Moderna Permit Application

Drug Substance Manufacturing Facility – Supporting Information Document

Moderna Biotech Manufacturing UK Limited

DATE
23 Jan 2024

REFERENCE
0693210

DOCUMENT DETAILS

DOCUMENT TITLE	Moderna Permit Application
DOCUMENT SUBTITLE	Drug Substance Manufacturing Facility – Supporting Information Document
PROJECT NUMBER	0693210
Date	23rd January 2024
Version	02
Author	Stephen Panton
Company name	Moderna Biotech Manufacturing UK Limited

DOCUMENT HISTORY

						APPROVAL TO ISSUE	
VERSION	REVISION	AUTHOR	REVIEWED BY	NAME	COMPANY	DATE	COMMENTS
1	01	Taraka Rhodes Liam Moore Rebekah Sayer	Kate Riley, Max Rooksby Hannah Beeby	Megan Thomas	ERM	19.12.2023	Draft for client review
1	02	Taraka Rhodes	Kate Riley	Megan Thomas	ERM	21.12.2023	Final for issue
2	01	Stephen Panton	Josef Johann Liebl		Moderna	23.01.2024	Final for issue Request for Commercial and Industrial Confidentiality (CInC)

SIGNATURE PAGE

Moderna Permit Application

Drug Substance Manufacturing Facility – Supporting Information Document

RC0693210

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ACRONYMS AND ABBREVIATIONS

Acronyms	Description
AA	Annual Average
AHU	Air Handling Unit
API	Active Pharmaceutical Ingredient
AQMA	Air Quality Management Area
AQS	Air Quality Standard
BAT	Best Available Techniques
BATc	BAT Conclusions
BOD	Biochemical Oxygen Demand
BREF	BAT Reference Document
BS	British Standard
CB	Clinical Biomarker
cGMP	Current Good Manufacturing Practice
CIP	Cleaning In Place
CMO	Contract Manufacturing Organisation
CNC	Clean Non-Classified
CO	Carbon Monoxide
COD	Chemical Oxygen Demand
COMAH	Control of Major Accident Hazards
COSHH	Control of Substances Hazardous to Health
CTU	Controlled Temperature Units
CWW	Common Waste Water and Common Waste Gas Treatment/Management Systems in the Chemical Sector BREF
DAA	Directly Associated Activity
dB	Decibels
DIEA	N,N-Diisopropylethylamine
DOAS	Dedication Outdoor Air System
DS	Drug Substance

Acronyms	Description
DSEAR	Dangerous Substances and Explosive Atmospheres Regulations 2002
DX	Direct Expansion
EA	Environment Agency
EAL	Environment Assessment Level
EHS	Environmental Health and Safety
ELV	Emission Limit Value
EMS	Environmental Management System
EP	Environmental Permit
EP Regulations	Environmental Permitting (England and Wales) Regulations 2016 (as amended)
EQS	Environmental Quality Standard
ETP	Effluent Treatment Plant
ha	Hectares
HAZOP	Hazard and Operability Analysis
HEPA	High Efficiency Particulate Air
HFIP	Hexafluoro-2-propanol
HLRA	High level Risk Assessment
HVAC	Heating, Ventilation and Air Conditioning
IED	Industrial Emissions Directive
IPA	Isopropyl Alcohol
IVT	In vitro Transcription
kg	Kilograms
Lab	Laboratory
LMX	Lipid Mixture
LNP	Lipid Nanoparticles
m	Metres
mg	Milligrams
m/s	Metres per second
m^3	Cubic Metres
m^3	Cubic metres/hour
MAC	Maximum Allowable Concentration
MAL	Material Air Lock
MCP	Medium Combustion Plant
MCPD	Medium Combustion Plant Directive
Moderna	Moderna Biotech Manufacturing UK Limited

Acronyms	Description
mRNA	Messenger Ribonucleic Acid
MWth	Megawatt (Thermal Input)
NaCl	Sodium Chloride
NaOH	Sodium Hydroxide
NGR	National Grid Reference
NH_3	Ammonia
NIA	Noise and vibration Impact Assessment
Nm^3	Normalised cubic meter
NO_2	Nitrogen Dioxide
NO_x	Oxides of Nitrogen
PC	Process Contribution
PEC	Predicted Environmental Concentration
PEG	Polyethylene Glycol
PES	Polyethersulfone
PM	Particulate Matter
PPM	Parts per million
PUW	Purified Water
QA	Quality Assurance
QC	Quality Control
RGN	Regulatory Guidance Note
RO	Reverse Osmosis
SAC	Special Area of Conservation
SCR	Selective Catalytic Reduction
SDS	Safety Data Sheet
SINC	Site of Importance for Nature Conservation
SO_2	Sulphur Dioxide
SOP	Standard Operating Procedure
SPZ	Source Protection Zone
SSSI	Site of Special Scientific Interest
STW	Sewage Treatment Works
SuDS	Sustainable Urban Drainage Systems
TEC	Trade Effluent Consent
TFF	Tangential Flow Filtration
Thames Water	Thames Water Utilities Limited

Acronyms	Description
TOC	Total Organic Carbon
TVOC	Total Volatile Organic Carbon
UV	Ultraviolet
VOC	Volatile Organic Compound
WFD	Water Framework Directive
WFI	Water for Injection
WIP	Work in Progress
μm	Micrometre
°C	Degrees Celsius
%	Percentage

APPLICATION CHECKLIST

Requirement	Topic	Location in Report
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Form B2 – Question 3d	Environmental Management Systems	See Section 6
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Form B3 – Appendix 2	Chemical Sector	See Form B3
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NON-TECHNICAL SUMMARY

Moderna Biotech Manufacturing UK Limited (Moderna) is currently constructing and plans to operate the new Moderna Innovation and Technology Centre at the Harwell Science and Innovation Campus, Harwell, Oxfordshire, OX11 0RL, which will consist of a Drug Substance (DS) Manufacturing facility (the Site). The Harwell Campus is located within The Science Vale UK area, an internationally significant location for innovation and science-based research and business and consists of numerous organisations predominantly working within the innovative technologies sector.

Adjacent to the DS facility, Moderna is developing a separate Clinical Biomarker Building for research and development purposes only. As the Clinical Biomarker Building has limited technical connection to the DS facility, it is considered to be a separate building to the Site and it has not therefore been considered any further in the context of this document.

The Site and buildings under construction are owned by the Harwell Science and Innovation Campus Limited Partnership and will be occupied by Moderna under a 15-year lease agreement. The lease arrangement will include environmental condition obligations for Moderna as the tenant, for when the Site is handed back to The Harwell Science and Innovation Campus (Harwell) Limited Partnership as the landlord.

The Site is a major investment in messenger Ribo-Nucleic Acid (mRNA) manufacturing comprising a new UK based mRNA DS manufacturing facility which will provide the UK with both endemic and pandemic response capability for Moderna COVID-19 vaccines and future respiratory virus vaccine candidates. Moderna has received supplementary funding from, and has a commitment to, the government to produce 250 million doses of vaccine in a pandemic scenario. The Site is scheduled to be operational in November 2024.

Following consultation with the Environment Agency (EA) permit pre-application advice service, it was determined that a new bespoke installation permit may be required for the proposed activity but is subject to an assessment of the environmental impact. Due to timescales, Moderna are submitting this application with a view that the EA will confirm whether an EP is still required on review of the information provided. The EA also confirmed the EA guidance for Speciality Organic Chemicals Sector (EPR 4.02) (which considers the basis of the Manufacture of Organic Fine Chemicals Best Available Techniques (BAT) Reference Document 2006) as the most applicable BAT requirement for the operation.

If required, Moderna wishes to apply for a new environmental permit (EP) for a Part A(1) activity that falls under Section 4.5 of Schedule 1, Part 2 of the Environmental Permitting (England and Wales) Regulations 2016 (as amended), namely "*Producing pharmaceutical chemicals*". In order to meet the commissioning start date of September 2024, Moderna requires an EP by July 2024.

Full planning permission has been granted by Vale of White Horse District Council (application ref: P22/V2435/FUL) under the Town and Country Planning Act 1990. While the EP sits outside this Act, parts of the assessment work undertaken to support the planning application are also used to support this EP application. This includes the noise modelling and assessment prepared by Carter Jonas LLP on behalf of the landlords Harwell.

The nearest designated ecological receptor to the Site is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. The Site does not fall within an Air Quality Management Area (AQMA) (nearest AQMA located approximately 10 km to the north).

In relation to groundwater sources, the Site does not fall within a groundwater source protection zone (SPZ). The nearest residential receptor is Chilton Field Way approximately 500m to the south of the Site.

The main point source emissions to air will be those arising from combustion activities (three emergency diesel generators and one firewater pump) and from fume hood ventilation systems. Emitted substances will comprise of oxides of nitrogen, carbon monoxide, particulates from the combustion plant, and Volatile Organic Compounds from the ventilation systems. An H1 assessment has been completed for emissions to air. VOC emissions have been based on a conservative assessment, assuming the release of raw materials and solvents at maximum storage volumes, rather than at actual usage which will be far less. Nevertheless, all VOC emissions have screened out and are therefore considered insignificant. Emissions from the emergency diesel generators were not screened out, however these generators are only for emergency use and will be tested for less than 50 hours per year.

There will be no point source emissions to surface water. All clean, uncontaminated surface water runoff from building roofs, roads and areas of hard standing will discharge to ground via a sustainable urban drainage basin to the northeast of the site building.

The Site will utilise an effluent treatment plant to adjust process effluent for pH and temperature. Treated process effluent will discharge to the Thames Water Utilities Limited sewer under a trade effluent consent. A H1 assessment has been undertaken to determine if the impact of the process effluent to the ultimate receiving surface water has a significant impact. The proposed discharge has been assessed independently of any mixing/addition of sanitary flows, providing a worst case, conservative assessment. Similarly, effluent composition has been assessed based on an assumed full annual consumption of raw materials used in process and discharged to the sewer. All emissions screened out of the H1 assessment and are therefore considered insignificant.

A detailed noise and vibration impact assessment (NIA) has been submitted on behalf of the landlord, Harwell, and approved by the Vale of Horse District Council for the construction of the Site. The assessment found that the noise emissions would not cause significant impact to receptors on the basis that they would not result in any increase in noise levels at the receptor sites. Subsequently, a planning condition was issued requiring compliance with plan noise levels designed to meet background noise levels at receptors, minus 5 dB overall. Moderna will take appropriate noise abatement measures to ensure the noise at the Site meets the planning conditions including a commissioning plan that will monitor noise levels during commissioning.

The Site will have one above ground bulk storage fuel tank and associated diesel day tanks for the emergency diesel generators and firewater diesel pump engine. The above ground storage tank will have appropriate secondary containment. An environmental risk assessment has been carried out to assess the potential impacts of emissions to air and water, odour, noise and vibration, and identifies the hazard, source, pathway, receptor and mitigating measures.

A full description of the condition of the Site at the time of this application is provided in the Site Condition Report, which provides a record of the Site and its baseline conditions at the time of permitting.

The Site will operate an environmental management system based on, and aligned to, the requirements of ISO 14001.

The EP application and supporting information has been prepared by Environmental Resources Management Limited (ERM) on behalf of Moderna. The supporting information document is based on the description of the Site provided by Moderna, as well as publicly available data.

1. INTRODUCTION

1.1 BACKGROUND

Moderna Biotech Manufacturing UK Limited (Moderna) is currently constructing and plans to operate the new Moderna Innovation and Technology Centre at the Harwell Science and Innovation Campus, Harwell, Oxfordshire, OX11 0RL, which will consist of a Drug Substance (DS) Manufacturing facility (the Site). The Harwell Campus is located within The Science Vale UK area, an internationally significant location for innovation and science-based research and business and consists of numerous organisations predominantly working within the innovative technologies sector.

Adjacent to the DS facility, Moderna is developing a separate Clinical Biomarker Building for research and development purposes only. As the Clinical Biomarker Building has limited technical connection to the DS facility (limited to firefighting pumps and sprinklers), it is considered to be a separate building to the Site, and it has not therefore been considered any further in the context of this document.

The Site and buildings under construction are owned by the Harwell Science and Innovation Campus Limited Partnership and will be occupied by Moderna under a 15-year lease agreement. The lease arrangement will include environmental condition obligations for Moderna as the tenant, for when the Site is handed back to the Harwell Science and Innovation Campus Limited Partnership as the landlord.

The Site is a major investment in messenger Ribo-Nucleic Acid (mRNA) manufacturing comprising a new UK based mRNA DS manufacturing facility which will provide the UK with both endemic and pandemic response capability for Moderna COVID-19 vaccines and future respiratory virus vaccine candidates. Moderna has received supplementary funding from, and has a commitment to, the government to produce 250 million doses of vaccine in a pandemic scenario. The Site is scheduled to go operational in November 2024.

The Site will be used to manufacture mRNA vaccines DS to be subsequently filled into syringes/vials (completed at a third-party Contract Manufacturing Organisation (CMO) facility). The Site will manufacture complete DS on a discrete batch basis throughout the year.

The DS production will be undertaken in accordance with and regulated under Current Good Manufacturing Practice (cGMP) standards. At the point of submission of this permit application, the Site is being built and fitted out for commissioning and eventual production of the complete drug substance. This vaccine production facility is part of several global developments by Moderna in parallel. This submission is therefore based on engineering design information provided by Moderna.

1.2 REASON FOR THE PERMIT APPLICATION

The main commercial activity taking place at the Site will be the production of pharmaceuticals. This activity is listed under Schedule 1, Part 2 of the Environmental Permitting (England and Wales) Regulations 2016 (as amended) (EP Regulations) as a Part A(1) activity. There is no threshold value in terms of manufacturing capacity for the application of the Regulations. The proposed activities at the Site are not covered under any Standard Rules Permit (SRP).

There are several additional activities associated with the production of the DS, including quality control checks on raw materials and complete drug substance, effluent treatment and discharge, waste treatment, combustion activities and materials storage and handling. All of the additional activities are detailed in Section 1.4**.**

The Site does not fall under the requirements of Schedule 14 of the EPR regarding solvent emission activities as the consumption of solvents at the maximum operational throughput scenario does not exceed the threshold of 50 tonnes per annum for manufacturing of pharmaceutical products defined in Annex VII of the Industrial Emissions Directive (IED) 2010/75/EU. Details of predicted annual solvent usage can be found in Section 8.2.

Moderna consulted the Environment Agency (EA) in October 2023 to confirm whether the Site's operations required an EP in accordance with the EP Regulations. An enhanced pre-application meeting (Ref. EPR/HP3728SN/P001) was held on 7th December 2023 with the EA. Following the meeting, the EA confirmed that an EP is likely to be required as the DS production process undertaken at the Site meets the definition of "chemical production" as outlined in the EA guidance note RGN2 "Understanding the Meaning of Regulated Facility", dependent on the environmental impact. Due to timescales, Moderna are submitting this application for full build capacity, with a view that the EA will confirm whether an EP is still required on review of the information provided. Other key topics discussed included:

- Advice for other types of permits including Medium Combustion Plant Standard Rules Permit.
- Assessment of impacts to site based on different production capacities.
- Approach to noise and air quality modelling; and
- Confirmation of the primary BAT requirement for the main activity (see Section ☐ for detailed BAT review) – this is the EA guidance for Speciality Organic Chemicals Sector (EPR 4.02)

EA pre-application advice is provided in Appendix A.

This EP application and supporting information for the Site have been prepared by Environmental Resources Management Limited (ERM) on behalf of Moderna. The supporting information document is based on the description of the Site provided by Moderna, as well as publicly available data. In the context of this application, the Site is the "installation" permitted boundary.

Separately, a planning application has been granted under the Town and Country Planning Act 1990 by the Vale of White Horse District Council for the erection of the facility building and associated landscaping. While the EP sits outside of this Act, parts of the assessment work undertaken to support the planning application are also used to support this EP application. This includes the noise modelling and assessment prepared by Carter Jonas LLP. An amendment will be submitted by Harwell Science and Innovation Campus Limited Partnership to the already extant planning conditions. This is for the inclusion of a sprinkler (firewater) tank that will be associated with Site.

1.3 LISTED ACTIVITY

The main commercial activity at the Site will be the production of pharmaceuticals (complete drug substance containing API). This activity is listed as a Part A activity in Schedule 1, Part 2 of the EP Regulations and can be seen in the Table 1.1 below.

TABLE 1.1 LISTED ACTIVITIES

Listed activity	Description	Limits
Section 4.5 Part A (1) (a) "Producing pharmaceutical products"	Producing pharmaceutical products using a chemical process; production of drug substance containing API in two mRNA production suites and two LNP production suites	From receipt of raw materials to production of drug substance to dispatch of product for storage and filling offsite (not included in permit boundary as completed at separate non-Moderna facility)

1.4 DIRECTLY ASSOCIATED ACTIVITIES

EP Regulations, Schedule 1, Part 1 (2)[1] defines a 'directly associated activity' (DAA) as an operation which:

- has a technical connection with the activity;
- is carried out on the same site as the activity, and
- could have an effect on pollution.

Table 1.2 sets out the activities that are directly associated with the activity listed in Table 1.1 above.

TABLE 1.2 DIRECTLY ASSOCIATED ACTIVITIES

Directly associated activity	Description	Limits
Effluent treatment and disposal	Operation of the effluent treatment plant with pH and temperature adjustment for control of releases to sewer	From collection and treatment of process effluent to dispatch into the sewer
Water Treatment	Raw water treatment in soft water and pure water preparation	From receipt of mains water to production of treated water for point of use
Storage, treatment and disposal of waste	From generation of waste to dispatch offsite Shredding of non-hazardous disposable consumable waste with 85% volume reduction	From receipt of raw materials to the treatment, storage and disposal of waste offsite
Surface water drainage	Discharge of uncontaminated surface water runoff (from the roof and external areas) to groundwater	Handling and storage of Site drainage until discharge to the Site surface water system via one interceptor. Including surface water storage in a Sustainable Drainage System (SuDS) attenuation basin
Combustion Plant	Combustion of diesel in three back up diesel generators each with a thermal rated input of 2.86 MWth, and one firewater	From receipt of fuel to emission of combustion products

[1] UK Government (2016). *Environmental Permitting (England and Wales) Regulations 2016 Schedule 1, Part 1*. Available at: https://www.legislation.gov.uk/uksi/2016/1154/schedule/1/part/1/made Last accessed: 25/07/2023

Directly associated activity	Description	Limits
	pump engine with a thermal rated input of 0.74 MWth	
Storage and handling of chemicals, raw materials and finish product	Storage, handling and distribution of raw materials	Point of receipt of raw materials, to dispatch of complete DS
Refrigeration	Operation of gas filled chiller, heat pumps and freezers for raw material and product storage	The storage and handling of refrigerants and operation of gas filled refrigeration/cooling rooms
Chillers	One air cooled chiller for process cooling, AHUs, and mechanical, electrical and utility spaces	From point of receipt to point of use
Compressed Air	Compressed air for instrumentation and general-purpose requirements as well as process air for process users	From point of receipt to point of use
Firewater management	Storage of firewater in a bulk storage tank for use in the firewater sprinkler system	From point of receipt of raw water to point of use and subsequent discharge to disposal offsite

1.5 DETAILS OF THE COMPANY

The details of the secretaries and directors for Moderna Biotech Manufacturing Limited as listed by Companies House are provided below:

- Cristoph Brackmann, Director, Date of birth October 1973;
- Brian Taylor Sandstrom, Director, Secretary, Date of birth October 1979; and
- Broughton Secretaries Limited, Secretary.

Moderna Biotech Manufacturing UK Limited company registration number is 14200882.

2. SITE DESCRIPTION

2.1 SITE LOCATION

The proposed Site is to be developed at the Harwell Science and Innovation Campus in Harwell, Oxfordshire, OX11 0RL. The centre of the Site is at National Grid Reference (NGR) SU 48246 86544.

Table 2.1 shows the Site setting and includes the installation permit boundary.

2.2 SITE OVERVIEW

The Site, currently an open parcel of land, is owned by The Harwell Science and Innovation Campus Limited Partnership and covers an area of approximately 1.86 hectares. Existing road access to the Site is via Frome Road to the South and the Perimeter Road entrance to the campus from Newbury Road.

The Site will comprise an industrial building with two components, as well as external yard areas that provide access and egress routes. The first component is a single-storey element on the eastern side that will accommodate office space and a staff café, but these are not considered to be part of the permitted activity. Behind this is a two-storey component accommodating the manufacturing facility. The manufacturing facility will consist of the mRNA production area, LNP production area, Chromatography Column pack area, Weigh and Dispense area, Buffer Preparation area, and a Quality Control (QC) Laboratory (lab). The facility will also provide areas for utilities and ancillary equipment including cleaning and support areas, storage areas for raw materials, chemicals, waste and cold storage, emergency diesel generators, a chiller and waste/ effluent treatment. Indicative Site layout plans are provided in Appendix B. Detailed descriptions of the Site activities are included in Section 3.

2.3 SITE CONTEXT

The Site will be located in Vale of White Horse District Council's administrative boundary. The Site is located within a predominantly commercial area. The following identifies surrounding receptors to the Site.

- *To the North*: Immediately to the north lies industrial land and other science research and manufacturing facilities. Approximately 1 km north lies agricultural land. The closest residential/farm buildings lie approximately 1.7 km northeast. Harwell lies approximately 2 km to the northeast. A surface water drainage ditch is located approximately 1.4 km north, and potentially discharges into the East Hendred Brook (statutory main river) located approximately 3.7 km northwest of the Site.
- *To the East:* Immediately to the east lies agricultural land. The closest residential land use is approximately 2.6 km to the east at Upton village. The Mill brook (statutory main river) is located approximately 5.6 km east of the Site.
- *To the South:* To the south is undeveloped land attached to the industrial park. The nearest residential properties are those located along Chilton Field Way which lies approximately 500 m to the south. Agricultural land continues from approximately 750 m to the south.
- *To the West:* Immediately to the west lies the European Space Agency building, beyond which is further industrial park and manufacturing facilities. Approximately 1.5 km west lies a deer park. The hamlets of West and East Ginge make up the closest residential land, lying approximately 3 km to the west.

A desktop study was undertaken to identify any nationally and internationally designated sites which may be affected by the proposed activities. The results of the desktop survey using the Multi-Agency Geographic Information for the Countryside (MAGIC) interactive mapping tool have been provided within Table 2.1. Separately the EA has provided a nature and heritage conservation screening report which is provided in Appendix A and identifies the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site.

TABLE 2.1 STATUTORY DESIGNATED SITES

Designated Site	**Search Radius**	**Name**	**Approximate Location from Site**
RAMSAR	10 km	No RAMSAR areas detected	-
Special Area of Conservation	10 km	No SACs detected	-
Special Protection Areas	10 km	No Special Protection Areas detected	-
Marine Protection Areas	10 km	No Marine Protection Areas detected	-
Site of Special Scientific Interest	2 km	No SSSIs detected	-
National Nature Reserve	2 km	No National Nature Reserves detected	-
Local Nature Reserve	2 km	No Local Nature Reserves detected	-

The Site does not fall within an Air Quality Management Area (AQMA) but is located near the Vale of White Horse District Council Marcham AQMA approximately 10 km to the north (declared an AQMA in 2015 by Vale of White Horse District Council for NO_2 pollutants). In relation to groundwater sources, the Site does not fall within a groundwater source protection zone (SPZ).

The Site context is shown geographically in Figure 2.3, Figure 2.4, and Figure 2.5. These show the search area for the Environmental Receptors, including Sites of Special Scientific Interest (SSSI) within a maximum of 2 km, European and Ramsar sites within a maximum of 10 km, Sensitive Built Receptors, Geology and Hydrogeology including Source Protection Zones (SPZs).

2.4 SITE CONDITION

A Site Condition Report has been prepared for the Site boundary (shown in Figure 2.1) in line with the Environment Agency's H5 requirements and is provided in Appendix C. The Site Condition Report provides the Site's baseline ground condition at the time of the permit application and the proposed pollution prevention measures taken to protect the environment in the event of a loss of containment or major accident.

The Site will have a number of measures in place to minimise the risk of accidental releases to land/groundwater which are presented in Section 4.2.2 and the Environmental Risk Assessment in Table 14.1 Environmental Risk Assessment.

FIGURE 2.1 SITE LOCATION PLAN

FIGURE 2.2 ENVIRONMENTAL RECEPTORS

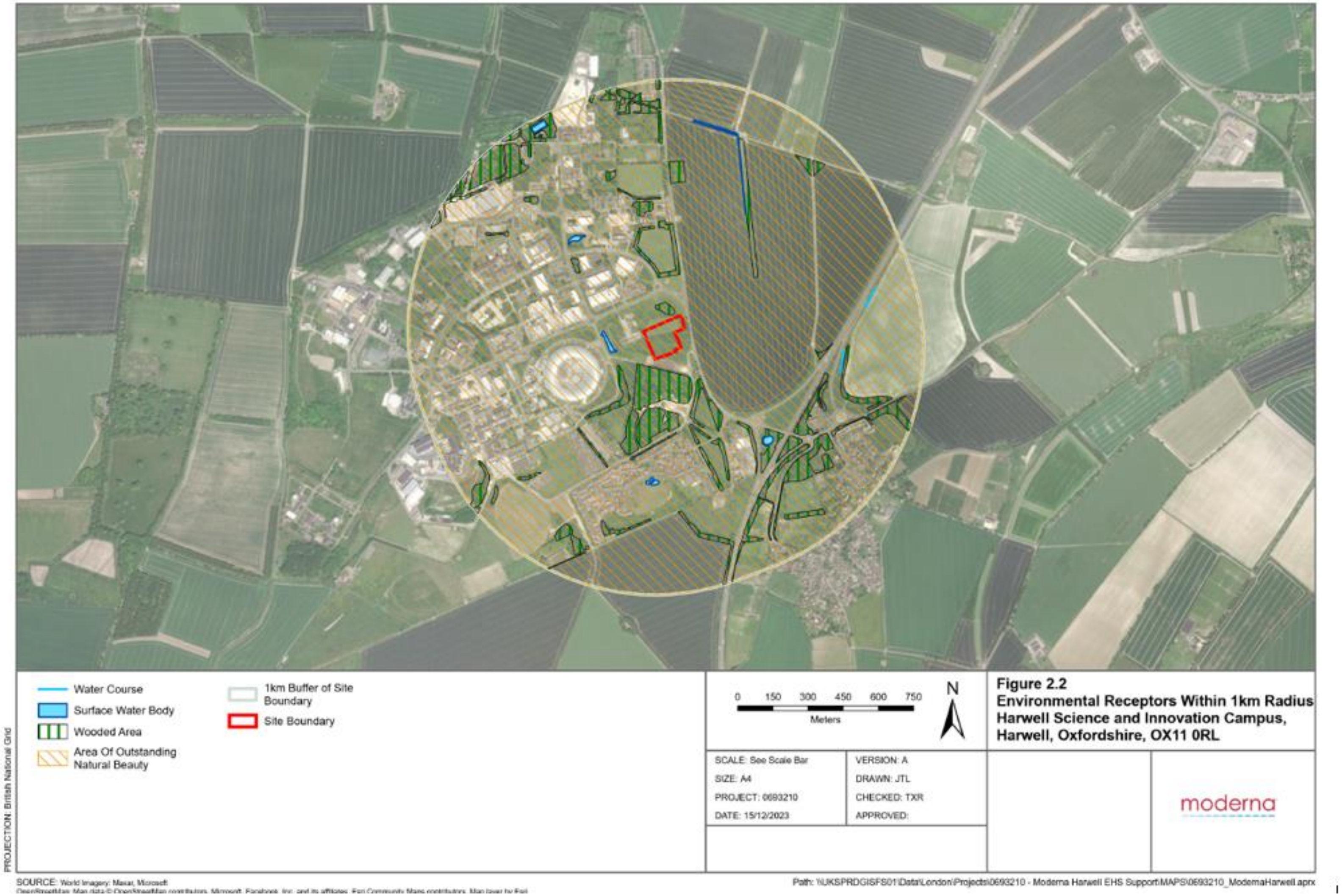


FIGURE 2.3 ENVIRONMENTAL RECEPTORS, EUROPEAN & RAMSAR SITES

FIGURE 2.4 SITE CONTEXT – SENSITIVE BUILT RECEPTORS

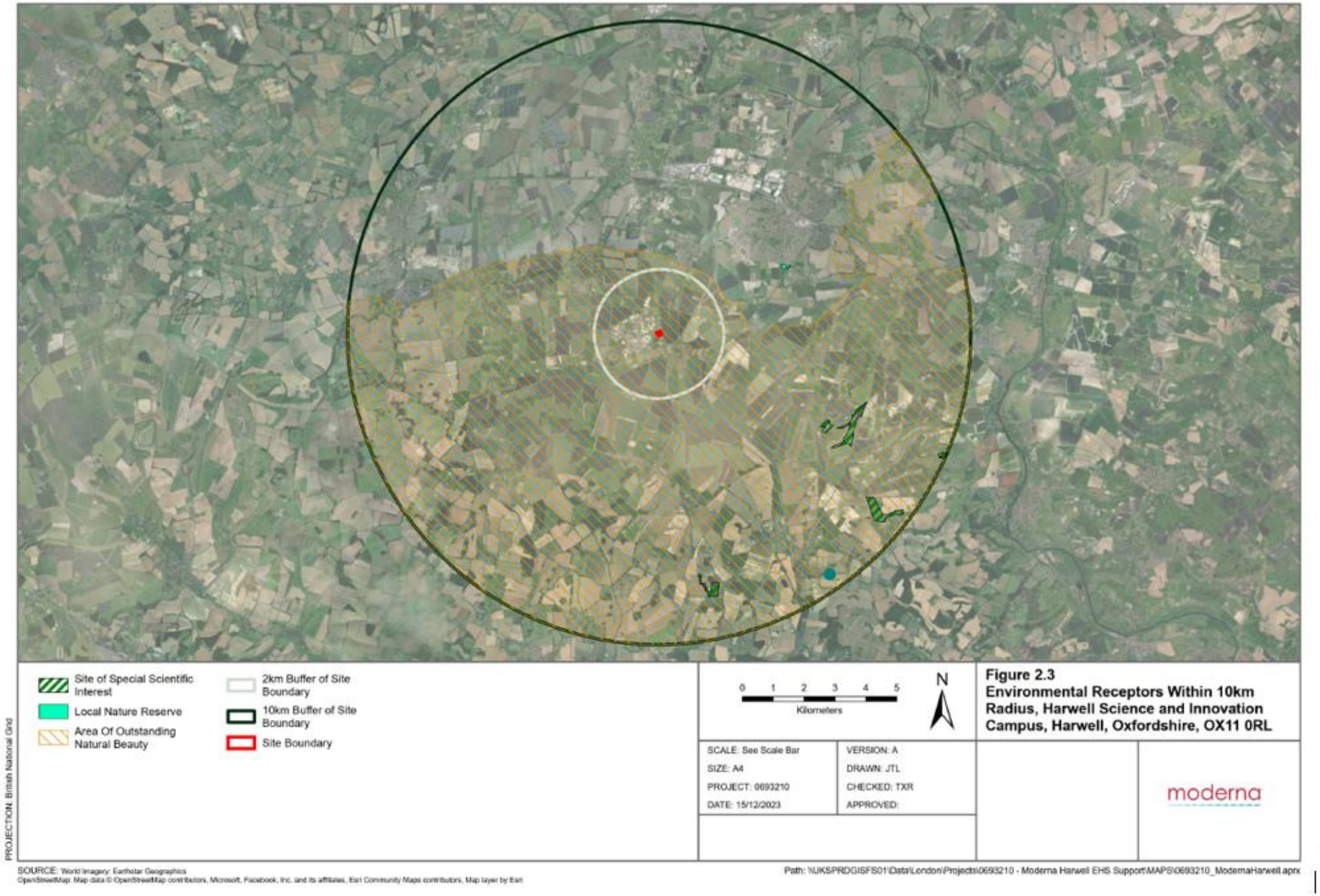
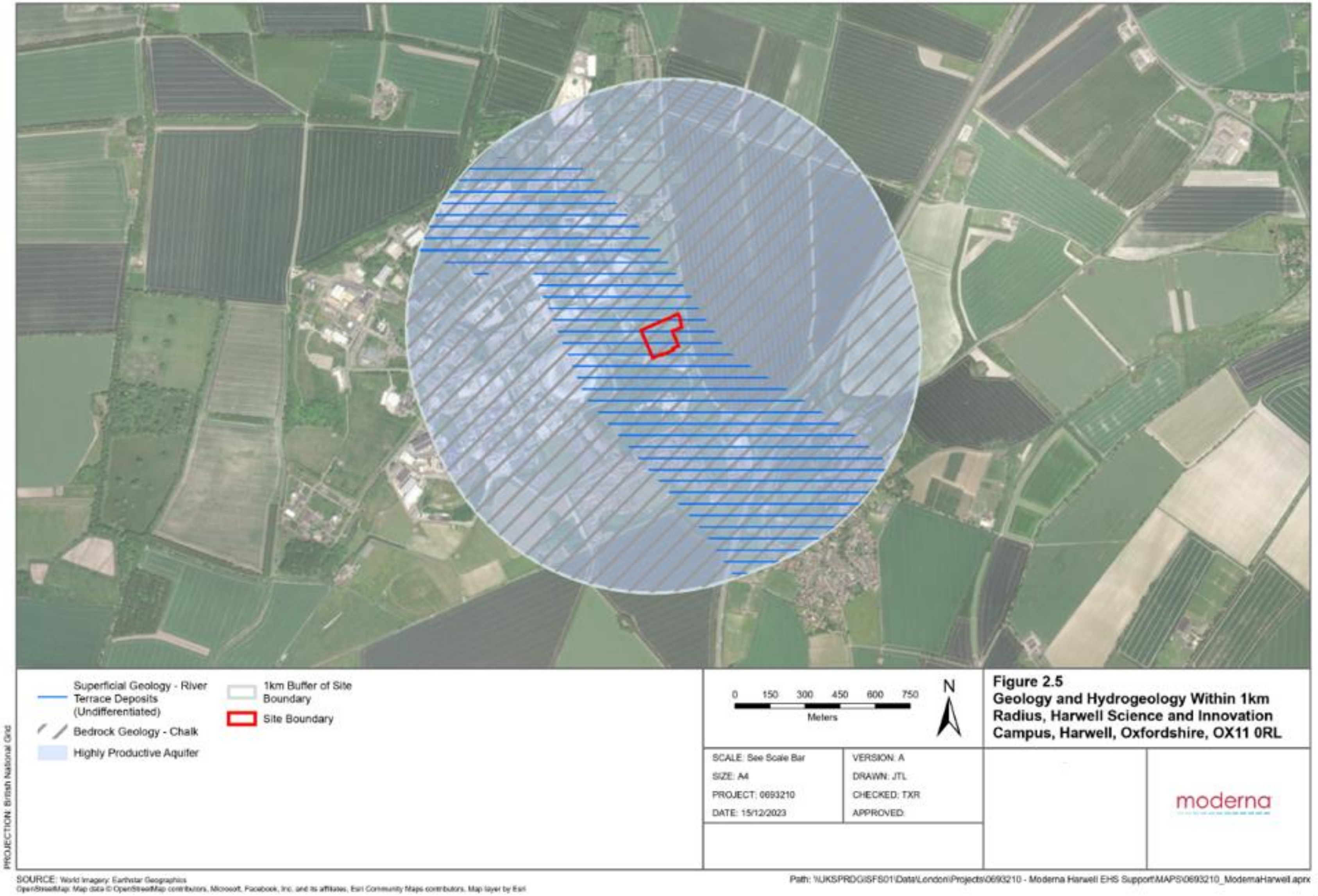


FIGURE 2.5 SITE CONTEXT – GEOLOGY AND HYDROGEOLOGY



3. SITE ACTIVITY

3.1 OVERVIEW

The primary activity of the Site is to produce the complete drug substance (DS). The following sections present a description of the proposed Site activities. An overview is first provided of the primary process activity (production of complete DS), and secondly of the associated activities/utilities which support these operations.

3.2 DRUG SUBSTANCE PRODUCTION

The drug substance production is divided into two processes in two suites on the Site with a QC lab. The first suite encompasses the production of the mRNA component, and the second suite encompasses the process of encapsulating the mRNA in Lipid Nanoparticles (LNPs) to complete the DS.

3.3 ASSOCIATED ACTIVITIES WITH DRUG SUBSTANCE PRODUCTION

3.3.1 QUALITY CONTROL LABORATORY

The Quality Control (QC) laboratory (lab) will include a microbiology, physical and chemical laboratory. The main experimental functions of the QC lab include microbial experiment and chromatography analysis. The QC experimental waste gas mainly comes from the use of reagents in the QC process. The waste gas is collected by fume hoods and then vented to the atmosphere through stacks (see Section 4.1 for emissions to air). QC lab effluent will be collected and treated using an Effluent Treatment Plant (ETP) before being discharge to the sewer (see Section 3.3.3.2 for effluent treatment).

3.3.2 WATER TREATMENT

3.3.2.1 RAW WATER PRE-TREATMENT

The Site will require water to produce the DS, including QC lab water, water for injection (WFI) in process, water used for backwash in process and other Purified Water (PuW) units, cleaning in place (CIP), steam for the humidification system (using one electric boiler), fire-protection, and for domestic use. The demand of approximately 7,910 m^3 /year will be met by means of raw water supply by Thames Water Utilities Limited (Thames Water).

The water used in the DS manufacturing process and associated utilities will undergo purification in order to prevent contamination and bring the water to a suitable quality for use. These are separated into soft water preparation and pure water preparation:

- Soft water preparation: Raw water will be supplied to the QC lab and treated through the Milli-Q system using ion exchange resins to produce ultrapure water low in organics. The treatment efficiency of the soft water preparation system is 90% (remaining reject is sent for treatment as described in the following section).
- Pure water preparation: Raw water will be treated using multi-media filtration, ion exchange resin filtration and activated carbon filtration, reverse osmosis (RO) and electro-deionisation. The treatment efficiency of the pure water preparation system is 70% (remaining reject is sent for treatment as described in the following section). Purified water will be used for the distillation system to prepare water for injection (WFI) in the mRNA synthesis reaction, and for humidification in the air conditioning system for the Site.

Reject from the raw water pre-treatment processes will be discharged via the ETP to the sewer as described in the following section. The spent materials (ion exchange resins, waste activated carbon and waste RO membranes) will be disposed of as solid non-hazardous waste for energy recovery.

Moderna will ensure that the water supply is maintained to the correct quality in accordance with applicable regulatory and corporate requirements. Water consumption will be monitored, logged and tracked.

3.3.2.2 EFFLUENT TREATMENT

The Site ETP will collect and treat process effluent to meet the required quality under a Trade Effluent Consent (TEC) to allow discharge to the Thames Water sewer. The ETP will be located inside on the ground floor to the south of the DS building.

Process effluent from the Site will be routed to the ETP through the onsite drainage system, which is segregated from other drainage onsite (clean uncontaminated water and foul waste water). See Section 3.3.3 for further information on Site drainage and segregation.

The ETP will receive effluents from the following streams:

- Process effluent
- CIP Cleaning effluent
- QC lab effluent
- Autoclave reject
- Soft water preparation reject
- Pure water system and backwash reject
- Distillation reject
- Steam condensate

The ETP system will comprise an influent waste lift station, a two-stage continuous flow through treatment process, and effluent monitoring. The influent waste lift station consists of a pump, 8.6 m^3 tank and a heat exchanger. In the influent waste lift tank, temperature will be monitored against a pre-set temperature. Where flow exceeds the pre-set temperature, flow will be prevented from discharge to the treatment tank and will be recirculated back to the heat exchanger where cooling water will be circulated in a cooling loop to adjust temperature.

From here, the effluent enters the first stage of the treatment tank with a capacity of ~ 0.66 m^3. Two pH control points are incorporated in this system. A pH probe is immersed directly into the first stage tank and, if the influent pH exceeds programmable limits, reagent will be injected directly into the first tank to neutralise 95% or more of the influent acidity or alkalinity through dosing of sulphuric acid and/or sodium hydroxide. Effluent then passes through a laminar flow baffle into the second stage tank with a capacity of ~1.35 m^3. In the second stage tank, a pH probe will be used to determine when the discharge is suitable for onwards treatment i.e. when the pH of the discharge falls between pH 6 and 8. Again, an appropriate amount of acid or caustic will be used to neutralise the effluent, to maintain the pH within the required range.

Treated effluent will then be discharged once the pH is within specification. The treated effluent will discharge to the Thames Water sewer to the south of the Site (emission point S1 in Figure

4.1). The discharge to sewer will be regulated in line with the TEC with Thames Water. Further details on monitoring and discharge consent requirements can be found in Section 13.3.

The ETP will be designed to discharge 23 m^3/day of non-hazardous effluent to the Thames Water sewer at maximum production capacity.

3.3.3 SITE DRAINAGE

The Site drainage will comprise three separate drainage subsystems:

- Surface water system
- Effluent treatment system
- Foul water system

These subsystems are described below. A Site drainage plan is presented in **Appendix** D.

3.3.3.1 SURFACE WATER SYSTEM

There will be provisions in place for the isolation of the surface water drainage system using an isolation valve in the event of an emergency (e.g. a fire or significant spill).

It is expected that the pipework for the surface water drainage system will be polyethylene pipes. During construction and commissioning, quality assurance checks will be undertaken to prove the structural integrity of the SuDS attenuation basin. Regular preventative maintenance as part of the Site EMS will ensure that the integrity of both the SuDS attenuation basin and any isolation valves is maintained throughout the lifetime of the Site operations. Preventative maintenance could include undertaking visual inspections of the material from which they are constructed and/or periodically emptying drainage systems including the attenuation system. Should it be identified that damage has occurred to the structures, repairs will be undertaken to ensure that integrity is suitably maintained.

3.3.3.2 EFFLUENT TREATMENT SYSTEM

As mentioned in Section 3.3.2.2 treated effluent from the ETP will be collected and discharged to the Thames Water sewer via emission point S1 (see Figure 4.1 for emission point location). Treated process effluent will then be sent to the sewage treatment works (STW) for further treatment subject to agreement with the Thames Water under a TEC.

3.3.3.3 FOUL WATER SYSTEM

Foul drainage from permanent welfare facilities will be collected in a dedicated drainage and treatment system where it will be combined with treated effluent downstream of the ETP and discharged via emission point S1 to the Thames Water sewer.

3.3.4 COMBUSTION PLANT

Three diesel generators will be used for emergency/backup purposes only, i.e. for electrical generation in the event of a failure of the national grid electrical supply. The gross thermal input for each combustion unit is 2.86 MWth. As the generators are being commissioned after 20th December 2018 and have a rated thermal input above 1 MWth, they are 'new medium combustion plants' under Schedule 25A of the EP Regulations. As the generators are for emergency back-up purposes only, they are exempt from being a 'Specified Generator' under the meaning of Schedule 25B of the EP Regulations.

The diesel generators will be tested regularly to demonstrate that they can fulfil the backup supply requirements. The build standard of the generators will not be 2g TA Luft compliant as per the EA recently published guidance[2] for emergency back-up generators on installations, however the standard achieved is expected to be of the order of 3g. A review of the potential for impact from the emissions is presented in Section 10.1.

The Site will also operate one firewater pump engine to supply power for a firewater pump system. As the engine will have a thermal input below 1 MWth, it is not a medium combustion plant and as such is not subject to EP Regulations.

The proposed testing regime for the emergency diesel generators and firewater diesel pump engine are presented in Table 3.1. Testing of the generators will take place individually for significantly less than 50 hours per year.

TABLE 3.1 PROPOSED TESTING REGIME

Unit	Fortnightly Load Test (hours)	Annual Load Test (hours)	Total Annual duration (hours)	Load
x3 Emergency Diesel Generator	0.5	4	17	100% maximum
Firewater Diesel Pump Engine	0.5	N/A	13	100% maximum

3.3.5 BOILERS

One electric boiler will be used to provide steam for the room humidification system. The humidification steam will serve all GMP, laboratory and warehouse air systems through the air handling units (AHUs) that serve the Heating Ventilation and Air Conditioning (HVAC) system. No dosing chemicals will be required as there will be no condensate lines in the steam generation that may give rise to scaling and corrosion in the equipment.

3.3.6 REFRIGERATION PACKAGE

The warehouse incorporates segregated areas for refrigerators dedicated to different purposes including:

- Raw material storage for mRNA and LNP;
- mRNA Work-in-Progress (WIP) storage, for bulk mRNA stored prior to LNP formation;
- DS storage, for Drug Substance; and
- Retained QC samples.

The freezer areas will be provided with airflow control stations and temperature gauges to provide the required minimum ventilation air and temperature standards outlined by the Medicines and Healthcare products Regulatory Agency (MHRA) during normal steady-state operations. The freezers are provided with a set of redundant direct expansion (DX) units, which remove heat from the area through evaporation and condensation of the refrigerant and provide increased reliability to the system. The requirement for refrigerant monitoring for the spaces

[2] Emergency backup diesel engines on installations: best available techniques (BAT) - GOV.UK (www.gov.uk), published 21 August 2023

shall be confirmed by the cold room vendor and shall meet the requirements listed in the International Mechanical Code.

The Site will maintain a register of all refrigerant gases used on the Site and their respective global warming potential, in compliance with regulations including maintenance and inspection. The Site will periodically review the refrigerant usage to establish if lower global warming potential gases can be used. New equipment will be specified for low global warming potential gases as standard.

3.3.7 CHILLERS

The chilled water plant will comprise of one air-cooled chiller required for process cooling, AHUs and mechanical, electrical and utility spaces, located in the utility yard near the perimeter of the generators to the north of the DS building. The chilled water system will be served with three pumps, a buffer tank, and system components and accessories, including an expansion tank and air separator.

3.3.8 COMPRESSED AIR

The compressed air system will provide compressed air for instrumentation and general-purpose requirements as well as process air for process users. The compressed air piping will be divided into two separate distribution systems. The process air and instrument air systems will be distributed at 7 bar. Instrument air will serve control devices and other equipment requiring high pressure. Process air will be regulated inside of each suite and upstream of certain equipment to meet the various pressure requirements.

3.3.9 BULK STORAGE, HANDLING AND DISTRIBUTION

A number of raw materials will be required to be transported to, stored and used on the Site. The only bulk storage tanks onsite will be the above ground diesel fuel storage tank for the emergency diesel generators and the firewater pump engine, and firewater storage tank.

The diesel fuel storage tank will be located outside to the southwest of the Site (see exterior plan in Appendix B). All other raw materials used onsite will be in various non-bulk container types located in the warehouse or QC lab (further described in Section 4.4.2).

The fuel tank will be a fixed roof tank with a capacity of 55 m^3 and will be designed in line with the Oil Storage Control of Pollution (Oil Storage) (England) Regulations 2001 guidelines. The fuel tank will incorporate a heavy-duty fabricated steel base frame and be provided with a fully bunded base. The bund will be designed to hold 110% of the capacity of the tank, to allow for tank failure and firewater management. The bund will be provided with a low point sump for removal and offsite disposal of captured liquids.

To detect releases, the tank will also have an electronic level gauge with an alarm output, including low- and high-level indication, that will be used to identify any leaks and prevent overfilling. For tank filling, the pump set will be fitted with isolation valves and non-return valves and the tank will be fitted with a vent to prevent over/under pressure when filling and emptying. A series of underground fuel pipelines will also transfer fuel from the bulk diesel storage tank to the diesel fire pump and emergency diesel generators. These pipelines will be double contained.

Each generator will have a diesel day tank (each with a capacity of 2.5 m^3) within the generator container, providing 10 hours run time. There will also be an associated day tank (0.7 m^3

capacity) for the firewater pump engine. The day tanks will also be designed to meet best practice on containment as detailed above, including bunding.

The firewater tank will have a capacity of 564 m^3 and will be located to the southwest of the Site as shown as 'sprinkler tank' in the exterior plan in Appendix B**.** Further details on firewater management are provided in the following section.

3.3.10 FIREWATER MANAGEMENT

The Site, when fully operational, will store flammable materials including hydrocarbons, resin solution, and cleaning products, however the quantities stored onsite are limited. The fire risk associated with these is therefore considered low. The Site will employ suitable fire protection measures to limit or prevent escalation of fire.

Firewater will be sourced from raw water provided by Thames Water and stored in a 709 m^3 bulk storage tank to supply firewater for process and utility areas during a fire scenario.

A firefighting and firewater containment system design is required to protect the plant equipment, personnel and the environment from the effects of a fire. The firewater system will consist of a firewater sprinkler system and wet risers. A diesel driven firewater pump engine (see Section 3.3.4 for firewater pump engine information) will supply power for the firewater sprinkler system in emergency situations.

Any firewater indoors will be contained and any discharge to the sewer will be by agreement with the sewerage undertaker. Any external firewater will be directed to surface water drains where isolation valves will provide the ability to contain water to test prior to discharge to the SuDs attenuation basin. 90% of the Site will also encompass hardstanding with verges that will help to prevent discharge to ground.

4. EMISSIONS

4.1 EMISSIONS TO AIR

4.1.1 POINT SOURCE EMISSIONS TO AIR

The main point source emissions to air are those arising from combustion activities (three emergency diesel generators and one firewater pump engine), and from fume hood ventilation systems.

The firewater pump engine is not considered an MCP, as described in Section 3.3.4, therefore no emission limit values are proposed, and no further assessment of impact is required.

The three emergency diesel generators will only operate in emergency situations and testing of the generators will take place for less than 50 hours a year. As a result, they are exempt from Specified Generator controls and also from MCP emission limit values. An H1 screening assessment has been undertaken for these generators (see Section 10.1).

Other point source emissions to air include those generated from fume hood exhaust from the weigh and dispense area, QC laboratory, and raw material sampling in the warehouse, that discharge to the atmosphere through stacks approximately 3.5 m above roof height. Emissions from these stacks are only expected to comprise mainly VOCs and will be unabated. Fumes from the weigh and dispense area fume hood will be generated from the weighing and dispensing of liquid raw materials used in buffer preparation. The QC lab will have three fume cupboards primarily from waste gas from quality control testing and use of reagents in the QC process. Fumes from the warehouse raw material sampling fume hood will arise from quality control sampling.

While the emissions from the fume hoods are considered to be minimal, an H1 screening assessment has been undertaken for emissions to air from the QC lab and weigh and dispense fume hoods in normal operations (see Section 10.1). Emissions to air from the warehouse raw material sampling is expected to be negligible since emissions from sampling are far below the worst-case consideration for the same chemicals used in the QC lab which were screened out in the H1 assessment. Each test for quality control and production is carried out against standard and licenced assay test and production methodology, which was developed with efficiency and sustainability goals in mind to minimise waste and emissions. No emission limits are proposed for these emission points.

Table 4.1 provides a list of point source emissions to air; the locations of emission points are shown in Figure 4.1.

TABLE 4.1 POINT SOURCE EMISSIONS TO AIR

Emission Point Reference	Emission Source	Use	Parameter	Proposed Limits	Abatement
A1	Weigh and Dispense Fume Hood	Fume hood exhaust from weighing and dispensing of liquid raw materials for the buffer preparation	Hydrochloric acid, acetic acid, ethanol	-	-

Emission Point Reference	Emission Source	Use	Parameter	Proposed Limits	Abatement
A2	Central QC Lab Fume Hood	x3 fume hood exhaust from the QC Chemical Lab, Sample Prep Area, and Micro-biological lab. Fumes from the decanting of liquid and preparation activities	Acetonitrile, formic acid, acetic acid, methanol, IPA, ethanol, HFIP, hydrochloric acid, tetrahydrofuran, DIEA, chloroform, hydrogen peroxide, phenol, isoamyl alcohol	-	-
A3	Raw Material Warehouse Fume Hood	Fume hood exhaust from raw material sampling	Acetonitrile, formic acid, acetic acid, methanol, IPA, ethanol, HFIP, hydrochloric acid, tetrahydrofuran, DIEA, chloroform, hydrogen peroxide, phenol, isoamyl alcohol	-	-
A4	Emergency Diesel Generator (2.86 MWth)	Usage during an emergency only for power generation	NO_x, CO and particulates	No limits set. Emergency back-up generation only and <50 hours of operation per year for testing	-
A5	Emergency Diesel Generator (2.86 MWth)				-
A6	Emergency Diesel Generator (2.86 MWth)				
A7	Firewater diesel pump engine (0.74 MWth)	Usage during an emergency only for power generation firewater sprinkler system		No limits set as not an MCP	-

4.1.2 FUGITIVE EMISSIONS TO AIR

There are not expected to be any significant fugitive emissions to air as a result of the proposed activity, only emission to air from point source emission points.

Fugitive emissions to air can arise from storage areas, building openings, pipes, valves and other transfer systems, tank breathing and open surfaces. The main sources of fugitive emissions are the release of VOCs in material storage and material transfer and the use of IPA and cleaning spray in laboratory and production areas. There will be no bulk storage of materials containing VOCs, all VOC raw materials will be stored in bottles/containers with lids.

Dispensing of raw materials shall be carried out within fume hoods as described in Section 4.1.1. Room environments will be controlled using HVAC systems (see Appendix E for schematic overview of HVAC system) including biological safety cabinets that will be fitted with high efficiency particulate air (HEPA) filters, in accordance with GMP. The QC Labs Biological safety cabinet's purpose is to protect workers from biohazardous agents and particulates, with most of the air circulation within the equipment and part of air discharge to the lab, and so emissions are considered to be insignificant. Due to the small volumes of solvents stored at the Site, techniques to reduce losses are not applicable as there are no storage tanks at the facility.

The only substance used onsite that could give rise to dust emissions are those used for the buffer prep, namely sucrose. The largest quantity of sucrose will be 45 kg per one buffer which is crystalline/granular solid instead of fine powders and will be mixed with other raw materials in closed vessels to control dust. The product will be decanted in a downflow booth in the weigh and dispense room which is located indoors. All raw materials and products will be kept in closed containers to prevent fugitive dust emissions. The exhaust ventilation system will be provided to protect employees from exposure to dust.

It is anticipated that fugitive emissions of odour will not be significant for the facility (see Section 1212 for more detail on odour emissions).

Management systems will be in place at the Site to minimise the risk of fugitive emissions to air, for example through regular inspection and maintenance of plant items and storage (see Section 6)**.**

4.2 EMISSIONS TO SURFACE WATER

4.2.1 POINT SOURCE EMISSIONS TO SURFACE WATER

The Site will not generate any process effluent that directly discharges to surface water. Therefore, there are no point source emissions to water associated with the Site to be included in this permit.

4.2.2 FUGITIVE EMISSIONS TO SURFACE WATER

There are no fugitive emissions to water associated with the Site as all surface water drainage is to groundwater as detailed in Section 3.3.3.1. The nearest watercourse to the Site is approximately 1.4 km north.

The Environmental Risk Assessment provided in Section 14 assesses the potential for and mitigation against spills or leaks onsite reaching offsite watercourses. The potential losses from chemical and raw material storage are considered low.

4.3 EMISSIONS TO SEWER

4.3.1 POINT SOURCE EMISSIONS TO SEWER

The Site will produce two streams of wastewater to the Thames Water sewer including process effluent from the onsite ETP and domestic/sanitary wastewater. Inputs into the ETP are described in more detail in Section 3.3.2.2**.** The ETP does not receive sanitary wastewater (inputted into foul water system downstream of ETP), and this is not considered any further in the context of this application. The Site's ETP will discharge to the Thames Water sewer under a TEC. The sewer discharge point will be located at emission point S1 as shown in Figure 4.1.

The point source emissions to sewer and the likely consent limits required by the Thames Water consent are detailed in Table 4.2.

TABLE 4.2 POINT SOURCE EMISSIONS TO SEWER

Emission Point Reference	Emission Source	Use	Parameter	Limits
S1	Effluent Treatment Plant	Treatment of process effluent	pH	6 – 11
			Temperature	< 43.3 deg C
			COD	-
			BOD	-
			TOC	-
			Suspended Solids	-
			NH_3-N	-
			Total N	-
			Total P	-

4.3.2 FUGITIVE EMISSIONS TO SEWER

There are no fugitive emissions to sewer associated with the Site.

4.4 EMISSIONS TO LAND AND GROUNDWATER

4.4.1 POINT SOURCE EMISSIONS TO LAND AND GROUNDWATER

A series of drains will direct the surface water arising from roofs and compound areas within the Site to soakaway around the Site, and a SuDS attenuation basin to the northeast of the Site boundary (as detailed in Section 3.3.3.1 and shown in the drainage plan in Appendix D).

4.4.2 FUGITIVE EMISSIONS TO LAND AND GROUNDWATER

The Environmental Risk Assessment assesses the potential for and mitigation against spills or leaks onsite reaching offsite watercourses. The potential losses from raw material storage are considered low. Raw materials stored in the warehouse will be in small quantities and will be stored in either storage racks, bunded pallets, cold storage, or cabinets with integral bunds. There are also no surface water drainage connections in the storage areas that could give rise to emissions to land and groundwater. Raw materials stored in the QC lab will all be stored in cabinets with integral bunds to prevent spillages or leakage of bottles (see Section 8.1 for details on raw materials). Further details on the diesel bulk storage design are described in Section 3.3.9.

The only potential for any fugitive emission to land and groundwater would be in the event of a catastrophic tank failure, a leak from the tank or pipework, or a spill during tanker unloading of fuel or other raw materials and loading of complete drug substance and waste. The Site will be covered by concrete hardstanding, limiting the likelihood of an overland spill reaching soil or groundwater. In the event of a spill onto the concrete hardstanding resulting in oil entering the surface water drainage network, an oil interceptor will be located prior to the SUDs collection basin to capture any spilled oil. The surface water drains will also have isolation valves that will provide the ability to contain water to test prior to discharge to the SuDs attenuation basin.

Regular inspections of the condition of the tank, secondary containment, oil interceptor and Site hardstanding will be included in the Site EMS.

In the event of a loss of integrity from the above ground diesel bulk tank, the Site will have an emergency response procedure to plan for such eventualities and checklists to audit the response in case such an event occurs. Spill kits will be available at various locations across the Site, including designated areas for material delivery. Should an accidental spill occur, the material/contaminated water will be contained as far as reasonably practicable using spill kits, will be removed offsite by a licenced contractor.

FIGURE 4.1 EMISSION POINTS

5. OPERATING TECHNIQUES

5.1 APPLICABLE TECHNICAL STANDARDS

The primary Site activity falls under Section 4.5 Part (A)(1): Pharmaceutical Production. To demonstrate that the Site will operate using Best Available Techniques (BAT) for the range of activities carried out at the Site, a review of the sector guidance note has been carried out to demonstrate BAT in the design and operation of the Site. The document reviewed was:

- Guidance for Speciality Organic Chemicals Sector (EPR 4.02)[3] presented in Table 5.1

The document considered above is presented in tabular form on the following pages. BAT that are not considered applicable are greyed out.

The EA guidance for Specialty Organic Chemicals Sector (EPR 4.02) has been defined on the basis of the Manufacture of Organic Fine Chemicals Best Available Techniques (BAT) Reference Document 2006[4]. EPR 4.02 was advised as the most applicable BAT requirement for the Site during pre-application engagement.

The EA also confirmed through pre-application that the following two documents should be considered in addition to EPR 4.02:

- Best Available Techniques (BAT) Reference Document for the Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (CWW) 2016[5]
- Best Available Techniques (BAT) Reference Document for Common Waste Gas Management and Treatment in the Chemical Sector (WGC) 2023

The CWW BAT Reference Document is predominantly for direct emissions to water but is dependent on the quality of the effluent i.e. if the discharge is comparatively benign, and is going to a sewage treatment works, this can be reflected in the risk assessment. A risk assessment has been completed which is detailed in Section 10. While emissions are considered to be insignificant, the CWW BAT Reference Document has been reviewed and presented in Table 5.2.

While the WGC BAT Reference Document is technically applicable, it was issued in January 2023 and as such is not legally enforceable in the UK. Moderna will consider the requirements under UK BAT once this is issued. At present Moderna consider the existing EPR 4.02 responses to sufficiently describe the control of waste gases from the Site activity.

5.2 OPERATING TECHNIQUES REVIEW TABLE

The document considered above is presented in tabular form on the following pages. BAT that are not considered applicable are greyed out.

[3] Environment Agency. *Specialty Organic Chemicals Sector (EPR 4.02).* Available at: https://assets.publishing.service.gov.uk/media/5a7c67c040f0b626628abd2c/geho0209bpiv-e-e.pdf Last Accessed: 18/12/2023

[4] European Commission (2006). *Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals.* Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/ofc_bref_0806.pdf Last Accessed: 18/12/2023

[5] European Commission (2016) Reference Document for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (CWW). Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/CWW_Bref_2016_published.pdf Last Accessed 19/12/2023

TABLE 5.1 GUIDANCE FOR SPECIALITY ORGANIC CHEMICALS SECTOR (EPR 4.02)

Environmental Performance Indicators	
Monitor and benchmark your environmental performance and review this at least once a year. Your plans for minimising environmental impacts should be incorporated into on-going Improvement programmes. Indicators can be derived using the Horizontal Guidance Note H1 Environmental Risk Assessment (see GTBR Annex 1). It is suggested that indicators are based on tonnes of organics produced (tOP) as they provide a good basis for measuring performance within an installation or a single company year on year.	Moderna's Environmental Management System (EMS) is based on, and will be aligned to the requirement of ISO 14001:2015 and to the EA's guidance: 'Develop a management system: environmental permits'. The EMS will include management commitments for monitoring, reviewing, and reporting procedures, as well as details on improvement programmes and how environmental impacts will be continually assessed on Site. Section 6 provides details of the EMS. To identify areas where environmental impacts can be minimised, an H1 risk assessment has been completed as described in Section 0 to assess the potential for significant impacts to the environment. The assessment considered the maximum production rate of the Site. The full H1 assessment is contained within Appendix F.
Accident Management	
In addition to the guidance in Getting the Basics Right, guidance prepared in support of the COMAH Regulations may help you in considering ways to reduce the risks and consequences of accidents, whether or not they are covered by the COMAH regime	Foreseeable accident and incident risks are identified in the Environmental Risk Assessment in Section 14. Given the Site activities and receptors, such risks are considered to be Low. An Accident Management Plan will be developed as part of the EMS (see Section 14.2). A High-Level Risk Assessment (HLRA) was undertaken by Moderna which identified further areas of assessments/studies required. Details of the HLRA and further assessments are given in Section 14.2. The Site is not classed as a COMAH site, as the inventory of materials stored on site does not exceed any of the limits listed under Schedule 1 of The Control of Major Accident Hazards Regulations 2015.
Energy Efficiency	

Assess the environmental impact of each process and choose the one with the lowest environmental impact. (We recognise that your choice may be constrained, for example, by the integration of processes on a complex site).	Energy consumption for the DS Manufacturing facility is 2.67 MW. The design and operation of the site incorporates energy efficiency measures including an Air Source Heat Pump heating system and the building HVAC system, which includes heat recovery from the extracted air to warm the air flow into the HVAC systems. See Section 9.1 for energy efficiency measures implemented at the Site.
Efficient use of raw materials and water	
1. Maximise heat transfer between process streams where water is needed for cooling. Use a recirculating system with indirect heat exchangers and a cooling tower in preference to a once-through cooling system. 2. Where water is used in direct contact with process materials, recirculate the water after stripping out the absorbed substances.	Procurement of raw materials used in the process will follow a strict management procedure to ensure materials meet regulated specifications. Other raw materials used on site, including those used in disinfection, have been selected in accordance with GMP requirements and suitability as an effective cleaning agent. Raw materials will be purchased on a minimum usage basis to reduce costs and minimise waste generation. The water supply will come from mains water supply. The water will be treated and will be used in the QC lab, in process (injection water in process and for CIP, and backwash/PUW unit), humidification, and steam generation. The water supply will be metered, and usage will be reviewed as part of the site EMS at least once a year. Building cooling is provided by a single air-cooled chiller via the HVAC system. The system will comprise two hydraulically isolated closed loops, a glycol loop to serve the chillers outside, to protect against freezing and damage, and a water system chilled water loop to serve the equipment and components inside. Indirect heat exchangers will transfer the heat energy between these two loops. See Section 8 for further detail on the use of raw materials and water.
Avoidance, recovery and disposal of wastes	
1. Demonstrate that the chosen routes for recovery or disposal represent the best environmental option. Consider avenues for recycling back into the process or reworking for another process wherever possible. 2. Provide a detailed assessment identifying the best environmental options for waste disposal where you cannot avoid disposing of waste.	See Section 0 for details of the different waste streams, quantities, and their management, including minimisation, storage, and disposal. See **BAT – Reaction Stage** response.

Design of a new process	
1. Consider all potential environmental impacts from the outset in any new project for manufacturing chemicals. 2. Undertake the appropriate stages of a formal HAZOP study as the project progresses through the process design and plant design phases. The HAZOP studies should consider amongst other things the points noted above.	1. Potential environmental impacts of the Site's operations have been assessed as part of this permit application in the Environmental Risk Assessment (see Section 14) and H1 assessment (see Section 10) 2. Assessment/studies required to understand the risk of equipment and processes (e.g. PHAs, HAZOPs, DSEAR), will be conducted where appropriate and according to legal requirements including accident management (See **BAT – Accident Management** response). Process Hazard Assessments will be developed for the Site as part of the design review and for all new plant. It is the intention of the Site to complete these by February 2024
Storage and handling of raw materials, products and wastes	
1. Store reactive chemicals in such a way that they remain stable, such as under a steady gas stream, for example. If chemical additions are necessary, then tests should be carried out to ensure the required chemical composition is maintained. Inhibitors may also be added to prevent reactions. 2. Vent storage tanks to a safe location. 3. Use measures to reduce the risk of contamination from large storage tanks. In addition to sealed bunds, use double-walled tanks and leak detection channels. 4. Use HAZOP studies to identify risks to the environment for all operations involving the storage and handling of chemicals and wastes. Where the risks are identified as significant, plans and timetables for improvements should be in place	The Site does not carry out large scale chemical reactions and does not have reactive chemicals onsite other than small laboratory scale quantities. 1. See Section 8 for details on storage of raw materials. 2. See Section 3.3.9 for details of bulk storage, handling and containment design. 3. See **BAT – Design of a new process** and environmental risk assessment in Section 14. Improvement plans will be incorporated in the EMS (Section 6).
Plant systems and equipment	
1. Formally consider potential emissions from plant systems and equipment and have plans and timetables for improvements, where the potential for substance or noise pollution from plant systems and equipment has been identified. 2. Carry out systematic HAZOP studies on all plant systems and equipment to identify and quantify risks to the environment. 3. Choose vacuum systems that are designed for the load and keep them well maintained. Install sufficient instrumentation to detect	1. See Section 4 for emissions identified from the Site activities. An H1 assessment of likely substances to be emitted to air and water from the process has also been carried out as part of the permit application (see Section 0). Performance improvement is included in the Site EMS (see Section 6). 2. See **BAT – Design of a new process** and environmental risk assessment in Section 14. 3. Not applicable – no dedicated vacuum system used on Site

reduced performance and to warn that remedial action should be taken.	
1. Carry out a systematic HAZOP study for all relief systems, to identify and quantify significant risks to the environment from the technique chosen. 2. Identify procedures to protect against overpressure of equipment. This requires the identification of all conceivable over-pressure situations, calculation of relief rates, selection of relief method, design of the vent system, discharge and disposal considerations, and dispersion calculations. In some cases, careful design can provide intrinsic protection against all conceivable over-pressure scenarios, so relief systems and their consequential emissions can be avoided. 3. Maintain in a state of readiness all equipment installed in the venting system even though the system is rarely used. 4. Consider leak detection, corrosion monitoring and materials of construction, preferably in a formal HAZOP study. Plans and timetables for improved procedures or replacement by higher integrity designs should be in place where the risks are identified as significant. 5. If corrosion is likely, ensure methods for rapid detection of leaks are in place and a regime of corrosion monitoring in operation at critical points. Alternatively, use materials of construction that are inert to the process and heating/cooling fluids under the conditions of operation. 6. For cooling water systems, use techniques that compare favourably with relevant techniques described in the Industrial Cooling Systems BREF.	1. **.** Further areas of assessment/studies required to understand the risk of equipment and processes (e.g. PHAs, HAZOPs, DSEAR), will be conducted where appropriate and according to legal requirements including accident management (See **BAT – Accident Management** response). Process Hazard Assessments will be developed for the Site as part of the design review and for all new plant. It is the intention of the Site to complete these by February 2024 2. Potential causes of overpressure will be identified in the design process/process hazard assessments (including HAZOP as detailed above) and will be eliminated by design where possible. If this is not possible, appropriate overpressure prevention/mitigation will be provided and documented. This may include relief devices (relief valves, bursting discs) or procedural controls. Procedures for commissioning, operation and maintenance will be developed. See Section 3.3.8 for further detail on compressed air systems. 3. All equipment installed in the venting system will be maintained in a state of readiness as part of the Site commissioning and ongoing maintenance. All relevant equipment will be included in the proactive Site inspection and maintenance schedule, and reviewed as part of the Site EMS performance evaluation. 4. See BAT– **Accident Management response**. See Section 3.3.9 for leak detection for bulk diesel storage. 5. Process contact metallic material components will be 316L stainless Steel or AL-6XN, both of which are corrosion resistant. Copper is used for the water to air heat exchanger construction materials in contact with liquid for both the air handling unit coils and glycol heat recovery coils, to avoid the risk of corrosion. The liquid raw materials are stored in small volume plastic or glass bottles, which are provided new with each batch. Bulk storage of fuel is designed to manage the risk of spills or leaks, including due to corrosion, see Section 3.3.9. 6. Industrial scale cooling is not required for the installation. Building cooling is provided by a single air cooled chiller via the HVAC system. The system will comprise two hydraulically isolated closed loops, a glycol loop to serve the chillers outside, to protect against freezing and damage, and a water system chilled water loop to serve the equipment and components inside. The cooling system therefore requires no make up water.

Purging Facilities	
Assess the potential for the release to air of VOCs and other pollutants along with discharged purge gas and use abatement where necessary.	N/A – There are no purging activities carried out at the Site
Reaction stage	
1. With a clear understanding of the physical chemistry, evaluate options for suitable reaction types using chemical engineering principles. 2. Select the reaction system from a number of potentially suitable reaction designs – conventional STR, process-intensive or novel-technology – by formal comparison of costs and business risks against the assessment of raw material efficiencies and environmental impacts for each of the options. 3. Undertake studies to review reaction design options based on process optimisation where the activity is an existing activity and achieved raw material efficiencies and waste generation suggest there is significant potential for improvement. The studies should formally compare the costs and business risks, and raw material efficiencies and environmental impacts of the alternative systems with those of the existing system. The scope and depth of the studies should be in proportion to the potential for environmental improvement over the existing reaction system. 4. Maximise process yields from the selected reaction vessel design, and minimise losses and emissions, by the formalised use of optimised process control and management procedures (both manual and computerised where appropriate). 5. Minimise the potential for the release of vapours to air from pressure relief systems and the potential for emissions of organic solvents into air or water, by formal consideration at the design stage – or formal review of the existing arrangements if that stage has passed.	1 - 3 The drug substance production stages, described in **Section 3.2.** are based on lab best practice methodology, that have been established for the same reaction types over a number of years but scaled up to meet the production capacity required under the government contract. The production at scale is novel and as part of the development of the approach each stage was evaluated to ensure the product quality, optimise the use of materials, avoid the loss of the product during the production process, and therefore ensuring efficiency in the process. The product will be manufactured according to current Good Manufacturing Practice under a manufacturer licence, issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) to ensure the product is consistently produced and controlled according to quality standards. The raw materials have been tested and selected during the process development and must be procured in line with strict specifications to ensure the product meets the product quality standards. Optimisation is achieved through procurement in line with this specification. 4. The production stages have been developed to minimise the risk of product loss during the process. As example of this is the use of single use plastic bags at different production stages, to minimise the potential for contamination of the process. These bags remain sealed during the process, except where materials are added or extracted. The bags are contained within steel 'reaction' vessels and mixing within the bags are achieve using magnetic stirrers, already included within the bags. The approach does result in a plastic bag waste stream however removes the potential for waste of the raw materials and product through improved containment and reduced risk of contamination. 5. Only very small amounts of organic solvents will be used as detailed in Section 8.2, and negligible emissions are expected (very minor during buffer preparation step, where ethanol will be decanted by hand within the

	fume hood to prepare a specific buffer). The small amounts of VOCs produced during the buffer prep stage will be vented through the building's HVAC systems that discharge to the atmosphere through stacks (detailed in Section 4.1)
Minimisation of liquid losses from reaction systems	
Use the following features that contribute to a reduction in waste arisings from clean-outs: a. low-inventory continuous throughput reactions with minimum surface area for cleaning b. minimum internals such as baffles and coils in the reaction c. smooth reaction walls, no crevices d. flush bottom outlet on reaction vessels e. all associated piping to slope back to the reaction or to a drain point f. sufficient headroom under the reaction for collection of all concentrated drainings in drums or other suitable vessel, if necessary g. minimal pipework, designed to eliminate hold-up and to assist drainage h. pipework designed to allow air or nitrogen blowing i. system kept warm during emptying to facilitate draining j. HAZOP studies used to assess the potential for the choking of lines by high-melting-point material k. campaigns sequenced so that cleaning between batches is minimised l. campaigns made as long as possible to reduce the number of products change-overs m. where a complete clean is necessary, use cleaning methods that minimise the use of cleaning agents, (e.g. steam-cleaning, rotating spray jets or high-pressure cleaning) or use a solvent which can be re-used n. carry out HAZOP studies to minimise the generation of wastes and to examine their treatment/disposal o. consider use of disposable plastic pipe-liners p. eliminate or minimise locations for solids to settle-out q. consider duplicate or dedicated equipment where it can reduce the need for cleaning that is difficult	Liquid losses are reduced through the containment of small batch enzymatic reactions in aqueous solutions at 37°C max and ambient pressure which are contained within enclosed reaction vessels. Reaction vessels are simple small vessels, with certain stages carried out in plastic bags that remove the frequency that liquids are moved between reaction vessels. Product and vessel washing is required at certain stages, see Section 3.2, to maintain the product quality and in line with the licenced production methodology, however all effluent is collected for treatment in the effluent treatment plant. Lab cleaning is carried out using surface spray to remove the need for water use and to maintain sterile conditions.
Minimisation of vapour losses	
1. Review your operating practices and review vent flows to see if improvements need to be made.	1. The process has minimal emissions to air and vapour losses as detailed in Section 4.1. Small amounts of organic solvent products are used

2. Consider opportunities to enhance the performance of abatement systems.	within the production workshop and QC lab areas for disinfecting and buffer preparation as discussed in Section 8.2. 2. Emissions are minimised by reducing vapour losses and there is no requirement for an abatement system.
Separation Stages – Liquid-vapour separations	
3. Choose your separation technique following a detailed process design and HAZOP study. Follow formal operating instructions to ensure effective separation and minimisation of losses. Adhere to design conditions such as heat input, reflux flows and ratios, etc. 4. Install instrumentation to warn of faults in the system, such as a temperature, pressure or low coolant-flow alarms.	Not applicable – The Site does not carry out any liquid-vapour separation processes
Separation Stages – Liquid-liquid separations	
1. Use techniques which maximise physical separation of the phases (and also aim to minimise mutual solubility) where practicable. 2. When the phases are separated, use techniques which prevent (or minimise the probability and size of) breakthrough of the organics phase into a waste-water stream. This is particularly important where the environmental consequences of subsequent releases of organics to air or into controlled waters may be significant (e.g. where the effluent is treated in a DAF unit or some of the organic components are resistant to biological treatment). 3. When a separation is done by hand, use a "dead man's handle", backed-up by good management, to improve the chance of the flow being properly controlled as the phase boundary approaches. 4. Consider if automatic detection of the interface is practicable. 5. Where you are discharging to drain, consider whether there should be an intermediate holding or "guard" tank to protect against accidental losses from the organics phase. 4. Consider if automatic detection of the interface is practicable 5. Where you are discharging to drain, consider whether there should be an intermediate holding or "guard" tank to protect against accidental losses from the organics phase.	1. There are two chromatography stages during mRNA synthesis requiring liquid-liquid separation (5-12 cycles each depending on the product). This technique is a standard commercial practice and considered to be best practice to produce the quality of product required. 2. Mass balance of process packages will be undertaken to identify waste and product streams. There are no direct releases to controlled waters; Spill response procedures will be implemented for any spill, floor drains connect to the neutralisation system which hold spill contents before pump out. The likelihood of organic phase breakthrough into the effluent stream is highly unlikely. 3. Not Applicable – no separation is done by hand 4. Ultraviolet light visibility checks of the product are undertaken by the operator after each stage to ensure no product is wasted. 5. Not applicable – All effluent on Site is directed to an effluent treatment plant (further details are provided within Section 3.3.2.2 and 3.3.3.2). Sanitary wastewater goes direct to the sewer.
Separation Stages – Solid-liquid separations	
1. Use techniques to minimise, re-use and/or recycle rinse water, and to prevent breakthrough of solids	Not applicable – The Site does not carry out any solid -liquid separation processes

2. Install instrumentation or other means of detecting malfunction as all of the techniques are vulnerable to solids breakthrough 3. Consider installing "guard" filters of smaller capacity downstream which, in the event of breakthrough, rapidly 'clog' and prevent further losses. 4. Have good management procedures to minimise loss of solids, escape of volatiles to air and excessive production of wastewater.	
Chemical Process Controls	
Monitor the relevant process controls and set with alarms to ensure they do not go out of the required range.	Process equipment throughout the Site will be operated by a mixture of automated and manual processes to ensure high process efficiency, yield and operability, with some key indicators being relayed to central alarms. The actual controls in place depend upon the vessel and process area, operators have a key role in monitoring the processes. Key process checks include pH and conductivity before buffers are released for use (manual checks), the chromatography stage is checked for pH and conductivity. All monitoring undertaken utilises a fully automatic computer system which will stop the process and notify the operator through the use of alarms. The automated control system will be validated by a digital team which will be implemented upon Site commissioning.
Analysis	
Analyse the components and concentrations of by products and waste streams to ensure correct decisions are made regarding onward treatment or disposal. Keep detailed records of decisions based on this analysis in accordance with management systems.	See Section 0 for details on the different waste streams, quantities, and their management, including minimisation, storage and disposal. All waste generated at the Site is managed by appropriately trained employees at the Site under the Waste Management Plan/EMS, which includes requirements relating to waste inventory, waste storage, waste inspections, packaging and labelling, off-site waste management and waste prevention, reduction, and recycling.
Point source emissions to air	

1. Formally consider the information and recommendations in the BREF on Common Wastewater and Waste Gas Treatment/ Management Systems in the Chemical Sector (see Reference 1) as part of the assessment of BAT for point-source releases to air, in addition to the information in this note. 2. Identify the main chemical constituents of the emissions, including VOC speciation where practicable 3. Assess vent and chimney heights for dispersion capability and assess the fate of the substances emitted to the environment. 4. Use the following measures to minimise emissions to air: a. recover emissions rich in organics by fractionation and then recycle b. recover and reuse solvents c. continuously monitor off-gas concentration from reaction vessels, dryers, condensers, evaporators and scrubbers where off-gases are shown to be environmentally significant	1. In normal operations, emissions to air of pollutants including NOx, SO2 and particulate matter from the backup generators and firewater pump engine are expected to be negligible. The emergency diesel generators will only operate in emergency situations and testing of the generators will take place for significantly less than 50 hours a year. As a result, it is exempt from Specified Generator controls and also from MCP emission limit values. One diesel fuelled firewater pump engine will also be onsite but is less than 1 MWth and is therefore not considered an MCP and is not subject to MCPD controls. 2. See Section 4.1 and Section 10.1 for emissions inventory of substances (including VOCs) to air. 3. See Section 10.1 for H1 assessment to air and impacts of stack vents heights for dispersion. 4. a. Not applicable – Only small quantities of VOCs are expected to be emitted to air, therefore abatement and recovery of emissions are not considered proportionate. b. Not applicable – See Section 8.2 for solvent recovery and reuse. c. Not applicable – No off-gases produced from process that will discharge to air except for the QC fume hood ventilation exhaust.
Point Source Emissions to Water	
1. Control all emissions to avoid a breach of water quality standards as a minimum. Where another technique can deliver better results at reasonable cost it will be considered BAT and should be used. 2. Use the following measures to minimise water use and emissions to water: a. where water is needed for cooling, minimize its use by maximising heat transfer between process streams b. use water in recirculating systems with indirect heat exchangers and a cooling tower rather than a once through system. (A water make-up treatment plant and a concentrated purge stream from the system to avoid the build-up of contaminants are likely to be necessary) c. leaks of process fluids into cooling water in heat exchangers are a frequent source of contamination. Monitoring of the cooling water at relevant points should be appropriate to the nature of the process fluids. In a recirculatory cooling system, leaks can be identified before significant emission to the environment has occurred. The potential for environmental impact is likely to be greater from a once	1. There will be no direct point source emissions to water from the Site except from uncontaminated surface water to groundwater as described in Section 4.2.1. All process effluent will be discharged to the sewer under a trade effluent consent via the ETP. The process effluent will be treated for pH and temperature in an ETP, and volumes and composition will be maintained to the satisfaction of the sewage undertaker as described in Section 4.3 and Section 13.3. 2. a. Cooling water will be a closed loop system. b. The heating hot water loop will consist of heat exchangers to preheat the cold outside air entering the mixed air and 100% outside air handling units. Cooling water will be a closed loop system. No cooling towers will be onsite. c. Planned maintenance procedures will be in place. Furthermore, the Site implements a closed loop system. d. Sprays will be used in the QC laboratory and production areas. In order to minimise rinse water in the column preparation step, rinsing will take place everyone or every two years. e. Not applicable – no distillation is undertaken as part of the process

through system. Planned maintenance can help to avoid such occurrences d. water used for cleaning can be reduced by several techniques, e.g. by spray cleaning rather than whole vessel filling e. strip process liquor and treat if necessary, then recycle/reuse f. use wet air oxidation for low volumes of aqueous effluent with high levels of organic content, such as waste streams from condensers and scrubbers g. neutralise waste streams containing acids or alkalis to achieve the required pH for the receiving water h. strip chlorinated hydrocarbons in waste streams with air or steam and recycle by returning to process where possible i. recover co-products for re-use or sale i. periodically regenerate ion exchange columns j. pass wastewater containing solids through settling tanks, prior to disposal k. treat wastewaters containing chlorinated hydrocarbons separately where possible to ensure proper control and treatment of the chlorinated compounds. Contain released volatile chlorinated hydrocarbons and vent to suitably designed incineration equipment l. non-biodegradable organic material can be treated by thermal incineration. However, the thermal destruction of mixed liquids can be highly inefficient and the waste should be dewatered prior to incineration.	f. Not applicable g. All process effluent will be neutralised in the effluent treatment plant before discharge to the sewer. There is no direct discharge to controlled water. h. Not applicable – The only chlorinated hydrocarbon used on Site is chloroform and amounts used are minimal (6 litres/year) i. For water purification resins, opportunities for recycling by a third party will be considered in line with the waste policy included in the EMS. j. Effluent will be segregated and assessed prior to disposal to the sewer (See Section 3.3.2.2) k. The only chlorinated hydrocarbon used on Site is chloroform, which is stored in small volumes and used in the QC lab in small quantities. It will not be present in the effluent. l. Only limited liquid waste will be produced (see Table 7.1) however all liquid waste will be hazardous waste. Therefore, this waste will be disposed via a hazardous waste incinerator. Wherever possible, recycling of liquid waste streams will be considered.
Point Source Emissions to Land	
Use the following measures to minimise emissions to land: a. use settling ponds to separate out sludge (Note: Sludge can be disposed of to incinerator, encapsulation, land or lagoon depending upon its make up.) b. chlorinated residues should be incinerated and not released to land. (Chlorinated hydrocarbons are not to be released to the environment due to their high global warming and ozone depletion potentials.) c. either recycle off spec product into the process or blend to make lower grade products where possible many catalysts are based on precious metals, and these should be recovered, usually by return to the supplier.	Not applicable – As described in Section 4.4, there are no point source emission to land. The only discharge to land is clean, uncontaminated surface water.

Fugitive emissions to air	
1. Identify all potential sources and develop and maintain procedures for monitoring and eliminating or minimising leaks and releases of VOCs from all non-process stream sources. 2. Choose vent systems to minimise breathing emissions (for example pressure/ vacuum valves) and, where relevant, should be fitted with knock-out pots and appropriate abatement equipment. 3. Use the following techniques (together or in any combination) to reduce losses from storage tanks at atmospheric pressure: a. maintenance of bulk storage temperatures as low as practicable, b. taking into account changes due to solar heating etc. c. tank paint with low solar absorbency d. temperature control e. tank insulation f. inventory management g. floating roof tanks h. bladder roof tanks i. pressure/vacuum valves, where tanks are designed to withstand j. pressure fluctuations k. specific release treatment (such as adsorption condensation).	4. See Section 4.1.2 for fugitive emissions to air including VOCs and control measures. 5. Not applicable – negligible fugitive VOC emissions 6. See Section 3.3.9 for details of bulk storage handling and containment design. All raw materials and products are kept in closed containers to protect the product and prevent fugitive dust emissions. Suitable bunding and alarms are provided for the diesel storage in addition to implementation of specific material delivery procedures.
Fugitive emissions to surface water, sewer and groundwater	
1. Provide hard surfacing in areas where accidental spillage or leakage may occur, e.g. beneath prime movers, pumps, in storage areas, and in handling, loading and unloading areas. The surfacing should be impermeable to process liquors. 2. Drain hard surfacing of areas subject to potential contamination so that potentially contaminated surface run-off does not discharge to ground. 3. Hold stocks of suitable absorbents at appropriate locations for use in mopping up minor leaks and spills and dispose of to leak-proof containers. 4. Take particular care in areas of inherent sensitivity to groundwater pollution. Poorly maintained drainage systems are known to be the main cause of groundwater contamination and surface/above-ground drains are preferred to facilitate leak detection (and to reduce explosion risks).	1. See Section 4.2.2, Section 4.3.2 and Section 4.4.2 for details on hard surfacing. 2. See Section 3.3.3 for drainage arrangements and Section 4.4.2 for control of fugitive emissions to ground. 3. See Section 4.4.2 for details of spill kit use and disposal. 4. The Site is not located in a ground water source protection zone and so is not inherently sensitive to pollution. No groundwater contamination was found on Site during the Site Investigation or follow up monitoring. Further details of the Site context are provided in Section 2. The drainage system is subject to the preventative maintenance systems as part of the site EMS, see Section 3.3.3. 5. Not applicable – the Site is not located within an area of particular environmental sensitivity as described above. 6. The installation will operate under an EMS, including appropriate procedures and controls for prevention and management of accidental

5. Additional measures could be justified in locations of particular environmental sensitivity. Decisions on the measures to be taken should take account of the risk to groundwater, taking into consideration the factors outlined in the Agency document, Policy and Practice for the Protection of Groundwater, including groundwater vulnerability and the presence of groundwater protection zones. 6. Surveys of plant that may continue to contribute to leakage should also be considered, as part of an overall environmental management system. In particular, you should consider undertaking leakage tests and/or integrity surveys to confirm the containment of underground drains and tanks.	spills; all site operatives will be trained in the application of the Site procedures including regular inspections of plant items.
Odour	
1. Manage the operations to prevent release of odour at all times. 2. Where odour releases are expected to be acknowledged in the permit, (i.e. contained and treated prior to discharge or discharged for atmospheric dispersion): a. for existing installations, the releases should be modelled to demonstrate the odour impact at sensitive receptors. The target should be to minimise the frequency of exposure to ground level concentrations that are likely to cause annoyance. b. for new installations, or for significant changes, the releases should be modelled, and it is expected that you will achieve the highest level of protection that is achievable with BAT from the outset. c. where there is no history of odour problems then modelling may not be required although it should be remembered that there can still be an underlying level of annoyance without complaints being made. d. where, despite all reasonable steps in the design of the plant, extreme weather or other incidents are liable, in our view, to increase the odour impact at receptors, you should take appropriate and timely action, as agreed with us, to prevent further annoyance (these agreed actions will be defined either in the permit or in an odour management statement). 3. Where odour generating activities take place in the open, or potentially odorous materials are stored outside, a high level of management control and use of best practice will be expected. 4. Where an installation releases odours but has a low environmental impact by virtue of its remoteness from sensitive receptors, it is expected that you will work towards achieving the standards	1. See Section 12 for management of odour emissions. 2. Not applicable – No odours expected to be acknowledged in the permit. No odour issues anticipated as described in Section 12. 3. See Section 12 for management of odour emissions from diesel bulk storage tank. 4. Not applicable – No odours anticipated with the activities onsite 5. Not applicable – No odours anticipated with the activities onsite

described in this guidance note, but the timescales allowed to achieve this might be adjusted according to the perceived risk. 5. Where further guidance is needed to meet local needs, refer to Horizontal Guidance Note H4 Odour (see GTBR).	
Noise and vibration	
1. Install particularly noisy machines such as compactors and pelletisers in a noise control booth or encapsulate the noise source. 2. Where possible without compromising safety, fit suitable silencers on safety valves. 3. Minimise the blow-off from boilers and air compressors, for example during start up, and provide silencers.	All external noise sources will be designed to meet noise emissions limits to achieve 5 dB below background at the Site boundary. Mitigation incorporated into the design will include the use of layout, acoustic enclosures, and silencers. See Section 11**.**
Monitoring and reporting of emissions to air and water	
1. Carry out an analysis covering a broad spectrum of substances to establish that all relevant substances have been taken into account when setting the release limits. The need to repeat such a test will depend upon the potential variability in the process and, for example, the potential for contamination of raw materials. Where there is such potential, tests may be appropriate. 2. Monitor more regularly any substances found to be of concern, or any other individual substances to which the local environment may be susceptible and upon which the operations may impact. This would particularly apply to the common pesticides and heavy metals. Using composite samples is the technique most likely to be appropriate where the concentration does not vary excessively. 3. If there are releases of substances that are more difficult to measure and whose capacity for harm is uncertain, particularly when combined with other substances, then "whole effluent toxicity" monitoring techniques can be appropriate to provide direct measurements of harm, for example, direct toxicity assessment.	Emissions to Air 1. Emissions to air have been identified based on the list of raw materials that will be used on the sites and using data from other Moderna sites. Emissions data from the emergency generators have been taken from the supplier data sheets. See Section 10.1.2. 2. No regular monitoring is proposed, based on all emissions being screened as having negligible risk to air quality, see Section 13.1 3. Not applicable – no anticipated release of substances whose capacity of harm is uncertain, even when combined with other substances. Only emissions to air are VOCs as described in Section 13.1. The firewater pump engine is < 1 MWth and therefore is not subject to monitoring and reporting requirements under the MCP Directive. No emission limits or periodic monitoring is proposed for the emergency diesel generators due to the emergency only nature of operation. Monitoring will be in line with web guide 'Monitoring stack emissions: low risk MCPs and specified generators', published 12 July 2022. The monitoring frequency is expected to be every 1,500 hours of operation or once every five years (whichever comes first). Flues for the three new generators will be designed so that suitable sampling points are incorporated to facilitate such monitoring. Emissions to water

	1. Emissions to water have been identified based on the list of raw materials that will be used on the sites and using data from other Moderna sites, see Section 10.2.2. 2. There will be no point source emissions to water. Process water will be discharge to the sewer under a Trade Effluent Consent. Monitoring and reporting requirements will be maintained and tested to the satisfaction of the sewerage undertaker. A sampling point will be used to monitor the effluent, and to demonstrate compliance with the Trade Effluent consent. Monitoring and reporting requirements shall be agreed with the EA to meet relevant permit conditions. 3. Not applicable – no anticipated release of substances whose capacity of harm is uncertain, even when combined with other substances.
Monitoring and reporting of waste emissions	
1. Monitor and record: a. the physical and chemical composition of the waste b. its hazard characteristics c. handling precautions and substances with which it cannot be mixed	The installation will maintain a Waste Inventory Register as part of the Waste Management Plan/EMS, including the nature of waste, hazard classification (as hazardous and non-hazardous waste) and applicable handling procedures. This ensures compliance with the Site's waste duty of care requirements (See Section 0) The disposal routes for hazardous and non-hazardous wastes will be regularly reviewed and are identified and tracked in accordance with best practice in order to achieve year on year improvements. The Site will implement a Duty of Care approach as part of its EMS.
Environmental monitoring (beyond installation)	
1. Consider the following in drawing up proposals: a. determinants to be monitored, standard reference methods, sampling protocols b. monitoring strategy, selection of monitoring points, optimisation of monitoring approach c. determination of background levels contributed by other sources d. uncertainty for the employed methodologies and the resultant overall uncertainty of measurement e. quality assurance (QA) and quality control (QC) protocols, equipment calibration and maintenance, sample storage and chain of custody/audit trail f. reporting procedures, data storage, interpretation and review of results, reporting format for the provision of information	The potential impact of the Site has been considered in the Environmental Risk Assessment (see Section 14) and H1 assessment (see Section 0). Additional monitoring (beyond the Site boundary) is not deemed necessary or proportionate for the Site.

TABLE 5.2 BEST AVAILABLE TECHNIQUES (BAT) REFERENCE DOCUMENT FOR COMMON WASTE WATER AND WASTE GAS TREATMENT/MANAGEMENT SYSTEMS IN THE CHEMICAL SECTOR (CWW)

Subsection	BAT#	BAT Text	Requirement	Comments
Environmental management systems				
	BAT 1	In order to improve the overall environmental performance, BAT is to implement and adhere to an environmental management system (EMS) that incorporates all of the following features presented in the BREF.	See BREF for detailed requirements	Moderna's Environmental Management System (EMS) is based on, and will be aligned to the requirement of ISO 14001:2015 and to the EA's guidance: 'Develop a management system: environmental permits'. The EMS will include management commitments for monitoring, reviewing, and reporting procedures, as well as details on improvement programs and how environmental impacts will be continually assessed on Site. **Section 6** provides details of the EMS.
	BAT 2	In order to facilitate the reduction of emissions to water and air and the reduction of water usage, BAT is to establish and to maintain an inventory of waste water and waste gas streams, as part of the environmental management system (see BAT 1), that incorporates all of the following features presented in the BREF	See BREF for detailed requirements	I.a. The Site process will be documented and maintained in Site Standard Operating Procedures (SOPs). Introduction of any new chemicals will be subject to review as part of the EMS. I.b. Simplified process flowsheets showing the origin of emissions will be made available in the Site Standard Operating Procedures (SOPs) I.c. A description of water treatment techniques including their performance will be maintained in a plant operating manual. II. a/b/(c if applicable). As part of the EMS, a record of the characteristics of the effluent will be maintained (see Section 13.3). III.a - d. Expected composition of waste gas streams are documented and included in the design and detailed in Section 10.1
Monitoring				

Subsection	BAT#	BAT Text	Requirement	Comments
	BAT 3	For relevant emissions to water as identified by the inventory of waste water streams (see BAT 2), BAT is to monitor key process parameters (including continuous monitoring of waste water flow, pH and temperature) at key locations (e.g. influent to pre-treatment and influent to final treatment).	*(No requirements specified)*	See response to Monitoring and reporting of emissions to air and water in Table 5.1 for monitoring of emissions to water.

	BAT 4	BAT is to monitor emissions to water in accordance with EN standards with at least the minimum frequency given below. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.	**TABLE** – Substance/Parameter | Standard | Minimum monitoring frequency
			Substance/Parameter
			• Total organic carbon (TOC)
			• Chemical oxygen demand (COD)
			• Total suspended solids (TSS)
			• Total nitrogen (TN)
			• Total inorganic nitrogen (Ninorg)
			• Total phosphorus (TP)
			• Adsorbable organically bound halogens (AOX)
			  ○ Metals
			  ○ Cr
			  ○ Cu
			  ○ Ni
			  ○ Pb
			  ○ Zn
			  ○ Other metals, if relevant
			• Toxicity
			  ○ Fish eggs (Danio rerio)
			  ○ Daphnia (Daphnia magna Straus)
			  ○ Luminescent bacteria (Vibrio fischeri)
			  ○ Duckweed (Lemna minor)
			  ○ Algae
				See response to Monitoring and reporting of emissions to air and water in Table 5.1 for monitoring standards of emissions to water.

Subsection	BAT#	BAT Text	Requirement	Comments
	BAT 5	BAT is to periodically monitor diffuse VOC emissions to air from relevant sources by using an appropriate combination of the techniques I – III or, where large amounts of VOC are handled, all of the techniques I – III. 1. sniffing methods associated with correlation curves for key equipment; 2. optical gas imaging methods; 3. calculations of emissions based on emissions factors periodically validated (e.g. once every two years) by measurements.	Where large amounts of VOCs are handled, the screening and quantification of emissions from the installation by periodic campaigns with optical absorption-based techniques, such as Differential absorption light detection and ranging (DIAL) or Solar occultation flux (SOF), is a useful complementary technique to the techniques I to III. **Description** See BREF Section 6.2	Not applicable – no anticipated release of substances whose capacity of harm is uncertain, even when combined with other substances. Monitoring of VOC emissions to air are described in Section 13.1.
	BAT 6	BAT is to periodically monitor odour emissions from relevant sources in accordance with EN standards.	**Description** Emissions can be monitored by dynamic olfactometry according to EN 13725. Emission monitoring may be complemented by measurement/estimation of odour exposure or estimation of odour impact. **Applicability** The applicability is restricted to cases where odour nuisance can be expected or has been substantiated.	See response to odour in Table 5.1.
Emissions to water				
Water usage and waste	BAT 7	In order to reduce the usage of water and the generation of waste	*(No requirements specified)*	See response to Efficient use of raw materials and water in Table 5.1.

Subsection	BAT#	BAT Text	Requirement	Comments
water generation		water, BAT is to reduce the volume and/or pollutant load of waste water streams, to enhance the reuse of waste water within the production process and to recover and reuse raw materials.		
Waste water collection and segregation	BAT 8	In order to prevent the contamination of uncontaminated water and to reduce emissions to water, BAT is to segregate uncontaminated wastewater streams from waste water streams that require treatment.	**Applicability** The segregation of uncontaminated rainwater may not be applicable in the case of existing wastewater collection systems	See Section 3.3.3 for Site drainage and details of water and waste water segregation.
	BAT 9	In order to prevent uncontrolled emissions to water, BAT is to provide an appropriate buffer storage capacity for wastewater incurred during other than normal operating conditions based on a risk assessment (taking into account e.g. the nature of the pollutant, the effects on further treatment, and the receiving environment), and to take appropriate further measures (e.g. control, treat, reuse).	**Applicability** The interim storage of contaminated rainwater requires segregation, which may not be applicable in the case of existing wastewater collection systems.	There are no direct discharges to surface water onsite. The discharge quantities of process effluent onsite are considered small. The ETP equalisation tank will have a capacity of 4 m^3 to retain any effluent that doesn't meet specification before discharge to the foul sewer. Rainwater will be segregated from process effluent (see Section 3.3.3 for drainage). See Section 4.2.2 and Section 4.3.2 for measures taken to reduce fugitive emissions to surface and groundwater.

Subsection	BAT#	BAT Text	Requirement	Comments
Waste water treatment	BAT 10	In order to reduce emissions to water, BAT is to use an integrated wastewater management and treatment strategy that includes an appropriate combination of the techniques in the priority order given.	*Technique* Process-integrated techniques Recovery of pollutants at source Waste water pre-treatment Final waste water treatment **Description** The integrated waste water management and treatment strategy is based on the inventory of waste water streams (see BAT 2). BAT-associated emission levels (BAT-AELs): see BREF Section 3.4.	See response to point source emissions to water in Table 5.1.
	BAT 11	In order to reduce emissions to water, BAT is to pre-treat wastewater that contains pollutants that cannot be dealt with adequately during final wastewater treatment by using appropriate techniques.	Description Waste water pre-treatment is carried out as part of an integrated waste water management and treatment strategy (see BAT 10) and is generally necessary to: • the final waste water treatment plant (e.g. protection of a biological treatment plant against inhibitory or toxic compounds); • remove compounds that are insufficiently abated during final treatment (e.g. toxic compounds, poorly/non-biodegradable organic compounds, organic compounds that are present in high concentrations, or metals during biological treatment); • remove compounds that are otherwise stripped to air from the collection system or during final treatment (e.g. volatile halogenated organic compounds, benzene); • remove compounds that have other negative effects (e.g. corrosion of equipment; unwanted reaction with other substances; contamination of waste water sludge). In general, pre-treatment is carried out as close as possible to the source in order to avoid dilution, in particular for metals. Sometimes, waste water streams with	See response to point source emissions to water in Table 5.1. Pre-treatment will be carried out to adjust temperature and pH and the effluent will be designed to meet the conditions under a TEC to protect the receiving STW.

Subsection	BAT#	BAT Text	Requirement	Comments
			appropriate characteristics can be segregated and collected in order to undergo a dedicated combined pre-treatment.	
	BAT 12	In order to reduce emissions to water, BAT is to use an appropriate combination of final wastewater treatment techniques.	**Description** Final wastewater treatment is carried out as part of an integrated wastewater management and treatment strategy (see BAT 10). Appropriate final wastewater treatment techniques, depending on the pollutant, include: **TABLE** – Technique | Typical pollutants abated | Applicability *Technique* Preliminary and primary treatment a. Equalisation b. Neutralisation c. Physical separation, e.g. screens, sieves, grit separators, grease separators or primary settlement tanks Biological treatment (secondary treatment), e.g. d. Activated sludge process e. Membrane bioreactor Nitrogen removal f. Nitrification/denitrification Phosphorus removal g. Chemical precipitation Final solids removal h. Coagulation and flocculation i. Sedimentation j. Filtration (e.g. sand filtration, microfiltration, ultrafiltration) k. Flotation	See response to point source emissions to water in Table 5.1. Final effluent treatment will be carried out at the STW.

Subsection	BAT#	BAT Text	Requirement	Comments
			See BREF Table 1,2,3 for BAT-AELs	
Waste				
	BAT 13	In order to prevent or, where this is not practicable, to reduce the quantity of waste being sent for disposal, BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered.		See response to Avoidance, recovery and disposal of wastes in Table 5.1.
	BAT 14	In order to reduce the volume of waste water sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of the techniques given below.	**TABLE** – Technique | Description | Applicability *Technique* Conditioning Thickening/dewatering Stabilisation Drying	Not applicable as no biological treatment onsite producing sludge.
Emissions to air				
Waste gas collection	BAT 15	In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is	**Applicability** The applicability may be restricted by concerns on operability (access to equipment), safety (avoiding concentrations close to the lower	See response to point source emissions to air in Table 5.1.

Subsection	BAT#	BAT Text	Requirement	Comments
		to enclose the emission sources and to treat the emissions, where possible.	explosive limit) and health (where operator access is required inside the enclosure).	
Waste gas treatment	BAT 16	In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques.	**Description** The integrated waste gas management and treatment strategy is based on the inventory of waste gas streams (see BAT 2) giving priority to process-integrated techniques.	Not applicable as waste gases considered to be minimal as described in response to point source emissions to air in Table 5.1.
Flaring	BAT 17	In order to prevent emissions to air from flares, BAT is to use flaring only for safety reasons or non-routine operational conditions (e.g. start-ups, shutdowns) by using one or both of the techniques given below.	**TABLE** – Technique | Description | Applicability *Technique* Correct Plant Design Plant management	Not Applicable – No flaring will take place at the site.
	BAT 18	In order to reduce emissions to air from flares when flaring is unavoidable, BAT is to use one or both of the techniques given below.	**TABLE** – Technique | Description | Applicability *Technique* Correct design of flaring devices Monitoring and recording as part of flare management	Not Applicable – No flaring will take place at the site.
Diffuse VOC emissions	BAT 19	In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given below.	**TABLE** – Technique | Applicability *Technique* Techniques related to plant design a. Limit the number of potential emission sources	The following techniques will be applied to reduce diffuse VOC emissions to air: <u>Plant Design</u> a. Measures to minimise the potential pathways for fugitive emissions of VOCs to air are incorporated into the design and detailed in Section 4.1.2.

Subsection	BAT#	BAT Text	Requirement	Comments
			b. Maximise process-inherent containment features c. Select high-integrity equipment (see the description in Section 4.6.2) d. Facilitate maintenance activities by ensuring access to potentially leaky equipment Techniques related to plant/equipment construction, assembly and commissioning e. Ensure well-defined and comprehensive procedures for plant/equipment construction and assembly. This includes using the designed gasket stress for flanged joint assembly (see the description in Section 4.6.2) f. Ensure robust plant/equipment commissioning and handover procedures in line with the design requirements Techniques related to plant operation g. Ensure good maintenance and timely replacement of equipment h. Use a risk-based leak detection and repair (LDAR) programme (see the description in Section 4.6.2) i. As far as it is reasonable, prevent diffuse VOC emissions, collect them at source, and treat them The associated monitoring is in BREF BAT 5.	b. Plant will be designed in a contained system to ensure product quality. c. High-integrity equipment will be used to maintain product quality and ensure a safe working environment. d. Maintenance access will be provided to equipment with potential for leakage (e.g. pumps, compressors, and control valves). Plant/equipment construction, assembly and commissioning e. A maintenance procedure will be available and followed during construction and assembly, which includes flange tightening and quality assurance requirements. f. Commission procedures will include pressure and leak tests. The criteria for replacement and repair of leaky equipment will be provided in the EMS. Techniques related to plant operation g. A preventative maintenance programme (SOP) will be developed during the detailed design stage. h. Not applicable due to scale of process (not a large scale chemical processing facility). i. Not applicable - no anticipated release of substances whose capacity of harm is uncertain, even when combined with other substances. Only emissions to air are VOCs as described in Section 13.1.
Odour emissions	BAT 20	In order to prevent or, where that is not practicable, to reduce odour emissions, BAT is to set up, implement and regularly review an odour management plan, as part of the environmental management system	**Applicability** The applicability is restricted to cases where odour nuisance can be expected or has been substantiated.	Odour nuisance is not expected - See response to odour in Table 5.1.

Subsection	BAT#	BAT Text	Requirement	Comments
		(see BAT 1), that includes all of the following elements: 1. a protocol containing appropriate actions and timelines; 2. a protocol for conducting odour monitoring; 3. a protocol for response to identified odour incidents; an odour prevention and reduction programme designed to identify the source(s); to measure/estimate odour exposure; to characterise the contributions of the sources; and to implement prevention and/or reduction measures.		
	BAT 21	In order to prevent or, where that is not practicable, to reduce odour emissions from waste water collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques given below.	**TABLE** – Technique | Description | Applicability *Technique* Minimise residence times Chemical treatment Optimise aerobic treatment Enclosure End of pipe treatment	Odour nuisance is not expected - See response to odour in Table 5.1. One or more of the listed techniques will be used if identified as required during the detailed design stage.
Noise emissions	BAT 22	In order to prevent or, where that is not practicable, to reduce	**Applicability**	See response to noise and vibration in Table 5.1.

Subsection	BAT#	BAT Text	Requirement	Comments
		noise emissions, BAT is to set up and implement a noise management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements: 1. a protocol containing appropriate actions and timelines; 2. a protocol for conducting noise monitoring; 3. a protocol for response to identified noise incidents; 4. a noise prevention and reduction programme designed to identify the source(s), to measure/estimate noise exposure, to characterise the contributions of the sources and to implement prevention and/or reduction measures.	The applicability is restricted to cases where noise nuisance can be expected or has been substantiated	
	BAT 23	In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to use one or a combination of the techniques given below.	**TABLE** – Technique | Description | Applicability *Technique* Appropriate location of equipment and buildings Operational measures Low-noise equipment	Significant noise emissions are not expected - see response to noise and vibration in Table 5.1. One or more of the listed techniques will be used if identified as required during the detailed design stage.

Subsection	BAT#	BAT Text	Requirement	Comments
			Noise-control equipment Noise abatement	

6. ENVIRONMENTAL MANAGEMENT SYSTEM

6.1 ISO 14001

Moderna’s Environmental Management System (EMS) will be based on the requirements of ISO 14001 and will cover the management system requirements detailed in ‘Develop a management system: environmental permits guidance’, the EA BAT guidance for manufacture of organic fine chemicals, the European Medicine Agency’s Good Manufacturing Practice (GMP) and is governed by the Moderna global Environmental Health and Safety (EHS) Management System.

The Site-based EMS will be implemented before the Site becomes operational. The target date for implementing the EMS for the Site is November 2024. The commissioning process shall be used to test the management procedures and ensure that any aspects required are addressed following commissioning.

The EMS will detail systems and procedures that Site operations are required to follow, with the objective of effective management and mitigation of the actual and potential environmental impacts of the Site’s activities. A review of the overall management system will be carried out annually.

Table 6.1 gives a summary of the documents which make up the EMS.

TABLE 6.1 EMS CONTENT SUMMARY

Section code	Documentation
1.0	**Scope**
2.0	**Reference Documents**
3.0	**Terms and Definitions**
4.0	**Context of the Organisation**
4.1	Understanding the organisation and its context
4.1.1	*Corporate EHS Context of the Organisational Standard*
4.1.2	*Corporate EHS Glossary*
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the EHS management system
4.4	EHS management system
5.0	**Leadership and Worker Participation**
5.1	Leadership and Commitment
5.2	Global Policies
5.2.1	*EHS Policy*
5.2.3	*Drug and Alcohol Policy*
5.2.4	*Smoking Policy*
5.2.5	*Wellbeing Policy*
5.2.6	*Bully and Harassment Policy*

Section code	Documentation
5.2.7	*Modern Slavery Policy*
5.2.8	*Worker Compensation and Rehabilitation Policy*
5.3	Organisational roles, responsibilities, accountabilities and authorities
5.4	Consultation and participation of workers
5.4.1	*Consultation and Participation Procedure*
6.0	**Planning**
6.1	Actions to address Risks and Opportunities
6.1.1	*General Considerations*
6.1.2	*Hazard identification and assessment of risks and opportunities*
6.1.3	*Determination of applicable legal requirements*
6.2	Planning and achieving EHS intended outcomes
6.2.1	*EHS Objectives*
6.2.2	*Planning actions to achieve EHS objectives*
7.0	**Support**
7.1	Resources
7.2	Competence of workers
7.2.1	*Corporate EHS Competency and awareness Standard*
7.3	Awareness and information for workers
7.3.1	*Site EHS Induction*
7.4	Communication
7.4.1	*Corporate EHS Communication and Engagement Standard*
7.4.2	*Internal Communication*
7.4.3	*External Communication*
7.5	Document Information
7.5.1	Corporate EHS Document Creation and Control Standard
8.0	**Operation**
8.1	Operational Planning and Control
8.1.1	*General*
8.1.2	*Eliminating hazards and reducing EHS risks – Site Standard Operating Procedures*
8.1.3	*Management of change*
8.1.4	*Procurement*
8.2	Emergency preparedness and response
8.2.1	*Corporate EHS Emergency Preparedness and Response Standard*
9.0	**Performance Evaluation**

Section code	**Documentation**
9.1	Monitoring, measurement, analysis and evaluation
9.1.1	*General*
9.2	Internal Audit
9.2.1	*Corporate EHS Audit Standard*
9.3	Management Review
9.3.1	*Corporate EHS Management Review Standard*
10.0	**Improvement**
10.1	General
10.1.1	*Corporate EHS Management Review Standard*
10.2	Incident, non-conformity and corrective
10.2.1	*Corporate EHS Nonconformance and CAPA Standard*
10.2.2	*Corporate EHS Event Management Standard*
10.3	Continual Improvement
10.3.1	*Corporate EHS Management Review Standard*

7. WASTE MANAGEMENT

7.1 WASTE GENERATION

In general, the main sources of waste at the Site will be produced from operations including the manufacturing process, quality control laboratory and utilities as well as maintenance activities. At full build out capacity, waste produced is not expected to exceed 368.5 tonnes per year of non-hazardous waste and 172.9 tonnes per year of hazardous waste, averaging at 1.01 tonnes per day of non-hazardous waste and 0.48 tonnes per day of hazardous waste, noting that the pandemic scenario is lower than this capacity and therefore waste generation volumes.

The Site will operate with a waste management procedure that is to be developed as part of the Site EMS. This will set out the scope of waste management activities, from segregation of waste onsite to its removal, including responsibilities and procedures of compliant storage and handling of waste, and waste contractor duty of care.

Table 7.1 presents the typical annual waste streams from the Site.

TABLE 7.1 EXPECTED WASTE STREAMS

Waste Stream	State	Quantity (tonnes / year)	Storage Location	Class	Destination
Waste disposable consumables	Solid	43	Waste Staging Room	Non – Hazardous	Internal pre-treatment (shredder) and then Energy Recovery
Waste chromatography columns	Solid	1.44	Waste Staging Room	Hazardous	Incineration
Spent Membrane	Solid	1.0	Waste Staging Room	Non Hazardous	Energy Recovery
Non-conforming products (drug substance reject)	Solid	2.5	Waste Staging Room	Hazardous	Incineration
Experimental waste liquid and expired chemicals	Liquid	25	Waste Staging Room	Hazardous	Recycling and Energy Recovery
Bioactive laboratory waste	Solid/Liquid	113	Waste Staging Room	Hazardous	Energy Recovery
Maintenance waste	Solid/Liquid	1.5	Waste Staging Room	Hazardous	Energy Recovery
Waste chemical packaging (plastics, glass)	Solid	30	Waste Staging Room	Non-hazardous	Energy Recovery
Ion exchange resins, Activated carbon, RO membranes	Solid	25	Waste Staging Room	Non-hazardous	Energy Recovery

Waste Stream	State	Quantity (tonnes / year)	Storage Location	Class	Destination
Primary, middle and high efficiency filters	Solid	10	Waste Staging Room	Non-hazardous	Energy Recovery
Domestic waste	Solid	140	Waste Staging Room	Non-hazardous	Energy Recovery and Recycling
Other packaging	Solid	150	Waste Staging Room	Non-hazardous	Recycling

7.2 WASTE COLLECTION AND STORAGE

During normal operations, waste disposable consumables from the main process suites are transferred via exit pass-throughs into the Clean Non-Classified (CNC) corridor. All other waste generated in the production areas are transferred through Material Air Lock into the CNC corridor. Waste is collected from various points across the Site in waste "wheely bins" that will then be brought directly out to the waste staging room located next to the labelling room (see '1307' in the ground floor plan in Appendix B) of the Site where it will be stored for offsite disposal.

Hazardous waste will be segregated from non-hazardous wastes and will be stored depending on the nature of the waste in either a hazardous container, covered or bunded. Waste will be stored in a manner to prevent:

- Corrosion or wear of waste containers.
- Leaching of waste unprotected from rainfall.
- Accident or weather breaking contained waste open and allowing it to escape.
- Waste blowing away of falling while be stored or transported.
- Scavenging of waste by vandals, thieves, children, trespassers, or animals; and

Liquid wastes will be collected in suitable bunded containers.

7.3 WASTE MINIMISATION AND TREATMENT

The Site manufactures to GMP standards to ensure products are consistently produced and controlled according to quality standards i.e. through the prevention of cross contamination. This limits options for material re-use and recycling. However, the principles of the waste hierarchy are adopted where appropriate. Waste generation is kept to a minimum onsite due to the nature of the operation. The Site inputs include mainly raw materials which will arrive in bulk to minimise packaging. Except for disinfection products, the raw materials themselves will be used up in the process and the product will be transported off-site for third party filling**.** Waste minimisation efforts will focus on the level of packaging (at customer and supplier level), onsite measures including the reuse of wooden pallets, and a requirement for a tidy workplace to prevent the unnecessary generation of waste. Waste minimisation will form part of the training for environmental awareness undertaken by all employees working at the Site.

A significant proportion of the waste arising onsite is hazardous, which restricts the options for material re-use and recycling. Certain non-hazardous wastes such as waste disposal consumables (e.g. bags, tubing and filters) are single use. In an effort to minimise the volume of non-hazardous waste disposal consumables leaving the Site, this will be reduced in volume by up to 85% through an onsite waste shredder system. The waste shredder system will be located inside in the waste staging room.

Potential future methods for waste minimisation are continuing to be explored by Moderna including the reuse of the waste disposal consumables. At present, the ability to wash these parts is undergoing further investigation. Waste minimisation will be reviewed on an annual basis as part of the EMS to identify where waste production can be reduced at source.

7.4 WASTE DISPOSAL

A variety of disposal sites and waste hauliers/disposers will be used depending on the type of waste, and where duty of care principles will be applied. Each waste type may therefore be disposed of via single or multiple operators/hauliers. Proposed waste disposal routes have been selected in line with the principles of the waste hierarchy considering the waste quality, whether any compromises to safety would have to be made, the availability of waste disposal technology (as well as the availability of necessary utilities onsite to enable the technology) and the consideration of generating new potential emission sources.

Where re-use or recycling of materials cannot be achieved (i.e. due to their hazardous nature), waste will be sent to high temperature incineration with energy recovery. Hazardous waste management will take into account impact consideration and achieve the best overall outcome.

Waste management options above waste recovery will be considered where they are demonstrated as appropriate following commissioning, such as a 'return for reuse' scheme for waste glass and reuse of waste pallets on or off site.

Segregated and treated waste will be removed from the Site by a registered waste carrier. All waste will have appropriate documentation and an inventory tracking system will be in place.

8. RAW MATERIALS

8.1 RAW MATERIAL USAGE AND STORAGE

The Site will utilise a number of different raw materials for the DS process and associated activities.

Storage of raw materials used in auxiliary (diesel fuel and firewater) will adhere to BAT and Oil Storage Regulations 2001 (see Section 3.3.9 for bulk storage arrangements). Likewise, raw materials will be procured in accordance with GMP standards and stored inside according to safety data sheet information. There will be no reactive chemicals handled onsite, other than small scale laboratory chemicals. To maintain their condition and quality, certain raw materials will be refrigerated including plasmid template, LMX, enzyme, and nucleotides.

Signage, storage, segregation and handling of hazardous substances (including refrigerants) will be managed using the Site Standard Operating Procedures (SOPs) and in accordance with COSHH Regulations to minimise hazards and reduce environmental, health and safety risks.

8.2 SOLVENTS

The facility does not fall under the requirements of Schedule 14 of the EP Regulations regarding solvent emission activities as the consumption of solvents at the maximum operational throughput scenario does not exceed the threshold of 50 tonnes per annum for manufacturing of pharmaceutical products defined in Annex VII of the IED

The Site is a biopharmaceutical manufacturing facility, and therefore the production workshop, quality control laboratory and other areas are required to be disinfected as per GMP requirements. Three types of disinfectants will be used in minimal quantities within the production workshop include Vesta Syde, Septihol and Sporklenz. The disinfectants used within the QC lab are isopropyl alcohol (70%) and a sodium hypochlorite-based disinfectant. Minor use of ethanol and glacial acetic acid will be used in buffer preparation and the QC lab for analysis and will be decanted in the fume hood.

All solvents will be stored inside in either the warehouse or QC Laboratory cabinets . There are some drains in clean rooms but not all.

The nature of the GMP manufacturing means cleaning agents is selected for their suitability as an effective cleaning agent

The Site manufactures GMP materials, which restricts the option of solvent recycling within the Site. The processes are single batch processes which precludes the use of a solvent reuse in the next product.

8.3 WATER USE

Water supply will come from the mains water and will serve a variety of users as described in Section 3.3.2.1. The water supply will be metered, and usage will be reviewed as part of the Site EMS and water profile.

All water supplied for use in the process will require treatment to ensure suitability prior to use. Water used in the cooling chilled water system will be supplied from the HVAC chilled water system. The chilled water system is a closed loop system comprising of one air cooled chiller requiring no cooling towers, condensers, heat trace system, and additional water usage. Remote evaporators will allow the facility to operate with a single water loop, requiring no glycol in the loop.

As the Site will be manufacturing GMP materials, there are no opportunities to recover/reuse water used in CIP and for washing buffer prep tanks (carried out once every one – two years) and this effluent will therefore be discharged to the sewer via the ETP. Effluent will be pumped to a dedicated storage tank prior to pH and temperature treatment and discharge to the sewer.

Opportunities for improving efficiency of water use onsite will be continually reviewed. A water profile will be maintained to provide data needed for regulatory compliance, operational risk assessment and to promote efficient operations.

9. ENERGY

9.1 ENERGY USAGE AND EFFICIENCY

Moderna's commitment to energy efficiency is reflected by the overarching corporate goals, which will be the basis for the Energy Management policies within the Site EMS.

To reduce the energy demand at the Site the following energy efficiency measures have been included in the design:

- Electrification of the processes onsite and no use of fossil fuels, except diesel fuel for the emergency generators and firewater pump engine.
- Air Handling Units (AHUs) associated with the building cooling system and air-cooled chiller will utilise an energy recovery system, consisting of an energy recovery coil and cooling coil, to heat the fresh air coming into the building using energy recovered from the exhaust air stream.
- A dedicated heat recovery chiller will be provided to recover energy from the chilled water return to generate heating hot water and cover the baseline hot water load during the cooling season. The heat recovery chiller is sized for base (summer) heating hot water system load of 370 KW.
- Building heating will be by the three air source heat pumps, to provide lower energy heating.
- One electric boiler will be used onsite to generate steam for the dehumidification system.
- Humidification control will be monitored for higher energy efficiency and accuracy by modulating the humidity levels of the air leaving the units.
- The building will be LEED (Leadership in Energy and Environmental Design) certified.
- Undertaking Power Factor Correction in an effort to increase energy efficiency and reduce overall load of the installation.
- Implementing lighting controls to reduce unnecessary energy use.
- Using LED lighting throughout the building.
- Compliance with CIBSE TM39 and building regulations for energy metering.
- All new equipment will be specified for energy efficiency prior to purchase and installation. Electricity use will be recorded using separate smart meters installed at the Site and continuous readings will be taken of energy consumption.

9.2 CLIMATE CHANGE AGREEMENT

Due to the nature of the activity and the Site's overall low energy use, the Site will not operate with a climate change agreement.

10. H1 RISK ASSESSMENT

An H1 risk assessment has been carried out to assess the potential associated impacts on air and the receiving waterbody from the Site activities. The Environment Agency (EA) H1 calculation methodology (H1) has been used following EA website guidance on "Surface water pollution risk assessment for your environmental permit[6]" and "Air emissions risk assessment for your environmental permit[7]". Where possible the H1 tool itself has been used.

The H1 tool is a screening tool, seeking to identify releases with no potential for adverse effects. As a result, it is highly conservative by design. The assessment has been completed based on the maximum production capacity of the Site.

10.1 EMISSIONS TO AIR SCREENING

10.1.1 METHODOLOGY

Using the H1 methodology, it is possible to screen out "insignificant" emissions and those emissions where further assessment is not required, using the appropriate Air Quality Standard (AQS) Objective or Environmental Assessment Level (EAL) for each substance.

A pollution emission is defined as "insignificant" if it passes two stages of tests. This first stage test uses simplified dispersion factors that are contained within the EA's H1 Technical Guidance, which are based on the effective stack height of the emission source. The predicted Process Contribution (PC) is then compared with the appropriate EAL or AQS to determine the significance of the pollutant emission with regards to impact on the environment. To screen out a PC from further assessment the PC must meet both of the following criteria:

- PC< 1% of the EAL or AQS for long term releases; and
- PC<10% of the EAL or AQS for short term releases.

If the PC does not meet both of these criteria, then a second stage of screening is required.

The second stage of screening tests consider the Predicted Environmental Concentration (PEC) for the substances, taking background levels into consideration. To screen out emissions from further assessment they must meet both of the following criteria:

- Short-term PC is < 20% of the short term EAL or AQS minus twice the long-term background concentration; and
- Long-term PC is < 70% of the long-term EAL or AQS.

If the emissions fail either criterion, then further modelling is required to understand the impact.

10.1.2 H1 INPUT DATA

The H1 tool is designed to screen impacts from point sources in normal operating conditions. As detailed in Section 4.1.1**4.1**, the main emissions to air are those arising from the combustion units onsite (three emergency diesel generators and one firewater pump), fume hood exhaust from the weigh and dispense area, QC laboratory, and raw material sampling in the warehouse,

[6] gov.uk (2022). *Surface water pollution risk assessment for your environmental permit*. Available at: https://www.gov.uk/guidance/surface-water-pollution-risk-assessment-for-your-environmental-permit Last accessed: 18/12/2023

[7] gov.uk (2023). *Air emissions risk assessment for your environmental permit*. Available at: https://www.gov.uk/guidance/air-emissions-risk-assessment-for-your-environmental-permit Last accessed: 18/12/2023

which will be vented through stacks approximately 3.5 m above roof height. Emissions to air from the warehouse raw material sampling is expected to be negligible since emissions from sampling are far below the worst-case consideration for the same chemicals used in the QC lab and have not therefore been screened in the H1 assessment.

10.1.2.1 FUME HOOD EXHAUSTS

The H1 methodology has been used to screen VOC emissions from emission points A1 and A2, and this is provided in Appendix F *(*titled – *H1_Moderna_VOC Air Emissions FINAL 13.12.23)*. The H1 methodology was used instead of the EA's developed tool since the majority of specific VOCs do not have environmental standards available in the tool. The presentation of the methodology included in Appendix F therefore provides a better illustration of the assessment inputs used.

Environmental standards are based on statutory air quality standard limits, targets and objectives where available, and upon human health protection environmental assessment levels (EALs) as provided in the H1 guidance. As per EA guidance, some substances do not have associated AQSs and so alternative standards have been used, for example based on workplace exposure limits.

An emissions inventory including substance concentrations, total flow and effective height have been provided by Moderna and used in the H1 risk assessment. There are no emission data available for the Site. In order to undertake an assessment of emissions to air, emissions have therefore been calculated on the basis of available data; this includes scaled up examples from other Moderna facilities that are currently being built globally. Emission concentrations are based on an overly conservative assessment of raw materials and solvents at maximum storage volumes rather than actual usage which will be far less. Dispersion factors used in the H1 assessment have been based on the effective height of the stack (m). The height of the stacks are more than 3 m, but they are less than the height of the tallest building (DS building ~12.7 m above finished floor level) within a distance that is five times the height of the building. The effective height has therefore been taken as 0m as per the EA website guidance. Where multiple emission points contain the same pollutants, these were combined for the PC.

10.1.2.2 EMERGENCY DIESEL GENERATORS

As described in Section 4.1.1, the diesel fired generators and firewater pump engines will only operate in emergency situations and testing of the generators will take place for significantly less than 50 hours a year. Since the firewater pump engine is not subject to MCP controls and are less than 1 MWth, it has not been assessed any further. For the emergency diesel generators, following the online permit application process for MCPs operating less than 500 hours a year, no air dispersion or H1 risk assessment is required. It is acknowledged that the engines will not meet the 2g TA Luft requirement as described in Section 3.3.4 and therefore emissions have been assessed using the H1 tool to assess impacts of NO_x and particulates.

An emissions inventory including substance concentrations, total flow, effective height and efflux velocity are provided in Table 10.1. A completed copy of the H1 tool used to assess the emergency diesel generators is provided in Appendix F *(Titled H1_Tool v8 – Moderna_EDGs FINAL 19.12.23).*

TABLE 10.1 PARAMETERS USED IN THE H1 TOOL ASSESSMENT – EMERGENCY DIESEL GENERATORS

Parameter	**Emergency Diesel Generator 1**	**Emergency Diesel Generator 2**	**Emergency Diesel Generator 3**
Oxides of Nitrogen (NO_x) (mg/Nm^3)[8]	3089	3089	3089
Particulates (PM) (mg/Nm^3)[8]	80	80	80
Effective height (m)	0	0	0
Efflux Velocity (m/s)	113.18	113.18	113.18
Total Flow (m^3/h)	14400	14400	14400
Operating Mode of Year (%)	0.15	0.15	0.15

Emissions of oxides of nitrogen (NO_x) have been recorded as nitrogen dioxide (NO_2) and the concentration halved for the short-term effects. Since one generator will be tested at any one time, only one generator has been screened through the H1 tool.

The generators will each only be tested for 17 hours per year, and 0.19% has therefore been used as the operating mode to calculate the PC. Air background concentrations have been taken from DEFRA Background Mapping data for local authorities 2018[9].

10.1.3 RESULTS OF THE H1 ASSESSMENT – EMISSIONS TO AIR

10.1.3.1 FUME HOOD EXHAUSTS

All substances passed stage 1 in that the short-term PC is less than 10% of the short-term environmental standard and the long-term PC is less than 1% of the long-term environmental standard. As such this did not progress to the second stage of screening tests and no further modelling is required.

10.1.3.2 EMERGENCY DIESEL GENERATORS

NO_x, NO_x – Ecological Daily Mean, and PM_{10} all failed stage 1 in that both the short-term PC was more than 10% of the short-term environmental standard and long-term PC was more than 1% of the long-term environmental standard. As such these were progressed to the second stage of screening tests.

In the second stage of screening the long-term PECs for NO_x and PM_{10} were less than 70% of the long-term environmental standard. However, the short-term PC is greater than 20% of the short-term environmental standard minus twice the long-term background concentration. As such, these parameters cannot be screened as insignificant. It is noted the guidance states that modelling should be carried out. However, the emergency generators are to be used for less than 50 hours per year, and only tested for half an hour every 2 weeks and four hours a year for the

8 At reference conditions 5% O2, dry, 273 K, 101.3 kPa
9 DEFRA (2023). *Background Mapping data for local authorities*. Available at: https://uk-air.defra.gov.uk/data/laqm-background-home Last Accessed: 14/12/2023

annual load test. Therefore, detailed dispersion modelling has not been carried out for this application.

10.1.3.3 SUMMARY

A H1 screening assessment has been undertaken to determine if the impact of point source emission to air at the Site represents a potential risk to air.

All VOC emissions from emission point A1 and A2 pass are screened out as insignificant. This is based on an overly conservative assessment due to assessment of raw materials and solvents at maximum storage volumes rather than actual usage which will be far less.

Emissions from the emergency diesel generators are not screened out using the H1 tool, however these generators are only for emergency use and will be tested for less than 50 hours per year.

10.2 EMISSION TO SEWER

10.2.1 METHODOLOGY

The H1 methodology entails screening tests to determine whether pollutants can be screened as insignificant. It requires the input of both annual average (AA) and maximum allowable concentrations (MAC) for substances of concern, for assessment of both long and short-term impacts. The tests check whether the Site is discharging potentially hazardous elements to receiving waters that are not considered insignificant.

For discharges to sewer that discharge, two parts of assessment (Part A and Part B) are required to check whether the discharge is a risk to the environment. Part A comprises of the following tests for discharges to freshwater:

- Test 1 evaluates whether the concentration of the pollutant in the discharge is more than 10% of the EQS
- Test 2 evaluates whether the PC makes up a significant proportion of the EQS. Emissions with PCs that are less than 4% of the EQS can be screened from further assessment as they are not likely to have a significant impact. For discharges to sewer, a sewage treatment reduction factor is applied to take into account the removal of pollutants by the sewage treatment works.
- Test 3 adds the PC to the background concentration in the receiving water to obtain the PEC and then compares the difference between these values to the EQS – effectively testing the increase in concentration of the pollutant in the river downstream of the discharge.
- Test 4 checks whether the PEC is higher than the EQS.

If the concentrations of substances fail Test 4, then the EA require modelling to be carried out.

Part B covers priority hazardous substances. This stage of screening reviews the load from the Site against the significant load (annual load set for the priority hazardous substance) within the watercourse. If the calculated annual load of the priority hazardous substance in the discharge exceeds the significant load for that substance, further assessment (modelling) is required.

10.2.2 H1 INPUT DATA

The Site has no point source emissions to surface water, as described in Section 4.2.1. The H1 methodology has been used to examine the proposed discharge of process effluent to the sewer via emission point S1 and is provided in Appendix F. It is noted that the discharge is combined with sanitary wastewater and effluent from the CB building prior to discharge via S1. However, the discharge has been assessed in isolation as this presents a worst-case conservative assessment without dilution.

10.2.3 WATER BODY TYPE

The Site drainage via S1 discharges to the sewer which falls within the Didcot Sewage Treatment Works (STW) catchment area. The Didcot STW is permitted (TH/CATCM.3651) to discharge into the Moor Ditch. The Moor Ditch is located within the 'Moor Ditch and Ladygrove Ditch', a Water Framework Directive (WFD) river waterbody (GB106039023630[10]). It has therefore been assumed that the release is to freshwaters.

10.2.4 RIVER FLOW RATE

In the absence of flow data for the Moor Ditch, a proxy source of flow data has been used:

- Thames at Days Weir (Q95 3.3 m^3/s) NRFA Station Data f–r 39002 - Thames at Days Weir (ceh.ac.uk)
- A flow of 3.3 m^3/s was used for the river flow in the H1 assessment.

10.2.5 EFFLUENT FLOW RATE

Maximum quantities of effluent to be discharged via S1 is estimated at an annual discharge volume of 0.00023 m^3/s. The flow rate value has been taken as the average and maximum flow rate of the S1 discharge.

10.2.6 EFFLUENT COMPOSITION

There is no monitoring data available for the Site. In order to undertake an assessment of emission to water, emissions have been calculated on the basis of available data and worst-case assumptions. This includes a very conservative assumption that the full annual consumption of solvents and raw materials that are used in processes discharge to the sewer.

The Environmental Quality Standards (EQS) for freshwater have been used in this assessment. These principally relate to priority substances or specific pollutants summarised in the WFD (Standards and Classification) Directions (England and Wales) 2015[11]. Where determinands of concern do not have associated WFD EQS, other appropriate values have been employed (e.g. LC50 values for toxicity to fish from ECHA or safety data sheets) (see Appendix F file *H1_Moderna_Water Emissions FINAL 14.12.23* for more information on where and why these values were selected). It is noted that no environmental standard was available for 4-Azaoctamethylenediamine and this was not therefore assessed, however only very small quantities (0.8 kg) will be consumed per year and the impact is not therefore expected to be significant.

10.2.7 RESULTS OF THE H1 ASSESSMENT – EMISSIONS TO WATER

10.2.7.1 TEST 1

Part A Test 1 evaluates whether the concentration of the pollutant in the discharge is more than 10% of the EQS.

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[10] Moor Ditch and Ladygrove Ditch | Catchment Data Explorer | Catchment Data Explorer

[11] The Water Framework Directive (Standards and Classification) Directions (England and Wales) 2015 (legislation.gov.uk)

Results: Potassium Hydroxide, EDTA, Phosphoric Acid, Dithiothreitol (DTT), Sodium Hydroxide, and Sulphuric Acid discharges are in excess of the relevant EQS and therefore are progressed to Test 2. All other substances screen out at Test 1.

10.2.7.2 TEST 2

Part A Test 2 calculates the process contribution (PC) as a proportion of the EQS. Emissions with PCs that are less than 4% of the EQS can be screened from further assessment including Part B as they are likely to have an insignificant impact.

Results: All substances that progressed to Test 2 pass Test 2 and therefore are screened out requiring no further assessment.

10.2.7.3 SUMMARY

A H1 screening assessment has been undertaken to determine if the impact of the treated effluent from the Site to the sewer represents a potential risk to the receiving water body. The proposed effluent discharge has been assessed independently of mixing/the addition of sanitary flows, therefore the H1 assessment did not take into account the additional dilution from these streams.

The impacts of the discharge to sewer have been screened out and are therefore considered to be insignificant.

11. NOISE

The source of noise emissions from the Site will include three air source heat pumps, one chiller, three transformers, one sprinkler pump house, emissions from roof vents, and auxiliary equipment including three standby diesel generators, a diesel fire pump and a jockey fire pump. Other noise generating process equipment will be within buildings and cause lower emissions, to meet acceptable internal working conditions. As such the building fabric will attenuate internal noise emissions. To meet the planning conditions detailed further below, external plant will be designed using appropriate mitigation including the use of layout, acoustic enclosures and silencers, to limit potential for annoyance and exceedance of appropriate noise limits as discussed below.

The Site is located in a commercial area with the nearest noise sensitive receptor being those immediately adjacent office spaces within the European Space Agency building. The closest residential receptor is approximately 500m South of the Site.

A detailed noise and vibration impact assessment (NIA) was carried out for the planning consent for the construction of the Site, led by the landlord. The assessment found that the noise emissions would not cause significant impact to receptors on the basis that they would not result in any increase in noise levels at the receptor sites. The planning consent included planning condition presented in Table 11.1 (also in document 'Decision Notice' in Appendix G).

TABLE 11.1 NOISE RELATED PLANNING CONDITIONS

Planning condition (as issued)
Condition 16: "*Prior to the first use of the development and associated noise mitigation, detailed in section 6.3 of the Noise Impact Assessment, dated 08/09/22, noise testing shall be carried out to establish that noise levels recorded from outside the identified residential receptors do not exceed the noise thresholds identified in section 5.1, Table 6 of the Noise Impact Assessment. If noise levels exceed the identified thresholds, use of the development shall not commence until an updated noise mitigation scheme with an accompanying noise assessment has been submitted to and approved in writing by Local Planning Authority.* *Reason: To ensure that the development is not unneighbourly in accordance with Policies DP23 and DP25 of the adopted Local Plan 2031 Part 2"*

The NIA was carried out in September 2022 in accordance to British Standard BS 4142 as presented in Appendix G, assessed the noise from the external plant area for the proposed development including three external chillers (only one now proposed for the Site), three emergency diesel generators and three transformers.

The NIA considered the noise sources operating continuously under normal operations and found that these would not give rise to significant noise issues if the plant noise rating levels are designed to meet background noise levels at the receptors, minus 5 dB overall, as specified in Table 6 of the NIA. Limits are given in the NIA for individual plant items that ensure that the overall noise emissions meet the required noise level (see Section 6.3). The risk of noise and vibration issues from the Site has been concluded in the NIA to be insignificant given compliance with this noise level and would be described as "low" in terms of BS 4142 and would comply with the Local Authority (Vale of White Horse District Council) Development Policy 25: Noise Pollution which sets this target.

Moderna will take appropriate noise abatement measures to ensure the noise at the Site meets the planning conditions. Moderna considers that the planning conditions, once discharged, deliver sufficient environmental protection and would represent BAT. No further mitigation measures are proposed or required through the permit application.

To demonstrate compliance with the noise planning limits in planning condition 16, Moderna will implement a commissioning plan that will monitor noise levels during commissioning, in line with the same planning condition.

12. ODOUR

The manufacturing process will be undertaken inside the building. Solvents by nature may have some potential odour emissions. The main solvent with a potential odour is acetic acid (0.48 – 1 ppm) which is used in small amounts for buffer preparation. No chemical additives will be used in the process that contain odours or odour causing materials, therefore no inadvertent products or by-products will result in the process to cause odours.

Raw materials including solvents will be stored inside in low quantities. Materials will be delivered in sealed containers and used within the buildings. Odour generated from the hazardous waste storage room will be collected through the ventilation system, and subsequently recirculated through the HVAC system. While the building HVAC system will primarily be used for air condition and internal air quality control, they will collect any odours from inside, which will be diluted and eventually discharged through the air condition process.

While the ETP has been identified as a potential source of odour, it does not utilise biological treatment (pH treatment only) and will be subject to regular planned maintenance as part of the Site’s maintenance programme. Similarly, the ETP is located indoors as described in Section 3.3.3.2, therefore the risk of odours is minimal.

The only external raw material storage is the bulk diesel storage tank and associated day tanks with potential for emissions of diesel fumes during filling of the tank whilst air is displaced through the vent. However, this is considered insignificant.

As such, there are no anticipated odour issues with the activities onsite. The nearest residential receptor is approximately 500m south of the Site, and the Site sits within a predominantly commercial area. The Site is not expected to give risk to odour outside of the Site boundary that will give rise to nuisance.

A further assessment of the risk of odour can be found in Table 14.1.

13. MONITORING

13.1 EMISSIONS TO AIR

13.1.1 PROPOSED EMISSIONS MONITORING

All point source emissions to air are presented in Table 13.1 and described in Section 4.1.1. Emissions from the fume hood exhaust (A1 – A3) are expected to be negligible and impacts are not significant (as detailed in Section 10.1) and therefore no monitoring is proposed due to the minimal impact.

TABLE 13.1 AIR EMISSIONS MONITORING

Emission Point ID	Location	Use	Parameter	Limits	Frequency	Method
A1	Weigh and Dispense Fume Hood	Fume hood exhaust from weighing and dispensing of liquid raw materials for the buffer preparation	Hydrochloric acid, acetic acid, ethanol	-	-	-
A2	Central QC Lab Fume Hood	x3 fume hood exhaust from the QC Chemical Lab, Sample Prep Area, and Micro-biological lab. Fumes from the decanting of liquid and preparation activities.	Acetonitrile, formic acid, acetic acid, methanol, IPA, ethanol, HFIP, hydrochloric acid, tetrahydrofuran, DIEA, chloroform, hydrogen peroxide, phenol, isoamyl alcohol	-	-	-
A3	Raw Material Warehouse Fume Hood	Fume hood exhaust from raw material sampling	Acetonitrile, formic acid, acetic acid, methanol, IPA, ethanol, HFIP, hydrochloric acid, tetrahydrofuran, DIEA, chloroform, hydrogen peroxide, phenol, isoamyl alcohol	-	-	-
A4	Emergency Diesel Generator (2.86 MWth)	Usage during an emergency only for	NO_x, CO, Particulates	Exempt from emission limit values, but testing running hours are to be recorded and reported within four months of permit issue or start of operation.		

Emission Point ID	Location	Use	Parameter	Limits	Frequency	Method
A5	Emergency Diesel Generator (2.86 MWth)	power generation	NO_x, CO, Particulates			
A6	Emergency Diesel Generator (2.86 MWth)		NO_x, CO, Particulates			
A7	Firewater diesel pump engine (0.74 MWth)	Usage during an emergency only for power generation for firewater sprinkler system	NO_x, CO, Particulates	Not an MCP and so monitoring requirements not required.		

13.1.2 MONITORING METHOD

No emission limits or periodic monitoring is proposed for the emergency diesel generators due to the emergency only nature of operation. Monitoring will be in line with web guide 'Monitoring stack emissions: low risk MCPs and specified generators', published 12 July 2022. The monitoring frequency is expected to be every 1,500 hours of operation or once every five years (whichever comes first). Flues for the three new generators will be designed so that suitable sampling points are incorporated to facilitate such monitoring.

13.2 EMISSIONS TO SURFACE WATER

13.2.1 PROPOSED EMISSIONS MONITORING

No monitoring or limits have been proposed as there are no direct discharges to surface water (See Section 4.2).

13.3 EMISSIONS TO SEWER

13.3.1 PROPOSED EMISSIONS MONITORING

The Site will continuously monitor the effluent discharge in line with the Thames Water TEC requirements for pH and temperature. Table 13.2 presents the likely monitoring limits required by the Thames Water consent. No emissions limits for other parameters expected in the discharge have been proposed as these are not direct emissions to water and compliance will be covered under the TEC.

TABLE 13.2 SEWER EMISSIONS MONITORING

Emission Point ID	Location	Use	Parameter	Limit	Frequency	Method
S1	Effluent Treatment Plant	Treatment of process effluent	pH	6 – 11	Continuous	CEMS
			Temperature	43.3	Continuous	CEMS

13.3.2 MONITORING METHOD

Monitoring and analysis for all consented parameters will be undertaken to demonstrate compliance with the TEC. pH, temperature and flow rate will be monitored continuously, with pH probe located on the outflow pipe of the ETP located inside to the north of the DS building of the Site. Sampling will be carried out in line with MCERTS requirements and carried out by a technically competent person.

Records of the volume and composition of the trade effluent to sewer will be kept in case of inspection by a Sewerage Undertaker representative.

14. ENVIRONMENTAL RISK ASSESSMENT

14.1 IDENTIFY AND CONSIDER RISKS FROM THE SITE

An environmental risk assessment has been conducted for the Site. This has included identification of sources, pathways and receptors and is presented in

Table 14.1.

Separately, the EA's H1 tool has been completed as a screening exercise to assess the environmental risks from normal operations to both air and sewer (as detailed in Section 0). The screening assessment has been used to inform this environmental risk assessment and the risk assessment uses the risk matrix provided in Appendix H.

14.2 ACCIDENT MANAGEMENT PLAN

As part of the EMS, Moderna will operate with an accident management plan which will describe risks associated with incidents which could potentially have health and safety and/or environmental effects and the control measures to be taken to minimise the impact. Moderna have conducted a High Level Risk Assessment that has been used to identify health, safety and environmental hazards arising from the proposed operations. The high-level risk assessment has identified further areas of assessment/studies required to understand the risk of equipment and processes (e.g. PHAs, HAZOPs, DSEAR), which will be conducted where appropriate and according to legal requirements.

A preliminary DSEAR assessment has been conducted for the Site to identify flammable substances alongside respective control measures, mitigations and recommendations to consider in the design process to reduce the risks. Process Hazard Assessments will be developed for the Site as part of the design review and for all new plant. It is the intention of the Site to complete these by February 2024. The outcomes of the further assessments will be incorporated into the Site H&S procedures and within the EMS where necessary.

TABLE 14.1 ENVIRONMENTAL RISK ASSESSMENT

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
Emissions to air (VOCs)	Normal operation	The closest residential buildings are approximately 500 m south of the Site. The closest designated residential receptor is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. See air quality impact assessment in **Section 10.1**	Dispersion through the air	The only point source emissions to air containing VOCs are from fume hood ventilations systems including the weigh and dispense area, QC lab, and raw material sampling in the warehouse. These sources of emissions are expected to be minimal. All operational staff will be fully trained and experienced in the key processes for which they will be responsible. This includes being knowledgeable about the standard operating procedures (SOP's) and Site EMS. Training will cover hazard and fault awareness and potential implications of failure to control the associated impact on the environment, as well as actions to take in the event of an issue. All equipment that could potentially give rise to VOC emissions will have preventative maintenance as part of the Site EMS. Should it be identified that damage has occurred to any equipment, repairs will be undertaken to ensure that integrity is suitably maintained.	Unlikely	Insignificant	Low
	Accidental releases Release of fugitive emissions	The closest residential buildings are approximately 500 m south of the Site.	Dispersion through the air	No bulk storage of VOC containing materials will occur onsite. All VOC raw material storage will be designed to minimise the risk of fugitive emissions as detailed in **Section 4.1.2.**	Rare	Minor	Low

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
	from raw materials storage	The closest designated residential receptor is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. See air quality impact assessment in **Section 10.1**		All dispensing of raw materials will be carried out within a fume cupboard. The operation of the fume cupboards and HVAC system are considered to channel unabated emissions of internal air from the normal operations and the concentration of VOCs is expected to be insignificant. All equipment that could potentially give rise to VOC emissions will have preventative maintenance as part of the Site EMS. Should it be identified that damage has occurred to any equipment, repairs will be undertaken to ensure that integrity is suitably maintained. Buffer prep materials that could give rise to dust emissions will be stored in closed vessels, used only within a circulating downflow booth with HEPA systems to filter particulates.			

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
Emissions to air *(VOCs, NOx, CO, Particulates)*	In case of fire	The closest residential buildings are approximately 500 m south of the Site. The closest designated residential receptor is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. See air quality impact assessment in **Section 10.1**	Dispersion through the air	Low quantities of flammable materials stored onsite and so fire risk is considered low. Firewater will be stored in a 709 m^3 bulk storage tank and used in a firewater sprinkler system and wet risers to provide firewater protection measure to limit or prevent escalation of fire. A fire suppression system will also be used for IT rooms. Fire safety and awareness will be maintained onsite to reduce the likelihood that a fire would occur onsite as part of the EMS.	Rare	Minor	Low
Emissions to air *(NO_x, CO, and particulates)*	Testing of Three Emergency Diesel Generators & Firewater Pump Diesel Engine	The closest residential buildings are approximately 500 m south of the Site. The closest designated residential receptor is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. See air quality impact assessment in **Section 10.1**	Dispersion through the air	The generators will be relatively small in size and will be maintained in accordance with manufacturer requirements. Testing of the generators and firewater engine will be scheduled individually to reduce impact and will take place for less than 50 hours per year per engine.	Likely	Minor	Medium

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
Emissions to air *(NO_x, CO, and particulates)*	Emergency operation of three Emergency Diesel Generators & Firewater Pump Diesel Engine	The closest residential buildings are approximately 500m south of the Site. The closest designated residential receptor is the Chilton Disused Railway Line Local Wildlife Site approximately 1.6 km southeast of the Site. See air quality impact assessment in **Section 10.1**	Dispersion through the air	The back-up generators and one firewater pump engine will only be used in emergency situations. The generators will be relatively small in size and will be maintained in accordance with manufacturer requirements. The Site will have uninterruptable power supply. The design will likely be for 20 minutes during a power failure.	Rare	Minor	Low
Emissions to land and groundwater *(Fuel bulk storage and chemicals)*	Accidental Loss of containme nt/damage /vandalism to tank and bund, spillage during loading/ offloading	Infiltration to groundwater The Site is not located within a Source Protection Zone	Direct or overland flow into the drainage system	Bulk diesel fuel storage will be stored within isolated bunds of 110% of the tank capacity that significantly reduces the risk of a spill entering the drainage system (as detailed in 3.3.9). Bunds will be provided with a low point sump for removal and offsite disposal of captured liquids. All other raw materials will be stored in low quantities inside in either storage racks, bunded pallets, cold storage or cabinets with integral bunding. The Site will be covered by concrete hardstanding internally and externally. Storage and delivery areas will be located on an impermeable surface. An oil interceptor will be located prior to	Unlikely	Moderate	Medium

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
				the SuDS attenuation basin to capture any oil. Spill kits will be located in close proximity to storage and delivery areas. Site operatives will be trained to manage substances onsite and trained to deal with any spills onsite (as part of the accident management plan). An inventory will be maintained of all substances and good standards of housekeeping will be maintained in all areas where the substances will be stored. Boundary fencing and 24 hour Site security to restrict entry/access by vandals.			
Emissions to land and groundwater *(Firefighting water)*	Emergency Fire resulting in firefighting water	Infiltration to groundwater Not located within a Source Protection Zone	Direct or overland flow into the drainage system	Low quantities of flammable materials stored onsite and so fire risk is considered low. Any firewater indoors will be contained and any discharge to the sewer by agreement with sewerage undertaker. External firewater will be directed to surface water drains with isolation valves to contain firewater. Any contained firewater will be tested prior to discharge to SuDs basin or removed offsite. Fire safety and awareness will be maintained onsite to reduce the	Rare	Moderate	Medium

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
				likelihood that a fire would occur onsite as part of the EMS			
Emissions to water *(Fuel bulk storage and chemicals)*	Accidental Loss of containme nt/ damage/ vandalism to tank and bund, spillage during loading/ offloading	Surface Waters East Hendred Brook (statutory main river) located approximately 3.7 km northwest of the Site.	Direct or overland flow into offsite surface water system which discharges into the East Hendred Brook	There will be no direct discharge to surface waters from the Site. See emissions to groundwater for chemicals and bulk storage of fuel.	Rare	Minor	Low
Emissions to water *(Firefighting water)*	Emergency Fire resulting in firefighting water	Surface Waters East Hendred Brook (statutory main river) located approximately 3.7 km northwest of the Site.	Direct or overland flow into offsite surface water system which discharges into the East Hendred Brook	As per emissions to groundwater from firefighting water.	Rare	Minor	Low
Emissions to sewer *(Process Effluent)*	Accidental Failure of ETP	Sewage Treatment Works (STW)	Direct to sewer	Records of volume and composition of trade effluent will be kept. A continuous monitoring system will be maintained and tested to measure pH and temperature to the satisfaction of the sewerage undertaker TEC. Regular preventative maintenance as part of the EMS to ensure the integrity of drainage and neutralisation systems is maintained.	Unlikely	Minor	Low

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
				The equalization tank within the neutralisation system will have a 4 m^3 capacity should effluent not meet the specification.			
Emissions to sewer *(Fuel bulk storage and chemicals)*	Accidental Loss of containme nt/ damage/ vandalism to tank and bund, spillage during loading/ offloading	STW	Sewer following a direct spill through catastrophic failure or overfill of tank/pipewor k/bunding/ surfacing penetrating sewer	Regular preventative maintenance as part of the EMS will ensure that integrity of drainage systems is maintained throughout the lifetime of the Site operations.	Rare	Minor	Low
Emissions to sewer *(Firefighting water)*	Emergency Fire resulting in firefighting water	STW	Direct to sewer	Emission is by arrangement with the sewerage undertaker.	Rare	Minor	Low
Odour	No known scenarios	The closest residential buildings are approximately 500 m south of the Site.	Dispersion through the air	Risk of odour is not considered to give rise to odour issues as described in **Section 12**. Raw materials used onsite will have some odour potential however all manufacturing processes are undertaken inside the building and storage will be in small quantities.	Rare	Insignificant	Low
Noise and vibration	Normal operation from	Operational staff	Sound propagation through air	Machinery generating noise will only be operated during working hours.	Unlikely	Minor	Low

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
	machinery, import and export vehicles	The closest residential buildings are approximately 500 m south of the Site.	and the ground.	Noise impacts are not expected to be significant as described in **Section 11**. Noise abatement measures will be taken to ensure equipment noise production meets planning conditions.			
Litter / pests	Normal operation	Neighbouring industrial and research units	Windblown, birds	Housekeeping will be given a high priority as company policy. Any putrescible waste generated by the Site will be appropriately stored to avoid pests. Any waste kept externally will be appropriately covered to stop wind and birds.	Unlikely	Insignificant	Low
Visible emissions	Generator testing/ emergency operations	Neighbouring commercial units. The closest residential buildings are approximately 500m south of the Site.	Airborne / visual	Minimisation of planned testing durations.	Unlikely	Minor	Low
Surface water flooding from weather event	All operational scenarios	Site operations restricted	Direct effects	Site operations are principally internal. Surface water drains to a SuDS drainage basin to the northeast of the Site.	Rare Risk of flooding due to surface water onsite is classified as 'very low'.	Minor	Low

Hazard	Operation scenario	Receptor	Pathway	Risk management techniques	Probability of exposure	Consequence	Overall Risk
					Site is categorised as ‘Flood Zone 1 – low risk of flooding’		

APPENDIX A EA PRE-APPLICATION ENGAGEMENT

APPENDIX B SITE LAYOUT PLANS

APPENDIX C SITE CONDITION REPORT

APPENDIX D SITE DRAINAGE PLAN

APPENDIX E HVAC OVERVIEW

APPENDIX F H1 ASSESSMENTS

APPENDIX G NOISE IMPACT ASSESSMENT & PLANNING CONDITION

APPENDIX H RISK ASSESSMENT MATRIX