Location
X812-H-01	
X812-H-02	
X812-H-03	
X812-H-04	
X812-H-05	
X812-H-06	
X812-H-07	
X812-H-08	
X812-H-09	
X812-H-10	
X812-H-11	
X812-H-12	
X812-H-13	
X812-H-14	
X812-H-15	

Post Indicator Valves (PIVs)		
Colour Code	PIV no.	Area Covered
	X812-PIV-02	Zone 1
		Zone 2
		PAS - 1
	X812-PIV-03	Zone 3
	X812-PIV-04	Zone 4
	X812-PIV-05	Zone 5
	X812-PIV-06	Zone 6
		PAS - 6
	X812-PIV-07	Zone 7
		PAS - 12
	X812-PIV-01	PAS - 2
		PAS - 3
		PAS - 4
		PAS - 5

Post Indicator Valves (PIVs)		
Colour Code	PIV no.	Area Covered
	X812-PIV-08	PAS - 7
		PAS - 8
		PAS - 9
		PAS - 10
		PAS - 11
	X812-PIV-09	Zones in Headblock (TBC)
	X812-PIV-10	Zones in QA/QC (TBC)
	X812-PIV-11	Not Used
	X812-PIV-12	Not Used

Direction Indicator Valves (DIVs)	
DIV no.	Location
X812-DIV-20	North Yard DIV near Warehouse Area
X812-DIV-21	SE DIV near PH-1
X812-DIV-22	SE DIV near PH-2
X812-DIV-23	South Yard Central DIV
X812-DIV-24	QA/QC South DIV
X812-DIV-25	QA/QC North DIV
X812-DIV-26	NW DIV near Utility Area