

Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Moderna Biotech Manufacturing UK Limited
Moderna Drug Substance Manufacturing Facility
Harwell Science and Innovation Campus
Harwell
Oxfordshire
OX11 0RL

Permit number

EPR/TP3822SV

Moderna Drug Substance Manufacturing Facility

Permit number EPR/TP3822SV

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows.

The installation is regulated for the following activity:

Section 4.5 A1 (a) Producing pharmaceutical products

The facility manufactures a COVID-19 mRNA vaccine drug substance, which is manufactured on a batch basis in two stages: production of the mRNA component and the encapsulation of the mRNA in lipid nanoparticles. The drug substance is subsequently filled into syringes or vials at a third-party facility.

Mains water is treated, prior to use in the process, to produce softened and purified water using a number of treatment techniques (ion exchange, filtration, reverse osmosis and electro-deionisation).

The main process point source emissions to air from the installation are volatile organic compounds from fume hood ventilations systems, which discharge to air unabated via emission points A1 to A3. Each emission point is served by two separate fans and outlet ducts, located adjacent to each other, although only one outlet duct will emit at any one time (one duty/one standby). The two ducts are designated A and B for each emission point. This is to provide operational resilience in the case of a fan fault.

Products of combustion (principally oxides of nitrogen and carbon monoxide) are emitted from three 2.86 MWth standby backup gas oil fuelled generators, which will only routinely be operated for testing and maintenance purposes. Each generator discharges emissions to air via two vents (emission points A4 to A9).

Process effluent is adjusted for pH and temperature before discharge to sewer (emission point S1).

There are no process emissions to surface water. Uncontaminated surface water run-off is discharged to ground via soakaways (emission points W1 and W2).

The site is located approximately two kilometres to the southwest of Harwell, centred at national grid reference SU 48246 86544, and surrounded to the north, east and south by agricultural or undeveloped land. To the west are further industrial park and manufacturing facilities.

Two conservation sites are located within relevant screening distances of the installation: the Chilton Disused Railway Line (local wildlife site) and Lyde Bank Plantation (ancient woodland), the closest of which is approximately 1.4 km to the southeast of the site. The nearest residential dwellings are approximately 500 metres to the south of the site.

The facility will be operated in accordance with the operator's Environmental Management System.

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

Status log of the permit		
Description	Date	Comments
Application EPR/TP3822SV/A001	Duly made 18/03/2024	Application for manufacture of pharmaceutical products.
Additional information received in response to Schedule 5 notice dated 18/04/2024	10/05/2024	Information regarding drainage and containment, risk assessment, environmental management system and emission point plan.

Status log of the permit		
Description	Date	Comments
Information received in response to request for information email dated 10/05/2024.	10/05/2024	Confirmation that the emergency generators testing will not take place during hours outside of 0800 and 1800 or at any time on Saturdays, Sundays or public holidays.
Additional information received in response to Schedule 5 notice dated 20/05/2024	30/05/2024	Information regarding risk assessment of effluent discharge to sewer.
Information received in response to request for information email dated 19/06/2024.	21/06/2024	Confirmation of the configuration of emission points A1-A3.
Permit determined EPR/TP3822SV	12/07/2024	Permit issued to Moderna Biotech Manufacturing UK Limited.

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/TP3822SV

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016

Moderna Biotech Manufacturing UK Limited (“the operator”),

whose registered office is

54 Portland Place

London

W1B 1DY

company registration number 14200882

to operate an installation at

Moderna Drug Substance Manufacturing Facility

Harwell Science and Innovation Campus

Harwell

Oxfordshire

OX11 0RL

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

Name	Date
Vicky Patchett	12/07/2024

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General management

1.1.1 The operator shall manage and operate the activities:

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

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

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

1.2 Energy efficiency

1.2.1 The operator shall:

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

1.3 Efficient use of raw materials

1.3.1 The operator shall:

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

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

1.4.1 The operator shall take appropriate measures to ensure that:

- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
- (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
- (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.

- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

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

2.2 The site

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

2.3 Operating techniques

- 2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.
- 2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation (“plan”) specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.4 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and
 - (e) the waste code of the waste.
- 2.3.5 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.
- 2.3.6 For the following activities referenced in schedule 1, table S1.1: AR2. The activities shall not operate for more than 500 hours in emergency use per annum.

2.4 Improvement programme

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

3 Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.
- 3.1.4 For the following activities referenced in schedule 1, table S1.1: AR2, the first monitoring measurements shall be carried out within four months of the issue date of the permit or of the date when the MCP is first put into operation, whichever is later.

3.2 Emissions of substances not controlled by emission limits

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

3.3 Odour

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

3.4 Noise and vibration

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

3.4.2 The operator shall:

- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;
- (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:

- (a) point source emissions specified in tables S3.1, S3.2 and S3.3.

3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

3.5.3 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2 and S3.3 unless otherwise agreed in writing by the Environment Agency.

4 Information

4.1 Records

4.1.1 All records required to be made by this permit shall:

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

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

4.2 Reporting

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

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

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

- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.
 - (d) where condition 2.3.6 applies, the hours of operation in any year.
- 4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:
- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
 - (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4; and
 - (c) giving the information from such results and assessments as may be required by the forms specified in those tables.
- 4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.3 Notifications

- 4.3.1 In the event:
- (a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
 - (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
 - (b) of a breach of any permit condition the operator must immediately—
 - (i) inform the Environment Agency, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
 - (c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.
- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- Where the operator is a registered company:
- (a) any change in the operator's trading name, registered name or registered office address; and
 - (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

Where the operator is a corporate body other than a registered company:

- (a) any change in the operator's name or address; and
- (b) any steps taken with a view to the dissolution of the operator.

In any other case:

- (a) the death of any of the named operators (where the operator consists of more than one named individual);
- (b) any change in the operator's name(s) or address(es); and
- (c) any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case of them being in a partnership, dissolving the partnership.

4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:

- (a) the Environment Agency shall be notified at least 14 days before making the change; and
- (b) the notification shall contain a description of the proposed change in operation.

4.3.6 The Environment Agency shall be given at least 14 days' notice before implementation of any part of the site closure plan.

4.4 Interpretation

4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.

4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made "immediately", in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
AR1	S4.5 A1 (a)	Producing pharmaceutical products - COVID-19 mRNA vaccine drug substance	From receipt of raw materials to despatch of finished product.
Directly Associated Activity			
AR2	Electrical power supply	<p>Operation of 3 emergency standby generators with a total thermal input of approximately 8.58 MWth.</p> <p>The generators will burn gas oil solely for the purpose of providing electricity to the installation in the event of a failure of supply from the National Grid and during maintenance testing.</p> <p>3 x 2.86 MWth (new medium combustion plants)</p>	<p>From receipt of fuel (gas oil) to generation of electricity.</p> <p>Electricity produced at the installation cannot be exported to the National Grid.</p> <p>The emergency operational hours of the installation shall not exceed the specifications set out in condition 2.3.6 of this permit.</p>
AR3	Raw material storage	Storage of raw materials for production and decontamination	From receipt of raw materials to use in the process.
AR4	Process effluent treatment	Operation of the effluent treatment plant	From receipt of process effluents to discharge via sewer.
AR5	Raw (mains) water pre-treatment	Production of soft water, using ion exchange resins, pure water, multi-media filtration, ion exchange resin filtration, activated carbon filtration, reverse osmosis and electro-deionisation.	From receipt of mains water to production of treated water prior to use in the process.
AR6	Storage and handling of waste produced onsite	Storage of waste materials awaiting collection for disposal off-site. Includes shredding of non-hazardous waste.	From receipt of wastes to disposal of offsite.
AR7	Fume hood ventilation system	Extraction of air via fume hoods in the weigh and dispense area, QC laboratory, and raw material sampling in the warehouse. Includes high efficiency particulate air (HEPA) filters.	From receipt of extracted air to discharge to atmosphere via emission points A1 to A3.
AR8	Surface water drainage system	Collection of uncontaminated surface water run-off and discharge to soakaways. Includes surface water storage in a Sustainable Drainage System (SuDS) attenuation basin and interceptors.	From receipt of uncontaminated site surface water run-off to discharge to soakaways.
AR9	Storage and handling of finished product.	Storage of product awaiting collection for transfer off-site.	From receipt of product to transfer offsite.

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
AR10	Gas oil storage	Storage of gas oil for use in backup generators.	From receipt of gas oil to use within the facility.

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application	Application forms B2, B2.5, B3 and B6 and all referenced supporting information, including document: Moderna Permit Application Drug Substance Manufacturing Facility – Supporting Information Document, ref: 0693210, dated 21/12/2023.	Duly Made 18/03/2024
Response to Schedule 5 notice dated 18/04/2024	Responses to question 1 (re: drainage, containment, (interceptors, fuel delivery procedures and containment and sampling during an emergency event) and question 3 (re: environmental management system: complaints procedures and preventive maintenance programme).	10/05/2024
Response to email dated 10/05/2024	Confirmation that the emergency generators testing will not take place during hours outside of 0800 and 1800 or at any time on Saturdays, Sundays or public holidays.	10/05/2024
Response to email dated 22/05/2024	Information on measures and procedures to prevent potentially polluting substances entering the soakaways in the event of a fire.	30/05/2024

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1	<p>BAT Compliance for standby generators</p> <p>The operator shall submit a written report to the Environment Agency for assessment, agreement and written approval. The report shall assess options for achieving BAT standards for the standby generators (activity reference: AR2 of Table S1.1). This shall include, but not be limited to:</p> <ul style="list-style-type: none"> • potential upgrades or other changes to infrastructure such that the generators: <ul style="list-style-type: none"> ○ comply with BAT emissions standards (i.e. TA Luft 2g or US EPA Tier II or an equivalent standard). ○ are refitted with vertical flues which are not obstructed by caps or cowls. • proposal of the shortest practical timescale for the implementation of the selected improvements. <p>The operator shall implement the agreed improvements within the timescales agreed with the Environment Agency.</p>	16/09/2024
IC2	<p>Sewer discharge – characterisation of effluent</p> <p>The operator shall conduct analytical testing of a representative sample of the discharge at emission point S1 to confirm whether hazardous chemicals or elements are present.</p>	16/09/2024

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
	<p>The testing shall be carried out in accordance with Environment Agency guidance: Surface water pollution risk assessment for your environmental permit (link) published 01 February 2016, last updated 25 February 2022 and Monitoring discharges to water: guidance on selecting a monitoring approach (link), published 11 June 2020, last updated 18 May 2021.</p> <p>Sample analysis must use a minimum reporting value of 10% of the Environmental Quality Standard (EQS), unless this is not achievable, in which case the operator shall provide a justification.</p> <p>The analysis results and/or justification shall be submitted to the Environment Agency for assessment and approval.</p> <p>If hazardous chemicals or elements are present, other than those assessed in application EPR/TP3822SV/A001, the operator shall include those parameters in the requirements of IC3.</p>	
IC3	<p>Sewer discharge – validation of assumptions</p> <p>The operator shall conduct a monitoring programme in accordance with Environment Agency guidance: Monitoring discharges to water: guidance on selecting a monitoring approach (link), published 11 June 2020, last updated 18 May 2021, in relation to the releases of pollutants to sewer at emission point S1.</p> <p>As a minimum the monitoring programme should include monthly monitoring frequency, for the first twelve months of operation, for the following parameters:</p> <ul style="list-style-type: none"> • dithiothreitol (DTT) • 4-Azaocta-methylenediamine • tetrasodium EDTA • disodium EDTA, and • any additional parameters identified in response to IC2. <p>The operator shall conduct a review of the discharge from emission point S1 using the results of the monitoring during the first year of operation. The review shall be used to validate the assumptions made in application EPR/TP3822SV/A001.</p> <p>The operator shall use the monitoring data to undertake further environmental risk assessment in accordance with the screening procedures in Environment Agency guidance: Surface water pollution risk assessment for your environmental permit (link) published 01 February 2016, last updated 25 February 2022.</p> <p>A written report shall be submitted to the Environment Agency for approval. The report shall include, but not be limited to:</p> <ul style="list-style-type: none"> • raw analysis data from the accredited laboratory used • environmental impact assessment using the H1 tool • appraisal of the results of the H1 risk assessment and conclusions drawn. 	16/09/2025

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
	<ul style="list-style-type: none"> • where appropriate, an improvement plan, with timescales for deliveries of these improvements, including monitoring of any parameters that cannot be demonstrated to be insignificant. <p>Once approved in writing, and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
Gas oil	Sulphur content 0.001% (w/w) max

Schedule 3 – Emissions and monitoring

Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 [Points A1A and A1B on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024]	Weigh and dispense fume hood (duty and standby)	No parameter set	No limit set	-	-	-
A2 [Points A2A and A2B on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024]	Central QC lab fume hood (duty and standby)	No parameter set	No limit set	-	-	-
A3 [Points A3A and A3B on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024]	Raw material warehouse fume hood (duty and standby)	No parameter set	No limit set	-	-	-
A4 to A9 [Points A4 to A9 on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024]	Gas oil fuelled generator exhausts (2.86 MWth)	Oxides of Nitrogen (NO and NO ₂ expressed as NO ₂)	No limit set	In line with web guide 'Monitoring stack emissions: low risk MCPs and specified generators' Published 16 February 2021	Every 1500 hours of operation or once every five years (whichever comes first) from date of acceptance of first monitoring measurements under condition 3.1.4	In line with web guide 'Monitoring stack emissions: low risk MCPs and specified generators' Published 16 February 2021
		Carbon monoxide	No limit set			

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1 [marked SUDS #1 on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024] Emission to soakaway	Uncontaminated site surface water run off via interceptor	No parameters set	No limit set	-	-	-

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

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W2 [marked SUDS #2 on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024] Emission to soakaway	Uncontaminated site surface water run off via interceptor	No parameters set	No limit set	-	-	-

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

Emission point ref. & location	Source	Parameter	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 [marked S1 on site plan in Schedule 7, ref: MUH 100-G-IGS4000 rev 1, dated 20/05/2024] Emission to Moor Ditch via Didcot Sewage Treatment Works	Site effluent treatment plant	- [Note 1]	- [Note 1]	- [Note 1]	- [Note 1]	- [Note 1]

Note 1 – Emission limits and monitoring requirements to be set following the completion of IC3.

Schedule 4 – Reporting

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

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Point source emissions to air Parameters as required by condition 3.5.1	A4 – A9	Every 1500 hours of operation or every five years (whichever comes first).	Within four months of the issue date of the permit or the date when the engine is first put into operation (whichever is later).
Point source emissions to sewer Parameters as required by condition 3.5.1	S1	- [Note 1]	- [Note 1]
Note 1 – Reporting requirements to be set following the completion of IC3.			

Table S4.2: Annual production/treatment	
Parameter	Units
COVID-19 mRNA vaccine drug substance	kg/year

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	m ³
Energy usage	Annually	MWh
Total raw material used	Annually	tonnes

Table S4.4 Reporting forms		
Parameter	Reporting form	Form version number and date
Point source emissions to air	Emissions to Air Reporting Form, or other form as agreed in writing by the Environment Agency	Version 1, 08/03/2021
Water usage	Water Usage Reporting Form, or other form as agreed in writing by the Environment Agency	Version 1, 08/03/2021
Energy usage	Energy Usage Reporting Form, or other form as agreed in writing by the Environment Agency	Version 1, 08/03/2021
Other performance parameters	Other Performance Parameters Reporting Form, or other form as agreed in writing by the Environment Agency	Version 1, 08/03/2021

Schedule 5 – Notification

These pages outline the information that the operator must provide.

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

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

Part A

Permit Number	
Name of operator	
Location of Facility	
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

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

(c) Notification requirements for the breach of permit conditions not related to limits	
To be notified within 24 hours of detection	
Condition breached	
Date, time and duration of breach	
Details of the permit breach i.e. what happened including impacts observed.	
Measures taken, or intended to be taken, to restore permit compliance.	

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

Part B – to be submitted as soon as practicable

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

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

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

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

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

“emissions to land” includes emissions to groundwater.

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

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

“gas oil” includes diesel and is defined in Article 3(19) of the MCPD.

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

“Industrial Emissions Directive” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions, as read in accordance with Schedule 1A to the Environmental Permitting (England and Wales) Regulations 2016.

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

“Medium Combustion Plant” or “MCP” means a combustion plant with a rated thermal input equal to or greater than 1 MW but less than 50 MW.

“Medium Combustion Plant Directive” or “MCPD” means Directive 2015/2193/EU of the European Parliament and of the Council on the limitation of emissions of certain pollutants into the air from medium combustion plants, as read in accordance with Schedule 1A to the Environmental Permitting (England and Wales) Regulations 2016.

“new MCP” means an MCP first put into operation on or after 20/12/2018.

Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels other than gas engines or gas turbines, 6% dry for solid fuels; and/or
- in relation to emissions from gas engines or gas turbines, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 15% dry for liquid and gaseous fuels ; and/or
- in relation to emissions 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 “year” means calendar year ending 31 December.

Schedule 7 – Site plan



END OF PERMIT