

## Regulatory Framework Permit with introductory note

Environment Protection Act (CAP. 549);  
Industrial Emissions (Framework) Regulations, S.L.549.76;  
Industrial Emissions (Integrated Pollution Prevention and Control) Regulations, S.L.549.77.

Installation **Medichem Manufacturing (Malta) Ltd & Combino Pharm (Malta) Ltd.**

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Permit Holders  
**Medichem Manufacturing (Malta) Ltd**  
**HF-61, Hal Far Industrial Estate**  
**Hal Far BBG 3000**

**Combino Pharm (Malta) Ltd.**  
**HF-60, Hal Far Industrial Estate**  
**Hal Far BBG 3000**

Approved Documents: Permit number  
IP 0002/05/E – Framework document

Sub-permit numbers

IP 0002/05/Ei– Medichem Manufacturing (Malta) Ltd  
IP 0002/07/Eii – Combino Pharma (Malta) Ltd.

## Contents

Introductory note .....	3
Permit .....	6
Conditions .....	7
1 General.....	7
2 Operating conditions .....	10
3 Records .....	24
4 Reporting.....	24
5 Notifications.....	25
6 Interpretation.....	26
Schedule 1 – Site layout Plan.....	30
Schedule 2 – Terms of Reference for Noise Monitoring.....	31
Schedule 3 – Notification of abnormal emissions and significant adverse effects.....	34

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## Introductory note

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, 2013 (S.L.549.76 (“the Industrial Emissions (Framework) Regulations”) to operate an installation carrying out activities covered by the description in Section 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) to the extent authorised by the Permit, i.e.

**“Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates”.**

Aspects of the operation of the installation which are not specifically regulated by conditions in the Permit may also be subject to the condition implied by Regulation 8 the Industrial Emissions (IPPC) Regulations, which require the Permit Holder(s) to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation.

Conditions marked with a ‘∞’ shall be construed as conditions which are to be enforced by the Authority responsible for such an issue.

Techniques include both the technology used and the way in which the installation is designed, built, maintained, managed, operated and decommissioned.

In some sections of the Permit conditions require certain Operators to use Best Available Techniques (BAT), in each of the aspects of the management of the installation, to prevent and where that is not practicable to reduce emissions. These conditions do not explain what is BAT.

A non-technical description of the installation is given in the Application, but the main features of the installation are summarized as follows:

- **Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs).**
- **Production of finished dosage forms**

Note that the Permit requires the submission of certain information to the Competent Authority. In addition, the Competent Authority has the power to seek further information at any time under regulation 11 of the Industrial Emissions (Framework) Regulations, provided that it acts reasonably.

### **Other IPPC Permits relating to this installation**

<b>Permit Holder(s)</b>	<b>Permit Number</b>	<b>Date of Granting</b>
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*Not applicable*

### **Superseded Licences/Authorisations/Consents relating to this installation**

<b>Holder</b>	<b>Reference Number</b>	<b>Date of Granting</b>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/A</i>	<i>20 October 2005</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/B</i>	<i>12 June 2009</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/C</i>	<i>11 January 2010</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/D</i>	<i>12 December 2013</i>

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## Public Registers

This IPPC Permit and application is available to the public through the Competent Authority website in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. Certain information may be withheld from the public where it is commercially confidential or contrary to national security. ERA has been supplied with all this information and has accepted the request of the applicant, because it was deemed to be commercially confidential.

### Multiple Operator installations

As indicated in Regulation 6(3) of S.L. 549.76, a permit may regulate several parts of an installation operated by different Operators. The importance of integrating the operations of each technical unit stems from the definition of "installation" in the provisions of S.L. 549.76, where this is defined as "a stationary technical unit within which one or more activities listed in the regulations concerning integrated prevention and control or in the regulations concerning organic solvents are carried out, and any other directly associated activities on the same site which have a technical connection with these activities and which could have an effect on emissions and pollution".

In accordance to guidance provided by the Commission, an activity is considered to be a directly associated activity with a Schedule 1 activity if it shares common features, for example: it is part of the same industrial complex; it operates in the same or a related sector; or operates with some collective aspects such as site security.

This installation is therefore being regarded as a multi operator installation.

### Functions of the permit

This **Permit** consists of three main parts structured as follows:

- **The Framework Permit** addressing the obligation of all Operators and coordinating these obligations due to the nature of the facility as a multi-operator installation (IP 0002/05/E).
- **Subsidiary Permit 1** addressing the operation carried out by Medichem Manufacturing (Malta) Ltd.(IP 0002/05/Ei).
- **Subsidiary Permit 2** addressing the operations carried out by Combino Pharm (Malta) Ltd.(IP 0002/05/Eii).

### Variations to the Permit

This Permit may be varied at any time in the future (by the Authority serving a Variation Notice on the Permit Holder(s)). If any of the Operators wants any of the Conditions of either the regulatory framework or to the operator specific Subsidiary Permit to be changed, a formal application must be submitted to the Competent Authority. When such an application is submitted to the Authority for its consideration, the decision shall be carried out in consultation with the other operators within this multi operator installation.

The Status Log within the Introductory Note to any such Variation Notice will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been granted.

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## **Surrender of the Permit**

Before this Permit can be wholly or partially surrendered, an Application for the surrender of the Permit has to be made to the Competent Authority by any of the Operators. For the application to be successful, the Operator(s) requesting this surrender must be able to demonstrate to the Competent Authority that there is no pollution and/or public health risk and that no further steps are required to return the site to a satisfactory state.

## **Transfer of the Permit or part of the Permit**

Upon the joint application of a Permit Holder(s) and a proposed transferee, the Permit Holder(s) may request to transfer an environment permit. The permit shall not be transferred from the Permit Holder(s) without prior approval from the Authority. Upon the Authority's decision to transfer the permit to the transferee, all rights, obligations, liabilities shall subsist onto the transferee.

## **End of Introductory Note**

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## Permit

Permit number

**IP 0002/05/E**

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority ERA) in exercise of its powers under Regulation 7 of the Industrial Emissions (Framework) Regulations, (S.L.549.76) (“the Industrial Emissions (Framework) Regulations”), hereby authorises:

**Dr. Dino Mangion obo Medichem Manufacturing (Malta) Ltd.** (hereinafter “The Permit Holder”), of/ whose Registered Office (or principal place of business) is at

**HF-61, Hal Far Industrial Estate, Hal Far BBG 3000**

**Dr. Dino Mangion obo Combino Pharm (Malta) Ltd.** (hereinafter “The Permit Holder”, of/ whose Registered Office (or principal place of business) is at

**HF-60, Hal Far Industrial Estate, Hal Far BBG 3000**

to operate an installation at

**HF-60 and HF-61, Hal Far Industrial Estate, Hal Far BBG 3000**

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

The permit is valid for a period of four (4) years from the date of the granting. The Permit Holder(s) is able to renew the permit upon application with the Authority expressing his/her intention at least nine (9) months prior to the expiry of this permit. The permit will be considered renewed once the official renewed permit is issued by the Authority.

Environment and Resources Authority	
<b>APPROVAL</b>	Date Granted:
Board No. _____ Held on _____	
Chairman _____ Secretary _____	24/3/2021

**Authorised to sign on behalf of the Competent Authority**

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## Conditions

### 1 General

This permit shall be read in conjunction with the Subsidiary Permits issued to Medichem Manufacturing (Malta) Ltd. and Combino Pharm (Malta) Ltd., which together with the Framework Permit comprise permit IP 0002/05/E.

#### 1.1 Permitted Activities

1.1.1 The Permit Holder(s) are authorised to carry out the activities as delineated in table 1.1.1 in the respective subsidiary permits.

#### 1.2 Site

1.2.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown in the Site Plan in Schedule 1 to this Permit.

1.2.2 The activities authorised under condition 1.1.1 addressing specific Permit Holders shall not extend beyond the operational boundaries as outlined in the Site Plan in Schedule 1 to this Permit.

#### 1.3 Overarching Management Condition

1.3.1 Without prejudice to the other conditions of this Permit, the Permit Holder(s) shall maintain an Environmental Management System (EMS), and an organisational structure and allocate resources that are sufficient to achieve compliance with the limits and conditions of this Permit. The EMS shall give information on the person responsible for environmental management on site, and standard operating procedures on environmentally relevant matters. An EMS can take the form of a standardised system (e.g. EN ISO 14001:2004 or EMAS) or a non-standardised ("customised") system, provided that is properly designed and implemented.

1.3.2 The Permit Holder(s) shall submit (including as part of the EMS) the following reports annually as part of the Annual Environmental Report, according to the timeframe specified in Condition 4.2:

- i. Environmental Policy containing the installation's environmental objectives and targets;
- ii. Environmental Management Programme report (for the reporting year);
- iii. Environmental Management Programme proposal (for the following year).

1.3.3 The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the application and subsequent responses to requests for information submitted as per the Status Log described in the respective subsidiary permits, or as otherwise previously agreed in writing by the Authority.

#### 1.4 Operational Changes

1.4.1 The Permit Holder(s) shall seek the Authority's written agreement to any operational change as defined by S.L.549.77, by sending to the Authority: written notice of the details of the proposed change including an assessment of its possible effects (including changes in emissions and waste production) on risks to the environment and to public health from the Permitted Installation; any relevant supporting assessments and drawings; and the proposed implementation date.

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- 1.4.2 Any such change shall not be implemented until agreed to in writing by the Authority. As from the agreed implementation date, the Permit Holder(s) shall operate the Permitted Installation in accordance with that change, and relevant provisions in the Application shall be deemed to be amended.
- 1.4.3 The Director of Environment and Resources and any officials to whom this role is delegated are hereby authorised to make decisions on variations to this permit, with the exception of the following cases:
- a. modifications which could lead to significant impact on human health or the environment;
  - b. any change in the nature or functioning or an extension of an installation where the change or extension in itself reaches the capacity thresholds set out in Schedule 1 of the Industrial Emissions (IPPC) Regulations;
  - c. variations covered by the Environmental Impact Assessment Regulations;
  - d. aspects of the operations specifically prohibited by this permit;
  - e. changes to emission limit values;
  - f. changes to fees;
  - g. renewal of the validity of this permit.

## **1.6 General Conditions**

- 1.6.1 The conditions and obligations of this permit are without prejudice to any other regulation, code of practice, conditions or requirements requested by other Authorities or entities, including but not limited to, the Planning Authority, the Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS) and the Environmental Health Directorate.
- 1.6.2 This permit is granted saving third party rights. The Permit Holder(s) are not excused from obtaining any other permission required by law.
- 1.6.3 The Permitted Installation shall be managed, controlled, supervised and operated by staff that are aware of the importance of environmental protection and suitably trained on the requirements of this Permit. All staff shall be provided with adequate training and written operating instructions to enable them to effectively carry out their duties. Such training shall be recorded and maintained in line with Section 3.
- 1.6.4 The site shall be maintained in a tidy condition, free from litter and waste (whether arising from own activities or external sources).
- 1.6.5 In these conditions and their interpretation, all terms shall have the same meaning as that assigned to them in CAP549 Environment Protection Act and its subsidiary legislation.
- 1.6.6 In case of any monitoring requirements specified in this permit, there shall be provided safe means of access to enable sampling/monitoring to be carried out by the Authority or by a third party if deemed necessary.
- 1.6.7 The Permit Holder(s) have the sole responsibility to ascertain compliance with legal obligations, permit conditions and to undertake activities on and off site in line with good environmental practices at all times



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- 1.6.8 All persons have a duty of care to protect the environment. The Permit Holder(s) shall become familiar with his legal obligations and good environmental practice.
- 1.6.9 The Permit Holder(s) are fully liable and responsible for managing the site in all its various aspects and to supervise the full adherence with all the conditions of this permit.
- 1.6.10 The Authority may carry out regular pre-set or unannounced compliance or monitoring checks that vary in frequency according to the site's compliance with the permit conditions and safeguarding of natural assets. Any checks or audits carried out by the Authority may be made at each of the Permit Holder(s) 's financial expense at rate and arrangement communicated by ERA's Compliance and Enforcement Directorate
- 1.6.11 The Authority's representatives may inspect and photograph any part of the site and ask for any closed or locked areas to be opened and may demand to be provided with any proof, documentation, plans, receipts or any other records. The Permit Holder(s) shall also provide all the necessary assistance to enable the Authority to take samples if necessary.
- 1.6.12 The Authority may add, amend, delete or substitute any of the conditions of this permit after notifying the Permit Holder(s) of its intention and after describing the changes to the Permit Holder(s). This is without prejudice to any prevailing circumstances that would preclude the Authority from following such a procedure.
- 1.6.13 The Authority may suspend or revoke this permit or part of this permit where significant mismanagement of the site is observed or any of the permit conditions are not respected after a written warning is given by the Authority or in any eventuality that gives the Authority enough reason to suspend/revoke this permit.
- 1.6.14 The validity of this permit is until four (4) years from the date of the permit granting. The Permit Holder(s) is able to renew the permit upon application with the Authority expressing his/her intention at least nine months prior to the expiry of the permit. The permit will be considered renewed once the official renewed permit is granted by the Authority
- 1.6.15 A copy of this permit shall be available at all times at the site office, including any variation notices of amendments to it.
- 1.6.16 The Authority may request additional monitoring and/or review of operational practices and any commission audits/reports as deemed necessary to address any circumstances that may affect the quality of the surrounding environment at the expense of the Permit Holder(s) .
- 1.6.17 The Authority may suspend or revoke this environmental permit in line with the provisions of CAP549.
- 1.6.18 Any incident including accidental release of liquid, solid or gaseous materials from the site shall be reported not later than within 24 hours to ERA, without prejudice to the emergency plan of the installation and Health and Safety.
- 1.6.19 The Permit Holder(s) shall undertake all necessary measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.
- 1.7 Off-site Conditions**
- 1.7.1 The Permit Holder(s) shall ensure that no chemicals or waste escape to the environment including when transporting such materials offsite or onsite.

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## **2 Operating Conditions**

### **2.1 In-Process Controls**

- 2.1.1 The Permitted Installation shall, subject to the conditions of this Permit, be operated using the techniques and in the manner described in the IPPC application and in the subsequent applications for renewal and variation, or as otherwise agreed in writing by the Authority in accordance with conditions 1.4.1 and 1.4.2 of this Permit.

### **2.2 Emissions to Air**

- 2.2.1 All processes which generate significant levels of airborne contaminants (such as dusts, toxic gases, odorous chemicals) shall have effective local collection and shall discharge (after treatment where necessary) through a stack or vent located and/or designed in such a way as to avoid local effect
- 2.2.2 The exhaust from general building ventilation (e.g. extractors or fans in walls or roofs) shall be vented in such a way as to avoid adverse environmental effects and in accordance with applicable legislation in this regard.
- 2.2.3 Should the Permit Holder(s) intend to install equipment, which could lead to additional emissions to air (e.g. an additional boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment

#### **API Handling**

- 2.2.4 Emissions to air from all areas where active pharmaceutical ingredients in dry powder form are handled (including weighed, processed, compacted and dried) shall be exhausted through abatement equipment having at least 99.9% efficiency.
- 2.2.5 The operational effectiveness of filters (such as HEPA filters) for the control of particulate emissions of pharmaceutical raw materials intermediates and products shall be monitored by means of a pressure differential recorder or equally effective means. Such recorders shall be visible and audible to personnel working on the equipment such that an out of range incident can be easily and immediately identified.
- 2.2.6 When filters are found to have reached the pressure alert limit indicated by filter manufacturer, these shall be immediately replaced as per approved Standard Operating Procedure and where applicable, damaged filters shall be treated as hazardous waste as per as per S.L.549.63. Records of filter changes should be kept in line with Section 3 of the Framework Permit.
- 2.2.7 Further to condition 2.2.5 and 2.2.6, the Permit Holder(s) shall carry out and document HEPA filter integrity monitoring for exhaust filters on a weekly basis. The results of the monitoring shall be submitted on a quarterly basis to the Authority. Such results shall also be submitted as part of the Annual Environmental Report, in the format specified in Schedule 1 of each respective subsidiary permit.
- 2.2.8 HEPA Filter efficiency certification for exhaust filters is to be submitted on an annual basis as part of the Annual Environmental Report, in the format specified in Schedule 1 of each respective subsidiary permit.
- 2.2.9 The HVAC system shall be regularly maintained. A maintenance log for the HVAC system shall be kept and made available to the Authority upon request.

#### **Combustion Plants**

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- 2.2.10 Industrial combustion plants (e.g. boilers, generators, etc.) shall be compliant with the provisions of S.L.549.50, Ambient Air Quality Regulations and S.L.549.122 Limitation of Emissions of Certain Pollutants into the air from Medium Combustion Plant Regulations.
- 2.2.11 Diesel (gas oil) used for generators shall have a sulphur content not greater than 0.1%.
- 2.2.12 The Permit Holder(s) shall keep the periods of start-up and shut-down of the combustion plant as short as possible.
- 2.2.14 The Authority may request monitoring of emissions to air for PS6 in Medichem Manufacturing (Malta) Ltd and PS1 & PS2 in Combino Manufacturing (Malta) Ltd. which shall be undertaken in accordance to the terms of reference provided by the Authority.
- 2.2.15 During each measurement, as specified in condition 2.2.14, the plant shall be operating under stable conditions at a representative even load. In this context, start-up and shut-down periods shall be excluded.
- 2.2.16 Should the Permit Holder(s) intend to install equipment which could lead to additional emissions to air (e.g. boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment.

#### **Monitoring Provisions and Emergency considerations**

- 2.2.17 Sampling and analysis of polluting substances and measurements of process parameters shall be based on methods enabling reliable, representative and comparable results. Methods complying with harmonised EN standards shall be presumed to satisfy this requirement.
- 2.2.18 In the event of non-compliance causing immediate danger to human health, operation of the activity must be suspended and the Competent Authority informed within 24 hours
- 2.2.19 In the event of, malfunction or breakdown leading to abnormal emissions, the Permit Holder(s) must:
- i. Investigate immediately and undertake corrective action, and
  - ii. Adjust the process or activity to minimise those emissions, and
  - iii. Record the events and actions taken
- 2.2.20 Further to condition 2.2.19, the Permit Holder(s) shall provide ERA with details of the specific cause of the malfunction and the remedial steps taken or to be taken to address the malfunction:
- i. Relocating / redesigning/ extending the stack(s) or vent(s) to a point where nuisance is minimised
  - ii. Replacement of fuel
  - iii. Preventative measures such as replacement of process materials (e.g. odorous solvents) by substances which are less detrimental to the environment
  - iv. Improved storage of materials
  - v. Use of additional abatement measures

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- 2.2.21 All abatement equipment and ducting shall be maintained on a regular basis (as per manufacturer specifications) in line with Section 2.10 of the Permit.

### **2.3 Discharges to surface water**

- 2.3.1 No discharges to surface water shall take place at the installation

### **2.4 Discharges to the sewer <sup>∞</sup>**

- 2.4.1 The Permit Holder(s) shall ensure the Sewer Discharge Permit from the Water Services Corporation (WSC) is obtained and updated every year and shall supply all the information requested by the WSC and take all the necessary actions as instructed by the WSC and/or the Authority. The Permit Holder(s) shall forward to the Authority a copy of any Sewer Discharge Permit issued by the Water Services Corporation within 10 days of its issue.
- 2.4.2 The Permit Holder(s) shall follow the conditions of the Sewer Discharge Permit, as may be updated from time to time by the Water Services Corporation and the provisions of the Sewer Discharge Control Regulations (S.L.545.08).
- 2.4.3 Foul sewer drains must be strictly segregated from stormwater drains.
- 2.4.4 All discharges to the foul sewer (other than from domestic sewage or equivalent), including reverse osmosis reject water, shall comply with the requirements of a Water Services Corporation Sewer Discharge Permit
- 2.4.5 Any accidental release of substances shall be duly reported to the Water Services Corporation and effluents treated/contained prior to discharge into the sewers (subject to clearance from the WSC), or disposed as waste. Records shall be kept of such discharges, including the volume discharged and other parameters, as agreed with the Water Services Corporation, as per the Sewer Discharge Permit.
- 2.4.6 Where any of the parameters stipulated by the Water Services Corporation are exceeded, it shall be ensured that any follow up actions requested by the WSC are implemented by both Medichem Manufacturing (Malta) Ltd. and Combino Pharma (Malta) Ltd.
- 2.4.7 Process effluents shall not be diluted prior to discharge to sewer or transfer off-site.
- 2.4.8 Where feasible rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates and/or products. If this is not possible, rainwater from areas where contamination by oil or chemicals is likely (such as loading/unloading and bunded areas) shall pass through an adequately designed wastewater treatment plant.

### **2.5 Discharges to groundwater<sup>∞</sup>**

- 2.5.1 The Permit Holder(s) shall not allow the introduction into groundwater of any substance included in the Regulations for the Protection of Groundwater against Pollution and Deterioration (S.L.549.63).
- 2.5.2 Further to conditions 2.5.1 the Permit Holder(s) shall not allow any discharges to groundwater.
- 2.5.3 The operations of the Permitted Installation shall not hinder the achievement of good chemical and quantitative status of groundwater as prescribed under the Water Policy Framework Regulations, S.L.549.100.

### **2.6 Fugitive emissions of substances to water and sewer**

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2.6.1 The operations of the Permitted Installation shall not hinder the achievement of good chemical and quantitative status of surface waters as prescribed under the Water Policy Framework Regulations, S.L. 549.100.

2.6.2 The Permit Holder(s) shall utilise BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to water (including-groundwater) and sewer from the Permitted Installation, in particular from:

- All structures under or over ground
- Surfacing
- Storage areas
- Bunded areas

provided always that the techniques used by the Permitted Installation shall be no less effective than those described in the Application, where relevant.

2.6.3 Catchment pits, reservoirs and bunds on site must be visually inspected and examined for odours at least once every month and maintained where necessary. Records of such inspections and maintenance are to be kept by the Permit Holder(s).

2.6.4 Engineered site containment and drainage systems (including catchment pits and bunds ) shall be designed, constructed, inspected, validated and maintained; and shall be fully documented and recorded to be fit for purpose while meeting the following construction quality assurance standards. All areas are to:

- Be fully impermeable;
- Be kept free from cracks which could increase permeability;
- Be leak-proof and resistant to physical, mechanical and chemical stresses to which they may be subjected;
- Fall towards the drainage system to prevent pond formation.

Such systems shall be certified by an independent, warranted civil engineer or engineer as being leak-proof and resistant to physical, mechanical and chemical stresses to which they may be subjected. Catchment pits and bunds on site must be tested and certified to be leak-proof by an independent, warranted civil engineer or engineer before any renewal of this IPPC permit. Such certification shall be also submitted as part of the AER, of the respective subsidiary permit, by end of March after the end of each year when testing has occurred.

2.6.5 All process and storage areas must be appropriately contained. Any accidental release of substances shall be duly treated prior to discharge into the sewers, or disposed according to The Waste Regulations S.L. 549.63 if treatment does not enable compliance with emission limit values. Records shall be kept of such discharges, including the volume discharged and other parameters, as agreed with the Water Services Corporation, as per the Sewer Discharge Permit.

## **2.7 Emission to Land**

2.7.1 No emission from the Permitted installations shall be made to land.

2.7.2 In the event of spillages or incidents which could have led to contamination of land, the Permit Holder(s) shall notify the Authority within 24 hours, forward a decontamination plan for the Authority's approval and execute it within an agreed time frame.

## **2.8 Odour**

2.8.1 The Permit Holder(s) shall use BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by:

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- a) Limiting the use of odorous materials
  - b) Restricting odorous activities
  - c) Controlling the storage conditions of odorous materials
  - d) Controlling processing parameters to minimise the generation of odour
  - e) Optimising the performance of abatement systems
  - f) Timely monitoring, inspection and maintenance
  - g) Employing, where appropriate, an approved odour management plan

provided always that the techniques used by the Permit Holder(s) shall be no less effective than those described in the Application, and where relevant approved by the Authority prior to their implementation.

2.8.2 There shall be no significant offensive odour, as perceived by an Authorised Officer of the Competent Authority, outside the boundary of the permitted installation.

2.8.3 In case of complaints from sensitive receptors regarding odours from the installation the Authority may require the Permit Holder(s) are to assist with the investigation being carried out by the Authority to assess the potential source of such a complaint. The Authority may require the Permit Holder(s) (where these are identified as the source of the complaint), to submit an odour management plan, which would include recommendations for abatement of the odour and timeframes for implementation.

## **2.9 Noise and vibration**

2.9.1 The Permit Holder(s) shall use BAT so as to prevent or where that is not practicable to reduce emissions of noise and vibration from the Permitted Installation, in particular by:

- a. equipment maintenance, e.g. of fans, pumps, motors, conveyors and mobile plant;
- b. use and maintenance of appropriate attenuation, e.g. silencers, barriers, enclosures;
- c. appropriate timing and location of noisy activities and vehicle movements;
- d. periodic checking of noise emissions, either qualitatively or quantitatively;
- e. mounting any equipment or machinery which may cause substantial vibrations on rubber mountings or other specialized vibration reduction mountings in order to reduce vibration impacts; and
- f. maintenance of building fabric,

provided always that the techniques used by the Permit Holder(s) shall be no less effective than those described in the Application, where relevant

2.9.2 Emergency generators/alarms/sirens/release valves shall only be tested between the hours of 10.00 and 17.00 Monday to Friday and not on any Public Holiday.

2.9.3 Based on the results of the noise monitoring as per the relevant subsidiary permit, the Permit Holder(s) may be requested to submit a proposal for an action plan aimed at reducing noise from those sources which have resulted in significantly high noise levels. Such proposal for an action plan is to be submitted and approved by the Authority, which reserves the right to request any additional measures as deemed necessary

2.9.4 As part of the AER, records of noise monitoring of the previous year or as otherwise agreed with ERA shall be submitted to the Competent Authority by not later than end of March after the end of each reporting year, in the format specified in Schedule 1 of the respective subsidiary permit. A detailed report shall also accompany such results.

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## **2.10 Maintenance**

- 2.10.1 All plant, equipment and technical means used in operating the Permitted Installation, shall be maintained in good operating condition and in such a manner to:
- a. Prevent corrosion as applicable
  - b. Ensuring access to potentially leaky equipment
  - c. Regularly controlling protective equipment.
- 2.10.2 The Permit Holder(s) shall maintain a record of plant and equipment covered by condition 2.10.1, and for such plant and equipment:
- i. A written or electronic maintenance programme; and
  - ii. Records of its maintenance.
- 2.10.3 The Permit Holder(s) shall maintain appropriate access to standby and/or spares of HEPA Filters to ensure the operation of the abatement system.

## **2.11 Waste**

### **Waste storage and handling**

- 2.11.1 The Permit Holder(s) shall use BAT in the design, maintenance and operation of all facilities for the storage and handling of waste on site such that there are no releases to water or land during normal operation and that emissions to air and risk of accidental release to water or land are minimised.
- 2.11.2 All operations concerning the management of waste are subject to the Waste Management Regulations (S.L.549.63) and the Waste Management (Activity Registration) Regulations (S.L.549.45).
- 2.11.3 The Permit Holder(s) shall be committed to reduce waste generation where possible.
- 2.11.4 Waste produced at the Permitted Installation shall be reused, recycled or recovered unless technically and/or economically unfeasible.
- 2.11.5 All wastes shall be stored within a designated and controlled storage area(s) prior to ultimate disposal. Wastes to be recycled shall be stored in a designated container or area and shall not be mixed with other wastes.
- 2.11.6 The Permit Holder(s) is to prevent litter or other wastes escaping from the site boundaries, particularly during loading/unloading. Any such escape of waste shall be collected immediately upon detection.
- 2.11.7 Unless approved in writing by the Authority, the Permit Holder(s) is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other waste, substances or materials.
- 2.11.8 Liquid and hazardous wastes shall be stored in a labelled, closed container(s) within a designated and controlled storage area(s) prior to ultimate disposal. Wastes of different natures and having different European Waste Catalogue codes as established by Commission Decision 2000/532/EC shall not be mixed in the same container.
- 2.11.9 Packaging and containers which came into contact with hazardous substances shall be regarded as hazardous waste and shall be disposed of in an appropriate manner.

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- 2.11.10 The Permit Holder(s) shall register with ERA as a producer of packaging and provide the required information, as well as achieve the targets as set out in S.L.549.43, Waste Management (the Packaging and Packaging Waste Regulations. Documentation as evidence of such should be maintained for a period of 3 years and be made available, upon request by ERA.
- 2.11.11 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited.
- 2.11.12 No treatment, dismantling or recovery of waste is allowed on site.
- 2.11.13 No storage of waste, equipment or materials is permitted on property outside the site premises.
- 2.11.14 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.
- 2.11.15 Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.
- 2.11.16 No storage of waste destined for disposal is permitted for a period exceeding 12 months. No storage of waste destined for recovery is permitted for a period exceeding 3 years.
- 2.11.17 The Permit Holder(s) shall ensure that waste transferred to another person is packaged and labelled in accordance with national, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage, leachate run-off and accidental damage. The waste is to be clearly labelled and appropriately segregated.

### **Waste Disposal**

- 2.11.18 In the case of waste that is sent for treatment or recovery to another facility locally or abroad, the audit trail shall cover all waste from the point of generation or collection to the end recovery or disposal facility.
- 2.11.19 The Permit Holder(s) shall ensure that no waste escape to the environment especially when transporting such materials offsite or onsite.
- 2.11.20 All wastes leaving the site after storage and/or processing must only be sent to facilities licensed to accept the individual waste stream, either locally or abroad.
- 2.11.21 The transboundary movement of waste shall be carried out in accordance with the following regulations, as amended from time to time:
- i. Regulation (EC) N° 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste as implemented through S.L. 549.65;
  - ii. Commission Regulation (EC) N° 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) N° 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply; and
  - iii. Any other applicable legislation



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- 2.11.22 The Permit Holder(s) shall make use of the services of a registered waste carrier for the transport of waste from the site in accordance activity 38 of schedule 1 of Subsidiary Legislation 549.45, the Waste Management (Activity Registration) Regulations. Where the company removes wastes using its own transport the vehicle(s) must also be registered as a waste carrier in accordance with S.L. 549.45 or any statutory provisions or regulations amending or replacing them.
- 2.11.23 Movement of hazardous waste to authorised facilities shall be covered by a valid consignment permit obtainable from the Competent Authority. Each movement shall also be covered by a consignment note obtainable from the Authority.
- 2.11.24 Should the Permit Holder require the services of a waste broker, it shall be ensured that any such broker is a duly registered waste broker in accordance with S.L. 549.45.

### **Waste Records**

- 2.11.25 The Permit Holder(s) shall ensure to keep records for every consignment of hazardous wastes, or other wastes, as deemed necessary by the Authority, removed from the Site indicating the EWC Code, description, quantities, date of removal, contractor name (including for transport), consignment note number (where applicable) and manner and place of final disposal/recovery.
- 2.11.26 Disposal and/or recovery certificates shall be kept on record and made available for inspection for a period of at least 3 years from date of their issue.
- 2.11.27 As part of the AER of the respective subsidiary permit, the Permit Holder(s) shall submit the name of each carrier used, in the format specified in Schedule 1 of each subsidiary permit, by end of March after the end of each reporting year.
- 2.11.28 As part of the Annual Environmental Report for each installation, the Permit Holder(s) shall produce a report on the off-site transfers of waste and wastes recycled/ recovered at the Permitted Installation over the previous calendar year, providing the information listed in Schedule 1 of each subsidiary permit.
- 2.11.29 Without prejudice to Condition 2.11.4, disposal of wastes including rejects, expired products, and other wastes are to be managed in accordance with the legal obligations of the Waste Regulations (S.L. 549.63). Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

## **2.12 Energy Efficiency**

- 2.12.1 As part of the Annual Environmental Report, the Permit Holder(s) shall produce a report on the energy consumed at the Permitted Installation over the previous calendar year, by the end of March of each year, providing the information listed in Schedule 1 of each respective subsidiary permit.
- 2.12.2 The Permit Holder(s) shall design, maintain and operate the Permitted Installation so as to secure energy efficiency, in particular by:
- a. Ensuring that the appropriate operating and maintenance systems are in place;
  - b. Ensuring that all plant is adequately insulated to minimise energy loss or gain;
  - c. Ensuring that the type of lighting used is energy-efficient;
  - d. Ensuring that all appropriate containment methods, (e.g. seals and self-closing doors) are employed and maintained to minimise energy loss;
  - e. Employing appropriate basic controls, such as simple sensors and timers, to avoid unnecessary discharge of heated water or air;

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Maintaining and implementing an energy efficiency plan which identifies energy saving techniques that are applicable to the activities and their associated environmental benefit and prioritises them.

## **2.13 Storage**

- 2.13.1 No storage of equipment or materials is permitted on property outside the site premises.
- 2.13.2 All storage areas for liquid chemicals, fuels and hazardous materials shall be provided with an adequately designed bund system with an impermeable base and walls. The capacity of the bund shall be a minimum of 110% of the largest tank within the bund or 25% of the total capacity of all the tanks within the bund, whichever is the greater. All filling and off-take points shall be located within the bund. Incompatible chemicals shall not be stored within the same bund.
- 2.13.3 Spillages of hazardous material shall receive immediate attention to prevent escape to drain, surface water or land. Spilled material shall be disposed of in an appropriate manner. Kits for the collection of liquid and powder spills shall be available on site at sensitive locations.
- 2.13.4 Bulk storage tanks for liquids and associated bunding and pipe work shall be visually inspected at least every three months. Such records shall be kept and made available to the Authority upon request.
- 2.13.5 Drums and containers of solvents, oils or any other chemicals shall be stored in designated and secure storage areas. Storage areas shall be designed so that surface and ground waters cannot be contaminated by spillages.
- 2.13.6 The storage of flammable, toxic and hazardous substances shall be in line with the measures specified in the Material Safety Data Sheets (SDS) for that substance and the maintenance of safety critical equipment shall correspond to manufacturer specifications.
- 2.13.7 Chemicals of different properties shall be stored as specified in respective SDS sheets. Such sheets shall be made available and accessible to personnel responsible for the management of the storage areas and for inspection by the Competent Authority. Incompatible chemicals shall not be stored within the same bund.
- 2.13.8 Storage and handling of cytotoxic/cytostatic materials shall be to the satisfaction of the Occupational Health and Safety Authority.<sup>∞</sup>

## **2.14 Transport <sup>∞</sup>**

- 2.14.1 Independent of any Environment Management System, the Permit Holder(s) shall be responsible for making use of the services of an ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road) certified carrier for transport of chemicals and hazardous wastes on land.

## **2.15 Ozone Depleting Substances and Fluorinated Greenhouse Gases<sup>∞</sup>**

- 2.15.1 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on substances that deplete the Ozone Layer & S.L. 549.58 on Substances that Deplete the Ozone Layer, shall be installed within the site.
- 2.15.2 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014

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on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

- 2.15.3 The use of HCFCs in the maintenance and servicing, in particular refilling, or products and equipment whose function relies on such substances shall be prohibited.
- 2.15.4 Maintenance and servicing of equipment containing ozone depleting substances and fluorinated greenhouse gases shall be carried out in accordance with the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 and its implementing acts and Regulation (EC) No. 1005/2009 on substances that deplete the Ozone Layer. All maintenance and servicing shall be reported in the AER as per template in Schedule 1 of each respective subsidiary permit.
- 2.15.5 For all equipment installed on site utilising Ozone Depleting Substances or Fluorinated Greenhouse Gases, information pertaining to installation, maintenance and servicing shall be provided as prescribed in Schedule 1 of each respective subsidiary permit. When any equipment is replaced by new equipment, The Authority shall be notified in this regard and details provided on the new equipment installed
- 2.15.6 Upon decommissioning of all equipment containing foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer & S.L. 549.58 on substances that deplete the ozone Layer, together with Regulation (EU) No. 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No.842/2006, or containing foam and insulation panels utilising such substances the waste gas should be treated as hazardous waste and any foam containing components need to be disposed of at specialised facilities where possible ODS/F gas can be extracted prior to disposal.
- 2.15.7 Where required, leak detection systems as per the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 shall be installed and well maintained.

## **2.16 Monitoring**

- 2.16.1 The Permit Holder shall maintain and implement an emissions monitoring programme which ensures that emissions are monitored as specified in each of the respective subsidiary permit, and that the results of such monitoring are assessed. The programme shall ensure that monitoring is carried out under an appropriate range of operating conditions, and that measurements for the determination of concentrations of substances specified in this permit is carried out representatively.
- 2.16.2 Sampling and analysis of all pollutants, as well as reference measurement methods to calibrate automated, continuous, measurement systems shall be carried out as specified by the appropriate CEN standards. If CEN standards are not available, ISO standards, national or international standards, which will ensure the provision of data of an equivalent scientific quality, as agreed in writing with the Authority, shall apply. VOC discharges shall be measured and assessed according to Regulation 8(2) of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations.
- 2.16.3 Monitoring equipment, techniques, personnel and organisations employed for the monitoring requirements of this Permit shall be from a laboratory accredited to at least EN ISO 17025:2017 or in the process of accreditation, as confirmed by the National Accreditation Body (NAB-Malta). As part of the Annual Environmental Report of each respective subsidiary permit, the Permit Holder(s) shall provide

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evidence of certification or accreditation of laboratories used for the emissions monitoring programme.

- 2.16.4 The Permit Holder(s) shall maintain records of all monitoring taken or carried out (this includes records of the taking and analysis of samples instrument measurements (periodic and continual), calibrations, examinations, tests and surveys) and any assessment or evaluation made on the basis of such data, for at least a period of 5 years. Such records may be requested at any time by the Authority.
- 2.16.5 There shall be provided safe and permanent means of access to enable sampling/monitoring to be carried out in relation to the emission points already mentioned in the respective subsidiary permit; and safe means of access to other sampling/monitoring points when required by the Authority.
- 2.16.6 The Permit Holder shall provide ERA with monitoring reports as indicated in section 4 of this permit.

## **2.17 Management and Technically Competent Person**

### **Training**

- 2.17.1 The Permitted Installation shall be supervised and controlled by staff who are suitably trained and fully conversant with the requirements of this Permit.
- 2.17.2 All staff shall be fully conversant with those aspects of the Permit conditions which are relevant to their duties and shall be provided with adequate professional technical development and training and written operating instructions to enable them to effectively carry out their duties.
- 2.17.3 The Permit Holder(s) shall maintain records of the skills and training requirements for all staff whose tasks in relation to the Permitted Installation may have an impact on the environment and shall keep records of all relevant training

### **Attendance of Technically Competent Person(s)**

- 2.17.3 The Technically Competent Person (TCP) is responsible for the implementation of all the obligations stipulated in this permit, must supervise the rest of the staff on site and shall be the Permit Holder(s)'s technical focal point for the implementation of the conditions of this permit.
- 2.17.4 Attendance of the technically competent person(s) at the Site shall be recorded on arrival and departure.
- 2.17.5 For the whole operational hours permitted for the Site under this Permit, the Technically Competent Person/s or their delegate/s shall be physically in attendance at the Site. The Technically Competent Person/s or their delegate/s has to be permanently present on site during the manufacture of APIs. The Permit Holder(s) is to provide details as to how he intends to provide this coverage in order to take into account unavoidable absences due to continuous operation, leave of absence
- 2.17.6 In the event of any short or long periods of leave of absence taken by the TCP for a period exceeding 10 days, the Permit Holder(s) is obliged to find a replacement for that member of staff without delay.
- 2.17.7 Where the Authority has been notified that the site is either non-operational or closed, the Technically Competent Person shall be capable of attending the Site within one hour.

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## **Changes in Technically Competent Persons**

- 2.17.8 Any changes in technically competent management (Person/s) and the name of any incoming person together with evidence that such person has the required technical competence and 24-hour contact details shall be submitted to the Authority in writing within 5 working days of the change in management.
- 2.17.9 In the event of the death, dismissal, resignation, leave, or of extended sick leave of the Technically Competent Management of the Site, the Permit Holder(s) shall immediately inform the Authority, and prove to the Authority that the Permit Holder(s) is actively seeking a replacement.

## **Incidents and Complaints**

- 2.17.10 The Permit Holder(s) shall maintain and implement written procedures for:
- i Taking prompt remedial action, investigating and reporting to the Competent Authority actual or potential non-compliance with operating procedures or emission limits and if such events occur.
  - ii Investigating incidents, (including any malfunction, breakdown or failure of plant, equipment or techniques, down time, any short-term and long-term remedial measures and near-misses) and prompt implementation of appropriate actions; and
  - iii Ensuring that detailed records are made of all such actions and investigations.
- 2.17.11 The Permit Holder(s) shall record and investigate complaints concerning the Permitted Installation's effects or alleged effects on the environment and public health. The record shall give the date and nature of complaint, time of complaint, name of complainant (if given), a summary of any investigation and the results of such investigation and any actions taken.
- 2.17.12 As part of the Annual Environmental Report, the Permit Holder(s) shall provide a summary record of incidents and complaints in the format specified in Schedule 1 of each respective subsidiary permit. These records shall also be made available upon request during any inspection on site.
- 2.17.13 Unpredicted impacts and nuisances which may arise from this operation and that may have a significant adverse effect on public health are to be immediately addressed by the Permit Holder(s) and the necessary mitigation measures taken.<sup>∞</sup>
- 2.17.14 Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the Permit Holder(s). All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested.<sup>∞</sup>

## **2.18 Accident prevention and control<sup>∞</sup>**

- 2.18.1 In the case of an accident (including chemical spills, fire etc.), the Permit Holder(s) shall follow the Emergency Response Plan and shall notify the Authority within 24 hours.
- 2.18.2 In case of a major accident causing an imminent risk to health and safety, the Civil Protection Department are to be immediately notified following detection.

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- 2.18.3 The plan shall be reviewed at least every 2 years or as soon as practicable after an accident, whichever is the earlier, and the Authority notified of the results of the review within 2 months of its completion.
- 2.18.4 The Permit Holder shall maintain and implement all health and safety measures in compliance with ACT XXVII of 2000; Occupational Health and Safety Authority Chapter 424 and all relevant subsidiary legislation.
- 2.18.5 The Permit Holder(s) shall have sufficient employees trained to deal with any emergency that may arise, e.g. fire-fighting and first aid.
- 2.18.6 The Permit Holder(s) is to keep the Authority updated on any major changes in operations that may impact on the health and safety of the employees, which shall be carried out in compliance with Act XXVII of 2000 (Occupational Health and Safety Authority Act, 2000 (Chapter 424)) and all relevant subsidiary legislation.
- 2.18.7 The Permit Holder(s) is to make available Health and Safety documentation freely available, in compliance with Act XXVII of 2000 (Occupational Health and Safety Authority Act, 2000 (Chapter 424)) and all relevant subsidiary legislation

## **2.19 Closure and Decommissioning**

- 2.19.1 The Permit Holder shall maintain and operate the Permitted Installation so as to prevent or minimise any pollution and public health risk, including the generation of waste, on closure and decommissioning in particular by:-
- a. Attention to the design of new plant or equipment;
  - b. The maintenance of a record of any events which have, or might have, impacted on the condition of the site along with any further investigation or remediation work carried out; and
  - c. outline-decommissioning plan as per conditions 2.19.2 and 2.19.3.
- 2.19.2 The Permit Holder(s) shall endeavour to carry out a full review of the Outline Decommissioning *Plan* at least every 4 years and shall include all the following information.
- 2.19.2.1 A draft waste management plan which shall include:
- i. The identification and characterisation of sources and types of wastes;
  - ii. Criteria for segregation of wastes;
  - iii. Proposed treatment, conditioning, transport, storage and disposal/ recovery methods;
  - iv. Potential reuse/recycling of such wastes
  - v. Details on decommissioning and disposal of equipment
- 2.19.2.2 A list of materials which will not be disposed of but transferred to third parties for re-use including any unprocessed raw materials and finished products.
- 2.19.2.3 A qualitative assessment of the potential for contamination of land and groundwater pollution which might arise from the historical and current processes carried out at the installation.
- 2.19.3 The Permit Holder(s) shall notify the Authority immediately upon a decision being taken to decommission all or part of the site, or planned cessation for a period greater than 6 months, of all or part of the permitted activities. The Authority may

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impose further requirements in the case of planned cessation for a period greater than 6 months.

- 2.19.4 The Permit Holder(s) shall notify the Authority prior to ceasing operations permanently in part or full, whereby an application for cessation of operations shall be made to the Authority and shall include a decommissioning plan.
- 2.19.5 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the installation in the permitted activity, the Permit Holder(s) shall to the satisfaction of the Authority, decommission, render safe or remove for disposal/recovery, any land, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution and that may pose a public health risk.
- 2.19.6 The Permit Holder covered by the respective Subsidiary Permits shall inform the other Permit Holder of any decision being taken to decommission any plant falling within their responsibility in part or as a whole.
- 2.19.7 One year before the planned decommissioning of all or part of the site, the Permit Holder(s) shall submit for approval to the Authority a full Decommissioning Plan which shall at least include:
- i. A systematic appraisal for the risk of land and groundwater contamination arising from the past activities within the permitted site. Depending on the outcome of such appraisal, a proposal for land and groundwater investigations may be required.
  - ii. Where the contamination of land and groundwater at the site poses a significant risk to human health or the environment as a result of the activities carried out on site, the Permit Holder(s) shall submit a report indicating the actions to be taken for removal, control, containment or reduction of relevant hazardous substances so that the site, taking into account its current or approved future use, ceases to pose such a risk.
  - iii. The methods which will be used in order to decontaminate the land. Such methods may also include isolation.
- i. A detailed waste management strategy which shall include:
- a. The identification and characterisation of sources, types and quantities of waste (including equipment, fuels, by-products such as ash, etc.);
  - b. Criteria for segregation of wastes;
  - c. Proposed treatment, conditioning, transport, storage and disposal/recovery methods;
  - d. Potential reuse/recycling of such wastes.
- i. The identification of potential sources of emissions to the atmosphere, land and water (both seawater and groundwater) pollution which might arise from the decontamination process and corresponding mitigation measures to minimise the likelihood of such emissions.
  - ii. Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the installation in the permitted activity, the Permit Holder(s) shall to the satisfaction of the Authority, decommission, render safe or remove for disposal/recovery, any land, subsoils, buildings, plant or equipment, or any waste, materials or

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substances or other matter contained therein or thereon, that may result in environmental pollution and that may pose a public health risk.

2.19.8 The approved Decommissioning Plan shall be implemented within 12 months of final cessation of the Permitted activities or part thereof or according to a timeframe as may be agreed with the Authority.

2.19.9 When deemed necessary, the authority may require the Permit Holder(s) to take such additional measures as it considers necessary with respect to after care obligations in relation, but not limited to the remedial action, rehabilitation, and monitoring of the site.

### **3 Records**

3.1 All records required to be made by this Framework Permit and any other records made by the Permit Holder(s) in relation to the operation of the Permitted Installation shall:-

3.1.1 be made available for inspection by the Authority upon request;

3.1.2 be supplied to the Authority on demand and without charge and in the format requested;

3.1.3 be legible

3.1.4 indicate any amendments which have been made and shall include the original record wherever possible; and

3.1.5 be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 3 years from the date when the records were made, unless otherwise agreed in writing.

3.2 A site daily operations log shall be made in a legible manner and kept on site and be made available for inspection by the Authority at any reasonable time. The following information shall be recorded on a daily basis and retained for 5 years:

i. Total amount of waste in kilos removed from site for disposal or further treatment

ii. Any incidents that took place on site such as mechanical faults in the machinery or equipment used on site, any spills, fires, etc and the remedial action taken

iii. Any other incidents that the Permit Holder(s) deems important to record in the Site daily operations log.

3.3 Each record shall be compiled within 24 hours of the relevant event. The records kept in the site daily operational log shall be available for inspection at any time when the Authority representatives request to inspect them.

### **4 Reporting**

4.1 All reports and written and or oral notifications required by this Permit and notifications required by Regulation 7 of the Industrial Emissions (IPPC) Regulations shall be made or sent to the Authority using the contact details notified in writing to the Permit Holder(s) by the Authority.

4.2 The Permit Holder(s) shall submit to the Authority an Annual Environmental Report (AER) of the previous year by not later than end of March of each year, providing the information listed in Schedule 1 of each respective subsidiary permit. It shall be



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ensured that all certification and documentation as per Schedule 1 are submitted. The AER shall be forwarded to the Authority in electronic format.

- 4.3 The European Pollutant Release and Transfer Register (E-PRTR) report for the installation shall be submitted as part of the Annual Environment Report, by end of March of each year, or as required by Legislation. All quantities shall be reported, even when these do not exceed the thresholds mentioned in EC Regulation 166/2006. The format used for reporting shall be that established by legislation, notably S.L. 549.47 and Government Notice 138 of 2017 or as subsequently amended.
- 4.4 In the event where operations cease temporarily (2 weeks or more), the TCP or Permit Holder of each installation are obliged to notify the Authority within two (2) days and are also to inform the Authority with regards to when the works are intended to resume.

## **5 Notifications**

- 5.1 This section is without prejudice to any other notification requirement in this Permit.

The Permit Holder(s) shall notify the Authority without delay of:-

- 5.1.1 the detection of an emission of any substance which exceeds any limit or criterion in the respective subsidiary permit specified in relation to the substance;
- 5.1.2 the detection of any fugitive emission which has caused, is causing or may cause exceedances of the emission limit values stipulated in the respective subsidiary permit;
- 5.1.3 the detection of any malfunction, breakdown or failure of plant or techniques which has caused, is causing or has the potential to cause exceedances of the emission limit values stipulated in the respective subsidiary permit; and
- 5.1.4 any accident which has caused, is causing or has the potential to cause significant pollution and/or public health risk.
- 5.2 The Permit Holder(s) shall submit written confirmation to the Authority of any notification under condition 5.1, by sending:
- 5.2.1 the information listed in Schedule 3 of the framework permit within 24 hours of such notification;
- 5.2.2 the information listed in Schedule 1 of the respective subsidiary permit and such information shall be in accordance with that Schedule as part of the AER according to the timeframe specified in Condition 4.2 in this permit.
- 5.3 The Permit Holder(s) shall give written notification as soon as practicable prior to any of the following:-
- 5.3.1 permanent cessation of the operation of part or all of the Permitted Installation;
- 5.3.2 cessation of operation of part or all of the Permitted Installation for a period likely to exceed 1 year; and
- 5.3.3 resumption of the operation of part or all of the Permitted Installation after a cessation notified under condition 5.3.2

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5.4 The Permit Holder(s) shall notify the Authority, as soon as practicable, of any information concerning the state of the site which affects or updates that provided to the Authority as part of the Site Report submitted with the application for this Permit.

5.5 The Permit Holder(s) shall notify the following matters to the Authority in writing within 10 working days of their occurrence: -

5.5.1 Where the Permit Holder(s) is a registered company:-

- i. Any change in the Permit Holder(s) 's trading name, registered name or registered office address;
- ii. any change to the particulars of the Permit Holder(s) corporate identity, and
- iii. Any steps taken with a view to the Permit Holder(s) going into administration, entering into a company voluntary arrangement or being wound up.

5.5.2 Where the Permit Holder(s) is a corporate body other than a registered company: -

- i. Any change in the Permit Holder(s) 's name or address; and
- ii. Any steps taken with a view to the dissolution of the Permit Holder(s)

5.5.3 In any other case: -

- i. The death of any of the named Permit Holder(s) s (where the Permit Holder(s) consists of more than one named individual);
- ii. Any change in the Permit Holder(s) 's name(s) or address(es);
- iii. Any steps taken with a view to the Permit Holder(s) , or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership

## **6 Interpretation**

6.1 In this Permit, the following expressions shall have the following meanings:-

“*AER*” means the Annual Environmental Report.

“*Application*” means the application for this Permit, together with any response to a notice served under Regulation 5 to the Industrial Emissions (IPPC) Regulations and any operational change agreed under the conditions of this Permit.

“*Authorised Officer*” means any officer of the Authority authorised in writing pursuant to the Environment Protection Act 2016 to exercise any of the powers specified therein.

“*Background concentration*” means such concentration of that substance as is present in:

- i. Where the Permitted Installation uses no significant amount of supplied or abstracted water, the precipitation onto the site. or
- ii. water supplied to the site; or

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- iii. where more than 50% of the water used at the site is directly abstracted from ground or surface water on site, the abstracted water;

“*BAT*” means best available techniques, which means the most effective and advanced stage of development of activities and their methods of operation which indicates the practical suitability of particular techniques to prevent and where that is not practicable to reduce emissions and the impact on the environment as a whole. For these purposes: “available techniques” means “those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the cost and advantages, whether or not the techniques are used or produced in Malta, as long as they are reasonably accessible to the operator”; “best” means “in relation to techniques, the most effective in achieving a high general level of protection of the environment as a whole” and “techniques” “includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned.”

“*BREF*” means the latest version of the BAT reference document published by the European Commission.

“*Conditions*” means the Conditions of the Framework Permit and the Subsidiary Permits.

“*Effluent*” shall refer to any discharge of water or waste water that can no longer be used as it is for the application it was originally intended

“*Engineer*” for engineering works specified in these conditions, means a person who works in the relevant branch of engineering and possesses a warrant to carry out the profession of an engineer in Malta.

“*Fugitive emission*” means an emission to air or water (including sewer) from the Permitted Installation which is not controlled by an emission or background concentration limit under conditions 2.1 of IP0002/05/Ei.

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

“*Industrial Emissions (IPPC) Regulations*” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) and words and expressions defined in the Industrial Emissions (IPPC) Regulations shall have the same meanings when used in this Permit save to the extent they are specifically defined in this Permit. It shall include any future amendments or superseding legislation.

“*mg.Nm<sup>-3</sup>*” or “*mg/Nm<sup>3</sup>*” means milligramme per normal metre cubed.

“*Monitoring*” includes the taking and analysis of samples, instrumental measurements (periodic and continual), calibrations, examinations, tests and surveys.

“*Permit*” means this Framework Permit (IP0002/05/E) together with the Subsidiary Permits (IP0002/05/Ei, IP0002/05/Eii) and the terms “Framework Permit” and “Subsidiary Permit” shall be defined accordingly.

“*Permitted Installation*” means the activities and the limits to those activities described in Table 1.1.1 of this Permit

“*Sewer*” means “*Public sewerage system*” means the sewerage system owned by the Water Services Corporation.

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“Staff” includes employees, directors or other officers of the Permit Holder, and any other person under the Permit Holder’s direct or indirect control, including contractors.

“Surface water” means inland waters, except groundwater; transitional waters and coastal waters

“Technically Competent Person” means a person possessing the qualifications, experience and technical competence to abide by the conditions of the Permit.

“Technically Competent Management” means the Technically Competent Person or Persons in control of the day-to-day activities authorised by the Permit and carried on at the Site.

“The Authority” or “the Competent Authority” or “ERA” means the Malta Environment and Resources Authority or such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe.

“The Permit Holder(s)” means the Permit Holder(s) specified in the Permit or other person to whom the Permit has been transferred in accordance with the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) and any statutory provisions or regulations amending or replacing them.

“The Permit Holder(s) ” / “ Operator” means:

- in relation to the Framework Permit each of Medichem Manufacturing (Malta Ltd. and Combino Pharma (Malta) Ltd. acting jointly unless otherwise specified;

- in relation to any Subsidiary Permits as follows:

For IP 0002/05/Ei– Medichem Manufacturing (Malta Ltd.

For IP 0002/05/Eii – Combino Pharma (Malta) Ltd.

“The Regulations” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77) and any regulations amending or replacing them.

“The Site” means the land, structures, plant and equipment to which this Permit relates;

“VOC Solvents Regulations” means the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L.549.79, as may be amended from time to time).

“VOC” means Volatile Organic Compound as defined by the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.77)

“Year” or “reporting year” means calendar year ending 31 December.

- 6.2 Where a minimum limit is set for pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.
- 6.3 Unless otherwise stated, any references in this Permit to concentrations of substances in emissions into air means:-
- 6.3.1 in relation to gases from combustion processes, all emission limit values are defined at a temperature of 273.15K, a pressure of 101.3 kPa after correction for the water vapour content of the waste gases and at a standardised O<sub>2</sub> for 6% medium combustion plants using solid fuels, 3%

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for medium combustion plants, other than engines and gas turbines, using liquid and gaseous fuels and 15% for gas turbines.

6.3.2 in relation to gases from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

6.4 Where any condition of this Permit refers to the whole or parts of different documents, in the event of any conflict between the wording of such documents, the wording of the document(s) with the most recent date shall prevail to the extent of such.

Schedule 1  
Site Plan

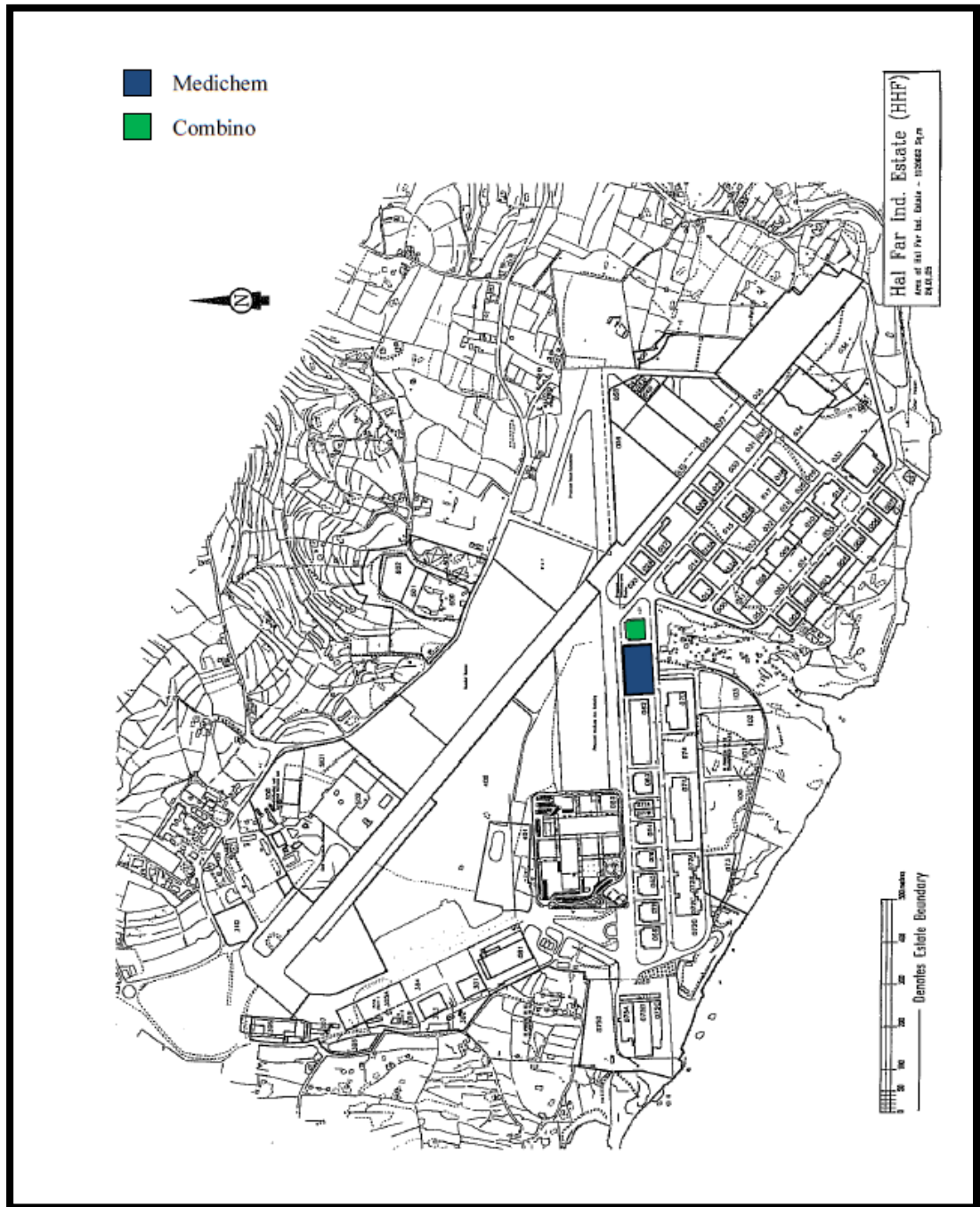


Figure 1: Site of permitted installation, showing extent of the permitted installation, for the carrying out of the activities specified in condition 1.1.1. The extent of the site boundary is indicative and should not be used for interpretation purpose

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## Schedule 2

### Terms of Reference for Noise Monitoring

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#### 1. Introduction

The noise monitoring shall be carried out by the Permit Holder. A consultant that is either an accredited Acoustic expert or qualified professional Engineer and is approved by ERA according to the following criteria shall be commissioned who will propose a monitoring procedure for measuring noise levels within and around the installation as described in section 2 below.

The person(s) undertaking the “on field monitoring” shall be in possession of a certification for the collection of data.

The noise monitoring and impact study report shall be compiled and reviewed by a person who is in possession of a:

- (a) Bachelors degree in Acoustics, or
- (b) Bachelors degree in any of the following: Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety, and an MQF Level 7 specialisation in Acoustics, or
- (c) Bachelors degree in any of the following: Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety and in addition the consultant must be at least an associate member of the Institute of Acoustics or be employed by an organization who are members of the Association of Noise Consultants or equivalent grade of Membership of a professional body for those working in acoustics and noise in any one of the EU member states or any other reputable professional body to the satisfaction of ERA, or
- (d) Certification for the collection of data, such as “Certificate of Competence in Environmental Noise Measurement” issued by the Institute of Acoustics (IoA) or any other equivalent qualification issued by a comparable Professional Association dealing with acoustics in any one of the EU and EEA Member States or any qualifications issued by an educational institution to the satisfaction of ERA and five (5) years experience in noise measurements and assessments.

Copies of such qualifications and certification shall be submitted to ERA prior to the monitoring proposal.

The consultant, in collaboration with ERA, may, where applicable need to consult and seek advice from the Local Council during the selection of the sensitive receptors.

#### 2. Content of monitoring study

The monitoring study should address the following issues:

1. A description of the installation – this shall include a description of all processes carried out on site and related equipment and infrastructures.
2. A description of the surrounding areas – this shall include identification of the types of activities, whether residential or commercial, roads and other amenities. These shall be location-specific taking into account their location with respect to the site.
3. Identification of the main sources of noise and vibration – this shall include all processes on site, including aspects such as transport noise on site, plant equipment, mechanical operations, etc (amongst others) and their times of operation.
4. Identification of the closest noise sensitive receptors – this shall be carried out after assessing the noise levels in the plant’s perimeter and in the other locations identified in

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point 2 above under normal operating conditions of the plant. The various monitoring points shall be identified with a unique code and an analyses of the ambient noise to which each monitoring point is subjected to.

5. Environmental Noise Study – this shall include details of the standards used for measurements, equipment used including calibration details and certificates, resultant measurement data, assessment methods and complaints significance scale. The study is to be carried out according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to the latest revisions of BS4142. The study should include perimeter noise levels, baseline noise study of sensitive receptor sites, noise impact on site sensitive receipts including day and night background levels.

The data compiled for both day and night is a typical representation of the current situation at all receptor points and the measurement time interval is sufficient enough to obtain representative value of a typical background when the specific noise source will be operating. For facilities that operate continuously for 24 hours, it may be appropriate to measure at a time when all other noises have subsided. If it is possible 'specific noise' is estimated by measuring the noise level with and without the facility running.

6. The monitoring shall be performed exclusively using a calibrated type 1 sound level meter conforming to BS 6698/IEC 61672 Class 1. The use of type 2 sound level meters or less is not considered acceptable and will not be considered. The sound level meter, calibrator and microphone must hold a valid current calibration certificate from an accredited laboratory (ex. UKAS)

7. Prior to the initial data collection and at the end of the monitoring day, all acoustic instrumentation system such as the sound level meters are calibrated, and checked immediately before and after each series of monitoring readings. Results must be within  $\pm 1.0\text{dB}$ , otherwise discarded and read again.

8. As a basis for the collection of background data, monitoring shall be carried out during a period when there are no operations at the facility. If this is not possible, operations are to be temporarily suppressed during readings. If this is still not possible, a measurement at an alternative location where the residual sound is comparable to the assessment location(s) with justifications shall be provided.

In case that operating conditions of the site are significantly different during the day, evening or night periods, the measurement procedure will be repeated for those periods of day/evening or night. Therefore, information from the Permit Holder is requested prior to the commencement of the measurements. If the information requested is not provided in time, the Consultants will assume that the site operates uniformly during the day, evening and night periods and measure during the daytime only. However, baseline noise levels would still need to be measured at the nearest noise sensitive locations at night in order to determine the impact.

9. The background noise measurements shall be accompanied by a critical listening of all the other noise sources present in the background. Due to certain acoustic features such as tonality, impulsivity and intermittency the inclusion of specific noise level plus any adjustment for the different noise characteristic features, the rating level,  $L_{Ar,Tr}$  should be reported in accordance with BS 4142:2014, and any revision thereof, depending on the subjective assessment made while taking the readings.

10. Monitoring shall consider seasonal variations including but not limited to the occurrence of the fireworks and any other similar typical seasonal predominant noise sources. The recommended time periods over a twenty-four hour period are categorized in terms of daytime, from 0700-2300 hrs ( $L_{Aeq,16hrs}$ ) and night-time period from 2300 – 0700 hrs ( $L_{Aeq,8hrs}$ ).



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11. For the propagation of noise from the power plant, the use of ISO 9613, ISO 8297: 1994, ISO 3744:2010 and ISO 3746:2010; and any revision thereof (as per the interim methods of the Environmental Noise Directive 2002/49/EC) is strongly recommended.

12. In the case of multioperator installations where the evaluation and monitoring needs to distinguish between the impact caused by different or interconnected operators within the same installation, the application of the following standards is deemed necessary: standard ISO 8297: 1994 and any revision thereof, and ISO 37XX series or specifically ISO 9614-2:1996.

13. Impact assessment of noise events on noise sensitive receptor site – this shall include an assessment according to the guidelines BS 4142:2014, ISO 1996 and ISO 9613 or any other standard and any other standard methodology stipulated by the Authority. A summary of the data obtained after the study has been carried out in relation to the noise sensitive receptors identified above shall be submitted.

14. Conclusions and Mitigation measures – this shall include a summary report of findings from the noise monitoring study including the impact assessment of noise events on noise receptors sites and any remedial action and/or mitigation measures to be implemented by the operator in order to reduce impacts resulting from the site of operation.

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### Schedule 3

#### Notification of abnormal emissions and significant adverse environmental effects

This page outlines the information that the Operator must provide to satisfy conditions 5.1.1 and 5.1.2 of the Framework Permit (IP0002/05/E).

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

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

#### Part A

Permit Number	
Name of Permit Holder	
Location of Installation	
Location of the emission	
Time and date of the emission	

Substance(s) emitted	Media (e.g. air, groundwater)	Best estimate of the quantity or the rate of emission (include units)	Time during which the emission took place

Measures taken, or intended to be taken, to stop the emission	
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#### Part B

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

Name*	
Post	
Signature	
Date	

\* authorised to sign on behalf of Permit Holder

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END OF PERMIT