

ENVIRONMENTAL PROTECTION AGENCY ACT 1992 AS AMENDED

NOTIFICATION OF A PROPOSED DETERMINATION OF A REVIEW OF AN INDUSTRIAL EMISSIONS LICENCE IN ACCORDANCE WITH SECTION 87(2) OF THE ENVIRONMENTAL PROTECTION AGENCY ACT 1992 AS AMENDED.

In pursuance of the powers conferred on it by the above mentioned Act the Agency proposes to determine the application for the review of the existing licence (Register No. P0643-02) granted to: AbbVie Ireland NL B.V., Manorhamilton Road, Ballytivnan, Sligo, County Sligo, CRO number 906838, under Section 90(2) of the said Act in the following manner:

The applicant submitted the application, plans, documents and other particulars on 17/09/2015. The number assigned to this Industrial Emissions licence review application in the Register of Licences is P0643-03.

It is proposed, for the reasons hereinafter set out, to grant a revised licence to the above named applicant to carry on the following activity

- : Production of pharmaceutical products including intermediates

at Manorhamilton Road, Ballytivnan, Sligo, County Sligo subject to twelve Conditions.

A copy of the proposed determination accompanies this notification.

OBJECTIONS/ORAL HEARING REQUESTS

The applicant and any other person may object to the proposed determination, in accordance with Section 87(5) of the EPA Act 1992 as amended. In accordance with Section 87(12) and Section 87(13) of the EPA Act 1992 as amended, objections must be received at any time no later than:

5.00 pm on 27th January 2016

A person making an objection may request an oral hearing of the objection, in accordance with Section 87(6) of the EPA Act 1992 as amended at any time no later than the date specified above.

It is important to note that any objection to the proposed determination/request for an oral hearing of the objection must be made either on-line on the Agency's website at www.epa.ie or by sending it by prepaid post to the Headquarters of the Agency, or by leaving it with an employee of the Agency **at the Headquarters of the Agency in Wexford**, during office hours, i.e. 9.00am to 5.00pm Monday to Friday.

An objection against the proposed determination must include the grounds for the objection. An objection and a request for an oral hearing of an objection must **each** be accompanied by the appropriate fee, and be addressed to the Office of Climate, Licensing & Resource Use, EPA Headquarters, P.O. Box 3000, Johnstown Castle Estate, County Wexford.

Note: The form and content of an objection is set out in the attached extract from the Environmental Protection Agency (Industrial Emissions) (Licensing) Regulations 2013. S.I. 137 of 2013.

The fees for an objection and request for an oral hearing of the objection are as set out in the Environmental Protection Agency (Licensing Fees) Regulations 1994 to 2006.



A valid objection/request for an oral hearing of the objection must be received at the headquarters of the Agency **no later than 5.00 pm on the applicable date above.**

In order to be considered valid, an objection and a request, each must also comply with the other statutory requirements in relation to objections and requests for oral hearings as set out in the EPA Act 1992, as amended, the EPA (Industrial Emissions) (Licensing) Regulations 2013 and the EPA (Licensing Fees) Regulations 1994 to 2013. Extracts from the Acts and the Regulations accompany this notification.

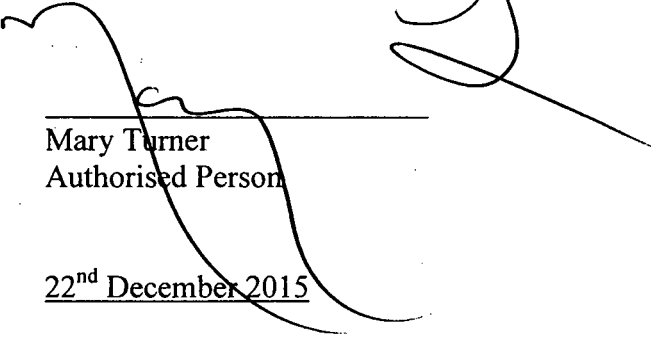
In the event that:

- (a) no objection is taken against the proposed determination or
- (b) an objection or objections is or are taken against the proposed determination and the objection or objections is or are withdrawn,

the Agency will make its decision in accordance with the proposed determination and grant the licence as soon as may be thereafter.

A copy of the proposed determination may be downloaded from the Agency's website www.epa.ie or obtained from the Office of Climate, Licensing & Resource Use, Environmental Licensing Programme, EPA Headquarters, P.O. Box 3000, Johnstown Castle Estate, County Wexford.

Signed on behalf of the said Agency:



Mary Turner
Authorised Person

Date of notification:

22nd December 2015

**Regulation 25 of the Environmental Protection Agency (Industrial Emissions)
(Licensing) Regulations 2013**

**Form and content
of objection**

- (1) An objection shall-
 - (a) be made in writing,
 - (b) state the name and address of the objector,
 - (c) state the reference number given under Regulation 38(2) to the application or the review in the register of licences and the subject matter of the objection,
 - (d) state the grounds for the objection and the reasons, considerations and arguments on which they are based, and
 - (e) be accompanied by a fee specified in accordance with Section 99A of the Act of 1992.
- (2) Without prejudice to Regulation 27, an objector shall not be entitled to elaborate in writing upon, or make further submissions in writing in relation to, the grounds for the objection stated in the objection, or to submit further grounds of objection and any such elaboration, submission or further grounds for the objection that is or are received by the Agency shall not be considered by it.
- (3)
 - (a) An objection shall be accompanied by such documents, particulars or other information relating to the objection as the objector considers necessary or appropriate.
 - (b) Without prejudice to Regulation 27, the Agency shall not consider any documents, particulars or other information submitted by an objector other than the documents, particulars or other information which accompanied the objection.
- (4) An objection shall be made -
 - (a) by sending the objection by prepaid post to the headquarters of the Agency, or
 - (b) by leaving the objection with an employee of the Agency at the headquarters of the Agency during office hours, or
 - (c) online via the website of the Agency where such facility is made available by the Agency.
- (5) The Agency shall as soon as may be after receipt of an objection acknowledge such receipt

Sections 87(6) & (7) of the Environmental Protection Agency Act 1992 as amended

Section 87
Processing of
applications for
licences or reviews
of licences

- (6) (a) A person making an objection under subsection (5) may request an oral hearing of the objection.
- (b) (i) A request for an oral hearing of an objection shall be made in writing to the Agency and shall be accompanied by such fee (if any) as may be payable in respect of such request in accordance with regulations under Section 99A.
- (ii) A request for an oral hearing of an objection which is not accompanied by such fee (if any) as may be payable in respect of such request shall not be considered by the Agency.
- (c) A request for an oral hearing of an objection shall be made before the expiration of the appropriate period, and any request received by the Agency after the expiration of that period shall not be considered by it.
- (7) An objection, or a request for an oral hearing under subsection (6), shall be made-
- (a) by sending the objection or request by prepaid post to the headquarters of the Agency, or
- (b) by leaving the objection or request with an employee of the Agency, at the headquarters of the Agency, during office hours, or
- (c) by such other means as may be prescribed.

FEES FOR OBJECTIONS AND ORAL HEARINGS

Summary of Environmental Protection Agency (Licensing Fees) Regulations 1994 to 2013

The following is a summary of the provisions of the above referenced regulations. Please refer to the full regulations for exact provisions.

Fees for an objection

- (1) A fee shall be paid to the Agency in respect of an objection.
- (2) Subject to (3) below, the fee payable under (1) above shall be the amount indicated in column (3) of the table below opposite the appropriate mention of objection in column (2) of the table below.
- (3) Where an objection is made to the Agency by -
 - (a) a local authority,
 - (b) a planning authority,
 - (c) a sanitary authority,
 - (d) the National Monuments Advisory Council,
 - (e) the Heritage Council
 - (f) Inland Fisheries Ireland,
 - (g) Failte Eireann
 - (h) in the case of an activity any part of which is situate within the functional area of the Shannon Free Airport Development Company Ltd., that Company, and
 - (h) An Taisce - The National Trust for Ireland,
 the fee payable in respect of the objection shall be the amount indicated in column (3) of the table below opposite the mention of a reduced fee for an objection in column (2) of the table below.

Fee for request for an oral hearing

- (1) Where a person making an objection under Section 87(5) of the Act of 1992, as amended, requests an oral hearing of the objection, a fee shall be paid to the Agency by that person. The fee payable in respect of a request for an oral hearing shall be the amount indicated in column (3) of the table below opposite the mention of the fee for an oral hearing in column (2) of the table below.

Column (1)	Column (2)	Column (3)
Objection Fees	Objection by the applicant or licensee	€253
	Objection by any other person other than a person mentioned at 3 above	€126
Reduced Objection fee (see 3 above)	Reduced fee for an objection	€63
Oral Hearing Fee	Fee for request for an oral hearing	€100



Headquarters
P.O. Box 3000
Johnstown Castle Estate
County Wexford
Ireland

**INDUSTRIAL EMISSIONS LICENCE
Proposed Determination**

Licence Register Number:	P0643-03
Company Register Number:	906838
Licensee:	AbbVie Ireland NL B.V.
Location of Installation:	Manorhamilton Road, Ballytivnan, Sligo, County Sligo

INTRODUCTION

This introduction is not part of the licence and does not purport to be a legal interpretation of the licence.

The installation is in a semi-rural location on the outskirts of Sligo town, on the Manorhamilton Road and operates 24 hours a day, seven days a week. The installation manufactures pharmaceutical products for a range of therapeutic areas, including antivirals, oncology and cardiovascular/renal, which can be delivered from small scale clinical trial supply to larger commercial manufacturing.

A new drug manufacturing process will include the increased use of dichloromethane. This licence review is principally to facilitate the abatement of chlorinated solvents by a new thermal oxidiser.

The licensed activity falls under the following category of Annex I of the Industrial Emissions Directive:

4.5. Production of pharmaceutical products including intermediates

The licence sets out in detail the conditions under which AbbVie Ireland NL B.V. will operate and manage this installation.

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Glossary of Terms

All terms in this licence should be interpreted in accordance with the definitions in the Environmental Protection Agency Act 1992 as amended, unless otherwise defined in the section.

Adequate lighting	20 lux measured at ground level.
AER	Annual Environmental Report.
Agreement	Agreement in writing.
Annually	All or part of a period of twelve consecutive months.
Application	The application by the licensee for this licence.
Appropriate Facility	A waste management facility, duly authorised under relevant law and technically suitable.
Attachment	Any reference to Attachments in this licence refers to attachments submitted as part of this licence application.
BAT	Best Available Techniques.
BAT conclusions	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, associated consumption levels and, where appropriate, relevant site remediation measures.
BAT reference document	A document drawn up by the Commission of the European Union in accordance with Article 13 of the Industrial Emissions Directive, resulting from the exchange of information in accordance with that Article of that Directive and describing, in particular, applied techniques, present emissions and consumption levels, techniques considered for the determination of best available techniques as well as BAT conclusions and any emerging techniques.
Biannually	At approximately six – monthly intervals.
Biennially	Once every two years.
BOD	5 day Biochemical Oxygen Demand (without nitrification suppression).
CEN	Comité Européen De Normalisation – European Committee for Standardisation.
COD	Chemical Oxygen Demand.

Consumption (in the context of Chapter V IED 2010/75/EU)	Shall mean the total input of organic solvents into an installation per calendar year, or any other 12-month period, less any volatile organic compounds that are recovered for reuse.
Containment boom	A boom that can contain spillages and prevent them from entering drains or watercourses or from further contaminating watercourses.
CRO Number	Company Register Number.
Daily	During all days of plant operation and, in the case of emissions, when emissions are taking place; with at least one measurement on any one day.
Day	Any 24 hour period.
Daytime	0700 hrs to 1900 hrs.
dB(A)	Decibels (A weighted).
Dioxin and furans	Means all polychlorinated dibenzo-p-dioxins and dibenzofurans listed in Part 2 of Annex VI of IED 2010/75/EU.
DO	Dissolved oxygen.
Documentation	Any report, record, results, data, drawing, proposal, interpretation or other document in written or electronic form which is required by this licence.
Drawing	Any reference to a drawing or drawing number means a drawing or drawing number contained in the application, unless otherwise specified in this licence.
Emission limits	Those limits, including concentration limits and deposition rates, established in <i>Schedule B: Emission Limits</i> , of this licence.
EMP	Environmental Management Programme.
Environmental damage	As defined in Directive 2004/35/EC.
EPA	Environmental Protection Agency.
European Waste Catalogue (EWC)	A harmonised, non-exhaustive list of wastes drawn up by the European Commission and published as Commission Decision 2000/532/EC, as amended by Commission Decision 2014/955/EU and any subsequent amendment published in the Official Journal of the European Community.
Evening Time	1900hrs to 2300hrs
Facility	Any site or premises used for the purpose of the recovery or disposal of waste.

Fortnightly	A minimum of 24 times per year, at approximately two week intervals.
Fugitive Emissions (in the context of Chapter V IED 2010/75/EU)	Fugitive emissions shall mean any emissions not in waste gases of volatile organic compounds into air, soil and water as well as, solvents contained in any products, unless otherwise stated in Part 2 of Annex VII of the Industrial Emissions Directive 2010/75/EU.
Gas Oil	Gas Oil as defined in Council Directive 1999/32/EC and meeting the requirements of S.I. No. 119 of 2008.
GC/MS	Gas chromatography/mass spectroscopy.
Groundwater	Has the meaning assigned to it by Regulation 3 of the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010).
ha	Hectare.
Hazardous Substances	Substances or mixtures as defined in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
Heavy metals	This term is to be interpreted as set out in "Parameters of Water Quality, Interpretation and Standards" published by the Agency in 2001. ISBN 1-84095-015-3.
Hours of operation	The hours during which the installation is authorised to be operational.
ICP	Inductively coupled plasma spectroscopy.
IE	Industrial Emissions.
Incident	The following shall constitute as incident for the purposes of this licence: <ul style="list-style-type: none"> (i) an emergency; (ii) any emission which does not comply with the requirements of this licence; (iii) any trigger level specified in this licence which is attained or exceeded; (iv) any indication that environmental pollution has, or may have, taken place.
Industrial Emissions Directive	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast).

Input (in the context of Chapter V IED 2010/75/EU)	Shall mean the quantity of organic solvents and their quantity in mixtures used when carrying out an activity, including the solvents recycled inside and outside the installation, and which are counted every time they are used to carry out the activity.
Installation	A stationary technical unit or plant where the activity concerned referred to in the First Schedule of EPA Act 1992 as amended is or will be carried on, and shall be deemed to include any directly associated activity, which has a technical connection with the activity and is carried out on the site of the activity.
Irish Water	Irish Water, Colvill House, 24/26 Talbot Street, Dublin 1.
K	Kelvin.
kPa	Kilopascals.
$L_{Aeq,T}$	This is the equivalent continuous sound level. It is a type of average and is used to describe a fluctuating noise in terms of a single noise level over the sample period (T).
$L_{Ar,T}$	The Rated Noise Level, equal to the L_{Aeq} during a specified time interval (T), plus specified adjustments for tonal character and/or impulsiveness of the sound.
Licensee	AbbVie Ireland NL B.V., Manorhamilton Road, Ballytivnan Sligo, County Sligo, CRO Number 906838.
List I	As listed in the EC Directives 2006/11/EC and 80/68/EEC and amendments.
List II	As listed in the EC Directives 2006/11/EC and 80/68/EEC and amendments.
Local Authority	Sligo County Council.
Maintain	Keep in a fit state, including such regular inspection, servicing, calibration and repair as may be necessary to perform its function adequately.
Mass flow limit	An emission limit value expressed as the maximum mass of a substance that can be emitted per unit time.
Mass flow threshold	A mass flow rate above which a concentration limit applies.
Monthly	A minimum of 12 times per year, at intervals of approximately one month.
Night-time	2300 hrs to 0700 hrs.
Noise-sensitive location (NSL)	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other installation or area of high amenity which for its proper enjoyment requires the absence of

	noise at nuisance levels.
Oil separator	Device installed according to the International Standard I.S. EN 858-2:2003 (Separator system for light liquids, (e.g. oil and petrol) – Part 2: Selection of normal size, installation, operation and maintenance).
Organic Compound	Shall mean any compound containing at least the element carbon and one or more of hydrogen, halogens, oxygen, sulphur, phosphorus, silicon or nitrogen, with the exception of carbon oxides and inorganic carbonates and bicarbonates.
Organic Solvent	As defined in Council Directive 2010/75/EU
PRTR	Pollutant Release and Transfer Register.
Quarterly	All or part of a period of three consecutive months beginning on the first day of January, April, July or October.
Relevant Hazardous Substances	Those substances or mixtures defined within Article 3 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) which, as a result of their hazardousness, mobility, persistence and biodegradability (as well as other characteristics), are capable of contaminating soil or groundwater and are used, produced and/or released by the installation.
Sample(s)	Unless the context of this licence indicates to the contrary, the term samples shall include measurements taken by electronic instruments.
Sanitary effluent	Wastewater from installation toilet, washroom and canteen facilities.
Soil	The top layer of the Earth's crust situated between the bedrock and the surface. The soil is composed of mineral particles, organic matter, water, air and living organisms.
SOP	Standard operating procedure.
Specified emissions	Those emissions listed in <i>Schedule B: Emission Limits</i> , of this licence.
Standard method	A National, European or internationally recognised procedure (e.g. I.S. EN, ISO, CEN, BS or equivalent); or an in-house documented procedure based on the above references; a procedure as detailed in the current edition of "Standard Methods for the Examination of Water and Wastewater" (prepared and published jointly by A.P.H.A., A.W.W.A. & W.E.F.), American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005, USA; or an alternative method as may be agreed by the Agency.
Storm water	Rain water run-off from roof and non-process areas.
The Agency	Environmental Protection Agency.
TOC	Total organic carbon.

Trade effluent	Trade effluent has the meaning given in the Water Services Act, 2007.
Trigger level	A parameter value, the achievement or exceedance of which requires certain actions to be taken by the licensee.
Volatile Organic Compound (VOC)	Shall mean any organic compound as well as the fraction of creosote, having at 293,15K a vapour pressure of 0,01kPa or more, or having a corresponding volatility under the particular conditions of use.
Waste	Any substance or object which the holder discards or intends or is required to discard.
Water Services Authority	Sligo County Council.
Weekly	During all weeks of plant operation and, in the case of emissions, when emissions are taking place; with at least one measurement in any one week.
WWTP	Waste water treatment plant.

Decision & Reasons for the Decision

The Environmental Protection Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this licence, any emissions from the activity will comply with and will not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Act 1992 as amended.

In reaching this decision the Environmental Protection Agency has considered the documentation relating to

- the existing licence, Register Number: P0643-02,
- the review application Register Number: P0643-03 and the supporting documentation received from the applicant;
- a submission received from a third party;
- the Inspector's Report dated 03/12/2015

and has carried out an Environmental Impact Assessment (EIA) and an Appropriate Assessment Screening of the likely significant effects of the licensed activity on European sites.

It is considered that the Inspectors Report dated 03/12/2015 contains a fair and reasonable assessment of the likely significant effects of the licensed activity on the environment, and adequately and accurately identify, describe and assess those effects. The assessment as reported in those documents is adopted as the assessment of the Agency. Having regard to this assessment, it is considered that the proposed activity, if managed, operated and controlled in accordance with the licence will not result in the contravention of any relevant environmental quality standards or cause environmental pollution.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects, is likely to have a significant effect on any European Site. In this context, particular attention was paid to the European sites at Sligo Harbour and Lough Gill. The Agency considered, for the reasons set out below, that the activity is not directly connected with or necessary to the management of the site as a European site and that it can be excluded, on the basis of objective information, that the activity, individually or in combination with other plans or projects will have a significant effect on a European site, and accordingly the Agency determined that an Appropriate Assessment of the activity was not required.

This determination was made in light of the scale and nature of emissions to the environment; in particular scale and nature of the emissions to air from the installation, and their distance to terrestrial habitats. Air dispersion modelling demonstrates that emissions from the proposed activity will not result in ground level concentrations which exceed the relevant air quality standards for the protection of vegetation and the environment. With regards to hydrologically linked sites, it has been determined that the Sligo municipal WWTP has the capacity to sufficiently treat the effluent discharges from the activity; and that furthermore, there are no direct emissions to surface water or emissions groundwater from the installation. Specific precautionary infrastructural and procedural measures are in place at the installation to prevent significant impacts occurring due to chemical spills or fire.

Part I Schedule of Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Act 1992 as amended, the Agency proposes to determine the review of the existing licence (Reg. No. P0643-02) granted to:

AbbVie Ireland NL B.V., Manorhamilton Road, Ballytivnan, Sligo, County Sligo, and CRO Number 906838

under Section 90(2) of the said Act to carry on the following activities:

:- Production of pharmaceutical products including intermediates

at Ballytivnan, Sligo, County Sligo subject to the following 12 Conditions, with the reasons therefor and associated schedules attached thereto.

Part II Schedule of Activities Refused

None of the proposed activities as set out in the licence application have been refused.

Part III Conditions

Condition 1. Scope

- 1.1 Industrial Emissions Directive activities at this installation shall be restricted to those listed and described in *Part I Schedule of Activities Licensed*, and shall be as set out in the licence application or as modified under Condition 1.4 of this licence and subject to the conditions of this licence.
- 1.2 Activities at this installation shall be limited as set out in *Schedule A: Limitations*, of this licence.
- 1.3 For the purposes of this licence, the installation authorised by this licence is the area of land outlined in red on Drawing No. IE0311237-22-DR-0001 of the application for this revised licence. Any reference in this licence to "installation" shall mean the area thus outlined in red. The licensed activity shall be carried on only within the area outlined.
- 1.4 No alteration to, or reconstruction in respect of, the activity, or any part thereof, that would, or is likely to, result in
- (i) a material change or increase in:
 - the nature or quantity of any emission;
 - the abatement/treatment or recovery systems;
 - the range of processes to be carried out;
 - the fuels, raw materials, intermediates, products or wastes generated, or
 - (ii) any changes in:
 - site management, infrastructure or control with adverse environmental significance;
- shall be carried out or commenced without prior notice to, and without the agreement of, the Agency.
- 1.5 The installation shall be controlled, operated and maintained, and emissions shall take place as set out in the licence. All programmes required to be carried out under the terms of this licence become part of this licence.
- 1.6 This licence is for the purpose of IE licensing under the EPA Act 1992 as amended only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.
- 1.7 This licence shall have effect in lieu of the licence granted on 21/11/2005 (Register No P0643-02).

Reason: *To clarify the scope of this licence.*

Condition 2. Management of the Installation

- 2.1 Installation Management
- 2.1.1 The licensee shall employ a suitably qualified and experienced installation manager who shall be designated as the person in charge. The installation manager or a nominated, suitably qualified and experienced deputy shall be present on the installation at all times during its operation or as otherwise required by the Agency.
- 2.1.2 The licensee shall ensure that personnel performing specifically assigned tasks shall be qualified on the basis of appropriate education, training and experience as required and shall be aware of the requirements of this licence.

2.2 Environmental Management System (EMS)

2.2.1 The licensee shall maintain and implement an Environmental Management System (EMS), which shall incorporate energy efficiency management. The EMS shall be reviewed by senior management for suitability, adequacy and effectiveness and updated on an annual basis.

2.2.2 The EMS shall include, as a minimum, the following elements:

2.2.2.1 Commitment of the management, including senior management.

2.2.2.2 An environmental policy defined for the installation that includes the continuous improvement for the installation by the management.

2.2.2.3 Management and Reporting Structure and responsibility.

2.2.2.4 The necessary procedures, objectives and targets, in conjunction with financial planning and investment.

2.2.2.5 Procedures that ensure employee involvement in ensuring compliance with environmental legislation.

2.2.2.6 A procedure for checking performance by sectoral benchmarking on a regular basis including energy efficiency.

2.2.2.7 Schedule of Environmental Objectives and Targets.

The licensee shall maintain and implement a Schedule of Environmental Objectives and Targets. The schedule shall, as a minimum, provide for a review of all operations and processes, including an evaluation of practicable options, for energy and resource efficiency, the use of cleaner technology, cleaner production and the prevention, reduction and minimisation of waste and shall include waste reduction targets. The schedule shall include time frames for the achievement of set targets and shall address a five-year period as a minimum. The schedule shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER).

2.2.2.8 Environmental Management Programme (EMP)

The licensee shall maintain and implement an EMP, including a time schedule, for achieving the Environmental Objectives and Targets prepared under Condition 2.2.2.3. The EMP shall include:

- designation of responsibility for targets;
- the means by which they may be achieved;
- the time within which they may be achieved.

The EMP shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER).

A report on the programme, including the success in meeting agreed targets, shall be prepared and submitted to the Agency as part of the AER. Such reports shall be retained on-site for a period of not less than seven years and shall be available for inspection by authorised persons of the Agency.

2.2.2.9 Documentation

- (i) The licensee shall maintain and implement an environmental management documentation system.
- (ii) The licensee shall issue a copy of this licence to all relevant personnel whose duties relate to any condition of this licence.

2.2.2.10 Corrective and Preventative Action

- (i) The licensee shall establish maintain and implement procedures to ensure that corrective and preventative action is taken should the specified requirements of this licence not be fulfilled. The

responsibility and authority for persons initiating further investigation and corrective and preventative action in the event of a reported non-conformity with this licence shall be defined.

- (ii) Where a breach of one or more of the conditions of this licence occurs, the licensee shall without delay take measures to restore compliance with the conditions of this licence in the shortest possible time and initiate any feasible preventative actions to prevent recurrence of the breach.
- (iii) All corrective and preventative actions shall be documented

2.2.2.11 Internal Audits

The licensee shall maintain and implement a programme for independent internal audits of the EMS. Such audits shall be carried out at least once every three years. The audit programme shall determine whether or not the EMS is being implemented and maintained properly, and in accordance with the requirements of the licence. Audit reports and records of the resultant corrective and preventative actions shall be maintained as part of the EMS in accordance with condition 2.2.2.9.

2.2.2.12 Awareness, Training and Competence

The licensee shall establish, maintain and implement procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment to ensure awareness and competence in their work area. Appropriate records of training shall be maintained.

2.2.2.13 Communications Programme

The licensee shall, maintain and implement a Public Awareness and Communications Programme to ensure that members of the public can obtain information at the facility, at all reasonable times, concerning the environmental performance of the facility.

2.2.2.14 Maintenance Programme

The licensee shall maintain and implement a programme for maintenance of all plant and equipment based on the instructions issued by the manufacturer/supplier or installer of the equipment. Appropriate record keeping and diagnostic testing shall support this maintenance programme. The licensee shall clearly allocate responsibility for the planning, management and execution of all aspects of this programme to appropriate personnel (see Condition 2.1 above). The maintenance programme shall use appropriate techniques and measures to ensure the optimisation of energy efficiency in plant and equipment.

2.2.2.15 Efficient Process Control

The licensee shall maintain and implement a programme to ensure there is adequate control of processes under all modes of operation. The programme shall identify the key indicator parameters for process control performance, as well as identifying methods for measuring and controlling these parameters. Abnormal process operating conditions shall be documented, and analysed to identify any necessary corrective action.

Reason: *To make provision for management of the activity on a planned basis having regard to the desirability of ongoing assessment, recording and reporting of matters affecting the environment.*

Condition 3. Infrastructure and Operation

- 3.1 The licensee shall establish and maintain, for each component of the installation, all infrastructure referred to in this licence in advance of the commencement of the licensed activities in that component, or as required by the conditions of this licence. Infrastructure specified in the application that relates to the environmental performance of the installation and is not specified in the licence, shall be installed in accordance with the schedule submitted in the application.
- 3.2 The licensee shall have regard to the following when choosing and/or designing any new plant/infrastructure:
- (i) Energy efficiency, and
 - (ii) The environmental impact of eventual decommissioning.
- 3.3 Installation Notice Board
- (i) The licensee shall maintain an Installation Notice Board on the installation so that it is legible to persons outside the main entrance to the installation. The minimum dimensions of the board shall be 1200 mm by 750 mm. The notice board shall be maintained thereafter.
 - (ii) The board shall clearly show:
 - (a) the name and telephone number of the installation;
 - (b) the normal hours of operation;
 - (c) the name of the licence holder;
 - (d) an emergency out of hours contact telephone number;
 - (e) the licence reference number; and
 - (f) where environmental information relating to the installation can be obtained.
- 3.4 The licensee shall maintain on all emission points such sampling points or equipment, including any data-logging or other electronic communication equipment, as may be required by the Agency. All such equipment shall be consistent with the safe operation of all sampling and monitoring systems.
- 3.5 In the case of composite sampling of aqueous emissions from the operation of the installation, a separate composite sample or homogeneous sub-sample (of sufficient volume as advised) shall be refrigerated immediately after collection and retained as required for EPA use.
- 3.6 The licensee shall clearly label and provide safe and permanent access to all on-site sampling and monitoring points and to off-site points as required by the Agency. The requirement with regard to off-site points is subject to the prior agreement of the landowner(s) concerned.
- 3.7 Tank, Container and Drum Storage Areas
- 3.7.1 All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds shall be designed having regard to Agency guidelines 'Storage and Transfer of Materials for Scheduled Activities' (2004).
- 3.7.2 All tank and drum storage areas shall, as a minimum, be bunded, either locally or remotely, to a volume not less than the greater of the following:
- (i) 110% of the capacity of the largest tank or drum within the bunded area; or
 - (ii) 25% of the total volume of substance that could be stored within the bunded area
- 3.7.3 All drainage from bunded areas shall be treated as contaminated unless it can be demonstrated to be otherwise. All drainage from bunded areas shall be diverted for collection and safe disposal, unless it can be deemed uncontaminated and does not exceed the trigger levels set for storm water emissions under 6.14.

- 3.7.4 All inlets, outlets, vent pipes, valves and gauges must be within the bunded area.
- 3.7.5 All tanks, containers and drums shall be labelled to clearly indicate their contents.
- 3.7.6 The licensee shall apply a leak detection system in accordance with BAT to all storage tanks, container and drum storage areas that contain liquid material other than water.
- 3.8 The licensee shall have in storage an adequate supply of containment booms and/or suitable absorbent material to contain and absorb any spillage at the installation. Once used, the absorbent material shall be disposed of at an appropriate facility.
- 3.9 A grease trap shall be maintained on the sewer pipeline in accordance with the manufacturer's instructions.
- 3.10 **Silt Traps and Oil Separators**

The licensee shall maintain silt traps and oil separators at the installation:

 - (i) Silt traps to ensure that all storm water discharges, other than from roofs, from the installation pass through a silt trap in advance of discharge;
 - (ii) Oil separators on the storm water discharge from yard areas. For the installation's tanker unloading area the oil separator shall be a Class I full retention separator. For general use yard areas the separator shall be a Class I by-pass separator.

The silt traps and separator shall be in accordance with I.S. EN-858-2: 2003 (separator systems for light liquids)
- 3.11 **Firewater Retention**
 - (i) In the event of a fire or a spillage to storm water, the site storm water shall be automatically diverted to the containment pond. The licensee shall have regard to any guidelines issued by the Agency with regard to firewater retention, including the Environmental Protection Agency Draft Guidance Note to Industry on the Requirements for Fire-Water Retention Facilities.
 - (ii) Firewater shall not be disposed of without the prior authorisation of the Agency.
- 3.12 All pump sumps, storage tanks, lagoons or other treatment plant chambers from which spillage of environmentally significant materials might occur in such quantities as are likely to breach local or remote containment or separators, shall be fitted with high liquid level alarms (or oil detectors as appropriate).
- 3.13 The provision of a catchment system to collect any leaks from flanges and valves of all over-ground pipes used to transport material other than water shall be examined. This shall be incorporated into a Schedule of Environmental Objectives and Targets set out in Condition 2. of this licence for the reduction in fugitive emissions.
- 3.14 All wellheads, as shown on Drawing No. IE0311237-22-DR-0002, attachment E of the application for this revised licence shall be adequately protected to prevent contamination or physical damage.
- 3.15 The licensee shall maintain in a prominent location on the site a wind sock, or other wind direction indicator, which shall be visible from the public roadway outside the site.
- 3.16 The thermal oxidiser when combusting waste streams with greater than 1% halogenated organic substances, expressed as chlorine, shall have and operate a system to prevent waste gas feed:
 - (i) At start-up, until the temperature of 1100°C has been reached;
 - (ii) Whenever the temperature of 1100°C is not maintained;
 - (iii) Whenever the continuous measurements show that any emission limit value is exceeded due to disturbances or failures of the purification devices;

- (iv) Whenever stoppages, disturbances, or failure of the purification devices or the measurement devices may result in the exceedance of the emission limit values.

Reason: *To provide for appropriate operation of the installation to ensure protection of the environment.*

Condition 4. Interpretation

4.1 Emission limit values for emissions to atmosphere in this licence shall be interpreted in the following way:

4.1.1 Continuous Monitoring

- (i) No 24 hour mean shall exceed the emission limit value.
- (ii) For TOC (as C) concentration limits, none of the arithmetic averages of all valid readings taken during any 24-hour period of operation of an installation or activity except start up and shut down operations and maintenance of equipment exceeds the emission limits values.
- (iii) 97% of all 30 minute mean values taken continuously over an annual period shall not exceed 1.2 times the emission limit value.
- (iv) No 30 minute mean value shall exceed twice the emission limit value.
- (v) For TOC (as C) concentration limits, none of the hourly averages exceeds the emission limits values by more than a factor of 1.5.

4.1.2 Non-Continuous Monitoring

- (i) For any parameter where, due to sampling/analytical limitations, a 30 minute sample is inappropriate, a suitable sampling period should be employed and the value obtained therein shall not exceed the emission limit value.
- (ii) For flow, no hourly or daily mean value, calculated on the basis of appropriate spot readings, shall exceed the relevant limit value.
- (iii) For TOC (as C) concentration limits, the emission limit values shall be considered to be complied with if (in one monitoring exercise):
 - (a) The average of all readings does not exceed the emission limit value and;
 - (b) None of the hourly values exceeds the emission limit values by more than a factor of 1.5.

At least three consecutive readings shall be obtained in each monitoring exercise.

- (iv) For all other parameters, no 30 minute mean value shall exceed the emission limit value.
- (v) Mass flow thresholds refer to a rate of discharge expressed in units of kg/h, above which the concentration emission limit value applies. Mass flow threshold rates shall be determined on the basis of a single 30 minute measurement (i.e. the concentration determined as a 30 minute average shall be multiplied by an appropriate measurement of flow and the result shall be expressed in units of kg/h).
- (vi) Mass flow emissions shall be calculated on the basis of the concentration, determined as an average over the specified period, multiplied by an appropriate measurement of flow. No value, so determined, shall exceed the mass flow limit value.

- 4.2 The concentration and volume flow limits for emissions to atmosphere specified in this licence shall be achieved without the introduction of dilution air and shall be based on gas volumes under standard conditions of:
- 4.2.1 From non-combustion sources:
Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).
- 4.2.2 From combustion sources:
Temperature 273K, Pressure 101.3 kPa, dry gas; 3% oxygen for liquid and gas fuels, 6% oxygen for solid fuels, 11% oxygen for thermal oxidiser (or as otherwise agreed by the Agency following the completion of the test programme).
- 4.3 Emission limit values for emissions to sewer/waters in this licence shall be interpreted in the following way:
- 4.3.1 Continuous Monitoring
- (i) No flow value shall exceed the specific limit.
 - (ii) No pH value shall deviate from the specified range.
 - (iii) No temperature value shall exceed the limit value.
- 4.3.2 Composite Sampling
- (i) No pH value shall deviate from the specified range.
 - (ii) For parameters other than pH and flow, eight out of ten consecutive composite results, based on flow proportional composite sampling, shall not exceed the emission limit value. No individual results similarly calculated shall exceed 1.2 times the emission limit value.
- 4.3.3 Discrete Sampling
- For parameters other than pH and temperature, no grab sample value shall exceed 1.2 times the emission limit value.
- 4.4 Where the ability to measure a parameter is affected by mixing before emission, then, with agreement from the Agency, the parameter may be assessed before mixing takes place.
- 4.5 Noise
- Noise from the installation shall not give rise to sound pressure levels ($L_{Aeq, T}$) measured at NSLs of the installation which exceed the limit value(s).

Reason: *To clarify the interpretation of limit values fixed under the licence.*

Condition 5. Emissions

- 5.1 No specified emission from the installation shall exceed the emission limit values set out in *Schedule B: Emission Limits*, of this licence. There shall be no other emissions of environmental significance.
- 5.2 No emissions, including odours, from the activities carried on at the site shall result in an impairment of, or an interference with amenities or the environment beyond the installation boundary or any other legitimate uses of the environment beyond the installation boundary.
- 5.3 No substance shall be discharged in a manner, or at a concentration, that, following initial dilution, causes tainting of fish or shellfish.
- 5.4 Emissions to Sewer
- 5.4.1 The licensee shall at no time discharge or permit to be discharged into the sewer any liquid matter or thing that is or may be liable to set or congeal at average sewer temperature or is capable of giving off any inflammable or explosive gas or any acid,

- alkali or other substance in sufficient concentration to cause corrosion to sewer pipes, penstock and sewer fittings or the general integrity of the sewer.
- 5.4.2 The licensee shall ensure that the effluent does not contain petroleum hydrocarbons or organic solvents (including chlorinated organic solvents) which would give rise to flammable or explosive vapours in the sewer.
- 5.4.3 No emission to sewer shall take place which gives rise to any reaction within the sewer, or to the liberation of by-products which may be of environmental significance.
- 5.4.4 The licensee shall at no time discharge or permit to be discharged to sewer any matter or thing that is capable of presenting any risk to the staff of the Agency, or of Irish Water (or its agents), whilst fulfilling any of their duties, or causes nuisance odours to arise from the sewer.
- 5.4.5 Non-trade effluent (e.g. firewater, accidental spillages) which occurs on-site shall not be discharged to sewer without the prior authorisation of Irish Water.
- 5.4.6 Only trade effluent wastewater which is generated within the boundary of the installation as a result of the licensed activities shall be permitted to be discharged to the Irish water sewer.
- 5.5 Any substance or mixtures which, because of their content of VOCs classified as carcinogens, mutagens, or toxic to reproduction under Regulation (EC) No 1272/2008, are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, (or the risk phrases R45, R46, R49, R60 or R61) shall be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time. Measures for replacement of such substances or mixtures, and the timeframe for replacement, shall be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2.2.2.7
- 5.6 Fugitive emission shall not exceed 15% of the total solvent input, where solvent consumption is greater than 50 tonnes per calendar year

Reason: *To provide for the protection of the environment by way of control and limitation of emissions and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended*

Condition 6. Control and Monitoring

- 6.1 Test Programme
- 6.1.1 The licensee shall prepare to the satisfaction of the Agency, a test programme for abatement equipment installed to abate emissions to atmosphere. This programme shall be submitted to the Agency in advance of implementation.
- 6.1.2 The programme, following agreement with the Agency, shall be completed within three months of the commencement of operation of the abatement equipment.
- 6.1.3 The criteria for the operation of the abatement equipment as determined by the test programme, shall be incorporated into the standard operating procedures.
- 6.1.4 The test programme shall as a minimum:
- (i) establish all criteria for operation, control and management of the abatement equipment to ensure compliance with the emission limit values specified in this licence; and
 - (ii) assess the performance of any monitors on the abatement system and establish a maintenance and calibration programme for each monitor.
- 6.1.5 A report on the test programme shall be submitted to the Agency within one month of completion.

- 6.2 The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out below and as in accordance with *Schedule C: Control & Monitoring*, of this licence.
- 6.2.1 Analyses shall be undertaken by competent staff in accordance with documented operating procedures.
- 6.2.2 Such procedures shall be assessed for their suitability for the test matrix and performance characteristics shall be determined.
- 6.2.3 Such procedures shall be subject to a programme of Analytical Quality Control using control standards with evaluation of test responses.
- 6.2.4 Where any analysis is sub-contracted it shall be to a competent laboratory.
- 6.3 The licensee shall ensure that:
- (i) sampling and analysis for all parameters listed in the Schedules to this licence; and
- (ii) any reference measurements for the calibration of automated measurement systems;
- shall be carried out in accordance with CEN-standards. If CEN standards are not available, ISO, national or international standards that will ensure the provision of data of an equivalent scientific quality shall apply.
- 6.4 All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activity is being carried on unless alternative sampling or monitoring has been agreed in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternative sampling and monitoring facilities shall be put in place. The use of alternative equipment, other than in emergency situations, shall be as agreed by the Agency.
- 6.5 Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission/discharge (or ambient conditions where that is the monitoring objective).
- 6.6 The licensee shall provide a proposal to be agreed by Irish Water, within a month of the date of grant of licence as to how it intends to accurately record the volume of effluent discharged to sewer.
- 6.7 The licensee shall ensure that groundwater monitoring well sampling equipment is available/installed on-site and is fit for purpose at all times. The sampling equipment shall be to Agency specifications.
- 6.8 All treatment/abatement and emission control equipment shall be calibrated and maintained in accordance with the instructions issued by the manufacturer/supplier or installer.
- 6.9 The frequency, methods and scope of monitoring, sampling and analyses, as set out in this licence, may be amended with the agreement of the Agency following evaluation of test results.
- 6.10 The licensee shall maintain a programme, to the satisfaction of the Agency, for the identification and reduction of fugitive emissions using an appropriate combination of best available techniques. This programme shall be included in the Environmental Management Programme.
- 6.11 The integrity and water tightness of all underground pipes, tanks, bunding structures and containers and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee. This testing shall be carried out by the licensee at least once every three years and reported to the Agency on each occasion. This testing shall be carried out in accordance with any guidance published by the Agency. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.
- 6.12 The stormwater drainage system (i.e., gullies, manholes, any visible drainage conduits and such other aspects as may be agreed) shall be visually inspected weekly, and desludged as necessary. Bunds, silt traps and oil separators shall be inspected weekly and desludged as

necessary. All sludge and drainage from these operations shall be collected for safe disposal. The drainage system, bunds, silt traps and oil interceptors shall be properly maintained at all times. The licensee shall maintain a drainage map on site. The drainage map shall be reviewed annually and updated as necessary.

6.13 An inspection system for the detection of leaks on all flanges and valves on over-ground pipes used to transport materials other than water shall be developed and maintained prior to the commencement of the activity.

6.14 Storm Water

6.14.1 A visual examination of the storm water discharges shall be carried out daily. A log of such inspections, shall be maintained.

6.14.2 A licensee shall, maintain suitable trigger levels for TOC in storm water discharges, such that storm waters exceeding these levels will be diverted for retention and suitable disposal. The licensee shall have regard to the Environmental Protection Agency "Guidance on the setting of trigger values for storm water discharges, to off-site surface waters at EPA IPPC and Waste licensed facilities" when establishing the suitable trigger levels.

6.15 Thermal Oxidiser

6.15.1 The temperature as measured within the combustion zone of the thermal oxidiser(s) shall be maintained at not less than the temperatures specified in *Schedule C: Control and Monitoring* of this licence. This temperature shall be continuously monitored and recorded and the results shall be available for inspection by authorised persons of the Agency at all reasonable times.

6.15.2 The thermal oxidiser shall be fitted with audible and visual alarms which shall be triggered when the temperature within the combustion chamber falls below that specified under Condition 6.15.1 above.

6.15.3 Gases shall only be introduced to the thermal oxidiser when the appropriate operating conditions [which as a minimum shall meet those set out in *Schedule C: Control and Monitoring* have been achieved. In particular:

(i) The burners in the combustion chamber are on and operating satisfactorily;

(ii) The temperature required under Condition 6.15.1 has been reached and maintained in the combustion chamber.

6.16 Solvent Management Plan

The licensee shall prepare and report a Solvent Management Plan (SMP) for the installation for each calendar year. The substances to be included in the SMP shall be determined with reference to the definition of an organic solvent in the IED 2010/75/EU and shall be agreed by the Agency each year. The SMP shall be prepared in accordance with any relevant guidelines in Annex VII Part 7 of the IED 2010/75/EU or as issued by the Agency and shall be submitted as part of the AER. The licensee shall keep records of the data from which the reported information was derived and supporting documentation including a description of the methodology used for data collection.

6.17 Noise

The licensee shall carry out a noise survey of the site operations as required by the Agency. The survey programme shall be undertaken in accordance with the methodology specified in the 'Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (NG4)' as published by the Agency.

6.18 Pollutant Release and Transfer Register (PRTR)

The licensee shall prepare and report a PRTR for the site. The substance and/or wastes to be included in the PRTR shall be determined by reference to EC Regulations No. 166/2006 concerning the establishment of the European Pollutant Release and Transfer Register. The PRTR shall be prepared in accordance with any relevant guidelines issued by the Agency and shall be submitted electronically in specified format and as part of the AER.

6.19 The licensee shall permit authorised persons of the Agency and Irish Water, to inspect, examine and test, at all reasonable times, any works and apparatus installed in connection with the process effluent and to take samples of the process effluent.

6.20 Soil Monitoring

The licensee shall carry out monitoring for relevant hazardous substances in soil and groundwater at the site of the installation. The substances for monitoring shall be identified by the licensee by undertaking a risk based assessment. The risk assessment, sampling and monitoring shall be carried out in accordance with any guidance published by the Agency. The licensee shall have regard to the 'Classification of Hazardous and Non-Hazardous Substances in Groundwater' as published by the Agency

6.20.1 Groundwater monitoring shall be carried out at least once every five years. Monitoring shall be carried out in accordance with *Schedule C.6 Groundwater Monitoring*, of this licence.

6.20.2 Soil monitoring shall be carried out at the site of the installation at least once every ten years. Monitoring shall be carried out in accordance with *Schedule C.6 Soil Monitoring*, of this licence.

Reason: *To provide for the protection of the environment by way of treatment and monitoring of emissions and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended.*

Condition 7. Resource Use and Energy Efficiency

7.1 The licensee shall carry out an audit of the energy efficiency of the site within one year of the date of grant of this licence. The audit shall be carried out in accordance with the guidance published by the Agency, "Guidance Note on Energy Efficiency Auditing". The energy efficiency audit shall be repeated at intervals as required by the Agency.

7.2 The audit shall identify all practicable opportunities for energy use reduction and efficiency and the recommendations of the audit will be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2 above.

7.3 The licensee shall identify opportunities for reduction in the quantity of water used on site including recycling and reuse initiatives, wherever possible. Reductions in water usage shall be incorporated into Schedule of Environmental Objectives and Targets.

7.4 The licensee shall undertake an assessment of the efficiency of use of raw materials and potential use of waste solvents in all processes, having particular regard to the reduction in waste generated. The assessment should take account of best international practice for this type of activity. Where improvements are identified, these shall be incorporated into the Schedule of Environmental Objectives and Targets.

Reason: *To provide for the efficient use of resources and energy in all site operations.*

Condition 8. Materials Handling

- 8.1 The licensee shall ensure that waste generated in the carrying on of the activity shall be prepared for re-use, recycling or recovery or, where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment.
- 8.2 Disposal or recovery of waste on-site shall only take place in accordance with the conditions of this licence and in accordance with the appropriate National and European legislation and protocols.
- 8.3 Waste sent off-site for recovery or disposal shall be transported only by an authorised waste contractor. The waste shall be transported from the site of the activity to the site of recovery/disposal only in a manner that will not adversely affect the environment and in accordance with the appropriate National and European legislation and protocols.
- 8.4 The licensee shall ensure that, in advance of transfer to another person, waste shall be classified, packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling.
- 8.5 The loading and unloading of materials shall be carried out in designated areas protected against spillage and leachate run-off.
- 8.6 Waste shall be stored in designated areas, protected as may be appropriate against spillage and leachate run-off. The waste shall be clearly labelled and appropriately segregated.
- 8.7 No waste classified as green list waste in accordance with the EU Shipment of Waste Regulations (Council Regulation EEC No. 1013/2006, as may be amended) shall be consigned for recovery without the agreement of the Agency.
- 8.8 Waste for disposal/recovery off-site shall be analysed in accordance with *Schedule C: Control & Monitoring*, of this licence.
- 8.9 Unless approved in writing, in advance, by the Agency the licensee is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.
- 8.10 The licensee shall neither import waste into the State nor export waste out of the State except in accordance with the relevant provisions of Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14th June 2006 on shipments of waste and associated national regulations.

Reason: *To provide for the appropriate handling of material and the protection of the environment.*

Condition 9. Accident Prevention and Emergency Response

- 9.1 The licensee shall ensure that a documented Accident Prevention Procedure is in place that addresses the hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment. This procedure shall be reviewed annually and updated as necessary.
- 9.2 The licensee shall ensure that a documented Emergency Response Procedure is in place, that addresses any emergency situation which may originate on-site. This procedure shall include provision for minimising the effects of any emergency on the environment. This procedure shall be reviewed annually and updated as necessary.

9.3 Incidents

9.3.1 In the event of an incident the licensee shall immediately:

- (i) carry out an investigation to identify the nature, source and cause of the incident and any emission arising therefrom;
- (ii) isolate the source of any such emission;
- (iii) evaluate the environmental pollution, if any, caused by the incident;
- (iv) identify and execute measures to minimise the emissions/malfunction and the effects thereof;
- (v) identify the date, time and place of the incident;
- (vi) notify the Agency and other relevant authorities.

9.3.2 Where an incident or accident that significantly affects the environment occurs, the licensee shall, without delay take measures to limit the environmental consequences of the incident or accident and to prevent further incident or accident.

Reason: *To provide for the protection of the environment.*

Condition 10. Decommissioning & Residuals Management

- 10.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal/recovery any soil, subsoil, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.
- 10.2 Decommissioning Management Plan (DMP)
- 10.2.1 The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted to the Agency for agreement within six months of the date of grant of the licence.
- 10.2.2 The plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the agreement of the Agency.
- 10.2.3 The licensee shall have regard to the Environmental Protection Agency's Guidance on Assessing and Costing Environmental Liabilities (2014) and, as appropriate, Guidance on Environmental Liability Risk Assessment, Residuals Management Plans, and Financial Provision (2006) and the baseline report, when implementing Condition 10.2.1 above.
- 10.3 The Decommissioning Management Plan shall include, as a minimum, the following:
- (i) a scope statement for the plan;
 - (ii) the criteria that define the successful decommissioning of the activity or part thereof, which ensures minimum impact on the environment;
 - (iii) a programme to achieve the stated criteria;
 - (iv) where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan; and
 - (v) details of the costings for the plan and the financial provisions to underwrite those costs.
- 10.4 A final validation report to include a certificate of completion for the Decommissioning Management Plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

Reason: To make provision for the proper closure of the activity ensuring protection of the environment.

Condition 11. Notification, Records and Reports

- 11.1 The licensee shall notify the Agency by both telephone and either email or webform, to the Agency's headquarters in Wexford, or to such other Agency office as may be specified by the Agency, as soon as practicable after the occurrence of any of the following:
- (i) an incident or accident that significantly affects the environment;
 - (ii) any release of environmental significance to atmosphere from any potential emissions point including bypasses;
 - (iii) any breach of one or more of the conditions attached to this licence;
 - (iv) any malfunction or breakdown of key control equipment or monitoring equipment set out in *Schedule C: Control and Monitoring*, of this licence which is likely to lead to loss of control of the abatement system; and
 - (v) any incident with the potential for environmental contamination of surface water or groundwater, or posing an environment threat to air or land, or requiring an emergency response by the Local Authority.
- The licensee shall include as part of the notification, date and time of the incident, summary details of the occurrence, and where available, the steps taken to minimise any emissions.
- 11.2 In the event of any incident which relates to discharges to sewer having taken place, the licensee shall notify the Local Authority and Irish Water as soon as practicable after such an incident.
- 11.3 The following shall be notified, as soon as practicable after the occurrence of any incident which relates to a discharge to water:
- (i) Inland Fisheries Ireland in the case of discharges to receiving waters
 - (ii) Marine Institute (MI), Sea Fisheries Protection Authority (SFPA), Food Safety Authority of Ireland (FSAI) and Bord Iascaigh Mhara (BIM) in the case of discharges likely to impact a shellfish water.
- 11.4 The licensee shall make a record of any notification made under Condition 11.1. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident or accident. The record shall include all corrective actions taken to manage the incident or accident, minimise wastes generated and the effect on the environment, and avoid recurrence. In the case of a breach of a condition, measures to restore compliance. The licensee shall, as soon as practicable following notification, submit to the Agency the record.
- 11.5 The licensee shall record all complaints of an environmental nature related to the operation of the activity. Each such record shall give details of the date and time of the complaint, the name of the complainant (if provided), and give details of the nature of the complaint. A record shall also be kept of the response made in the case of each complaint.
- 11.6 The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all other such monitoring which relates to the environmental performance of the installation.
- 11.7 The licensee shall as a minimum ensure that the following documents are accessible at the site:
- (i) the licences relating to the installation;
 - (ii) the current EMS for the installation including all associated procedures, reports, records and other documents;
 - (iii) the previous year's AER for the installation;
 - (iv) records of all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all

other such monitoring which relates to the environmental performance of the installation;

- (v) relevant correspondence with the Agency;
- (vi) up-to-date site drawings/plans showing the location of key process and environmental infrastructure, including monitoring locations and emission points;
- (vii) up-to-date Standard Operational Procedures for all processes, plant and equipment necessary to give effect to this licence or otherwise to ensure that standard operation of such processes, plant or equipment does not result in unauthorised emissions to the environment; and
- (viii) any elements of the licence application or EIS documentation referenced in this licence.

This documentation shall be available to the Agency for inspection at all reasonable times.

11.8 The licensee shall submit to the Agency, by the 31st March of each year, an AER covering the previous calendar year. This report, which shall be to the satisfaction of the Agency, shall include as a minimum the information specified in *Schedule D: Annual Environmental Report*, of this licence and shall be prepared in accordance with any relevant guidelines issued by the Agency.

11.9 A full record, which shall be open to inspection by authorised persons of the Agency at all times, shall be kept by the licensee on matters relating to the waste management operations and practices at this site. This record shall as a minimum contain details of the following:

- (i) the tonnages and EWC Code for the waste materials sent off-site for disposal/recovery;
- (ii) the names of the agent and carrier of the waste, and their waste collection permit details, if required (to include issuing authority and vehicle registration number);
- (iii) details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its permit/licence details and issuing authority, if required;
- (iv) written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site;
- (v) details of all waste consigned abroad for Recovery and classified as 'Green' in accordance with the EU Shipment of Waste Regulations (Council Regulation EEC No. 1013/2006, as may be amended). The rationale for the classification must form part of the record;
- (vi) details of any rejected consignments;
- (vii) details of any approved waste mixing;
- (viii) the results of any waste analyses required under *Schedule C: Control & Monitoring*, of this licence; and
- (ix) the tonnage and EWC Code for the waste materials recovered/disposed on-site.

11.10 The licensee shall submit report(s) as required by the conditions of this licence to the Agency's Headquarters in Wexford, or to such other Agency office as may be specified by the Agency.

11.11 All reports shall be certified accurate and representative by the installation manager or a nominated, suitably qualified and experienced deputy.

11.12 The licensee shall provide to Irish Water plans and details, in formats outlined below, and within six months of date of grant of licence. These details shall include:

- (i) Location of pipes and sewers, manholes, storage tanks, effluent treatment systems.
- (ii) Diameters, materials, and upstream and downstream invert levels of all sewers on site.
- (iii) Cover level, invert level, chamber dimensions for each manhole on site.
- (iv) Details of effluent treatment systems, including dimensions.
- (v) The condition of all sewers and manholes.

- (vi) Plans and details of the discharge point to the Irish Water sewer.
 - (vii) Location and invert level of the discharge point or chamber.
 - (viii) Details of the discharge chamber including internal dimensions, type of construction, incoming and outgoing pipe diameter, incoming and outgoing pipe material, internal features or devices such as flow control and backdrops.
 - (ix) The plan drawings and relevant information shall be provided in ESRI shapefile or AutoCAD DWG format, with attributes geo-coordinated to Irish National Grid or Irish Transverse Mercator. All levels shall be to Malin Head OD. The adopted coordinate system shall be clearly identified.
- 11.13 A summary report of daily volumes of effluent discharged to sewer, along with monitoring and analysis data, as specified in *Schedule B: Emission Limits*, of this licence and *Schedule C: Control & Monitoring*, of this licence, shall be forwarded on a quarterly basis to both Irish Water and Water Services section, Sligo County Council.
- 11.14 The license shall notify Irish Water and the Water Services section of Sligo County Council (along with the Agency) in advance of any changes which may result in a change in nature, characteristics or volume of the treated wastewater.
- 11.15 The licensee shall submit details of the operation, maintenance, calibration, monitoring, and backup of control equipment, for the aqueous water solvent stripper to the Agency for agreement within one month of date of grant of licence. The criteria for the operation of the solvent stripper shall be incorporated into standard operating procedures.
- 11.16 Thermal Oxidiser

In the event of any of the following:

- (i) The failure of any piece of control equipment related to the thermal oxidiser or failure of any continuous monitor related to operating parameters or emissions of the thermal oxidiser, where a contingency system, which must have been previously agreed by the Agency, is not implemented;
- (ii) the failure of the thermal oxidiser to achieve the operating parameters and emission limit values given in *Schedule B: Emission Limits* of this licence;
- (iii) where a by-pass of the thermal oxidiser is initiated;

The relevant processes shall, be shut down immediately and in a manner consistent with safety and the protection of the environment, unless otherwise agreed by the Agency. Emission of contaminated exhaust air through the by-pass shall be notified to the Agency in accordance with the requirements of Condition 11 of this licence or such relevant guidance as issued by the Agency.

The licensee shall maintain a detailed log of all bypass events, including date, time, duration, operational activities at the time of bypass, and time taken to shut down all relevant processes. A log of bypass events shall be submitted to the Agency on a quarterly basis, and shall also be reported annually as part of the AER.

The licensee shall maintain a record of the operation of thermal oxidiser. The record shall include the date and time, operating temperature, residence time and percentage of halogenated organic substances, expressed as chlorine, treated in the thermal oxidiser.

Reason: *To provide for the collection and reporting of adequate information on the activity.*

Condition 12. Financial Charges and Provisions

12.1 Agency Charges

12.1.1 The licensee shall pay to the Agency an annual contribution of €10,842.96, or such sum as the Agency from time to time determines, having regard to variations in the extent of reporting, auditing, inspection, sampling and analysis or other functions carried out by the Agency, towards the cost of monitoring the activity as the Agency considers necessary for the performance of its functions under the Environmental Protection Agency Act 1992 as amended. The first payment shall be a pro-rata amount for the period from the date of grant of this licence to the 31st day of December, and shall be paid to the Agency within one month from the date of grant of the licence. In subsequent years the licensee shall pay to the Agency such revised annual contribution as the Agency shall from time to time consider necessary to enable performance by the Agency of its relevant functions under the Environmental Protection Agency Act 1992 as amended and all such payments shall be made within one month of the date upon which demanded by the Agency.

12.1.2 In the event that the frequency or extent of monitoring or other functions carried out by the Agency needs to be increased, the licensee shall contribute such sums as determined by the Agency to defray its costs in regard to items not covered by the said annual contribution.

12.2 Irish Water Charges

12.2.1 The licensee shall pay to Irish Water such sum as may be required for any additional monitoring other than the scheduled monitoring required under this licence. These charges cover the cost of sample collection, and analysis, by Irish Water. Payment shall be made on demand.

12.2.2 The licensee shall pay to Irish Water such sum as may be determined from time to time, having regard to the variations in the cost of providing drainage and the variation in effluent reception and treatment costs. Payment to be made on demand.

12.3 Environmental Liabilities

12.3.1 The licensee shall as part of the AER, provide an annual statement as to the measures taken or adopted at the site in relation to the prevention of environmental damage, and the financial provisions in place in relation to the underwriting of costs for remedial actions following anticipated events (including closure) or accidents/incidents, as may be associated with the carrying on of the activity.

12.3.2 The licensee shall arrange for the completion, by an independent and appropriately qualified consultant, of a comprehensive and fully costed Environmental Liabilities Risk Assessment (ELRA) which addresses the liabilities from past and present activities. The assessment shall include those liabilities and costs identified in Condition 10 for execution of the DMP. A report on this assessment shall be submitted to the Agency for agreement within twelve months of date of grant of this licence. The ELRA shall be reviewed as necessary to reflect any significant change on site, and in any case every three years following initial agreement. Review results are to be notified as part of the AER.

12.3.3 Within twelve months of date of grant of this licence, the licensee shall, to the satisfaction of the Agency, make financial provision to cover any liabilities associated with the operation (including closure, restoration and aftercare). The amount of indemnity held shall be reviewed and revised as necessary, but at least annually. Proof of renewal or revision of such financial indemnity shall be included in the annual 'Statement of Measures' report identified in Condition 12.3.1.

12.3.4 The licensee shall revise the cost of closure, restoration and aftercare annually and any adjustments shall be reflected in the financial provision made under Condition 12.3.3.

- 12.3.5 The licensee shall have regard to the Environmental Protection Agency's Guidance on Assessing and Costing Environmental Liabilities (2014) and, as appropriate, Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision (2006) and the baseline report, when implementing Conditions 12.3.2 and 12.3.3 above.

Reason: *To provide for adequate financing for monitoring and financial provisions for measures to protect the environment and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended.*

SCHEDULE A: Limitations

There shall be no solid or liquid waste material combusted in any thermal oxidiser operating at the installation.

SCHEDULE B: Emission Limits**B.1 Emissions to Air**

Emission Point Reference No.:	A1-1, A1-2 (Boilers)	
Location:	North of Utilities building (170604E, 337494N)	
Volume to be emitted:	Maximum in any one day:	313,128 m ³
	Maximum rate per hour:	13,047 m ³
Minimum discharge height:	26 m above ground	

Parameter	Emission Limit Value
Oxides of sulphur (as SO ₂)	70 mg/m ³
Nitrogen oxides (as NO ₂)	180 mg/m ³
Carbon Monoxide	100 mg/m ³

Emission Point Reference No.:	A2-1(a) (Existing Thermal Oxidiser) ^{Note 1}	
Location:	Eastern side of Utilities building (170669E, 337475N)	
Volume to be emitted:	Maximum in any one day:	95,088 m ³
	Maximum rate per hour:	3,692 m ³
Minimum discharge height:	10 m above ground	

Parameter	Emission Limit Value
Oxides of sulphur (as SO ₂)	70 mg/m ³
Nitrogen oxides (as NO ₂)	200 mg/m ³
Carbon monoxide	300 mg/m ³
Class I Organics ^{Note 2}	20mg/m ³ (at mass flows of >0.1 kg/hour)
Class II Organics ^{Note 2}	100mg/m ³ (at mass flows >0.5 kg/hour)
Total Organic Carbon (as C)	20 mg/m ³
Sum of individual VOCs (hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61)	2 mg/m ³ (at mass flows >0.01kg/h)

Note 1: To be decommissioned upon completion of the commissioning phase of the new thermal oxidiser.

Note 2: Limits set for a class total as specified in section 6.1 of BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals.

Emission Point Reference: A2-1(b) Exhaust from Cryogenic condenser

Location: Eastern side of Utilities building (170637E, 337473N)

Volume to be emitted: Maximum in any one day: 21,600 m³
Maximum rate per hour: 900 m³

Minimum discharge height: 10 m above ground

Parameter	Emission Limit Value
Total Organic Carbon (as C)	20 mg/m ³
Class I Organics ^{Note 1}	20 mg/m ³ (at mass flows of >0.1 kg/hour)
Class II Organics ^{Note 1}	100 mg/m ³ (at mass flows of >0.5 kg/hour)
Sum of individual VOCs (hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61)	2 mg/m ³ (at mass flows >0.01kg/h)
Sum of Individual Halogenated VOCs (hazard statements H341, H351 or risk phrases R40, R68)	20 mg/m ³ (at mass flows >0.10kg/h)

Note 1: Limits set for a class total as specified in section 6.1 of BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals.



Emission Point Reference No.: A2-1(c) (New Thermal Oxidiser)

Location: Eastern side of Utilities building (170674E, 337478N)

Volume to be emitted: Maximum in any one day: 95,088 m³
Maximum rate per hour: 3,692 m³

Minimum discharge height: 15 m above ground

Parameter	Emission Limit Value
Oxides of sulphur (as SO ₂)	70 mg/m ³
Nitrogen oxides (as NO ₂)	200 mg/m ³
Carbon monoxide	300 mg/m ³
Total Organic Carbon (as C)	20 mg/m ³
Sum of individual VOCs (hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61)	2 mg/m ³ (at mass flows >0.01kg/h)
Class I Organics ^{Note 1}	20mg/m ³ (at mass flows of >0.1 kg/hour)
Class II Organics ^{Note 1}	100mg/m ³ (at mass flows >0.5 kg/hour)
Sum of Individual Halogenated VOCs (hazard statements H341, H351 or risk phrases R40, R68)	20 mg/m ³ (at mass flows >0.10kg/h)
Chlorides (as HCl)	10 mg/m ³

Note 1: Limits set for a class total as specified in section 6.1 of BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals.

Parameter	Emission Limit Value
Dioxins/Furans (as TEQ) ^{Note 1}	6-8 hour sample - 0.1 ng/m ³

Note 1: The emission limit value refers to the total concentration of dioxins and furans calculated using the concept of toxic equivalence in accordance with Annex VI Part 2 of Council Directive 2010/75/EC.

Emission Point Reference No.: A2-2 (Scrubber)
Location: Eastern side of Utilities building (170634E, 337472N)
Volume to be emitted: Maximum in any one day: 19,200 m³
Maximum rate per hour: 800 m³
Minimum discharge height: 11.2 m above ground

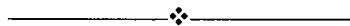
Parameter	Emission Limit Value
Chlorides (as HCl)	10 mg/m ³
Formic acid	10 mg/m ³

Emission Point Reference No.: A2-3 (Dust extraction system Building 40)
Location: Building 40 (170578E, 337466N)
Volume to be emitted: Maximum in any one day: 432,000 m³
Maximum rate per hour: 18,000 m³
Minimum discharge height: 15.4 m above ground

Parameter	Emission Limit Value
Total Dust	1 mg/m ³
Dust (as active pharmaceutical ingredients)	0.15 mg/m ³ (at mass flow > 1g/h)

Emission Point Reference No.: A2-4 (Central dust extraction system Building 20)
Location: Building 20 (170586E, 37414N)
Volume to be emitted: Maximum in any one day: 96,480 m³
Maximum rate per hour: 4,020 m³
Minimum discharge height: 16.9 m above ground

Parameter	Emission Limit Value
Total Dust	1 mg/m ³
Dust (as active pharmaceutical ingredients)	0.15 mg/m ³ (at mass flow > 1g/h)



Emission Point Reference No.: A2-5 (Synthroid dust extraction system)
Location: Building 20 (170586E, 337414N)
Volume to be emitted: Maximum in any one day: 72,000 m³
 Maximum rate per hour: 3,000 m³
Minimum discharge height: 15.2 m above ground

Parameter	Emission Limit Value
Total Dust	1 mg/m ³
Dust (as active pharmaceutical ingredients)	0.15 mg/m ³ (at mass flow > 1g/h)



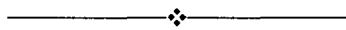
B.2 Emissions to Water

There shall be no emissions to water of environmental significance.

B.3 Emissions to Sewer

Emission Point Reference No: SE1
 Name of Receiving Waters: Irish Water sewer
 Location: South of site, close to southern boundary (170637E, 337413N)
 Volume to be emitted: Maximum in any one day: 300 m³
 Maximum rate per hour: 12.5 m³

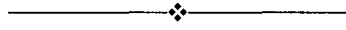
Parameter	Emission Limit Value
Temperature	40 °C (max)
pH	6 - 9
Toxicity	10 TU
	mg/l
BOD	450
COD	1,300
Suspended Solids	350
Ammonia (as N)	25
Total Phosphorus (as P)	10
Sulphates	1,000
Chlorides	1,500
Detergents (as MBAS)	20
Oils, Fats and Grease	10



B.4 Noise Emissions

Daytime dB L _{Ar,T} (30 minutes)	Evening time dB L _{Ar,T} (30 minutes)	Night-time dB L _{Aeq,T} (15-30 minutes)
55	50	45 ^{Note 1}

Note 1: There shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise-sensitive location.



SCHEDULE C: Control & Monitoring

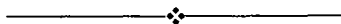
C.1.1 Control of Emissions to Air

Emission Point Reference No.: A2-1(a)

Description of Treatment: Thermal oxidiser

Control Parameter	Monitoring	Key Equipment ^{Note 1}
Burner flame operation	Continuous	Flame sensor
Inlet and outlet temperature	Continuous	Thermocouple
Inlet and exhaust air flow	Continuous	Flow meter
Pressure of flue gas	Continuous	Pressure transmitter
Temperature	Continuous	Thermocouple

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

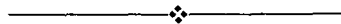


Emission Point Reference: A2-1(b) Exhaust from Cryogenic condenser

Description of Treatment: Cryogenic condenser

Control Parameter	Monitoring	Key Equipment ^{Note 1}
Temperature	Continuous	Thermocouple
Pressure drop	Continuous	Pressure transmitter

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.



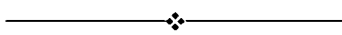
Emission Point Reference No.: A2-1(c) New thermal oxidiser

Description of Treatment: Thermal oxidiser

% halogenated organic substances, expressed as chlorine	Minimum thermal oxidiser operating temperature	Minimum residence time
Less than or equal to 1%	900°C	1 second
Greater than 1%	1100°C	2 seconds

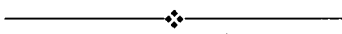
Control Parameter	Monitoring	Key Equipment Note 1
Burner flame operation	Continuous	Flame sensor
Inlet and outlet temperature	Continuous	Thermocouple
Inlet and exhaust air flow	Continuous	Flow meter
Pressure of flue gas	Continuous	Pressure transmitter
Temperature	Continuous	Thermocouple
Quench Note 2	To be agreed by the Agency	To be agreed by the Agency

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.
 Note 2: Quench control parameters to be agreed by the Agency under test programme specified in Condition 6.1.



Control Parameter	Monitoring	Key Equipment Note 1
pH – scrubber liquid	Continuous	pH meter and recorder
Liquid flow	Continuous	Flow indicator
Air flow	Continuous	Differential pressure gauge

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.



Control Parameter	Monitoring	Key Equipment Note 1
HEPA filter efficiency	Continuous differential pressure	Pressure sensor and alarm
Air flow	Annually	Pitot tube and manometer

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Emission Point Reference No.:
 Description of Treatment:

A2-3, A2-4, A2-5
 HEPA extraction

C.1.2. Monitoring of Emissions to Air

Emission Point Reference No.: A1-1, A1-2

Parameter	Monitoring Frequency	Analysis Method/Technique
SO _x	Biannually	Flue gas analyser
NO _x	Biannually	Flue gas analyser
CO	Biannually	Flue gas analyser
Particulates	Annually	Isokinetic/Gravimetric
Combustion efficiency	Biannually	Flue gas analyser

Emission Point Reference No.: A2-1(a) Existing Thermal Oxidiser

Parameter	Monitoring Frequency	Analysis Method/Technique
Oxides of Sulphur (as SO ₂)	Continuous	Infra-red analyser
Nitrogen of oxides (as NO ₂)	Continuous	Infra-red analyser
Carbon monoxide	Continuous	Infra-red analyser
Oxygen	Continuous	Electrochemical cell
Total Organic Carbon (as C)	Continuous	Flame ionisation detection or other method to be agreed by the Agency
Temperature	Continuous	Temperature probe
Flow	Continuous	Continuous flow meter
VOCs with hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61	Monthly, when in use	To be agreed by the Agency
Class I Organics	Quarterly	Adsorption/GC-MS or other method to be agreed by the Agency
Class II Organics	Quarterly	Adsorption/GC-MS or other method to be agreed by the Agency

Emission Point Reference:

A2-1(b) Exhaust from Cryogenic condenser

Parameter	Monitoring Frequency ^{Note 1}	Analysis Method/Technique
Total Organic Carbon (as C)	Continuous	Flame ionisation detection or other method to be agreed by the Agency
Class I organics	Monthly	Adsorption/GC-MS or other method to be agreed by the Agency
Class II organics	Monthly	Adsorption/GC-MS or other method to be agreed by the Agency
VOCs with hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61	Monthly	Adsorption/GC-MS or other method to be agreed by the Agency
Halogenated VOCs (hazard statements H341, H351 or risk phrases R40, R68)	Monthly	Adsorption/GC-MS or other method to be agreed by the Agency

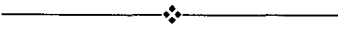
Note 1: Monitoring required only for when in use.



Emission Point Reference No.:

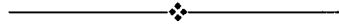
A2-1(c) New Thermal Oxidiser

Parameter	Monitoring Frequency	Analysis Method/Technique
Oxides of Sulphur (as SO ₂)	Continuous	Infra-red analyser
Nitrogen of oxides (as NO ₂)	Continuous	Infra-red analyser
Carbon monoxide	Continuous	Infra-red analyser
Oxygen	Continuous	Electrochemical cell
Total Organic Carbon (as C)	Continuous	Flame ionisation detection or other method to be agreed by the Agency
Temperature	Continuous	Temperature probe
Flow	Continuous	Continuous flow meter
VOCs with hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61	Monthly	To be agreed by the Agency
Sum of Individual Halogenated VOCs (hazard statements H341, H351 or risk phrases R40, R68)	Monthly	To be agreed by the Agency
Class I Organics	Quarterly	Adsorption/GC-MS or other method to be agreed by the Agency
Class II Organics	Quarterly	Adsorption/GC-MS or other method to be agreed by the Agency
Dioxins/Furans	Biannually	Standard Method.
HCl	Monthly	Standard Method.



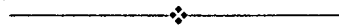
Emission Point Reference No.: A2-2 Scrubber

Parameter	Monitoring Frequency	Analysis Method/Technique
Chlorides (as HCl)	Monthly	Standard Methods
Formic acid	Monthly	Standard Methods



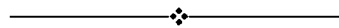
Emission Point Reference No.: A2-3, A2-4, A2-5 Dust Extraction

Parameter	Monitoring Frequency	Analysis Method/Technique
Dust (as active pharmaceutical ingredients)	Annually	Isokinetic/gravimetric



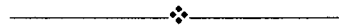
C.2.1. Control of Emissions to Water

There are no Emissions to Water of environmental significance.



C.2.2. Monitoring of Emissions to Water

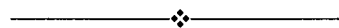
There shall be no emissions to water of environmental significance.



C.2.3. Monitoring of Storm Water Emissions

Emission Point Reference No.: SW 1

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	Continuous	pH electrode/meter
TOC	Continuous	TOC analyser
COD	Weekly	Standard Method
Visual Inspection	Daily	Sample and examine for colour and odour



C.3.1. Control of Emissions to Sewer

Emission Point Reference No.: SE 1

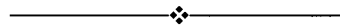
Description of Treatment: Waste Water Treatment

Equipment:

Control Parameter	Monitoring	Key Equipment ^{Note 1}
Flow (Final Effluent)	Continuous	Flow Meter/Recorder
pH (Final Effluent)	Continuous	pH Meter/Recorder
Aqueous waste solvent stripper	As agreed by the Agency ^{Note 2}	As agreed by the Agency
Grease traps	Monthly	Visual Inspection

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Note 2: Monitoring programme to be agreed by the Agency under Condition 11.15



C.3.2. Monitoring of Emissions to Sewer

Emission Point Reference No.: SE 1

Parameter	Monitoring Frequency	Analysis Method/Technique
Flow	Continuous	On-line flow meter with recorder
pH	Continuous	pH electrode/meter and recorder
Temperature	Daily	Thermometer
TOC	Continuous	On-line TOC meter with recorder
Chemical Oxygen Demand	Daily ^{Note 1}	Standard Method
Biochemical Oxygen Demand	Weekly ^{Note 1}	Standard Method
Suspended Solids	Daily ^{Note 1}	Gravimetric
Total Nitrogen (Kjeldahl, nitrate, nitrite)	Monthly ^{Note 1}	Standard Method
Ammonia (as N)	Weekly ^{Note 1}	Ion selective electrode
Total Phosphorus (as P)	Weekly ^{Note 1}	Standard Method
Chlorides	Monthly ^{Note 1}	Standard Method
Sulphates (as SO ₄)	Monthly ^{Note 1}	Standard Method
Total Heavy Metals	Annually ^{Note 1}	Atomic Absorption/ICP
Organic Solvents ^{Note 2}	Quarterly ^{Note 1}	Gas Chromatography
Oils, fats & greases	Quarterly ^{Note 1}	Standard Method
Detergents (as MBAS)	Quarterly ^{Note 1}	Standard Method
Pharmaceutical Actives	Annually and as required by the Agency under Condition 6.7 ^{Note 1}	To be agreed by the Agency
Respirometry	Annually	Standard Method

Note 1: All samples shall be collected on a 24 hour flow proportional composite sampling basis.

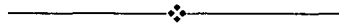
Note 2: Screening for priority pollutant list substances. (such as US EPA volatile and/or semi-volatile compounds). This analysis shall include those organic solvents in use in the process, which are likely through normal process operations to be diverted to the waste water streams.

C.4 Waste Monitoring

Waste Class	Frequency	Parameter	Method
Solvent waste from manufacture of API and from solvent stripper.	Per consignment ^{Note 1}	See Note 2	Standard analytical methods
Chlorinated Solvent Waste from manufacture of API (containing Dichloromethane)	Per consignment ^{Note 1}	See Note 2	Standard analytical methods
Aqueous Waste	Per consignment ^{Note 1}	See Note 2	Standard analytical methods
Aqueous Waste (containing Chlorinated Solvent)	Per consignment ^{Note 1}	See Note 2	Standard analytical methods
Other ^{Note 2}			

Note 1: Analysis shall be per consignment unless otherwise agreed by the Agency.

Note 2: Analytical requirements to be determined on a case by case basis.



C.5 Noise Monitoring

Period	Minimum Survey Duration
Daytime	A minimum of 3 sampling periods at each noise monitoring location ^{Note 2}
Evening-time	A minimum of 1 sampling period at each noise monitoring location.
Night-time ^{Note 1}	A minimum of 2 sampling periods at each noise monitoring location.

Note 1: Night-time measurements should be made between 2300hrs and 0400hrs, Sunday to Thursday, with 2300hrs being the preferred start time.

Note 2: Sampling period is to be the time period T stated as per *Schedule B.4 Noise Emissions, of this licence*. This applies to day, evening and night time periods.



C.6 Ambient Monitoring

Groundwater Monitoring

Location: M1-1, MW-2, MW-3 and MW-4 ^{Note 1}

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	Biannually	pH electrode/meter
COD	Biannually	Standard Method
Conductivity	Biannually	Standard Method
Major anions	Biannually	Standard Method
Major cations	Biannually	Standard Method
Heavy metals	Biannually	Atomic Absorption/ICP
Trace organics ^{Note 2}	Biannually	(1) United States Environmental Protection Agency Method 524.2 – Measurement of purgeable organic compounds in water by capillary column gas chromatography / mass spectrometry. (2) Non-purgeable organic compounds by GC or GC/MS.
Relevant hazardous Substances ^{Note 3}	Every five years	Standard method

Note 1: Locations as per Drawing No. 011048-22-DR-0002 submitted with the application for this revised licence..

Note 2: This analysis shall reflect and include those organic solvents used on-site.

Note 3: Soil monitoring for relevant hazardous substances shall be in accordance with Condition 6.21



Soil Monitoring

Monitoring Location: To be agreed by the Agency within six months of date of grant of licence.

Parameter	Monitoring Frequency	Analysis Method/Techniques
Relevant hazardous Substances ^{Note 1}	Every ten years	Standard Method

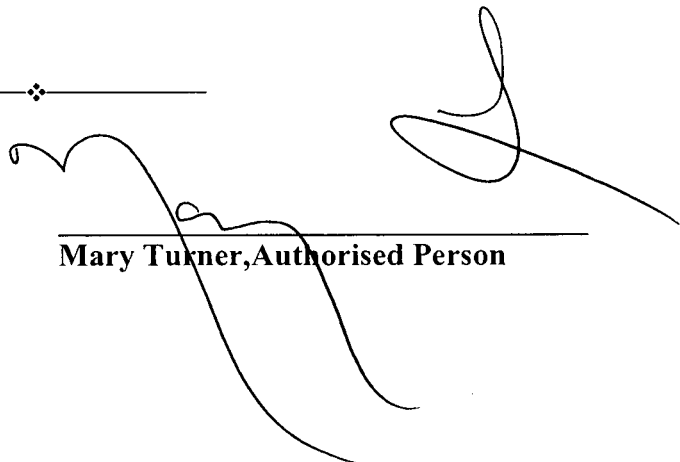
Note 1: Soil monitoring for relevant hazardous substances shall be in accordance with Condition 6.20

SCHEDULE D: Annual Environmental Report

Annual Environmental Report Content <small>Note 1</small>
<p>Emissions from the installation.</p> <p>Waste management record.</p> <p>Resource consumption summary.</p> <p>Complaints summary.</p> <p>Schedule of Environmental Objectives and Targets.</p> <p>Environmental management programme – report for previous year.</p> <p>Environmental management programme – proposal for current year.</p> <p>Pollutant Release and Transfer Register – report for previous year.</p> <p>Pollutant Release and transfer Register – proposal for current year.</p> <p>Noise monitoring report summary.</p> <p>Ambient monitoring summary.</p> <p>Tank and pipeline assessment report.</p> <p>Reported incidents summary.</p> <p>Energy efficiency audit report summary.</p> <p>Report on the assessment of the efficiency of use of raw materials in processes and the reduction in waste generated.</p> <p>Report on progress made and proposals being developed to minimise water demand and the volume of trade effluent discharges.</p> <p>Development/Infrastructural works summary (completed in previous year or prepared for current year).</p> <p>Review of Closure, restoration & aftercare management Plan.</p> <p>Statement of measures in relation to prevention of environmental damage and remedial actions (Environmental Liabilities).</p> <p>Environmental Liabilities Risk Assessment Review (every three years or more frequently as dictated by relevant on-site change including financial provisions.</p> <p>Any other items specified by the Agency.</p>

Note 1: Content may be revised subject to the agreement of the Agency.

Signed on behalf of the said Agency
 On the 22nd day of December, 2015



Mary Turner, Authorised Person