

Notice: Variation of Permit

This permit has been varied by the Scottish Environment Protection Agency (SEPA) in exercise of its powers under Regulation 46 of the Pollution Prevention and Control (Scotland) Regulations 2012 (“the Regulations”). The terms used in this notice, unless otherwise defined, have the same meaning as in the Regulations.

Permit Number:	PPC/A/1008835/CP01
Site address:	Earls Road, Grangemouth, FK3 8XG
Operator:	Piramal Healthcare UK Limited Company Number – 05370591 Whalton Road, Morpeth, Northumberland, NE61 3YA
Variation Number:	VAR01
Effective Date of Variation:	29 November 2023
Details of Variation:	The permit is varied as specified in the Schedule attached.

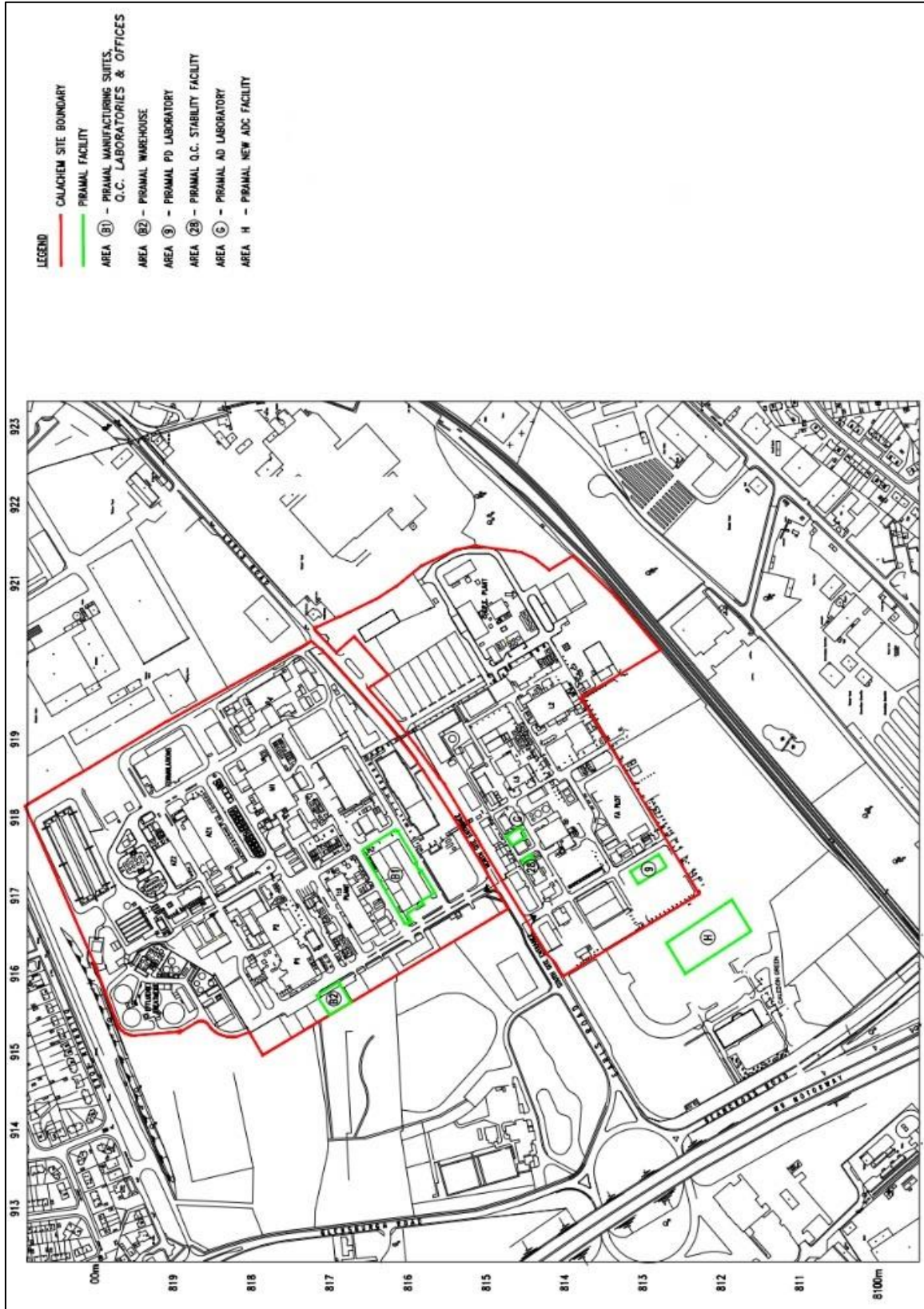
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Schedule

The permit has been varied as follows:

1. Condition 1.1.4.1, has been deleted and replaced by a new Condition 1.1.4.1, as follows:
 - 1.1.4.1 Facilities comprising of batch, multi - purpose chemical plant for the manufacture of pharmaceuticals in High Potency Substance Suites 1, 2, 5, 6, Pharma 1, and Pharma 2.
2. Condition 1.2 Site Plan, has been deleted and replaced by a new Condition 1.2 Site Plan, as follows:

1.2 Site Plan



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3. Table 2.1 Reporting Requirements, has been deleted and replaced by a new Table 2.1 Reporting Requirements, as follows:

Table 2.1 – Reporting Requirements

Summary of information to be reported/notified	Condition	Date/Within period/Frequency to be reported	Date next report due
Primary and deputy point of contact with SEPA	2.1.1, 2.1.2	Without delay in the event of a different person being appointed	As required
Incident initial report	2.4.4, 2.4.5	Without delay by telephone, confirmation in writing by next working day	As required
Incident investigation report	2.4.6	Within 14 days of the date of the incident unless otherwise agreed in writing with SEPA	As required
Incident Prevention and Mitigation Plan and review thereof	2.4.7	2 years	N/A
Resource utilisation systematic assessment and review and summary report of summary of raw material consumption efficiency/waste minimisation projects	2.5.3	4 years	Every 4 years from issue date of permit
Systematic inspection report on the condition of the internal floors, external yard surfaces, bunding, foul drainage systems and process drains	2.7.5	4 years	31 December 2024
Intention to cease permitted activities, or part thereof	2.9.2	No later than 2 months prior to the date of cessation	As required

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Summary of information to be reported/notified	Condition	Date/Within period/Frequency to be reported	Date next report due
Noise and Vibration Assessment	3.9.1	At least every 4 years	31 August 2014
Solvent mass emissions to air	4.2.2	Annually, within one month of the end of the reporting period	31 January 2014
Solvent mass emissions to air	5.2.2	Annually, within one month of the end of the reporting period	31 January 2014

4. Section 2.4 Incidents, has been deleted and replaced by a new Section 2.4 Incidents, as follows:

2.4 Incidents

2.4.1 In the event of an Incident, all necessary measures shall immediately be taken:

- a) to prevent, or where that is not practicable, to reduce emissions from the Permitted Installation;
- b) to limit the environmental consequences as a result of that Incident; and
- c) to prevent further possible Incidents.

2.4.2 Without prejudice to the requirements of Condition 2.4.1, in the event of a breach of any condition of this Permit the operator shall immediately take the measures necessary to ensure that compliance is restored in the shortest possible time.

2.4.3 Notwithstanding the requirements of Condition 2.4.1 and 2.4.2 where a breach of any condition of this Permit poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator shall suspend operation of the Permitted Installation or relevant part thereof until such time as it can be operated in compliance with this Permit.

2.4.4 In the event of an Incident and/or a breach of any condition of this Permit, the Operator shall notify SEPA by telephone without delay to 0800 80 70 60. A notification that relates to an incident shall include, as far as practicable, the information specified in Condition 2.4.5.

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- 2.4.5 The Operator shall confirm any Incident to SEPA in writing to the address specified by SEPA by the next working day after identification of the Incident. This confirmation shall include: the time and duration of the Incident; the receiving environmental medium or media where there has been any emission as a result of the Incident; an initial estimate of the quantity and composition of any emission; the measures taken to prevent or minimise any emission or further emission; and, a preliminary assessment of the cause of the Incident.
- 2.4.6 Any Incident notified to SEPA shall be investigated by the Operator, and a report of the investigation sent to SEPA. The report shall detail, as a minimum: the circumstances of the Incident; an assessment of any harm to the environment; and, the steps taken by the Operator to bring the Incident to an end. The report shall also set out proposals for remediation, where necessary, and for preventing a repetition of the Incident.
- 2.4.7 The Operator shall prepare, implement, and maintain an “Incident Prevention and Mitigation Plan”. This plan shall set out the steps to be taken by the Operator to ensure that all preventative measures are in place to avoid an Incident to any medium, and that any Incident that does occur is mitigated in the most appropriate manner.
- 2.4.8 At least every two years the Operator shall review the Incident Prevention and Mitigation Plan required under Condition 2.4.7. Each review of the Incident Prevention and Mitigation Plan shall be recorded and where the Operator makes any revisions to the said plan said revisions shall be recorded.

5. Section 2.5 Resource Utilisation, has been deleted and replaced by a new 2.5 Resource Utilisation, as follows:

2.5 Resource Utilisation

- 2.5.1 Over the specified four year period, the Operator shall carry out a systematic assessment to determine:-
- a) how and where raw materials (including water and fuel) and energy are used within the Permitted Installation;
 - b) the quantities of raw materials (including water and fuel) and energy that are used within the Permitted Installation;
 - c) how and where emissions and wastes are generated within the Permitted Installation;
 - d) the quantities of emissions and wastes generated within the Permitted Installation;

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- e) how and where raw materials (including water) and energy can be utilised more efficiently within the Permitted Installation to minimise emissions and waste; and
- f) which identified opportunities/projects, within a specified timeframe, will be implemented at the Permitted Installation.

2.5.2 The objective of this systematic assessment is to identify and implement any opportunities and/or projects, on an on-going basis, to:

- a) increase the efficiency of raw materials (including water and fuel) and energy;
- b) prevent, or where that is not practicable, minimise emissions and wastes generated through the inefficient operation of the Permitted Installation or associated processes; and
- c) reuse by-products (including heat and power) generated, where applicable, either from the Permitted Installation or from other activities.

When submitting the findings of the assessment, a summary of the progress of each of the opportunities / projects identified from the systematic assessment must be included. SEPA reserve the right to periodically review progress of these opportunities and projects during inspections of the Permitted Installation undertaken throughout the four year assessment period.

2.5.3 The assessment shall be recorded using the “systematic assessment of resource use and efficiency template”, (IED-T-04 available at www.sepa.org.uk) or equivalent format as agreed by SEPA and reported to SEPA at the end of the four year assessment cycle as specified in Table 2.1 and Table 2.2.

2.5.4 Annual data totals of raw materials (including water and fuel consumed) energy utilised, emissions and waste produced within the Permitted Installation, shall be recorded by the Operator annually in the relevant section of the “systematic assessment of resource utilisation” template. The Operator shall report that data to SEPA within 28 days of the end of the four year assessment cycle.

2.5.5 For the purposes of Conditions 2.5.1 and 2.5.2, “raw materials, energy and fuel” shall mean the materials listed in Table 2.2.

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6. Table 2.2 Raw Materials, Energy and Fuel, has been deleted and replaced by a new Table 2.2 Raw Materials, Energy and Fuel, as follows:

Table 2.2 – Raw Materials, Energy and Fuel

Raw material, Energy or Fuel	Unit of Measurement
All raw materials used in the manufacture of pharmaceutical products	Kg
Water	(m ³)
Electricity	(MWhrs)

7. Section 2.6, Waste Management, has been deleted.
8. After Condition 2.7.3, new Conditions 2.7.4 to 2.7.7, have been added as follows:
- 2.7.4. The Operator shall maintain plans that identify the configuration and specification of all drains and sub-surface pipework and the position and purpose of all sub-surface sumps and storage vessels that are used or have been used within the Site from the date of this Permit until the Permit is surrendered.
- 2.7.5. The operator shall at least every four years carry out a systematic inspection and review of the condition of the internal floors, external yard surfaces, bunding, foul drainage systems and process drains, the purpose of which shall be to ensure compliance with Condition 2.7.1. Each assessment shall be recorded and reported to SEPA.
- 2.7.6. The Operator shall at least once per year carry out a systematic assessment and inspection of internal floors, external yard surfaces and bunding in order to ensure compliance with Condition 2.7.1.
- 2.7.7. Any remedial action or upgrade identified by the systematic assessment and inspection required by Conditions 2.7.5 and 2.7.6 shall be completed within three months of completion of the survey or within such a timescale as is agreed in writing with SEPA.
9. Condition 5.1.2 has been deleted and replaced by a new Condition 5.1.2, as follows:
- 5.1.2 The Chemical Production Process specified in Condition 5.1.1 shall only be operated in High Potency Substances (HPS) Suite 2, Suite 4, Suite 5, Suite 6, Pharma 1, and Pharma 2.

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10. Condition 5.5.1 has been deleted and replaced by a new Condition 5.5.1, as follows:

5.5.1 In the event of a spillage of any material containing, or suspected to contain, a high potency substance within HPS Suite 2, Suite 5, Suite 6, Pharma 1, or Pharma 2 the effluent sump shall be sealed as soon as practicable so as to contain the spillage.

11. Table 5.1 Emissions to Air has been deleted and replaced by a new Table 5.1 Emissions to Air, as follows:

Table 5.1 – Emissions to Air

Emission Point Number	HPS2/1	HPS2/2	HPS5/1	HPS5/2	HPS5-6/1
Vent Plan Reference	7	12	45	50	44
Source of Emission	HPS Suite 2 store room extract fan EF3 exhaust	HPS Suite 2 HVAC extract fan EF1 exhaust	HPS Suite 2 HVAC extract fan 97/202B exhaust	HPS Suite 2 HVAC extract fan 97/203 exhaust	HPS Suite 2 HVAC extract fan 97/202 exhaust
Height (m)	6.0	6.0	6.0	6.0	6.0

Emission Point Number	AHU 03	AHU 01	AHU 02	AHU 04	AHU 05
Vent Plan Reference	AHU 03	AHU 01	AHU 02	AHU 04	AHU 05
Source of Emission	Pharma 1 Access Corridor	Pharma 1 Production Area	Pharma 1 Buffer Preparation Room	Pharma 2 Buffer Preparation	Pharma 2 Production Area
Height (m)	14.5	14.5	14.5	14.5	14.5

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Emission Point Number	AHU 06	AHU 07	AHU 08	AHU09	AHU 10
Vent Plan Reference	AHU 06	AHU 07	AHU 08	AHU09	AHU 10
Source of Emission	Pharma 2 Access Corridor	Primary Change Area	Micro Labs	Chemistry Labs/QC	Dispensary
Height (m)	14.5	14.5	18	18	18

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12. The Explanatory Notes have been deleted and replaced by new Explanatory Notes, as follows:

EXPLANATORY NOTES

(These Explanatory Notes do not form part of the Permit)

1. BAT

It should be noted that Regulation 22 of the Regulations specifies that it is a condition of a permit that the operator must use the best available techniques (BAT) for preventing or, where that is not practicable, reducing emissions from the installation. This is referred to as the 'general' BAT condition.

This does not apply to the extent that any other condition of the permit, or a standard rule which has effect as a standard rules condition, has the same effect.

Examples of aspects of the operation that have not been regulated by specific Conditions are general maintenance requirements.

BAT is defined in Regulation 4 of the Regulations as follows:

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

"available techniques" means those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the cost and advantages, whether or not the techniques are used or produced inside the UK, as long as they are reasonably accessible to the operator;

"best" means in relation to techniques, the most effective in achieving a high general level of protection of the environment as a whole;

"techniques" includes both the technology used and the way in which an installation is designed, built, maintained, operated and decommissioned.

"BAT conclusions" means a document containing the parts of a BAT reference document laying down the conclusions on best available techniques, their description, information to assess their applicability, the emission levels associated with the best available techniques, associated monitoring,

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associated consumption levels and, where appropriate, relevant site remediation measures.

“emerging technique” means a novel technique for an industrial activity that, if commercially developed, could, when compared to existing best available techniques provide a higher level of protection of the environment, or at least the same level of protection of the environment and higher cost savings.

“emission levels associated with best available techniques” means the range of emission levels obtained under normal operating conditions using a best available technique, or combination of best available techniques, as described in BAT conclusions, expressed as an average over a given period of time, under specified reference conditions.

Schedule 3 of the Regulations specifies the matters to be taken into account in determining BAT.

In considering BAT, SEPA would expect the Operator to have regard to all relevant PPC sector or other technical guidance, including BAT Reference Documents published by the European Commission and UK technical guidance published by the Environment Agency.

2. GENERAL STATUTORY REQUIREMENTS

The permit does not detract from any other statutory requirements applicable to you in respect of the Permitted Installation, such as any need to obtain planning permission or building regulations approval or any responsibilities under legislation for health, safety and welfare in the workplace.

3. APPEALS

If you are aggrieved by any of the conditions of the permit, you should initially contact the local SEPA Office at the address or telephone number below. Further information on your right of appeal and the appeals procedure is contained Regulation 58 and Schedule 8 of the Regulations.

4. SUBSISTENCE CHARGES

An annual subsistence charge will be payable in respect of the permit in terms of the current Pollution Prevention and Control (Scotland) Charging Scheme, or any relevant charging scheme made under Section 41 of the Environment Act 1995, copies of which are available from SEPA.

5. ADDRESS AND TELEPHONE NUMBERS

The contact address and telephone number for all information to be reported in terms of the permit is as follows:

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Type of communication	Address	Telephone/ Fax	Email
Initial notification of Pollution incident	N/A	0800 80 70 60 24 hour pollution hotline	N/A
Application for New Permit/Variation/ Transfer or Surrender	Scottish Environment Protection Agency 6 Parklands Avenue Eurocentral Holytown North Lanarkshire ML1 4WQ	03000 99 66 99	registry@sepa.org.uk
For all other communications including change notifications, data returns, incident reports and general enquiries	Scottish Environment Protection Agency 6 Parklands Avenue Eurocentral Holytown North Lanarkshire ML1 4WQ	03000 99 66 99	registry@sepa.org.uk

6. REVIEW OF CONDITIONS

The conditions of the permit will be periodically reviewed by SEPA.

7. PROPOSED CHANGE IN OPERATION OF INSTALLATION

It is a requirement of Regulation 45 of the Regulations that, if you propose to make a change in the operation of the installation, you must notify SEPA at least 14 days before making the change. The requirement under Regulation 45 does not apply if you have already made an application to SEPA for the variation of the conditions of the permit containing a description of the proposed change.

N.B. the requirements of Regulation 45 are in addition to any obligations you may have under the permit itself to only operate the Permitted Installation in the manner set out in the permit and to notify SEPA of proposed changes to the Permitted Installation.

Regulation 46 and Schedule 7 of the Regulations provide details on applications for variation of the permit in respect of proposed changes and substantial changes in operation.

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“Change in operation” and “substantial change in operation” are defined in Regulation 2 of the Regulations.

8. ENFORCEMENT & OFFENCES

If SEPA is of the opinion that you have contravened, or are contravening or are likely to contravene a Condition of the Permit, or an Incident or accident significantly affecting the environment has occurred as a result of the operation of the Installation it may serve an Enforcement Notice. Further details on Enforcement Notices are provided in Regulation 55 of the Regulations.

If SEPA is of the opinion that the operation of an installation poses an immediate danger to human health, threatens to create an immediate significant adverse effect upon the environment or involves a risk of serious pollution it must, in certain circumstances, serve a Suspension Notice on you. Further details on Suspension Notices are provided in Regulation 56 of the Regulations.

It is an offence to operate an installation covered by the Regulations without a permit or in breach of the conditions of the permit. It is an offence to fail to comply with the requirements of an Enforcement or Suspension Notice. It is an offence to intentionally make a false entry in any record required to be kept under a condition of a permit. Further details on offences and on penalties liable to be imposed upon conviction of an offence are provided in Regulation 67 of the Regulations.

Directors, managers and other individuals within a company may be held personally liable for offences under the Regulations.

All personnel who are responsible for fulfilling any condition of the permit should be made aware of these facts.

9. BREACH OF A PERMIT CONDITION

Regulation 52 of the Regulations specifies that the Operator of an Installation must immediately give notice to SEPA of any breach of a condition of the permit. It is an offence to fail, without reasonable excuse to comply with Regulation 52.

Any statement made by an operator to SEPA for the purposes of complying with regulation 52 may only be used in a prosecution for an offence where in giving evidence the operator makes a statement inconsistent with the initial notification.

All personnel who are responsible for fulfilling any Condition of the Permit should be made aware of these facts.

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**10. RECORDED SYSTEMS, PROCEDURES OR INFORMATION RECORDING/
RETURN REQUIREMENTS**

Where a condition requires any system, procedure or information record/return, the Operator may demonstrate compliance by making use of any relevant existing written system used for any other purpose and which meets the requirements of the relevant condition.

11. SYSTEMATIC ASSESSMENT (AND REVIEW)

Where a condition of the permit requires a “systematic assessment (and review)”, the assessment should be undertaken in a methodical and arranged manner. If you require guidance on the scope or extent of any assessment (and review) required to be undertaken, you should contact your local SEPA office at the address or telephone number given above.

12. COMMERCIAL CONFIDENTIALITY

Regulation 64 of the Regulations requires that SEPA maintain a register (“a Public Register”), whilst Schedule 9 of the Regulations sets out what the Public Register shall contain. Regulation 66(2) provides you with an opportunity to apply for exclusion from the Public Register for certain confidential information. Where you are required to supply SEPA with information whether via a condition in this permit, or otherwise, and that information falls under Schedule 9, if you wish it to be excluded from the public register as confidential information, then such a submission must include an application made under Regulation 66(2).