

Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Purolite Limited

**Unit C
Llantrisant Business Park
Llantrisant
CF72 8LF**

Permit number
EPR/AB3894ZF

Purolite

Permit number EPR/AB3894ZF

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows:

The operator has developed a range of chromatographic resins; these resins are based on agarose for sale into the pharmaceutical industry where they are used in the production of biosimilars and antibody therapies. The resin is manufactured from agarose, a naturally occurring polysaccharide.

The manufacturing process involves taking the powdered polysaccharide and making an aqueous solution with a specific concentration to give the final properties of the product. The solution is then mixed with an immiscible organic phase using a viscosity modifier to create an emulsion. The process is highly controlled to use the agitation speed in the emulsion to give highly specific particle size distributions. The emulsion is then cooled to create the solid resin bead. The organic phase and viscosity modifier is washed out using a solvent and then water.

The next stage of the process is to take the washed resin and crosslink the batch to increase the rigidity. This process uses a crosslinking agent which is accurately dosed into the process along with reagents to control the pH and added to prevent discolouration of the resin. Temperature control of this stage of the process is essential to achieve optimum crosslinking. The resin is then washed with water to remove excess reagents. During the process of creating the resin beads, a wide normal distribution of particle sizes is formed. For optimum performance in customer processes, the range of particles is reduced to a specification for each product. Screening removes the fine and coarse resin from the batch.

There are several emission points to air associated with the main process. These are listed in the site permit, however all emissions to air are insignificant and therefore no monitoring is required. All process effluents are discharged to foul sewer in-line with an authorised trade effluent consent, there are no direct discharges to surface water or land from the installation.

The site has a small gas fired boiler used to produce steam for the process.

The status log of the permit sets out the permitting history, including any changes to the permit reference number

Status Log of the permit		
Detail	Date	Comments
Application PAN-000869	Duly made 23/01/18	Application for an organic chemical manufacturing plant
Permit Issued EPR/AB3894ZF	31/05/18	

End of Introductory Note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/AB3894ZF

The Natural Resources Body for Wales (“Natural Resources Wales”) authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016

Purolite Limited (“the operator”),

whose registered office is

Unit D

Llantrisant Business Park

Llantrisant

Rhondda Cynon Taff

CF72 8LF

company registration number **01840987**

to operate an installation at

Unit C

Llantrisant Business Park

Llantrisant

Rhondda Cynon Taff

CF72 8LF

to the extent authorised by and subject to the conditions of this permit.

Name	Date
<i>A.M. Lewis</i>	31/05/18

Anna Lewis, Principal Permitting Officer

Authorised on behalf of Natural Resources Wales

Conditions

1 Management

1.1 General management

1.1.1 The operator shall manage and operate the activities:

- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
- (b) using sufficient competent persons and resources.

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Energy efficiency

1.2.1 The operator shall:

- (a) take appropriate measures to ensure that energy is recovered with a high level of energy efficiency and energy is used efficiently in the activities.
- (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
- (c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

1.3.1 The operator shall:

- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
- (b) maintain records of raw materials and water used in the activities;
- (c) review and record at least every four years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and
- (d) take any further appropriate measures identified by a review.

1.4 Avoidance, recovery and disposal of wastes produced by the activities

1.4.1 The operator shall take appropriate measures to ensure that:

- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and

- (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

- 2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the “activities”).

2.2 The site

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 to this permit.

2.3 Operating techniques

- 2.3.1
 - (a) The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Natural Resources Wales.
 - (b) If notified by Natural Resources Wales that the activities are giving rise to pollution, the operator shall submit to Natural Resources Wales for approval within the period specified, a revision of any plan specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.
- 2.3.2 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.3 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
 - (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and
 - (e) the waste code of the waste.
- 2.3.4 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

2.4 Improvement programme

- 2.4.1 The operator shall complete the improvements specified in Schedule 1 Table S1.3 by the date specified in that table unless otherwise agreed in writing by Natural Resources Wales.
- 2.4.2 Except in the case of an improvement which consists only of a submission to Natural Resources Wales, the operator shall notify Natural Resources Wales within 14 days of completion of each improvement.

3 Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 For the following activities referenced in schedule 1, table S1.1 (A1 to A2) where a substance is specified in schedule 3 tables S3.2 or S3.3 but no limit is set for it, the concentration of such substance in emissions to water from the relevant emission point shall be no greater than the background concentration.
- 3.1.4 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

- 3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.2.2 The operator shall:
 - (a) if notified by Natural Resources Wales that the activities are giving rise to pollution, submit to Natural Resources Wales for approval within the period specified, an emissions management plan which identifies and minimises the risks of pollution from emissions of substances not controlled by emission limits;
 - (b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.
- 3.2.3 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.3 Odour

- 3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of Natural Resources Wales, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.

- 3.3.2 The operator shall:
- (a) if notified by Natural Resources Wales that the activities are giving rise to pollution outside the site due to odour, submit to Natural Resources Wales for approval within the period specified, an odour management plan which identifies and minimises the risks of pollution from odour;
 - (b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.

3.4 Noise and vibration

- 3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of Natural Resources Wales, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.
- 3.4.2 The operator shall:
- (a) if notified Natural Resources Wales that the activities are giving rise to pollution outside the site due to noise and vibration, submit to Natural Resources Wales for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;
 - (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.

3.5 Monitoring

- 3.5.1 The operator shall, unless otherwise agreed in writing by Natural Resources Wales, undertake the monitoring specified in the following tables in schedule 3 to this permit:
- (a) point source emissions specified in tables S3.1, S3.2 and S3.3;
- 3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.
- 3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by Natural Resources Wales.
- 3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in Schedule 3 Tables S3.1, S3.2, S3.3 unless otherwise agreed in writing by Natural Resources Wales.

4 Information

4.1 Records

- 4.1.1 All records required to be made by this permit shall:
- (a) be legible;

- (b) be made as soon as reasonably practicable;
- (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and
- (d) be retained, unless otherwise agreed in writing by Natural Resources Wales, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
 - (i) off-site environmental effects; and
 - (ii) matters which affect the condition of the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by Natural Resources Wales.

4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by the permit to Natural Resources Wales using the contact details supplied in writing by Natural Resources Wales.

4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to Natural Resources Wales by 31 January (or other date agreed in writing by Natural Resources Wales) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;
- (b) the annual production /treatment data set out in schedule 4 table S4.2;
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by Natural Resources Wales, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
- (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to Natural Resources Wales, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.3 Notifications

4.3.1 The Operator shall

- (a) in the event that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
 - (i) inform Natural Resources Wales,

- (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
 - (b) in the event of a breach of any permit condition, the operator must immediately—
 - (i) inform Natural Resources Wales, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
 - (c) in the event of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.
- 4.3.2 Any information provided under condition 4.3.1(a)(i), or 4.3.1 (b)(i) where the information relates to the breach of a limit specified in the permit, shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where Natural Resources Wales has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform Natural Resources Wales when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to Natural Resources Wales at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 Natural Resources Wales shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- Where the operator is a registered company:
- (a) any change in the operator's trading name, registered name or registered office address; and
 - (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
- Where the operator is a corporate body other than a registered company:
- (a) any change in the operator's name or address; and
 - (b) any steps taken with a view to the dissolution of the operator.
- In any other case:
- (a) the death of any of the named operators (where the operator consists of more than one named individual);
 - (b) any change in the operator's name(s) or address(es); and
 - (c) any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case of them being in a partnership, dissolving the partnership.
- 4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) Natural Resources Wales shall be notified at least 14 days before making the change; and
 - (b) the notification shall contain a description of the proposed change in operation.

- 4.3.6 Natural Resources Wales shall be given at least 14 days' notice before implementation of any part of the site closure plan.

4.4 Interpretation

- 4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.
- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made "immediately", in which case it may be provided by telephone.

Schedule 1 - Operations

Activity ref.	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity and WFD Annex I and II operations	Limits of specified activity and waste types
A1	S4.1 A1 (a)(viii) Producing organic chemicals such as – plastic materials (for example polymers, synthetic fibres and cellulose based fibres)	Manufacture of agarose based resins for pharmaceutical use.	100 tonnes of product produced per annum All activities to be carried out within a dedicated building All activities to be carried out on an impermeable surface with sealed drainage
Directly Associated Activities			
A2	Raw materials and waste tanks	Tank farms	Storage of raw materials, intermediates, products & waste and associated emissions. All storage tanks are contained within a bund complying with CIRIA C736 and in an area with sealed drainage.

Table S1.2 Operating techniques

Description	Parts	Date Received
Application	The response to questions 3a and 3b in application form B3	20/12/2017
Application	The response to question 4 in application form B3	20/12/2017
Application	The response to Appendix 2 of application form B3	20/12/2017
Application	Air quality and odour impact assessment. Doc ref – ED 62380131	20/12/2017
Application	Best Available Techniques assessment. Doc ref – SPC0055/ME17.11.23/BAT Assessment/Purolite/December 2017	20/12/2017
Application	Emissions Management Plan (EMP) for an organic chemical manufacturing plant. Doc Ref - SPC0055/ME17.11.23/Emissions Management Plan/V1/December 2017	20/12/2017

Table S1.3 Improvement programme requirements

Ref.	Requirement	Date
1	The operator shall carry out monthly emission testing of AGE and Epichlorohydrin for 3 months from the main stack (A1) to ensure that the predictions made in the application are accurate and emissions are insignificant. The emissions will be compared to the emission benchmark for Benzene as quoted in the ' <i>Additional guidance for Speciality Organic Chemicals Sector guidance EPR 4.02</i> ' A report shall be submitted to NRW within 6 months for approval, if the results show emissions are not insignificant then additional measures will be proposed.	3 months of emission monitoring from date of commencement of operation.

Schedule 2 - Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels

Raw materials and fuel description	Specification
-	-

Schedule 3 – Emissions and monitoring

Table S3.1 Point source emissions to air – emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard(s) or method(s)
A1	Main vent stack					
A2	Hydrogen vent routing					
A3	Epichlorohydrin tank vent					
A4	Steam boiler					

No Monitoring Required

Table S3.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1 – tributary of the Nant Muchudd on the Eastern boundary of the site	Accumulated surface and roof water run-off					

No Monitoring Required

Table S3.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
S1 (trade effluent discharge to Dŵr Cymru Welsh Water Sewer	Process Effluent					

No Monitoring Required

Schedule 4 - Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S4.1 Reporting of monitoring data

Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air Parameters as required by condition 3.5.1		No Monitoring Required	
Emissions to water Parameters as required by condition 3.5.1		No Monitoring Required	

Table S4.2: Annual production/treatment

Parameter	Units
Total amount of product produced	tonnes

Table S4.3 Performance parameters

Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Total raw material used	Annually	tonnes
Waste disposal and/or recovery	Annually	tonnes

Table S4.4 Reporting forms

Media/parameter	Reporting format	Date of form
Energy Usage	Form Energy1 or other form as agreed in writing with Natural Resources Wales	31/05/18
Water Usage	Form Water Usage1 or other form as agreed in writing with Natural Resources Wales	31/05/18
Performance Indicators	Form Performance1 or other form as agreed in writing with Natural Resources Wales	31/05/18

Schedule 5 - Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the EP Regulations.

Part A

Permit Number	
Name of operator	Purolite Limited
Location of Facility	Unit C, Llantrisant Business Park, Llantrisant
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution

To be notified within 24 hours of detection

Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit

To be notified within 24 hours of detection unless otherwise specified below

Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B - to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 - Interpretation

“abatement equipment” means that equipment dedicated to the removal of polluting substances from releases from the installation to air or water media.

“accident” means an accident that may result in pollution.

“application” means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 5 to the EP Regulations.

“authorised officer” means any person authorised by Natural Resources Wales under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

“bi-annual” means twice per year with at least five months between tests;

“CEM” Continuous emission monitor

“CEN” means Comité Européen de Normalisation

“daily average” for releases of substances to air means the average of valid half-hourly averages over a calendar day during normal operation.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2016 No.1154 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“emissions of substances not controlled by emission limits” means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are not controlled by an emission limit.

“groundwater” means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Industrial Emissions Directive” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions

“ISO” means International Standards Organisation.

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

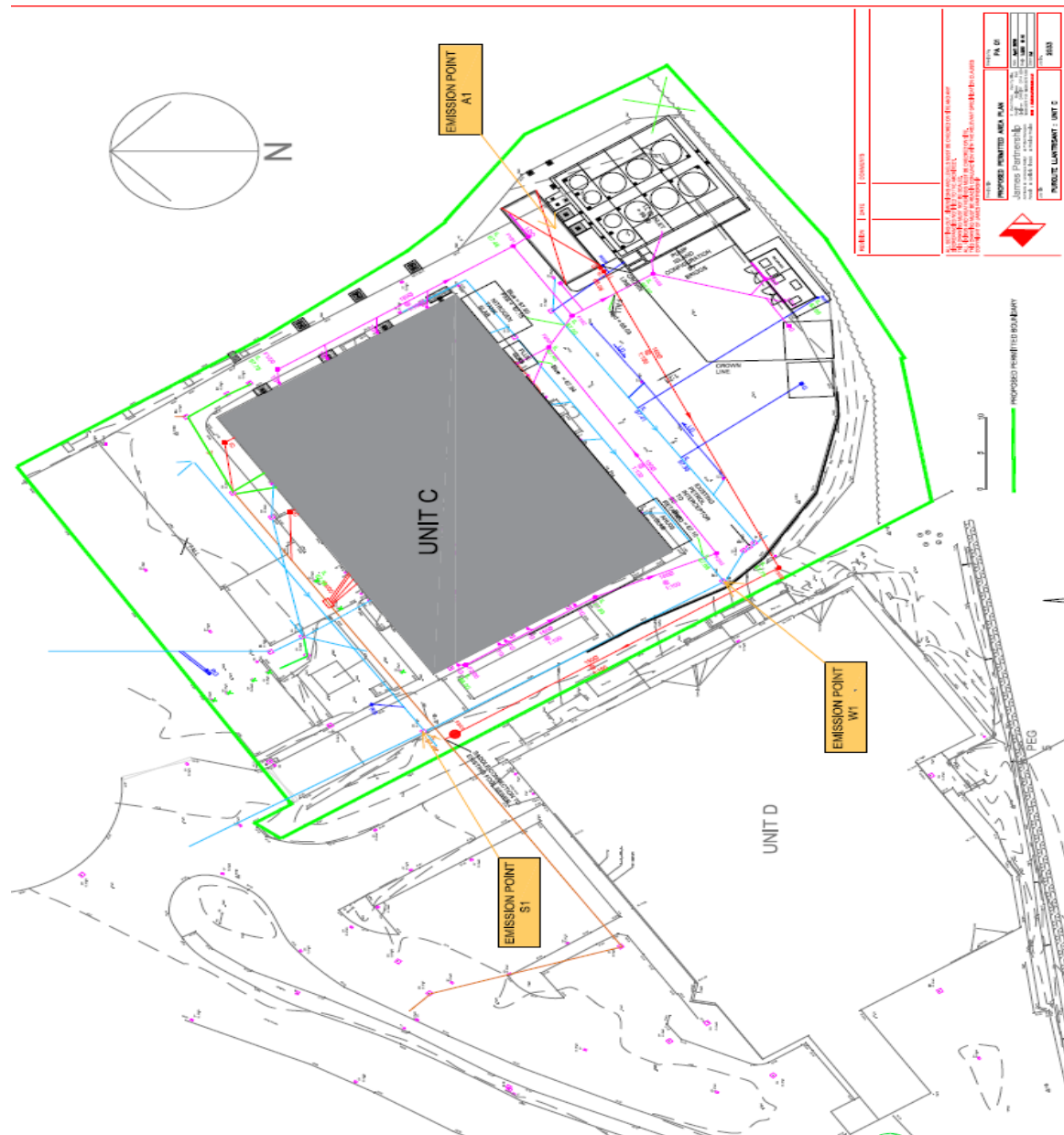
“quarter” means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

“quarterly” for reporting/sampling means after/during each 3-month period, January to March; April to June; July to September and October to December and, when sampling, with at least 2 months between each sampling date.

“Waste Framework Directive” or “WFD” means Waste Framework Directive 2008/98/EC of the European Parliament and of the Council on waste

“year” means calendar year ending 31 December.

Schedule 7 - Site plan



END OF PERMIT