Pfizer Ireland Pharmaceuticals

Outline Closure Plan

Attachment-9-2-3

April 2024

Licence Application (LA011637)

1.0 INTRODUCTION

This outline Closure Plan relates to the Pfizer Ireland Pharmaceuticals facility located in the Grange Castle Business Park, Nangor Road, Dublin 22 (the 'Facility' under this licence review application). The location of the subject site is shown on Drawing Ref: 3.1 Site Location Map, included with this application, this application relates to the entire Installation, (hereafter referred to as the 'Site').

The outline Closure Plan has been prepared in accordance with EPA guidance for assessing and costing environmental liabilities[1] and the guidance for the closure of licensed sites[2]. The overall purpose of this plan is to outline the scope of necessary measures that would be undertaken at the time of site closure to avoid risk of environmental pollution and, where pollution has been caused, to return the site to a satisfactory state.

The Facility is involved in the manufacture of therapeutics and vaccines covering a range of areas including inflammation, oncology, pneumococcal and meningococcal disease, COVID-19, and a number of rare diseases. The technology platforms span mammalian cell culture, protein purification, vaccines conjugation, and aseptic syringe-filling. The facility also has extensive QC testing laboratories, Manufacturing Sciences & Technology (MSAT) facilities and large molecule Pre-clinical Discovery laboratories.

Pfizer intends to initiate a review of their existing Industrial Emissions ('IE') Licence, Reg. No. P0652-01 (the 'Licence') in accordance with the Environmental Protection Agency Act 1992, as amended (the 'EPA Act'), as the permitted DS2 expansion development at the site that was subject to an Environmental Impact Assessment ('EIA') will be constructed and will increase the capacity of the site.

This plan outlines and addresses the key issues, which would occur in an orderly shutdown of all the site activities on a phased basis over approximately twelve months.

1.1 SITE DESCRIPTION

The Facility operates 24/7 and 365 days a year. The site is a biopharmaceutical plant with the main operational areas as follows:

- Drug Substance Building (DS1);
- Drug Substance Building (DS2) (permitted);
- Manufacturing Suites Building;
- QA/QC Building;
- Administration/Canteen;
- Pilot Laboratory and Drug Development Facility;
- Warehouse;
- CUB (Central Utility Building) and Yard Area;
- Tank Farm; and
- Drum Stores East and West.

The site also contains the necessary piping, surface water drainage, and process drainage systems to suitably manage storm water and waste water emissions from the site.

1 Ireland. Environmental Protection Agency. *Guidance on Assessing and Costing Environmental Liabilities*. Johnstown Castle: EPA, 2014.
2 Ireland. Environmental Protection Agency. Guidance to Licensees on Surrender, Cessation and Closure of Licensed Sites. Johnstown Castle: EPA, 2012

1.2 ACTIVITIES LICENCE/PERMIT DETAILS

The site is currently applying for a review of the Licence by the EPA. The requirement for an IE Licence is outlined within the First Schedule of the EPA Act. Activity 5.16 provides that an IE licence is required for: "*The production of pharmaceutical products including intermediates* and 2.1 *Combustion of Fuels in installations with total rated thermal input of 50 MW or more."*

The AHP Manufacturing B.V. trading as Wyeth Medica Ireland facility was granted the Licence from the EPA on 31 October 2003. The Licence was transferred to Pfizer Ireland Pharmaceuticals on 25 January 2011. The Licence was amended to an IE Licence on 18 December 2013.

Planning permission for the Pfizer Ireland Pharmaceuticals DS2 Expansion (SDCC Reg. Ref.: SD23A/0123), the subject of the Licence review application, was granted by South Dublin County Council ('SDCC') on 25 August 2023. Planning permission for minor amendments to the design of DS2 has subsequently been granted by SDCC, under Reg. Ref.: SD23A/0257, dated 03 January 2024, and Reg. Ref.: SD23A/0320, dated 24 November 2023.

The Facility also holds a Greenhouse Gas Emissions permit (Ref IE-GHG026-10355-3) and a GMO Permit (Ref G0637-03).

1.3 CLOSURE SCENARIOS

This report covers a single closure scenario: it has been assumed that any closure of the site will be expected and therefore will be a well-planned and well-resourced event. It has been assumed that the on-site plant and equipment will be decommissioned, but that the site infrastructure (i.e. the building and associated services/utilities) will remain and will continue to be used for a similar use or repurposed for an alternative development.

Upon cessation of activities at the Facility there will be no further wastewater emissions to sewer or emissions to atmosphere. There will also be no substances with the potential to release fugitive emissions remaining on site once the Facility is closed, i.e. a 'Clean Closure' is expected.

The applicant will have the financial and personnel resources to implement the Closure Plan and will utilise staff resources to form a team to manage and execute the plan, supplemented where appropriate by external specialists. This team will be responsible for managing and executing the plan. Outside contractors required for cleaning, waste disposal or recycling activities will be fully approved and licensed.

It is anticipated that an orderly shutdown of all the site activities would occur on a phased basis over twelve months.

1.4 RESTORATION/AFTERCARE PLAN

The Facility is located on a site with no history/evidence of existing contamination, and based on current and historic Facility operations, it is anticipated that there will be no environmental liabilities once closure, decommissioning and residuals management are completed. Therefore, in accordance with EPA guidance only a Closure Plan is required and not a Restoration and Aftercare Management Plan.

2.0 SITE EVALUATION

2.1 OPERATOR PERFORMANCE

The site has been evaluated in the Complete Baseline Report (Attachment-4-8-2) this outlines the conditions that existed prior to the commencement of construction and site operations. The site, prior to the development, was greenfield agricultural land and there was no known existing contamination.

The Facility currently operates with a series of standard operating procedures and spill response procedures to avoid contamination of ground or water.

The applicant has had no complaints in 2021, 2022 and 2023. There were two minor incidents in 2023 relating to breaches of ELV at discharge point SW1. There was one minor incident in 2022 and one in 2021 as a direct result of the facility involving a breach of ELV at discharge TE-1 and a leak from a chiller. All incidents were investigated, and mitigation measures were applied as soon as reasonably possible.

2.2 ENVIRONMENTAL PATHWAYS AND SENSITIVITY

The site has been evaluated in the Complete Baseline Report (Attachment-4-8-2). The Complete Baseline Report sets the benchmark for site closure.

The site has no formal designation, the closest ecologically designated site is the Grand Canal Proposed Natural Heritage Area (pNHA) which lies approximately 0.5 km from the site. The Liffey Valley pNHA lies a little further away at 3.5 km distance from the site and the Royal Canal pNHA at 5 km.

The closest Natura 2000 site is the Rye Water Valley / Carton Special Area of Conservation (SAC). It lies approximately 5 km from the site however there is no hydrological linkage to this site. There is no other SAC, SPA or NHA that need to be considered. The environmental sensitivity of the site is low as the site is > 1km from protected sites.

2.3 SITE PROCESSES, ACTIVITIES, BUILDINGS, PLANT AND EQUIPMENT

The site and all major plant and equipment is described in the Attachment-4-8-1 Operational Report and summarised below.

The Drug Substance (DS1) building is a multi-product facility located at the southwest corner of the Grange Castle site. The building comprises of five-floors with GMP operations located on the first, second and third floors and is used for the commercial manufacture of their drug products.

The DS2 facility is designed for the manufacture of six commercial products, with sufficient in-built flexibility to allow the production of a range of other known and unknown products both commercially and for clinical trials. The DS2 facility will have a production bioreactor capacity of 75,000L (six no. 12,500L units), feeding multiple modular purification streams. It is intended that this facility will operate 24/7, at a large industrial scale. Processing will take place within a controlled environment.

The Manufacturing Suites Building; which holds 5 manufacturing suites producing different drug products, the Drug Development Facility consisting of a number of non-

GMP laboratory areas, the QA/QC Laboratory and the Administration offices complete the total manufacturing processes at the facility.

To support manufacturing operations, a number of onsite utilities including chemical storage and handling facilities, boilers, and a CHP unit are required. These provide the raw materials and conditions necessary for the pharmaceutical manufacturing process.

The site has a Central Utility Building which controls several sitewide systems including water systems, compressed air, CHP and the process wastewater neutralisation plant.

Figure 2.1 *Site Location (source: Google Earth Pro, 2024)*

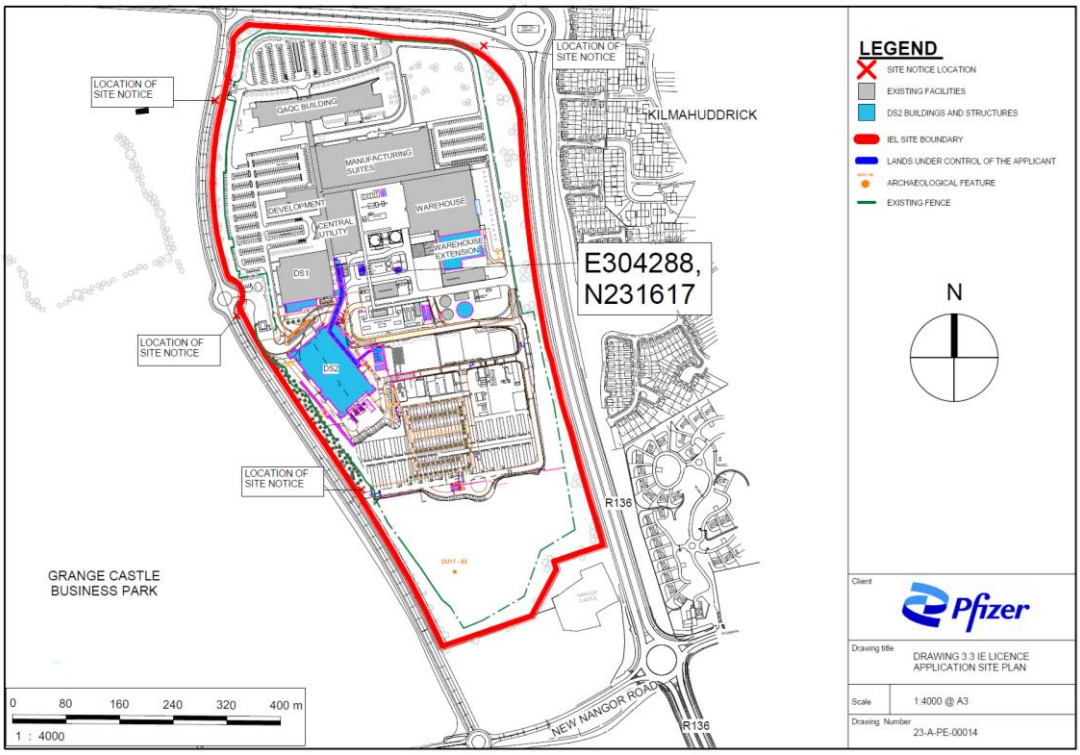

Figure 2.2 *Site Plan (Drawing 3.3 IE Licence Application Site Plan)*

The site includes underground foul and storm water drainage network, off site attenuation, and underground water supply network, hard and soft landscaping, and perimeter fencing.

Once Site Closure is determined, subject to confirming details in the Final Closure Plan, an inventory of all buildings, plant and equipment, and inventory of raw materials, products and wastes, as well as testing of bunds and underground services will take place.

2.4 RAW MATERIALS, PRODUCTS AND WASTES

The site has raw materials that are classified as hazardous that are stored in an area with a dedicated spill diversion system, where spills can be diverted to a dedicated spill containment tank located in the CUB yard, adjacent to the West Drum store. The expected storage volume is detailed below of these bulk materials. In a worst-case scenario the quantity stored of each material will be managed at closure.

Table 2-1*: Storage of raw materials and expected storage.*

Substance	Area Served/Purpose	Expected Volume of storage (tonnes)
Acetic Acid (glacial)	Production	0.6
2M hydrochloric acid	Production	0.5
10% hydrochloric acid	Production	0.5
37% hydrochloric acid	Production	0.5
Insulin PowerCHO2	Production	0.6
Benzyl alcohol	Production	8

Calcium chloride dihydrate CaCl2.2H2O	Production	47.2
Citric acid monohydrate	Production	0.4
Cupric sulphate Pentahydrate CuSO4.5H2O	Production	0.03
EDTA	Production	17.4
Ferrous sulphate Heptahydrate FeSO4.7H2O	Production	0.03
Glycine hydrochloride C2H6ClNO2	Production	1.8
Hydrocortisone C21H30O5	Production	0.03
L-Cystine dihydrochloride monohydrate	Production	3.1
L-Cystine Disodium Salt Dihydrate C6H10N2Na2O4S2.H2O	Production	0.9
Potassium Carbonate K2CO3	Production	1.2
Putrescine -2HCL C4H12N2.2HCl	Production	0.03
Sodium phosphate Na3PO4	Production	13
Spermine Tetrahydrochloride C10H26N4.4HCl	Production	0.03
Tris HCl	Production	6.2
Triton X-100 C14H22O(C2H4O)10	Production	3.2
R513A	Production	0.5
R1233zd	Production	0.5
Ammonia (R717)	Production	0.5
Diesel	Production	72
CIP 95	Production	23
SODIUM HYDROXIDE SOLU 25% BULK TANK	Production	51
Ethanol	Production	63
Sulphuric Acid	Production	76
SODIUM HYDROXIDE 10N SOLUTION	Production	40
DIMETHYL SULFOXIDE (DMSO)	Production	11
ACETIC ACID, GLACIAL 99%	Production	15
IMX 7.0-008 MEDIUM W/O PVA	Production	2
ETHANOL 20%	Production	9
Ferric Citrate PowerCHO2	Production	12

There is a Standard Operating Procedure (SOP-12247) in place for the Facility regarding procedure for waste management. This SOP outlines the proper management and recycling of wastes generated at the installation, in accordance with law. The waste at the facility during regular operation is primarily comprised of bulky waste from general production and waste aqueous wash liquids. A reasonable assumption is that 1 month of waste would potentially be stored at the decision of closure. The table below approximates 1 month of generated waste assuming normal/average business operations leading up to the decision to close:

Table 2-2: *Estimated maximum potential storage of waste.*

Waste	Maximum potential storage (tonne)
Bulky Waste	20
Mixed Municipal Waste	1.5
Metals	4
Hazardous WEEE	0.2
Waste material potentially contaminated with GMOs	0.1
Hazardous chemical waste from laboratory and some production activities	0.1
Flammable liquids/solids (unused raw materials)	0.3
Corrosive liquids/solids (unused raw materials)	0.2
Packaging with residual hazardous material	0.0
Cardboard	1
Waste Resins from Chromatography	0.0
Hazardous solid waste	3.5
Solvent waste from lab processes	0.0
Spent organic wash liquids	0.0
Spent aqueous liquids	5
Spent caustic solution	2

The closure process will include undertaking an inventory of all materials and wastes on the site.

3.0 CLOSURE TASKS AND PROGRAMMES

Upon cessation of operations and subsequent decommissioning at the Facility, it is anticipated that there will be no remaining environmental liabilities, i.e. Clean Closure is expected.

3.1 PLANT AND EQUIPMENT DECONTAMINATION REQUIREMENTS

All plant and equipment at the site will be decontaminated to remove hazardous materials. Equipment will be verified either analytically or through a visual inspection, as appropriate.

3.2 PLANT AND EQUIPMENT DECOMMISSIONING REQUIREMENTS

During the planning phase prior to closure a cost benefit-analysis and risk assessment will take place to determine the future use of the Facility plant and equipment.

It is anticipated that all temporary fixtures and fittings will be cleaned/decontaminated and removed, and what is not recoverable will be recycled or disposed of as appropriate.

It is expected that no major demolition will take place and the Facility buildings and infrastructure will be left in place for future commercial/industrial use.

After decontamination, plant and equipment may be removed for use at other facilities, on sold, or left in place for a future owner of the Facility.

3.3 SURFACE WATER DRAINAGE PROTECTION

The following surface water drainage network protection measures will be implemented during decommissioning:

- Dismantling of equipment will take place indoors, where possible, isolated from any clean surface water collection points;
- All loading and unloading of vehicles as part of the decommissioning process will be isolated from clean surface water collection points and will be carried out at tanker delivery areas where any spills will be routed to the spill containment tank;
- All waste oils/greases drained from equipment will be stored in containers on hard-stand surfaces that are either bunded or have other retention mechanisms in place to quickly manage and contain any potential hazardous material spills;
- The facility's procedures for accident prevention and emergency response will be adhered to in the event of any potential spill; and
- Additional spill kit equipment will be brought on site during decommissioning works.

3.4 DEMOLITION

No demolition is anticipated.

3.5 RAW MATERIALS, PRODUCTS AND WASTE DISPOSAL AND/OR RECOVERY REQUIREMENTS

It is assumed that any shutdown of the site will be a well-planned event known in advance. Therefore, the process schedules and cancellation of raw material inputs will be factored in. It is anticipated that all usable raw materials on the site would be consumed prior to closure.

Any residual raw materials will be documented and labelled. An inventory of any materials will be taken along with the identification of materials suitable for return to suppliers, transport to other facilities, or for sale to third parties.

All waste, both non-hazardous and hazardous, will be removed off-site for re-use, recycling, recovery, and/or disposal by licensed waste contractors in accordance with regulatory requirements.

3.6 CONTAMINATED LAND TREATMENT, REMOVAL AND/OR DISPOSAL

There is no known existing contamination of soil at the facility and, by implementing the procedures outlined in this report, it is not anticipated that any contamination will occur as a result of the decommissioning process. It is not anticipated that there will be any contaminated soil requiring removal/treatment upon closure.

The areas of the site where decontamination of equipment will take place are hard-stand surfaces that are either bunded or have other retention mechanisms in place so any potential hazardous material spills can be quickly managed and contained.

In the case that there has been a risk of soil contamination, appropriate soil testing will be undertaken by qualified, independent consultants and, if warranted by the results, a cost benefit-analysis and risk assessment will take place to assess treatment options.

If removal of the soil is required, it will be disposed of at an appropriate non-hazardous or hazardous waste disposal facility in accordance with prudent industry practices and all applicable laws.

3.7 CLOSURE PROGRAMME

This section outlines the phased procedures to be followed in the event of a site closure. It is anticipated that the date of closure will be known in advance and detailed closure planning and an independent closure audit will take place. After detailed planning, it is expected that the closure of the site will take place over six months. The programme and tasks involved have been summarised in the sections below.

Detailed closure planning

Prior to the closure of the Facility a detailed planning phase will take place that will include several actions including but not limited to; setting dates and timeframes for the closure and planning to run down raw material.

During the planning stage an inventory of any raw materials will be taken along with the identification of materials suitable for return to suppliers, transport to other facilities, or for sale to third parties. It is noted that in the event of a sudden closure, running down the quantities of raw materials on site will not be possible and the quantities to be removed may be up above the volume outlined in Table 2-1.

A cost benefit-analysis and risk assessment will take place to determine the future use of the facility plant and equipment. Plant and equipment decontamination and decommissioning requirements will be determined, and contractors will be engaged.

All contracts relating to the delivery of supplies and materials will be cancelled. All contracts other than those that are concerned with the Closure Plan, or related to safety of personnel or the environment will be terminated.

Notification to the Agency regarding the planned closure of the facility will be supplied with the following information:

a) The date when the activity will stop/stopped at the site.
b) Expected date of vacation of all staff from the site.
c) The proposed future use of the premises e.g. similar industrial use or redevelopment.
d) Contact details for the company, post-exit from the site.
e) Contact details for the following:
    - Proprietor of the land on which the site is situated,
    - Owners of the building and ancillary plant in which the activity is situated (if different from the operator of the activity),
    - Local Authority, and
    - Current occupiers of the building (where applicable).
f) Proposals for revised sampling, analysis, and reporting arrangements on foot of the changes on site, for agreement with the Agency.
g) Status of any associated bonds or financial provisions.

Independent Closure Audit

An Independent Closure Audit (ICA) of the site will be undertaken prior to cessation of operations and decommissioning of the facility. The ICA will be prepared in accordance

with all relevant Agency guidance. The scope of the ICA will have prior written approval by the Agency before being conducted, but will include:

- The identification and documentation of any soil, sub-soils, buildings, plant, equipment, waste materials or substances that may result in environmental pollution.
- The identification of how environmental liabilities will be dealt with post-closure, and whether any remediation measures are necessary.

3.7.1 Stage 1 – Disconnection and decommissioning of non-essential site services/utilities

This task will include disconnecting and decommissioning all electrical connections and associated plant equipment. This will likely include, subject to confirming details in the Final Closure Plan, the disconnection of the emergency generators, CHP, boilers and water connections, and all other relevant operational equipment that will not be required for the closure phase.

There are many fans, pumps and motors located throughout the site with HVAC equipment these will be disconnected.

The Facility has administration areas, offices and a canteen. It is assumed that only partial administration facilities will be required for the remaining site decommissioning operations and the successful completion of this plan. The non-essential areas will be cleared of office, catering, equipment and furniture etc. Outside of the wastepaper and other recyclables, the only anticipated difficult residuals associated with decommissioning of the administration buildings include office waste electrical and electronic equipment (WEEE). Due to the short life span of most office electronic equipment and sensitivity of the equipment due to confidential data, it is assumed that most of the electronic equipment will be considered waste.

3.7.2 Stage 2 – Removal of excess raw materials, equipment, and furniture from site

Any excess raw materials, furniture, electronic equipment, catering equipment will likely be removed from the site in accordance with the Final Closure Plan. The following disposition options will be implemented in a hierarchical format:

- Return to suppliers;
- Transfer of materials to other sites;
- Transfer/sale to other companies or nonprofits in Ireland;
- Transfer to recovery/recycling companies; or
- Treating the material as a hazardous/non-hazardous waste (Stage 3).

3.7.3 Stage 3 – Removal of hazardous/non-hazardous wastes from site

It is assumed that any materials that can be recovered or recycled will have been done so in Stage 2. The remaining material on site will be considered waste, either hazardous or non-hazardous.

Removal of both hazardous and non-hazardous waste materials will be removed and disposed of in accordance with the facility's IE Licence requirements and appropriate National and EU Legislation;

In the case of hazardous waste disposal, all requirements of the IE License will be applied, especially in relation to hazardous waste that is not typically generated at the

facility. Therefore, the management of some of this material may require the prior written approval of the Agency before the waste can be removed from the site.

Administrative organisation of relevant paper work will take place, according to EPA Guidelines, ensuring all waste shipments during this period are accounted for. This will facilitate the requirement to have stated criteria for validation of decommissioning.

3.7.4 Stage 4 – Decontamination

This task specifically includes cleaning and decontamination procedures for all operational plant equipment. It is envisioned in this closure scenario on-site plant and equipment will be decommissioned but will remain in place and will likely include, subject to confirming details in the Final Closure Plan continue to be used for a similar use or repurposed for an alternative development.

Contaminated solid waste arising from wipe-downs of equipment etc. will be collected in containers as hazardous waste, stored in the waste storage area.

Cleaning of tanks/vessels

This stage is started when storage tanks are emptied, there are a limited number of storage tanks associated with the storage of raw materials which will be cleaned with standard procedures. Liquid wastes not suitable for discharge to sewer will be disposed of using a licenced / permitted contractor.

Cleaning and decommissioning generators / boilers / CHP

The equipment will be cleaned and will include the removal and recovery/disposal of engine oil, greases, and coolant, including pumping dry the fuel from tanks.

Cleaning of ducts, vents, and pipework and decommissioning of HVAC units

All ducts, vents, and pipework connecting various equipment and areas of the site will be cleaned and decontaminated by a specialist cleaning contractor where necessary.

Cleaning of bunds, sumps, interceptors and drainage

There are bunds, sumps and a significant process drainage network at the facility associated with material storage areas, production, utilities, and abatement equipment.

3.7.5 Stage 5 – Disconnection of remaining (essential) utilities

One of the final stages of decommissioning will likely include, subject to confirming details in the Final Closure Plan include the disconnection of the water and electrical supply.

Once these have been rendered safe, it is assumed that decommissioning will be carried out by maintenance staff.

3.7.6 Stage 6– Removal of decommissioning waste and any residual hazardous materials

Any other waste or hazardous materials identified during the closure or required during decontamination or decommissioning will be stored in appropriate receptacles and will be disposed of by licenced / permitted contractor.

Each major area of the site will have segregated skips allocated for the hazardous and non-hazardous waste. This waste will include things like:

- Spent mechanical parts; WEEE and waste decommissioning equipment;
- Solid hazardous waste (absorbent mats, contaminated PPE) stored in sealed and labelled containers;
- Contaminated containers, contaminated empty drums, IBC's and other packaging;
- Non-hazardous solid waste (non-contaminated containers, drums, pallets, packaging and PPE); and
- General miscellaneous waste.

3.7.7 Stage 7 – Documentation and certification of decommissioning and decontamination

Documentation of cleaning and decontamination/decommissioning of equipment to remain onsite will be retained if accordance with law and Company document retention policies. All transfers of raw materials, product and waste materials off-site will be appropriately recorded and maintained throughout the process for verification. Records of sales for value products will be kept for inspection and waste transfer documentation and consignment notes will be maintained on site for the duration of the decommissioning process and will be available after closure if required.

4.0 CRITERIA FOR SUCCESSFUL CLOSURE

The basis of the Closure Plan is to help ensure that, upon completion of the implementation phase of the plan, the facility will be in a suitable state for future use and will not pose a risk to public health and safety or the environment.

Subject to confirming details in the Final Closure Plan it is not intended to remove all structures, systems, or plant equipment from the site in this scenario. In general, specialised equipment, cabling, electronic equipment, office equipment, etc will be, where possible, sold for reuse, or disposed of off-site. The facility buildings and common external utility features will remain in a suitable condition for future site users.

Assuming an orderly shutdown, key staff resources will be used to form a team to manage and execute the requirements of this Closure Plan, supplemented where appropriate by external resources. This closure team will be responsible for managing and executing the complete plan.

The benchmark criteria against which to evaluate successful closure is as follows:

- The Environmental Management System at the facility will be continually implemented throughout the closure process;
- All buildings, facilities, and plant equipment decontaminated and secured from unauthorised access;
- The asset is left in a condition in which there will be no constraints on future land use due to residual contamination;
- All residual materials/wastes arising from decommissioning will be handled, packaged, stored and disposed or recovered in such a manner that;
    - The equipment or decontaminated materials can be sold for re-use or sold for scrap; or

- The contaminated materials will be disposed of using authorised hazardous waste contractors.

- All relevant documents relating to waste, material movements, transfer or disposal will be managed and retained throughout the closure process;
- Sufficient funds will be available to cover the full cost of closure; and
- Agreement is reached with the Agency that the site has been returned to a satisfactory state.

5.0 CLOSURE PLAN VALIDATION

5.1 ENVIRONMENTAL MONITORING

Environmental monitoring will be conducted upon agreement and request of the Agency. Once production at the facility ceases and CHP/boilers are decommissioned, there will be no significant emissions to atmosphere at the facility so monitoring of emissions will not be required.

In terms of the test programme, it is proposed to comprise the sampling and analysis presented in Table 5-1 as a minimum. It is anticipated that this scope will be refined and agreed with the Agency in advance of the assessment following confirmation of closure.

Table 5-1: *Proposed sampling and analysis plan for the facility during and after closure*

Media	No of Samples/Parameters	Description/Locations
Soil	Samples at varying depths for soil chemistry for all known contaminants used/present on site at the time of closure.	To be agreed with the Agency.
Groundwater	Samples for chemical characterization including all known contaminants used/present on site at the time of closure.	To be agreed with the Agency.
Sewer	Sampling as per IE licence requirements over the 6-month closure period	To be agreed with the Agency.
Surface Water Drainage	At minimum, weekly visual inspection during closure period.	To be agreed with the Agency.
Ambient Dust and PM_{10}	Sampling at a number of locations (upwind and downwind) for total dust and PM_{10}.	To be agreed with the Agency.

5.2 CLOSURE VALIDATION AUDIT

Following completion of the site closure, a validation audit will take place to document that the details outlined in this Closure Report and factors raised by the approved Independent Closure Audit have been implemented.

As previously noted, it is not envisioned that there will be any residual contamination, and therefore an audit to assess the potential for contamination is not expected.

5.3 CLOSURE VALIDATION AUDIT REPORT

As required by the IE Licence, a final validation report for the site will be submitted to the Agency upon of execution of the Closure Plan. The report will present the information required to demonstrate that the criteria for successful closure has been

achieved as well as the information necessary for making an application for surrender of IE Licence, where appropriate.

This audit will contain the following details:

- Name of person(s) completing closure audit;
- Any environmental liabilities or remediation issues and how these shall be dealt with post closure;
- Proposal for revised sampling analysis and reporting arrangements on foot of changes on-site for agreement with the Agency;
- Name of person(s) completing contaminated land/hydrogeological investigation; and
- Names of all waste handling contractors during closure i.e. waste contractors, proposed final destination etc. and waste disposal documents.

5.4 CLOSURE VALIDATION CERTIFICATE

The site operations staff and its consultants will carry out the above tests and investigations and submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

6.0 FINANCIAL PROVISION / COSTING

The costings have not been estimated and will be completed at a later stage as required and will include at a minimum:

- Plant and equipment decontamination costs
- Plant and equipment decommissioning costs
- Demolition costs
- Waste recovery or disposal costs
- Environmental monitoring costs
- Site security costs
- Validation costs
- Management and utility costs

The financial provision (if required) is to be agreed with the EPA subject to the approval of the costs by the EPA, set out in this Closure Plan.

7.0 CLOSURE PLAN REVIEW AND UPDATE

As made clear in the introduction this is report an outline Closure Plan only provided to support the IE application. A Final Closure Plan and costing of the closure activities will be provided to the EPA at request, after the IE licence has been granted.

This outline Closure Plan may be reviewed and updated as necessary to take account of any significant changes to the site, processes, available technology, or costs.

The Final Closure Plan, if required, will include a review and update section that will detail an annual review as a part of the facility Annual Environmental Report (AER). Any proposed amendments will be notified to the EPA for agreement with the AER.