Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Headquarters,
Johnstown Castle Estate,
County Wexford, Ireland

GREENHOUSE GAS EMISSIONS PERMIT

Permit Register Number: IE-GHG182-10506-1

Operator: Alexion Pharma International Operations Unlimited Company
College Business & Technology Park,
Blanchardstown Road North
Dublin 15
D15 R925

Installation Name: Alexion College Park

Site Name: Alexion College Park

Location: College Business & Technology Park
Blanchardstown Road North
Dublin 15
Ireland

Introductory Note

This introductory note does not form a part of the Greenhouse Gas Emissions Permit.

This Greenhouse Gas Emissions Permit authorises the holder to undertake named activities resulting in emissions of Carbon Dioxide from the listed emission sources. It also contains requirements that must be met in respect of such emissions, including monitoring and reporting requirements. This Greenhouse Gas Emissions Permit places an obligation on the Operator to surrender allowances to the Agency equal to the annual reportable emissions of carbon dioxide equivalent from the installation in each calendar year, no later than four months after the end of each such year.

Contact with Agency:

If you contact the Agency about this Greenhouse Gas Emissions Permit please quote the following reference: Greenhouse Gas Emissions Permit Nº IE-GHG182-10506.

All correspondence in relation to this permit should be addressed to:

Email: help.ets@epa.ie

By Post: Climate Change Unit, Environmental Protection Agency
P.O. Box 3000, Johnstown Castle Estate,
Co. Wexford

Updating of the permit:

This Greenhouse Gas Emissions Permit may be updated by the Agency, subject to compliance with Condition 2. The current Greenhouse Gas Emissions Permit will normally be available on the Agency's website at www.epa.ie and ETSWAP.

Surrender of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially surrendered, a written application must be made to the on-line ETS portal, and written permission received from, the Agency through ETSWAP.

Transfer of the permit or part of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially transferred to another Operator a joint written application to transfer this Greenhouse Gas Emissions Permit must be made (by both the existing and proposed Operators) to, and written permission received from, the Agency through the on-line ETS portal ETSWAP.

Licence held pursuant to the Environmental Protection Agency Act 1992, as amended. (as of the date of this permit)**:**

IPC/IE Licence Register Number
P1030-01

Status Log

Current Permit

Permit number	Date application received	Date Permit issued	Comment
IE-GHG182-10506-1	22 February 2017	25 July 2017	

Previous Permits

Permit number	Change Type	Date application received	Date Permit issued	Comment
IE-GHG182-10506-1	GHG Permit Application	22 February 2017		

End of Introductory Note

Glossary of Terms

For the purposes of this permit the terms listed in the left hand column shall have the meaning given in the right hand column below:

The Agency	Environmental Protection Agency.
Agreement	Agreement in writing.
Allowance	Permission to emit to the atmosphere one tonne of carbon dioxide equivalent during a specified period issued for the purposes of Directive 2003/87/EC by the Agency or by a designated national competent authority of a Member State of the European Union.
Annual Reportable Emissions	Reportable Emissions of carbon dioxide made in any calendar year commencing from 1 January 2005 or the year of commencement of the activity, whichever is the later.
A & V Regulation	Commission Regulation (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Category A Installation	As defined in Article 19.2 (a) of the M&R Regulation.
Category B Installation	As defined in Article 19.2 (b) of the M&R Regulation.
Category C Installation	As defined in Article 19.2 (c) of the M&R Regulation.
The Directive	Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.
Emissions	The release of greenhouse gases into the atmosphere from sources in an installation.
EPA	Environmental Protection Agency.
Fall-Back Methodology	As defined in Article 22 of the M&R Regulation.
GHG	Greenhouse gas.
GHG Permit	Greenhouse gas emissions permit.
Greenhouse Gas	Any of the gases in Schedule 2 of the Regulations.
IPC/IE	Integrated Pollution Control/Industrial Emissions.
Installation	Any stationary technical unit where one or more activities listed in Schedule 1 to the Regulations are carried out. Also any other directly associated activities which have a technical connection with the activities carried out on that site and which could have an effect on emissions and pollution. References to an installation include references to part of an installation.

Installation with low emissions	As defined in Article 47 of the M&R Regulation.
Major Source Streams	As defined in Article 19.3 (c) of the M&R Regulation.
M&R Regulation	Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Mis-statement	An omission, misrepresentation or error in the Operators reported data, not considering the uncertainty permissible pursuant to Article 12(1)(a) of Regulation (EU) no 601/2012.
N/A	Not applicable.
Monitoring Plan	The Plan submitted and approved in accordance with Condition 3.1 of this permit and attached at Appendix 1.
Non-conformity	Any act or omission by the Operator, either intentional or unintentional, that is contrary to the greenhouse gas emissions permit and the requirements of the Monitoring Plan.
The National Administrator	The person so designated in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC.
The Operator (for the purposes of this permit)	Alexion Pharma International Operations Unlimited Company
"operator"	Any person who operates or controls an installation or to whom decisive economic power over the functioning of the installation has been delegated.
Person	Any natural or legal person.
Reportable emissions	The total releases to the atmosphere of carbon dioxide (expressed in tonnes of carbon dioxide equivalent) from the emission sources specified in Table 2 and arising from the Schedule 1 activities which are specified in Table 1.
The Regulations	European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 (S.I. No 490 of 2012) and any amendments or revisions thereto.
The Verifier	A legal person or another legal entity carrying out verification activities pursuant to Regulation (EU) No 600/2012 and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and Regulation (EU) No 600/2012 or a natural person otherwise authorised, without prejudice to Article 5(2) of Regulation (EC) No 765/2008, at the time a verification report is issued.
The Registry	The Registry as provided for under Article 19 of Directive 2003/87/EC.

Schedule 1	Schedule 1 to the Regulations.

Reasons for the Decision

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this permit, the Operator is capable of monitoring and reporting emissions in accordance with the requirements of the Regulations.

Activities Permitted

Pursuant to the Regulations the Agency issues this Greenhouse Gas Emissions Permit, subject to any subsequent revisions, corrections or modifications it deems appropriate, to:

The Operator:

Alexion Pharma International Operations Unlimited Company
College Business & Technology Park,
Blanchardstown Road North
Dublin 15
D15 R925

Company Registration Number: 528478

to carry out the following

Categories of activity:

Annex 1 Activity
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

at the following installation(s):

Alexion College Park **Installation number:**

located at

College Business & Technology Park
Blanchardstown Road North
Dublin 15
Ireland

subject to the five conditions contained herein, with the reasons therefor and associated tables attached thereto.

Conditions

Condition 1. The Permitted Installation

1.1 This is the first GHG permit granted to the installation.

1.2 The Operator is authorised to undertake the activities and/or the directly associated activities specified in Table 1 below resulting in the emission of carbon dioxide:

Table 1 - Activities which are listed in Schedule 1 of the Regulations and other directly associated activities carried out on the site:

Installation No.:

Activity Description
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

Directly Associated Activity Description
N/A

1.3 Carbon dioxide from Schedule 1 activities shall be emitted to atmosphere only from the emission sources as listed in Table 2 below:

Table 2 Emission Sources and Capacities:

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S1	Steam Boiler 1	8.8	MW
S2	Steam Boiler 2	8.8	MW
S3	Steam Boiler 3	8.8	MW
S4	LPHW Boiler 1	1.55	MW
S5	LPHW Boiler 2	1.55	MW
S6	LPHW Boiler 3	1.55	MW
S7	Emergency Generator 1	5.34	MW
S8	Emergency Generator 2	5.34	MW

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S9	Emergency Generator 3	3.29	MW
S10	Fire Water Pump	0.6	MW
S11	Kitchen ovens and cookers	0.1	MW

1.4 The activity shall be controlled, operated and maintained so that emissions of carbon dioxide shall take place only as set out in this GHG Emissions Permit. The permit does not control emissions of gases other than carbon dioxide. All agreed plans, programmes and methodologies required to be carried out under the terms of this permit, become part of this permit.

1.5 This GHG Permit is for the purposes of GHG emissions permitting under the European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 and any amendments to the same only and nothing in this permit shall be construed as negating the Operator's statutory obligations or requirements under any other enactments or regulations unless specifically amended by the Regulations.

1.6 Any reference in this permit to 'installation' shall mean the installation as described in the Greenhouse Gas Emissions Permit application and any amendments approved by the Agency.

Reason: To describe the installation and clarify the scope of this permit.

Condition 2. Notification

2.1 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in a change in:

2.1.1 the nature or functioning of the installation;

2.1.2 the capacity of the installation as detailed in this permit;

2.1.3 the fuels used at the installation;

2.1.4 the range of activities to be carried out at the installation

that may require updating of the GHG permit shall be carried out or commenced without prior notice to and without the prior written agreement of the Agency.

2.2 The Operator shall notify the Agency in writing of the cessation of all or part of any activity listed in Table 1 of this permit no later than one month from the date of cessation or by 31 December of the year of cessation, whichever is sooner.

2.3 The Operator shall apply for an update of this GHG Permit where there is a change to the Operator name and/or registered address of the Operator, within seven days of the change.

2.4 For installations or parts of installations which have not come into operation when the application for this permit was made the Operator shall notify the Agency of the date of commencement of the activity within seven days of commencement.

2.5 The Operator shall notify the Agency in writing within three days of becoming aware of any factors which may prevent compliance with the conditions of this permit.

2.6 The Operator shall submit to the Agency by 21 January of each year a declaration of operability. The declaration submitted shall be in the format required by the Agency.

2.7 All notifications required under Condition 2 above shall be made to the address given in the Explanatory Note included with this permit.

2.8 The Operator shall submit to the Agency by 31 December of each year all relevant information about any planned or effective changes to the capacity, activity level and operation of an installation. The information submitted shall be in the format required by the Agency.

Reason: To provide for the notification of updated information on the activity.

Condition 3. Monitoring and Reporting

3.1 The Operator shall monitor and record greenhouse gas emissions on site in accordance with the M&R Regulation and the approved Monitoring Plan attached at Appendix 1 to this GHG permit and in compliance with any other guidance approved by the Agency for the purposes of implementing the Directive and/or the Regulations.

3.2 The Operator shall modify the monitoring plan in any of the following situations:

3.2.1 new emissions occur due to new activities carried out or due to the use of new fuels or materials not yet contained in the monitoring plan;

3.2.2 the change of availability of data, due to the use of new measurement instrument types, sampling methods or analysis methods, or for other reasons, leads to higher accuracy in the determination of emissions;

3.2.3 data resulting from the previously applied monitoring methodology has been found incorrect;

3.2.4 changing the monitoring plan improves the accuracy of the reported data, unless this is technically not feasible or incurs unreasonable costs;

3.2.5 the monitoring plan is not in conformity with the requirements of the M&R Regulation and the Agency requests a change;

3.2.6 it is necessary to respond to the suggestions for improvement of the monitoring plan contained in the verification report.

The Operator shall notify any proposals for modification of the monitoring plan to the Agency without undue delay. Any significant modifications of the monitoring plan, as defined in Article 15 of the M&R Regulation, shall be subject to approval by the Agency. Where approved these changes shall be implemented within a timeframe agreed by the Agency.

3.3 Temporary changes to the monitoring methodology:

3.3.1 Where it is for technical reasons temporarily not feasible to apply the tier in the monitoring plan for the activity data or each calculation factor of a fuel or material stream as approved by the Agency, the Operator shall apply the highest achievable tier until the conditions for application of the tier approved in the monitoring plan have been restored. The Operator shall take all necessary measures to allow the prompt restoration of the tier in the approved monitoring plan. The Operator shall notify the temporary change to the monitoring methodology without undue delay to the Agency specifying:

(i) The reasons for the deviation from the tier;

(ii) in detail, the interim monitoring methodology applied by the Operator to determine the emissions until the conditions for the application of the tier in the monitoring plan have been restored;

(iii) the measures the Operator is taking to restore the conditions for the application of the tier in the approved monitoring plan;

(iv) the anticipated point in time when application of the approved tier will be resumed.

3.3.2 A record of all non-compliances with the approved monitoring plan shall be maintained on-site and shall be available on-site for inspection by authorised persons of the Agency and/or by the Verifier at all reasonable times.

3.4 The Operator shall appoint a Verifier to ensure that, before their submission, the reports required by Condition 3.5 below are verified in accordance with the criteria set out in Schedule 5 of the Regulations, the A&V Regulation and any more detailed requirements of the Agency.

3.5 The written report of the verified annual reportable emissions and the verification report in respect of each calendar year shall be submitted to the Agency by the Operator no later than 31 March of the following year. The reports shall be in the format required by the Agency and meet the criteria set out in the M&R and A&V Regulations.

3.6 The Operator shall enter the verified annual reportable emissions figure for the preceding year into the Registry no later than 31 March of the following year. This figure shall be electronically approved by the Verifier in the registry no later than 31 March of each year.

3.7 Where an Operator is applying the Fall-Back methodology, the Operator shall assess and quantify each year the uncertainties of all parameters used for the determination of the annual emissions in accordance with the ISO Guide to the Expression of Uncertainty in Measurement or another equivalent internationally accepted standard and include the verified results in the written report of the verified annual reportable emissions to be submitted to the Agency by 31 March each year.

3.8 An Operator shall submit to the Agency for approval a report containing the information detailed in (i) or (ii) below, where appropriate, by the following deadlines:

(a) for a category A installation, by 30 June every four years;

(b) for a category B installation, by 30 June every two years;

(c) for a category C installation, by 30 June every year.

(i) Where the Operator does not apply at least the tiers required pursuant to the first subparagraph of Article 26(1) and to Article 41(1) of the M&R Regulation, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply the required tiers. Where evidence is found that measures needed for reaching those tiers have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan and submit proposals for implementing appropriate measures and its timing.

(ii) Where the Operator applies a fall-back monitoring methodology, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply at least tier 1 for one or more major or minor source streams. Where evidence is found that measures needed for reaching at least tier 1 for those source streams have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan, submit proposals and a timeframe for implementing appropriate measures.

3.9 Where the verification report states outstanding non conformities, misstatements or recommendations for improvements the Operator shall submit a report to the Agency for approval

by 30 June of the year in which the verification report is issued. This requirement does not apply to the Operator of an installation with low emissions where the verification report contains recommendations for improvements only. The report shall describe how and when the Operator has rectified or plans to rectify the non-conformities identified and to implement recommended improvements. Where recommended improvements would not lead to an improvement of the monitoring methodology this must be justified by the Operator. Where the recommended improvements would incur unreasonable costs the Operator shall provide evidence of the unreasonable nature of the costs. The Operator shall implement the improvements specified by the Agency in response to the report submitted in accordance with this Condition in accordance with a timeframe set by the Agency.

3.10 The Operator shall make available to the Verifier and to the Agency any information and data relating to emissions of carbon dioxide which are required in order to verify the reports referred to in Condition 3.5 above or as required by the Agency to facilitate it in establishing benchmarks and/or best practice guidance.

3.11 Provision shall also be made for the transfer of environmental information, in relation to this permit, to the Agency's computer system, as may be requested by the Agency.

3.12 The Operator shall retain all information as specified in the M&R Regulation for a period of at least 10 years after the submission of the relevant annual report.

3.13 A record of independent confirmation of capacities listed in this permit shall be available on-site for inspection by authorised persons of the Agency at all reasonable times.

3.14 The Operator shall keep records of all modifications of the monitoring plan. The records shall include the information specified in Article 16.3 of the M&R Regulation.

3.15 The Operator shall ensure that members of the public can view a copy of this permit and any reports submitted to the Agency in accordance with this permit at all reasonable times. This requirement shall be integrated with the requirements of any public information programme approved by the Agency in relation to any other permit or licence held by the Operator for the site.

Reason: To provide for monitoring and reporting in accordance with the Regulations.

Condition 4. Allowances

4.1 Surrender of Allowances

4.1.1 The Operator shall, by 30 April in each year, surrender to the Agency, or other appropriate body specified by the Agency, allowances equal to the annual reportable emissions in the preceding calendar year.

4.1.2 The number of allowances to be surrendered shall be the annual reportable emissions for the preceding calendar year plus such allowances as may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due. This includes allowances to cover the amount of any annual reportable emissions in respect of which allowances were not surrendered in accordance with Condition 4.1.1 in the previous year, and the amount of any reportable emissions which were discovered during the previous year to have been unreported in reports submitted under Condition 3 in that or in earlier years.

4.1.3 In relation to activities or parts of activities which have ceased to take place and have been notified to the Agency in accordance with Condition 2.2 above, the Operator shall surrender to the Agency allowances equal to the annual reportable emissions from such activities in the preceding calendar year or part thereof, together with such allowances as

may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due as described in Condition 4.1.2 above.

4.1.4 The Operator may, from 2008 onwards, subject to the provisions of the Regulations and the relevant National Allocation Plan for that compliance year, surrender emission reduction units (ERUs) and certified emission reduction units (CERs) in place of allowances.

4.2 The holding, transfer, surrender and cancellation of allowances shall be in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC, any amendment or revision to the same and any guidance issued by the Agency or the National Administrator.

4.3 The Operator shall provide the National Administrator with all the necessary information for the opening of an Operator holding account for the installation described in Condition 1 of this permit within twenty working days of the issue of this permit, unless such an account is already open.

Reason: *To provide for the surrendering, holding, transfer and cancellation of allowances in respect of reported emissions.*

Condition 5. Penalties

5.1 Any Operator who fails to comply with Condition 4.1 above shall be subject to the provisions of the Regulations, including, but not limited to the payment of penalties.

Reason: To provide for the payment of excess emissions penalties as required under the Regulations.

Sealed by the seal of the Agency on this the 25 July 2017:

PRESENT when the seal of the Agency was affixed hereto:

_____

Ms. Annette Prendergast
Inspector/ Authorised Person

Appendix 1 to Greenhouse Gas Emissions Permit Number IE-GHG182-10506

Monitoring Plan

1. Guidelines & Conditions

1. Directive 2003/87/EC as amended by Directive 2009/29/EC (hereinafter "the (revised) EU ETS Directive") requires operators of installations which are included in the European Greenhouse Gas Emission Trading Scheme (the EU ETS) to hold a valid GHG emission permit issued by the relevant Competent Authority and to monitor and report their emissions and have the reports verified by an independent and accredited verifier.

The Directive can be downloaded from:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003L0087:20090625:EN:PDF

2. The Monitoring and Reporting Regulation (Commission Regulation (EU) No 601/2012) (hereinafter the "MRR") defines further requirements for monitoring and reporting.

The MRR can be downloaded from:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:181:0030:0104:EN:PDF

Article 12 of the MRR sets out specific requirements for the content and submission of the monitoring plan and its updates. Article 12 outlines the importance of the Monitoring plan as follows:

The monitoring plan shall consist of a detailed complete and transparent documentation of the monitoring methodology of a specific installation [or aircraft operator] and shall contain at least the elements laid down in Annex I.

Furthermore Article 74(1) states:

Member States may require the operator and aircraft operator to use electronic templates or specific file formats for submission of monitoring plans and changes to the monitoring plan as well as for submission of annual emissions reports tonne-kilometre data reports verification reports and improvement reports. Those templates or file format specifications established by the Member States shall at least contain the information contained in electronic templates or file format specifications published by the Commission

3. All Commission guidance documents on the Monitoring and Reporting Regulation will be published at the link below as they become available:

http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm

(a) Information sources:

EU Websites:

EU-Legislation: http://eur-lex.europa.eu/en/index.htm
EU ETS general: http://ec.europa.eu/clima/policies/ets/index_en.htm

Monitoring and Reporting in the EU ETS: http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm

Environmental Protection Agency Website:

http://www.epa.ie

Environmental Protection Agency Contact:

GHGpermit@epa.ie

2. Application Details

The Installation Name, Site Name and the address of the site of the installation are detailed below. The Site Name and address can be updated from the Organisation Details Page on the ETSWAP website. The Installation Name can only be updated by your Competent Authority.

Installation name	Alexion College Park
Site name	Alexion College Park
Address	College Business & Technology Park Blanchardstown Road North Dublin 15 Ireland
Grid reference of site main entrance	E 307953 N 240879
Licence held pursuant to the Environmental Protection Agency Act 1992, as amended.	Yes

IPC/IE Licence Register Number	Licence holder	Competent body
P1030-01	Alexion Pharma International Operations UC	Environmental Protection Agency

Has the regulated activity commenced at the Installation?	No
Expected date of commencement	28 July 2017

3. About the Operator

The information about the "Operator" is listed below. The "Operator" is defined as the person who it is proposed will have control over the relevant Regulated Activities in the installation in respect of which this application is being made.

(b) Operator Details

The name of the operator and where applicable the company registration number are detailed below. These details can only be updated by the Environmental Protection Agency.

Operator name	Alexion Pharma International Operations Unlimited Company
Company Registration Number	528478

Operator Legal status

The legal status of the operator is:	Company / Corporate Body

(c) Company / Corporate Body

Is the trading / business name different to the operator name?	No

Details of the individual authorised to submit this application on behalf of the company / corporate body.

Title	[redacted]
Forename	[redacted]
Surname	[redacted]
Position	Associate Director, EHS & Security

Registered office address

Address Line 1	College Business & Technology Park,
Address Line 2	Blanchardstown Road North
City/Town	Dublin 15
County	N/A
Postcode	D15 R925

Principal office address

Is the principal office address different to the registered office address?	No

Holding company

Does the company belong to a holding company?	No

(d) Operator Authority

Does the operator named above have the authority and ability to:

a.	manage site operations through having day-to-day control of plant operation including the manner and rate of operation	Yes
b.	ensure that permit conditions are effectively complied with	Yes
c.	control monitor and report specified emissions	Yes
d.	be responsible for trading in Allowances so that at the	Yes

end of a reporting period allowances can be balanced against reported emissions.

4. Service Contact

e. Service Contact

Name [redacted]

Address / Email Address [redacted]

5. Installation Activities

f. Installation Description

Below is a description of the installation and its activities, a brief outline description of the site and the installation and the location of the installation on the site. The description also includes a non-technical summary of the activities carried out at the installation briefly describing each activity performed and the technical units used within each activity.

Alexion Pharma International Operations UC (Alexion) is a biopharmaceutical manufacturing campus at College Business & Technology Park, Blanchardstown, Dublin 15. The site is 16.8ha. site within the IDA Ireland College Park, Blanchardstown, Dublin 15. Once operational Alexion intend to manufacture a variety of therapeutic proteins at College Park that are either approved for marketing by various region or country regulatory bodies or are involved in late stage clinical studies. These proteins will be produced to the bulk or formulated state, and filled for shipping from the site at College Park. The construction of the campus is in 2 phases. Phase 1 of the campus consists of a 5 storey office building and roof top plant room, QC laboratories, packaging / warehouse, utility building and spine corridor and a data centre. Phase 2 consists of a manufacturing facility incorporating the development of a manufacturing building, Central Utilities Building (CUB), warehouse and associated support buildings and external utilities.

Alexion has an Industrial Emissions Licence under Class 5.16 of the First Schedule of the Environmental Protection Agency Act 1992, as amended - Class 5.16: The production of pharmaceutical products including intermediates.

As part of Phase 1 three (3) LPHW boilers were installed for the supply of steam and hot water requirements and 1 diesel fired emergency generator for use during emergency situations.

As part of Phase 2 three (3) no. natural gas-fired boilers are located in the CUB Building and 2 diesel fired emergency generators are located in the outside utilities area for use in emergency situations.

The site will also be equipped 1 fire water pump that will be available for use during emergency situations.

g. Annex 1 Activities

The table below lists the technical details for each Annex 1 activity carried out at the installation.

Note that 'capacity' in this context means:

- Rated thermal input (for combustion installations) which is defined as the rate at which fuel can be burned at the maximum continuous rating of the installation multiplied by the calorific value of the fuel and expressed as megawatts thermal.
- Production capacity for those specified Annex I activities for which production capacity determines ETS eligibility.

Annex 1 Activity	Total Capacity	Capacity units	Specified Emissions
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)	45.72	MW	Carbon Dioxide

h. Site Diagram

The table below lists attachments (if available) that provide a simple diagram showing emissions sources source streams sampling points and metering/measurement equipment.

Attachment	Description
IE0311488_22_DR_0013_A.pdf	GHG Permit Application - Emission Point Sources
ADMF Gas Supply IE0311488_30_SK_0032_A_Draft2.pdf	Site map updated for Gas Meter locations.

i. Estimated Annual Emissions

Detail of the estimated annual emission of CO_2 equivalent. This information enables categorisation of the installation in accordance with Article 19 of the MRR and is based on the average verified annual emissions of the previous trading period data OR if this data is not available or is inappropriate a conservative estimate of annual average emissions including transferred CO_2 excluding CO_2 from biomass.

Estimated Annual Emissions (tonnes $CO_{2(e)}$)	30000
Justification for the use of a conservative estimate of CO_2 emissions.	In the absence of historical emission data, conservative estimate for annual CO2 emissions is based on the emissions from a similar biopharmaceutical facility.

Installation Category: A

6. Emissions Details

j. About your emissions

Annex I of the Monitoring and Reporting Regulations (MRR) requires that monitoring plans include a description of "the installation" and activities to be carried out and monitored including a list of emission sources and source streams. The information provided in this template relates to the Annex I activity(ies) comprised in the installation in question and should relate to a single installation. It includes any activities carried out by the operator and does not include related activities carried out by other operators.

k. Emission Sources

The table below lists all the emission sources at the installation, which may include directly associated activities/excluded activities.

Emission Source Reference	Emission Source Description
S1	Steam Boiler 1
S2	Steam Boiler 2
S3	Steam Boiler 3
S4	LPHW Boiler 1
S5	LPHW Boiler 2
S6	LPHW Boiler 3
S7	Emergency Generator 1
S8	Emergency Generator 2
S9	Emergency Generator 3
S10	Fire Water Pump
S11	Kitchen ovens and cookers

The table below lists the emission sources which are linked to the Regulated Activities at the installation.

Emission Source Reference	Emission Source Description
S1	Steam Boiler 1
S2	Steam Boiler 2
S3	Steam Boiler 3
S4	LPHW Boiler 1
S5	LPHW Boiler 2
S6	LPHW Boiler 3
S7	Emergency Generator 1
S8	Emergency Generator 2
S9	Emergency Generator 3

Emission Source Reference	Emission Source Description
S10	Fire Water Pump
S11	Kitchen ovens and cookers

l. Emission Points

The table below lists all the emission points at the installation, which may include directly associated activities/excluded activities.

Emission Point Reference	Emission Point Description
A1-1	Steam Boiler 1
A1-2	Steam Boiler 2
A1-3	Steam Boiler 3
A3-1	LPHW Boiler 1
A3-2	LPHW Boiler 2
A3-3	LPHW Boiler 3
A3-75	Emergency Generator 1
A3-76	Emergency Generator 2
A4-9	Emergency Generator 3
A4-11	Fire Water Pump
N/A	Kitchen ovens and cookers

m. Source Streams (fuels and/or materials)

The table below lists the source streams which are used in Schedule 1 Activities at the installation.

Source Stream Reference	Source Stream Type	Source Stream Description
F1 (Natural Gas)	Combustion: Other gaseous & liquid fuels	Natural Gas
F2 (Natural Gas)	Combustion: Other gaseous & liquid fuels	Natural Gas
F3 (Gas/Diesel Oil)	Combustion: Commercial standard fuels	Gas/Diesel Oil

n. Emissions Summary

The table below provides a summary of the emission source and source stream details in the installation.

Source streams (Fuel / Material)	Emission Source Refs.	Emission Point Refs.	Annex 1 Activity
F1 (Natural Gas)	S1,S2,S3	A1-1,A1-2,A1-3	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)
F2 (Natural Gas)	S4,S5,S6,S11	A3-1,A3-2,A3-3,N/A	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)
F3 (Gas/Diesel Oil)	S7,S8,S9,S10	A3-75,A3-76,A4-9,A4-11	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

o. Excluded Activities

Certain activities that result in greenhouse gas emissions may be excluded under the EU ETS Directive for example truly mobile sources such as vehicle emissions.

Do you have any excluded activities which need to be identified in your monitoring plan? No

7. Low Emissions Eligibility

p. Low Emissions Eligibility

The operator may submit a simplified monitoring plan for an installation where no nitrous oxide activities are carried out and it can be demonstrated that:

(a) the average verified annual emissions of the installation during the previous trading period was less than 25 000 tonnes $CO_{2(e)}$ per year or;

(b) where this data is not available or inappropriate a conservative estimate shows that emissions for the next 5 years will be less than 25 000 tonnes $CO_{2(e)}$ per year.

Note: the above data shall include transferred CO_2 but exclude CO_2 stemming from biomass.

Does the installation satisfy the criteria for installations with low emissions (as defined by Article 47 of the MRR)? No

8. Monitoring Approaches

q. Monitoring Approaches

Emissions may be determined using either a calculation based methodology ("calculation") or measurement based methodology ("measurement") except where the use of a specific methodology is mandatory according to the provisions of the MRR. [MRR Article 21].

Note: the operator may subject to competent authority approval combine measurement and calculation for different sources. The operator is required to ensure and demonstrate that neither gaps nor double counting of reportable emissions occurs.

Please specify whether or not you propose to apply the following monitoring approaches. Select all monitoring approaches that are applicable to you. The consecutive sections will become mandatory based on the selected approaches.

Calculation	Yes
Measurement	No
Fall-back approach	No
Monitoring of N_2O	No
Monitoring of PFC	No
Monitoring of transferred / inherent CO_2	No

9. Calculation

r. Approach Description

The calculation approach including formulae used to determine annual CO_2 emissions:

For natural gas data collection, supplier bills are collected and the gas consumption in gross kWh is used as the initial basis for activity data. For net calorific value conversion of natural gas, the gross to net gas calorific value conversion method specified by the Agency is used as listed in “Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Reports” for the relevant reporting year.

Emission factors and oxidation factors are taken from the annual "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Report" document issued by the Agency. Natural gas is divided into 2 source streams. Bord Gais intend provide a Gas Metering System Summary for each meter annually.

Diesel (gas oil) is classified as a de minimis source. Diesel is accounted for by systematically capturing and checking all diesel delivery dockets and using these as the basis for quantifying diesel fuel coming onto the site. Density for diesel is taken from supplier data sheet. Diesel stock levels will be established by annual physical inventory checks on the site diesel storage tanks carried at the start/end of year by the tank owners. The volumes of diesel in litres are converted to tonnes by multiplying by the density of diesel.

The annual diesel consumption is calculated by:

= Vol. Diesel Purchased + (Starting inventory – Closing inventory)

Net calorific value, emission factor and oxidation factor are taken from the annual "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Report" document issued by the Agency.

s. Measurement Devices

Below is a description of the specification and location of the measurement systems used for each source stream where emissions are determined by calculation

Also a description of all measurement devices including sub-meters and meters used to deduct non-Annex I activities to be used for each source and source stream.

Source Stream Refs.	Emission Source Refs.	Measurement Device Ref.	Type of Measurement Device	Measurement Range	Metering Range Units	Specified Uncertainty (+/- %)	Location
F1 (Natural Gas)	S1,S2,S3	Bord Gais Flow Meter S/N 10522552	Turbine meter	0-100%	Nm3	1.5	Bod Gais AGI
F2 (Natural Gas)	S4,S5,S6,S11	Bord Gais Flow Meter	Turbine meter	0-100%	Nm3	3	Phase 1
F3 (Gas/Diesel Oil)	S10,S7,S8,S9	N/A	Supplier Dockets	N/A	N/A	N/A	Engineering Dept.

Source Stream Refs.	Measurement Device Ref.	Determination Method	Instrument Under Control Of	Conditions Of Article 29(1) Satisfied	Invoices Used To Determine Amount Of Fuel Or Material	Trade Partner And Operator Independent
F1 (Natural Gas)	Bord Gais Flow Meter S/N 10522552	Continual	Trade partner	Yes	Yes	Yes
F2 (Natural Gas)	Bord Gais Flow Meter	Continual	Trade partner	Yes	Yes	Yes
F3 (Gas/Diesel Oil)	N/A	Batch	Trade partner	Yes	Yes	Yes

t. Applied Tiers

The table below identifies the tiers applied against the relevant input data for each source stream and confirms whether a standard (MRR Article 24) or mass balance (MRR Article 25) approach is applied.

(i) The highest tiers as defined in Annex II of the MRR should be used by Category B and C installations to determine the activity data and each calculation factor (except the oxidation factor and conversion factor) for each major source stream. Category A installations should apply as a minimum the tiers listed in Annex V.

(ii) Operators may apply a tier one level lower than those referred to in sub paragraph (i) above for Category C installations and up to two levels lower for Category A and B installations with a minimum of tier 1 if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier. The justification for not applying the higher tier should be recorded when completing the tier table.

(iii) The competent authority may allow an operator to apply even lower tiers than those referred to in the sub paragraph (ii) with a minimum of tier 1 for a transition period of up to three years if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier and provides an improvement plan detailing how and by when at least the tier referred to in sub paragraph (ii) will be achieved. The improvement plan should be referenced in subsequent table and provided to the competent authority at the time of submission of this plan.

(iv) For minor source streams operators shall apply the highest tier which is technically feasible and will not lead to unreasonable costs with a minimum of tier 1 for activity data and each calculation factor. For de-minimis source streams operators may use conservative estimations rather than tiers unless a defined tier can be achieved without additional effort (MRR Article 26(2)).

(v) Installations with low emissions as identified in section 6(d) may apply as a minimum tier 1 for determining activity data and calculation factors for all source streams unless higher accuracy is achievable without additional effort.

* Note 1: For commercial standard fuels the minimum tiers listed in Annex V of the MRR may be applied for all activities in all installations.

* Note 2: If you are intending to apply a fall-back approach please complete the table below and select "n/a" for the tiers to be applied for each source stream where a fall-back approach is used. Section 10 "Fall-back" must also be completed for these source streams.

* Note 3: For biomass or mixed fuels the emission factor is the preliminary emission factor as defined in Definition 35 Article 3 of the MRR.

Source Stream Refs.	**Emission Source Refs.**	**Measurement Device Refs.**	**Overall Metering Uncertainty (less than +/- %)**	**Applied Monitoring Approach**	**Activity Data Tier Applied**	**Net Calorific Value Tier Applied**	**Emission Factor Tier Applied**	**Carbon Content Tier Applied**	**Oxidation Factor Tier Applied**	**Conversion Factor Tier Applied**	**Biomass Fraction Tier Applied**	**Estimated Emissions $tCO_{2(e)}$**	**% of Total Estimated Emissions**	**Source Category**	**Highest Tiers Applied**	**Justification for not applying the highest tiers**	**Improvement Plan Reference (where applicable)**

Source Stream Refs.	**Emission Source Refs.**	**Measurement Device Refs.**	**Overall Metering Uncertainty (less than +/- %)**	**Applied Monitoring Approach**	**Activity Data Tier Applied**	**Net Calorific Value Tier Applied**	**Emission Factor Tier Applied**	**Carbon Content Tier Applied**	**Oxidation Factor Tier Applied**	**Conversion Factor Tier Applied**	**Biomass Fraction Tier Applied**	**Estimated Emissions $tCO_{2(e)}$**	**% of Total Estimated Emissions**	**Source Category**	**Highest Tiers Applied**	**Justification for not applying the highest tiers**	**Improvement Plan Reference (where applicable)**
F1 (Natural Gas)	S1,S2,S3	Bord Gais Flow Meter S/N 10522552	<1.5%	Standard	2	2b	2a	N/A	1	N/A	N/A	24000	97.17	Major	Yes	n/a	n/a
F2 (Natural Gas)	S4,S5,S6,S11	Bord Gais Flow Meter	<7.5%	Standard	1	2b	2a	N/A	1	N/A	N/A	500	2.02	De-minimis	Yes	n/a	n/a
F3 (Gas/Diesel Oil)	S10,S7, S8,S9	N/A	N/A	Standard	No tier	2a	2a	N/A	1	N/A	N/A	200	0.81	De-minimis	N/A	n/a	n/a

Total Estimated Emissions for Calculation (tonnes $CO_{2(e)}$) 24700

u. Uncertainty Calculations

The table below lists evidence attached to the application that demonstrates compliance with the applied tiers in accordance with Article 12 of the MRR.

Attachment	**Description**
Uncertainty Calculation Approach_Natural Gas.pdf	Uncertainty Calculation Approach (Natural Gas)
IE0311488-22-RP-0032_A_01(DRAFT) (3).pdf	Final uncertainty

v. Applied tiers

Applied tiers for each source stream

Source Stream Ref.	Emission Source Refs.	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied
F1 (Natural Gas)	S1,S2,S3	2	2b	2a	N/A	1	N/A	N/A
F2 (Natural Gas)	S4,S5,S6,S11	1	2b	2a	N/A	1	N/A	N/A
F3 (Gas/Diesel Oil)	S10,S7,S8,S9	No tier	2a	2a	N/A	1	N/A	N/A

w. Justification for Applied tiers

Justifications for the applied tiers for each major source stream where highest tiers are not currently achieved.

Source Stream Ref.	**Emission Source Refs.**	**Justification for the applied tier**	**Improvement Plan Reference (where applicable)**
N/A	N/A	N/A	N/A

10. Calculation Factors

x. Default Values

The table below lists, for each parameter, where default values are to be used for calculation factors.

Source Stream Refs.	Emission Source Refs.	Parameter	Reference Source	Default Value applied (where appropriate)
F1 (Natural Gas),F2 (Natural Gas)	S1,S2,S3,S4,S5,S6,S11	EF	EPA Guidance 'Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emission Report - YEAR'	N/A
F1 (Natural Gas),F2 (Natural Gas)	S1,S2,S3,S4,S5,S6,S11	OxF	M&R Regulation	N/A
F3 (Gas/Diesel Oil)	S7,S8,S9,S10	NCV,EF	EPA Guidance 'Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emission Report - YEAR	N/A
F3 (Gas/Diesel Oil)	S10,S7,S8,S9	OxF	M&R Regulation	N/A

Sampling and Analysis

Do you undertake sampling and analysis of any of the parameters used in the calculation of your CO_2 emissions? No

11. Management

y. Monitoring and Reporting Responsibilities

Responsibilities for monitoring and reporting emissions from the installation are listed below:

Relevant job titles/posts and provide a succinct summary of their role relevant to monitoring and reporting are listed below.

Job Title / Post	**Responsibilities**
Engineering Lead	The Engineering Lead or designee responsibilities include but are not limited to the following: • Ensuring all data relating to GHG emissions is collected • Ensuring all monitoring equipment is calibrated by competent personnel and in accordance with the monitoring and reporting plan. • Acting as the Secondary Operational Contact for the GHG permit and the Secondary Registry Contact (SRC) for the emissions trading registry. • Ensuring that all data relating to GHG emissions is collected and all monitoring equipment is calibrated and in operation with the monitoring and report plan of the GHG permit.
EHS Lead	The EHS Lead or designee responsibilities include but are not limited to the following: • Ensuring all aspects of the GHG emissions and legislation are complied with, and to ensure that quality control mechanism on data, data storage and retention, management programs and management review requirements are implemented. • Preparing the AEM report in compliance with the Greenhouse Gas Emissions Trading Regulation and the Monitoring and Reporting Regulation. • Acting as the Primary Operational Contact for the GHG permit and the Primary Registry Contact (PRC) for the Emissions Trading Registry. • Appointing a verifier that is a competent, independent, accredited verification body who will perform and report on the verification process, in accordance with the detailed requirements established by the EPA pursuant to Schedule 5 of the Greenhouse

Job Title / Post	**Responsibilities**
	Gas Emissions Trading Regulation.

Attachment	**Description**
Org Chart.doc	Alexion Pharma International Operations UC Org Chart

z. Assignment of Responsibilities

Details of the procedure used for managing the assignment of responsibilities for monitoring and reporting within the installation and for managing the competencies of responsible personnel in accordance with Article 58(3)(c) of the MRR:

This procedure identifies how the monitoring and reporting responsibilities for the roles identified above are assigned and how training and reviews are undertaken.

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	The purpose of this procedure is to describe how the assignment of responsibilities for monitoring and reporting within the installation are managed and for managing the competencies of responsible personnel in accordance with Article 58(3)(c) of the MRR such as : - Quantifying the amount of carbon dioxide emitted from the relevant combustion activities on the site. -Accurately reporting all emissions to the Environmental Protection Agency (EPA) as part of the EU Emissions Trading Scheme (EU ETS). This procedure identifies how the monitoring and reporting responsibilities for the roles identified above are assigned and how training and reviews are undertaken.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

aa. Monitoring Plan Appropriateness

Details of the procedure used for regular evaluation of the monitoring plan's appropriateness covering in particular any potential measures for the improvement of the monitoring methodology:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.7 of this procedure details the requirement for Alexion to carry a regular review of the appropriateness of the Monitoring Plan. This includes checking the list of

	emissions sources and source streams, ensuring completeness of the emissions and source streams and that all relevant changes in the nature and functioning of the installation will be included in the monitoring plan; assessing compliance with the uncertainty thresholds for activity data and other parameters (where applicable) for the applied tiers for each source stream and emission source; and assessment of potential measures for improvement of the monitoring methodology applied.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

bb. Data Flow Activities

Details of the procedures used to manage data flow activities in accordance with Article 57 of the MRR:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	The purpose of this procedure is to describe the procedure to be followed for: - Quantifying the amount of carbon dioxide emitted from the relevant combustion activities on site. - Accurately reporting all emissions as part of the EU ETS.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A
List of primary data sources	Natural gas volume and calorific value - Monthly Natural Gas Invoices Diesel/gas Oil volume - delivery dockets
Description of the relevant processing steps for each specific data flow activity. Identify each step in the data flow and include the formulas and data used to determine emissions from the primary data. Include details of any relevant electronic data processing and storage systems and other inputs (including manual inputs) and confirm how outputs of data flow activities are recorded	Em = AD X EF X OF Where: Em - Emissions [tonnes CO2] AD - Activity data [amount of fuel in tonnes or Nm3] x NCV EF - Emission factor [t CO2/t or t CO2/Nm3]

OF - Oxidation factor [dimensionless]

The quantity of Natural Gas (NG) delivered to the site will be measured via a continuous flow meter. A monthly invoice for NG supply will forwarded by Bord Gais (BG) each month containing the volume of gas delivered in m3 and the fuel energy in kWh based on the Gross Calorific Value.

The NG volume in the gas bills is reported at 288.15oK and must be corrected to standard temperature (273.15oK) as per the revised Monitoring and Reporting Regulations which require the annual reporting of standardised (temperature 273.15 K, pressure 101,325 Pa) volume of gas consumed in addition to the net calorific value of the fuel (TJ/Nm3). The formula to be used for the temperature correction is:

Vs (Nm3) = (Va*273.15)/288.15

Where

Vs = standardised gas volume

Va = actual gas volume determined from the gas bills

Gas bills show kWh based on Gross Calorific Value. To convert to NCV multiply by the gross to net conversion factor and convert to TJ by multiplying by 3.6 x 10-6. Note these values may change year to year and should be checked versus the latest EPA guidance.

The NCV of the fuel (in TJ/Nm3) is then calculated as follows:

NCV = Annual TJ /Annual standardised gas volume. Tonnes

CO2 emitted from NG combustion are calculated as per the equation: Em = AD X EF X OF where Emission Factor and Oxidation Factor are as per EPA Guidance.

All of the calculations for CO2 emissions from NG combustion will be carried out in the relevant tab of the year specific version of the EHS spreadsheet “Annual CO2 Emissions YEAR".

Diesel (gas oil) deliveries to the site will be recorded via the delivery dockets based on the tanker meters of the delivery trucks. Copies of all diesel delivery dockets will be retained by the EHS Department as part of the information for the annual GHG emissions verification audit. Diesel stock levels will be established by annual physical inventory checks on

	the site diesel storage tanks carried at the start/end of year by the tank owners. The volumes of diesel in litres are converted to tonnes by multiplying by the density of diesel as per the suppliers Safety Data Sheet. The annual diesel consumption is calculated by: = Vol. Diesel Purchased + (Starting inventory – Closing inventory) The NCV, EF and oxidation factor for diesel are country specific values and may be updated periodically by the EPA. The current NCV and EF is available in the EPA Guidance "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emission Report - YEAR". The CO2 emissions (Em) from diesel are calculated by the following formula: Em (tCO2) = AD (fuel consumed*NCV) * EF * Oxidation factor. All of the calculations for CO2 emissions from diesel combustion will be carried out in the relevant tab of the year specific version of the EHS spreadsheet "Annual CO2 Emissions YEAR"

Submit relevant documents to record data flow activities

Attachment	**Description**
N/A	N/A

cc. Assessing and Controlling Risks

Details of the procedures used to assess inherent risks and control risks in accordance with Article 58 of the MRR:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.6 of this procedure is to describe the risk assessment to be used to comply with section 4 of the MRR Guidance Document No. 6 on Data flow activities and control system. The risk assessment lists the control activities and how they are commensurate with the identified inherent and control risks in accordance with the steps outlined in section 4.3 of the MRR guidance

	document.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

dd. Quality Assurance of Metering / Measuring Equipment

Details of the procedures used to ensure quality assurance of measuring equipment in accordance with Article 58 and 59 of the MRR.

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.7 gives details on the quality assurance of metering and measuring equipment: The calibration and maintenance records of the metering/measuring equipment identified in the Monitoring Plan will be reviewed in December of each year by the Engineering Lead or designee in advance of the annual emission period to ensure correct operation and that any required calibration and maintenance is scheduled. These records will be stored on the site's Computerised Maintenance Management System (INFOr). All maintenance and calibration of equipment will be maintained in line with current site procedures (PRC-0001602 Maintenance System, PRC-0001603 Site Calibration System). For external originating calibration equipment i.e. Natural Gas supplier meters, the Engineering Lead or designee will request meter calibration certificates annually and they shall be stored electronically at O Drive: EHS\College Park - Env\Phase II\GHG. Copies of calibration records are reviewed when received and appropriate action taken if required.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

ee. Quality Assurance of Information Technology used for Data Flow Activities

Details of the procedures used to ensure quality assurance of information technology used for data flow activities in accordance with Article 58 and 60 of the MRR:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.7 gives details on the quality assurance of IT used: Alexion corporate IT Policies ensure the quality assurance of the information technology used for the data flow activities. These policies address the control of access, back-up, recovery, continuity planning and the security of the information technology used to support the GHG monitoring and reporting requirements as per SOP-IT-0001 Alexion Network Security Policies and Procedures.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

ff. Review and Validation of Data

Details of the procedures used to ensure regular internal reviews and validation of data in accordance with Articles 58 and 62 of the MRR.

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.7 gives details on the review and validation of data: The EHS Lead or designee, in collaboration will the Engineering Lead or designee, will perform annual internal reviews on the processes outlined in this procedure (including data validation where relevant) along with a review of the items contained in Article 62 of the MRR. Data assessed as part of this review needs to conform to the associated Tier uncertainty level. Any items identified during the internal review which require correction will be logged in the enviroManager for follow-up and actioned for closure. Any non-conformances to the monitoring and reporting

	plan are to be identified as part of the internal review.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

gg. Corrections and Corrective Actions

Details of the procedures used to handle corrections and corrective actions in accordance with Articles 58 and 63 of the MRR:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.8 of the procedure gives details on the corrections and corrective actions: In the event of a failure of the monitoring and reporting methodology for the site, the site will put in place an interim monitoring and reporting methodology (to the highest tier available) until the conditions for application of the approved tiers have been restored. All necessary measures shall be taken to allow prompt restoration of the agreed monitoring methodology. The EPA will be notified without undue delay. This notification will include details of the reasons for deviation from monitoring methodology, interim measures taken and the plan of action to achieve a prompt restoration of compliance. Examples include failure to secure delivery details, compile reports as required under the monitoring and reporting methodology. A record of non-compliances to the Monitoring Plan will be maintained by the EHS Lead or designee and logged in enviroManager for follow-up. All deviations from the conditions of the GHG permit will be handled as per EHS-06 EHS Incident Reporting & Investigation).
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

hh. Control of Outsourced Activities

Details of the procedures used to control outsourced processes in accordance with Articles 59 and 64 of the MRR.

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.7 of the procedure gives details on the control of outsourced activities: All data relevant to the monitoring and reporting of GHG emissions is annually verified by an external qualified person per the requirements of the Accreditation and Verification Regulations (Commission Regulation (EC)). Consultants will be used to assist in the internal audits. These are the only out-sourced activities relevant to Articles 59 and 64 of the MRR.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

ii. Record Keeping and Documentation

Details of the procedures used to manage record keeping and documentation:

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.5 of the procedure gives details on record keeping and documentation: The site will keep records as required by the MRR for a period of at least 10 years. The records will be stored at the following Alexion electronic storage location unless as otherwise specified in this procedure: O Drive: EHS\College Park - Env\Phase II\GHG
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive
List of EN or other standards applied	N/A

jj. Risk Assessment

The results of a risk assessment that demonstrates that the control activities and procedures are commensurate with the risks identified:

Attachment	Description
EHS Risk Assessment - Emissions Trading.pdf	Risk Assessment

kk. Environmental Management System

Does your organisation have a documented Environmental Management System? No

12. Changes in Operation

ll. Changes in Operation

Article 24(1) of Commission Decision 2011/278/EC requires that Member States must ensure that all relevant information about any planned or effective changes to the capacity activity level and operation of an installation is submitted by the operator to the competent authority by 31 December each year. Article 12(3) of the MRR further provides that Member States may require information to be included in the monitoring plan of an installation for the purposes of meeting these requirements.

Details of the procedure used to ensure regular reviews are carried out to identify any planned or effective changes to the capacity activity level and operation of the installation that have an impact on the installation's allocation:

The procedure specified below cover the following:

- planning and carrying out regular checks to determine whether any planned or effective changes to the capacity activity level and operation of an installation are relevant under Commission Decision 2011/278/EC; and
- Procedures to ensure such information is submitted to the competent authority by 31 December of each year.

Title of procedure	Procedure for the Management of GHG Emissions
Reference for procedure	EHS-34

Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 6.9 of the procedure details the changes in operation: New GHG sources will be identified and their impact upon the Monitoring plan will be assessed as part of the site Management of Change system described in PRC-0500890 Design Change Management. All changes to the monitoring plan will be notified to the EPA without delay. The EHS Lead or designee shall without delay propose changes to the monitoring methodology and notify the EPA when: - Data availability has changed, allowing higher accuracy in the determination of emissions. - A change occurred in greenhouse gas emission sources - A change in the monitoring and reporting plan - The range of fuels detailed in the approved monitoring and reporting proposal has changed - Errors are detected in data resulting from the monitoring methodology - The EPA has requested a change. Each year in advance of the AEM report preparation or as necessary during the year the Engineering Lead or designee will determine if any planned or effective changes to the capacity, activity level and operation of an installation are relevant under Commission Decision 2011/278/EC. Such information shall be submitted to the EPA by 31 December each year.
Post or department responsible for the procedure and for any data generated	EHS Department
Location where records are kept	O Drive: EHS\College Park - Env\Phase II\GHG
Name of IT system used	Alexion O Drive

13. Abbreviations

mm. Abbreviations Acronyms or definitions

Abbreviations acronyms or definitions that have been used in this monitoring plan:

Abbreviation	Definition
ADMF	Alexion Dublin Manufacturing Facility
AEM	Annual Emissions
EHS	Environmental Health and Safety
EPA	Environmental Protection Agency
ETSWAP	EU Emissions Trading Scheme Monitoring and Reporting website for Ireland
GHG	Greenhouse Gas
M&R	Monitoring and Reporting

14. Additional Information

Any other information:

Attachment	Description
Phase I Boilers Burner Data Sheet.pdf	S4-S6 Data Sheet (a)
Phase I Emergency Generator Data Sheet.pdf	S9 Data Sheet
Phase I Gas cooker.pdf	S11 Data Sheet (a)
Phase I Gas Ovens.pdf	S11 Data Sheet (b)
Phase I Schedule of LPHW Boilers.pdf	S4-S6 Data Sheet (b)
Phase II Emergency Generators Data Sheet.pdf	S7-S8 Data Sheet
Phase II Gas Meter Cert.pdf	Gas Meter Calibration Cert
Phase II_Cochran Boilers_Tech Data Schedule.pdf	S1-S3 Data Sheet
EHS-35.01 Procedure for the preparation of the GHG Annual Emissions Report.pdf	Procedure for the preparation of the GHG Annual Environmental Report
Correspondence_Phase I Gas Supply.pdf	Correspondence - Phase I Gas Supply.pdf
GHg182 RFI Permit V1.docx	Additional Information request
Revised Thermal Inputs 2.xlsx	Calculation of thermal inputs
PRC-0501238 July 17.pdf	Procedure for the Management of GHG Emissions

15. Confidentiality

nn. Confidentiality Statement

It is the Environmental Protection Agency's policy to make information received by it in the course of its work open to inspection by any person on request. This is in accordance with the provisions of the European Communities (Access to Information on the Environment) Regulations 2007 to 2011.

In the event that you considered that some of the information being submitted of a confidential nature, then the nature of this information and the reasons why it should be considered confidential, with reference to the European Communities (Access to Information on the Environment) Regulations 2007 to 2011 and any amendments must be explicitly requested using the facility below. The Board of the Environmental Protection Agency will consider the requests and if the information can be deemed as confidential and necessary.

Notwithstanding any request for confidentiality, the Environmental Protection Agency explicitly reserves the right to release data to the Commission, including emissions and allocations to the public, on the basis that the data will be used for the purposes foreseen in Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

Please tick this box if you consider that any part of your form should be treated as commercially confidential/sensitive:	false

END of Appendix I.