

Permitting Decisions- Bespoke Permit

We have decided to grant the permit for Moderna Drug Substance Manufacturing Facility operated by Moderna Biotech Manufacturing UK Limited.

The permit number is EPR/TP3822SV.

The permit was granted on 12/07/2024.

The application is for a new facility that manufactures COVID-19 vaccine mRNA drug substance in two stages: production of the mRNA component and the encapsulation of the mRNA in lipid nanoparticles. The drug substance is subsequently filled into syringes or vials at a third-party facility.

There are three emergency gas-oil fuelled generators, which each emit via two vents. In the event of a failure of the electrical supply, the operator will utilise the generators to maintain power to the facility. The generators will be used solely for the purpose of providing a back-up power supply, with no electricity being exported from the installation.

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document provides a record of the decision-making process. It:

- summarises the decision making process in the [decision considerations](#) section to show how the main relevant factors have been taken into account
- highlights [key issues](#) in the determination
- shows how we have considered the [consultation responses](#)

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Read the permitting decisions in conjunction with the environmental permit.

Key issues of the decision

Solvent use

The operator uses a number of different solvents for disinfection purposes. To a lesser extent solvents are used in buffer preparation and in the Quality Control (QC) laboratory for analysis purposes. The use of solvents at the installation does not fall under the requirements of Schedule 14 of the Environmental Permitting Regulations regarding solvent emission activities because the total 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.

Operating techniques

We have reviewed the measures proposed by the operator and compared them against the indicative BAT set out in our sector guidance note EPR 4.02 (How to comply with your environmental permit Additional guidance for: Speciality Organic Chemicals Sector). A summary of the key operating techniques are provided below. We are satisfied that these measures represent BAT for the installation.

The facility will be operated in accordance with Moderna's Environmental Management System (EMS) which includes management commitments for continual assessment of environmental impacts and improvement programmes. All process equipment is included in the operator's proactive site inspection and maintenance schedule and will be reviewed as part of EMS performance evaluation.

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

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

Reaction vessels are simple, small vessels with some stages carried out in plastic bags. Product and vessel washing is required at certain stages, however all effluent is collected for treatment (temperature and pH adjustment) prior to discharge to sewer.

Process equipment at the site is operated by a mixture of automated and manual processes to ensure high process efficiency, yield and operability, with some key process indicators relayed to central alarms.

Air Quality

The main point source emissions to air from the installation are from three standby generators and from fume hood ventilation systems. In the application, the operator also described a firewater pump engine, but as this is not directly associated with the permitted activity, it is not considered further.

Point source emissions from the manufacturing process arise principally from fume hoods within the weigh and dispense area, the quality control (QC) laboratory and the raw material warehouse (QC sampling). Emissions are minimised via management techniques that reduce vapour losses, such as use of lidded containers and closed vessels. The emissions, which comprise mainly volatile organic compounds (VOCs), are released to air via three stacks approximately 3.5 metres above roof height. Each emission point is served by two separate fans and outlet ducts located adjacent to each other, although only one outlet duct will emit at any one time (one duty/one standby). The two ducts are designated A and B for each emission point. This is to provide operational resilience in the case of a fan fault. There is no emissions abatement in place.

The operator provided an H1 Risk Assessment for emissions to air from the QC laboratory and the weigh and dispense area based on the anticipated maximum production rate of the site (16 hours per day for 10 months of the year).

Emissions from the warehouse were not assessed because they are 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.

The site is not yet operational, therefore the operator's assessment used data scaled up from other Moderna facilities and maximum storage volumes (rather than actual usage, which will be less) to ensure a conservative, worst-case assessment. The operator assessed emissions of acetonitrile, acetic acid, methanol, 2-propanol, hydrochloric acid, tetrahydrofuran and chloroform against published Environmental Assessment Levels (EALs) in accordance with our guidance.

For the following substances, there are no published EALs in our guidance, and the operator either used benzene as a proxy substance, in accordance with our guidance, or derived EALs based on Workplace Exposure Levels (WELs): formic acid, ethanol, 1,1,1,3,3,3-hexafluoro-2-propanol, N,N-diisopropylethylamine, hydrogen peroxide, phenol and isoamyl alcohol.

The operator's assessment indicates that for all substances the long-term process contribution (PC) is less than 1%, and the short-term PC is less than 10%, of the relevant EAL. The impacts of all emissions to air are therefore considered to be insignificant.

Whilst the operator's approach to the derivation of EALs is not in accordance with our guidance, we have reviewed the H1 assessment, substituting proxy substances with greater toxicity, for substances without published EALs, and we agree with the operator's conclusions. We also considered continuous operation (24 hours per day, 365 days per year) and the impacts were predicted to be insignificant for all parameters.

The operator also assessed the risk of fugitive emissions to air as low, comprising mainly VOCs from cleaning, laboratory and production areas. There is no bulk storage of process raw materials containing VOCs; all VOC raw materials are stored in bottles/containers with lids and dispensing will be carried out within fume hoods. The rooms are controlled using heating, ventilation and air conditioning systems including biological safety cabinets that will be fitted with high efficiency particulate air (HEPA) filters, but this is primarily for the protection of workers.

The only substance used on site that could give rise to dust emissions is sucrose, used in buffer preparation, which is mixed with other raw materials in closed vessels to control dust. The product is decanted in a downflow booth located indoors. All raw materials and products will be kept in closed containers.

The operator will undertake regular inspection and maintenance of plant items and storage areas to minimise the risk of fugitive emissions to air.

With regard to the three backup generators, we did not require dispersion modelling of emissions because they will only be used for limited circumstances – routinely for testing and maintenance purposes and in the event of an emergency power outage. For context, if the generators were standalone plant they would meet the screening distance criteria of the standard rules SR2018 No7 and not require further assessment.

The generators do not fully comply with our guidance, Emergency backup diesel engines on installations: best available techniques (BAT) in two regards:

- the generators do not currently comply with the stated emissions standard (i.e. approximately 2,000 mg/m³ oxides of nitrogen NO_x (as NO₂) at 5% O₂ standard temperature and pressure, dry, 273K and 101.3kPa (commonly termed '2g') at a typical emergency load, instead emitting approximately 2,800 mg/m³ NO_x (as NO₂) at the same reference conditions.
- they are not fitted with vertical flues.

However, the site mains power supply has been engineered with 2 ring mains providing resilience against an on-site power failure and therefore minimising the likelihood that the generators would be required to operate beyond the testing and maintenance regime which, for each engine, is scheduled to consist of a fortnightly half-hour test plus an annual four-hour test (total testing time of 17

hours per engine per year). Additionally the engines will be tested one at a time to minimise short-term impacts.

Whilst not specifically required for the assessment of air quality impacts, the operator an air quality assessment of short-term (hourly) impacts of NO_x from the generators at relevant human health receptors, '*Assessment of Emergency Diesel Generator Emissions at Moderna Harwell Dispersion Modelling Comparison of Environmental Impacts from BAT Compliant Engines and Non-BAT Compliant Engines*', Project No: 7042, version 1.2 and dated 11/03/2024. This was submitted to support the permitting of non-BAT compliant engines.

The assessment concluded that, whilst the process contribution of NO_x from each generator is greater than 1% of the relevant air quality standard (AQS), and therefore cannot be screened out as insignificant, there are no instances of the predicted environmental concentration (PEC) exceeding the AQS at any relevant receptor. The short-term impact from each generator is therefore considered not significant.

For two other receptors assessed by the operator, the PEC did exceed 100% of the AQS, but these are points adjacent to the site boundary, identified as 'assumed to be walking routes', and are not considered relevant receptors for the assessment. This is because it is unlikely that members of the public are regularly present at those locations during the averaging time of the relevant assessment criteria (in this case, one hour).

The generators have already been purchased and the earliest the operator could realistically arrange for abatement to be fitted is later than the first scheduled production run, potentially delaying the commencement of operation of critical national infrastructure.

Considering the specific nature of this case, we have decided to permit the proposed engines, but we have included an improvement condition IC1 to require the operator to implement improvements to achieve BAT standards, as agreed in writing with the Environment Agency, within the shortest practicable timescale.

Water quality

The installation discharges process wastewater to sewer (discharging to Moor Ditch, via Didcot Sewage Treatment Works), after temperature and pH adjustment (emission point S1). The operator submitted an initial H1 assessment with the application. Because the site is not yet operational the effluent composition was based on a number of assumptions, including that the full annual consumption of raw materials used in the process is discharged to sewer.

Our initial review of the H1 assessment indicated the operator's use of an inappropriate Q95 flow rate (the flow of a river which is exceeded on average for 95% of the time i.e. low flow) for the receiving watercourse. In response to our Schedule 5 notice, the operator subsequently submitted a revised H1

assessment using an appropriate Q95 flowrate and focussing on the hazardous chemicals they expect to be in the discharge that are not sanitary pollutants (as defined in our H1 Annex D2 guidance Assessment of sanitary and other pollutants within surface water discharges): disodium EDTA, tetrasodium EDTA, dithiothreitol (DTT) and 4-Azaoctamethylenediamine. The assessment compared the predicted impacts of the two EDTA salts against the Environmental Quality Standard (EQS) for EDTA. In the absence of published EQSs for 4-Azaoctamethylenediamine and DTT, the operator derived Predicted No-Effect Concentration (PNEC) values for use in their assessment.

We have reviewed the operator's assessment and are satisfied that it has been carried out in accordance with our guidance: [Surface water pollution risk assessment for your environmental permit](#), and that the operator's use of the EDTA EQS and derived PNECs are suitable for use as indicative values in the assessment.

The operator's assessment indicated that the impacts of all emissions of all four pollutants to the Moor Ditch Point screen out as insignificant.

The H1 assessment was based on an assumed effluent composition. We have therefore included two improvement conditions in Table S1.3 of the permit. IC2 requires analytical testing of a representative sample of the discharge to establish which hazardous chemicals or elements are present in the effluent once the plant is operational.

IC3 requires twelve monthly samples of the sewer discharge during the first year of operation in order to validate the assumptions made in the application regarding the concentrations and associated impacts of DTT, 4-Azaoctamethylenediamine and the two EDTA salts.

If additional hazardous chemicals or elements are identified following the completion of IC2, the operator is required to also monitor and assess those parameters in accordance with the requirements of IC3.

Drainage and containment

The site is covered in concrete hardstanding and drainage is arranged as follows:

- Uncontaminated surface water system draining (via interceptors) to two soakaways
- Effluent treatment system, linked from process floor drains and discharging to sewer via emission point S1

The only bulk storage tank associated with the process is the above ground gas oil fuel storage tank that supplies the emergency generators. This is a fixed roof 55 m³ tank designed in line with the Oil Storage Control of Pollution (Oil Storage) (England) Regulations 2001 guidelines and is provided with a bund that

can hold 110% of the capacity of the tank, with sump for removal and offsite disposal of captured liquids.

The underground pipelines which transfer fuel from the bulk gas oil storage tank to the emergency generators are double contained.

Each generator has an associated 2.5 m³ gas oil day tank within the generator container, providing 10 hours run time. The day tanks are also designed to meet best practice on containment as described above.

All other raw materials are stored in small quantities in the warehouse or QC lab in storage racks, banded pallets, cold storage, or cabinets with integral bunds. There are no surface water drainage connections in the storage areas.

The effluent treatment plant includes one underground receiving tank, which sits within an epoxy coated chemically resistant pit. The tank and pit are fully visible from above so any leaks or lining degradation would be immediately apparent. If a leak is detected, production will cease until remedial actions are completed to effect a repair.

Noise

The operator considered the risks of noise and vibration from the facility in their environmental risk assessment in accordance with our web guidance, [Risk assessments for your environmental permit](#). The overall risk with respect to noise is assessed to be low.

The main external noise sources from the installation comprise a chiller and the three standby gas oil generators, which all incorporate noise mitigation including the use of layout, acoustic enclosures and silencers. The generators will only run routinely for testing and maintenance (17 hours per engine per year) and the operator has confirmed this will only occur during daytime.

Other noise generating process equipment will be located within buildings and as such the building fabric attenuates internal noise emissions.

All equipment is operated by fully trained staff in accordance with the operators' standard operating procedures and maintained in accordance with the operator's planned preventative maintenance regime to ensure equipment remains fit for purpose and operates within optimum conditions to minimise the likelihood of noise and/or vibration.

Any noise complaints will be handled in accordance with the operator's complaints procedure, which will be incorporated into the site Environmental Management System once fully finalised. In summary, any complaints received will be directed as soon as possible (and in any case no longer than one working day) to the Associate Director EHS who will instigate the complaint handling and investigation procedure, via telephone or face-to-face meeting with the

complainant as appropriate. Details of the complaint are recorded, corrective action defined and implemented as required.

As part of their permit application submission, the operator included a noise impact assessment that was prepared as part of their planning application.

We have reviewed the requirement for a noise impact assessment using our qualitative noise screening criteria. Based on the nature of the installation and its location and the proposed noise mitigation measures, we anticipate that the risk of noise impacts will not be significant.

Consequently, we have not assessed the noise impact assessment in detail, and we have not required a noise management plan, as part of this determination. However, we have included our standard noise condition in the variation notice, which allows us to ask for a noise management plan if we become aware of noise-related problems on site.

Odour

The operator considered the risks of odour from the facility in their environmental risk assessment in accordance with our web guidance, [Risk assessments for your environmental permit](#). The overall risk with respect to odour is assessed to be low.

Whilst the manufacturing process involves the use of solvents, which have the potential to cause odour emissions, all materials are delivered in sealed containers and stored and used in low quantities in closed vessels, inside buildings.

The effluent treatment plant does not carry out odorous processes, correcting for temperature and pH only. The treatment plant is also located indoors.

All equipment is operated by fully trained staff in accordance with the operators' standard operating procedures and maintained in accordance with the operator's planned preventative maintenance regime to ensure equipment remains fit for purpose and operates within optimum conditions to minimise the likelihood of odour emissions.

Any odour complaints will be handled in accordance with the operator's complaints procedure as already described above.

Based on the nature of the installation and its location and the proposed odour mitigation measures, we anticipate that the risk of odour impacts will not be significant.

Consequently we have not required an odour management plan, as part of this determination. However, we have included our standard odour condition in the variation notice, which allows us to ask for an odour management plan if we become aware of odour-related problems on site.

Accidents

An accident management plan will be developed for inclusion in the operator's EMS.

Whilst flammable materials, including hydrocarbons, resin solution, and cleaning products are stored, this is only in relatively small quantities, so the fire risk associated with these is considered low. The operator has procedures in place to limit or prevent escalation of a fire, including arrangements for firefighting water supply and storage on site, a firewater sprinkler system, wet risers and a dedicated firewater pump engine to supply power to the sprinkler system in emergency situations.

The applicant initially proposed the inclusion of isolation valves in the surface water drainage system but later amended the proposal. The applicant considers the risk of pollution to surface water from site activities to be sufficiently low that isolation valves will not be installed prior to the soakaways.

For gas oil tank filling, the pump set is fitted with isolation valves and non-return valves and the tank is equipped with an electronic level gauge with an alarm output, including low- and high-level indication, that will identify any leaks and prevent overfilling, and a vent to prevent over/under pressure when filling and emptying. Fuel delivery will be supervised and conducted under a permit to work, and includes fitting of a drain seal on the open drain channel near this location.

Under normal operating conditions the generators will only run for testing and maintenance purposes. Actual fuel consumption therefore will be low and deliveries of fuel infrequent. However, the operator will incorporate refuelling and spill response procedures into the site's environmental management system. These will include measures such as routine bund inspections and covering surface water drains during fuel delivery. Spill kits (including drain covers) are provided in the refuelling area. The surface water in this area is routed via an interceptor prior to discharge to the soakaway.

The building is fitted with an automatic sprinkler system, which is controlled to minimise the volume of polluted water generated during a fire. The sprinkler system comprises 5 zones, each served by a separate fire water supply. Compartmentation of the building using fire resistant structures reduces the potential for and extent of fire water run-off.

All raw materials are stored in small quantities indoors in storage racks, banded pallets, cold storage, or cabinets with integral bunds. There are no surface water drainage connections in the storage areas.

Staff will receive training on preventive and response measures to minimise the potential for run-off to drain. The Environmental Management system will include fire procedures such as the use of surface water drainage covers to prevent run-off to drain and emergency drills.

Decision considerations

Confidential information

A claim for commercial or industrial confidentiality has been made.

We have accepted the claim for confidentiality. We have excluded information regarding the manufacturing process. We consider that the inclusion of the relevant information on the public register would prejudice the applicant's interests to an unreasonable degree.

The decision was taken in accordance with our guidance on confidentiality.

Identifying confidential information

We have not identified additional information provided as part of the application that we consider to be confidential.

The decision was taken in accordance with our guidance on confidentiality.

Consultation

The consultation requirements were identified in accordance with the Environmental Permitting (England and Wales) Regulations (2016) and our public participation statement.

The comments and our responses are summarised in the [consultation responses](#) section.

The application was publicised on the GOV.UK website.

We consulted the following organisations:

Vale of White Horse District Council Environmental Protection Team

Health and Safety Executive

Sewerage Authority

No responses were received from Health and Safety Executive and Sewerage Authority.

The comments from Vale of White Horse District Council and our responses are summarised in the [consultation responses](#) section.

Operator

We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with our guidance on legal operator for environmental permits.

The regulated facility

We considered the extent and nature of the facility at the site in accordance with RGN2 'Understanding the meaning of regulated facility', Appendix 2 of RGN2 'Defining the scope of the installation' and Appendix 1 of RGN 2 'Interpretation of Schedule 1'.

The extent of the facility is defined in the site plan and in the permit. The activities are defined in table S1.1 of the permit.

The site

The operator has provided a plan which we consider to be satisfactory. These show the extent of the site of the facility including the discharge points. The plan is included in the permit.

Site condition report

The operator has provided a description of the condition of the site, which we consider is satisfactory. The decision was taken in accordance with our guidance on site condition reports and baseline reporting under the Industrial Emissions Directive.

Nature conservation, landscape, heritage and protected species and habitat designations

We have checked the location of the application to assess if it is within the screening distances we consider relevant for impacts on nature conservation, landscape, heritage and protected species and habitat designations. The application is within our screening distances for these designations: Chilton Disused Railway Line (local wildlife site) and Lyde Bank Plantation (ancient woodland)

We have assessed the application and its potential to affect sites of nature conservation, landscape, heritage and protected species and habitat designations identified in the nature conservation screening report as part of the permitting process.

We consider that the application will not affect any site of nature conservation, landscape and heritage, and/or protected species or habitats identified.

We have not consulted Natural England.

The decision was taken in accordance with our guidance.

Environmental risk

We have reviewed the operator's assessment of the environmental risk from the facility. The operator's risk assessment is satisfactory.

General operating techniques

We have reviewed the techniques used by the operator and compared these with the relevant guidance notes and we consider them to represent appropriate techniques for the facility.

The operating techniques that the applicant must use are specified in table S1.2 in the environmental permit.

Operating techniques for emissions that screen out as insignificant

Emissions to air of acetonitrile, acetic acid, methanol, 2-propanol, hydrochloric acid, tetrahydrofuran, chloroform, formic acid, ethanol, 1,1,1,3,3,3-hexafluoro-2-propanol, N,N-diisopropylethylamine, hydrogen peroxide, phenol and isoamyl alcohol, oxides of nitrogen and carbon monoxide have been screened out as insignificant, and so we agree that the applicant's proposed techniques are Best Available Techniques (BAT) for the installation.

Based on the operator's H1 assessment, emissions to sewer of dithiothreitol (DTT), 4-Azaocta-methylenediamine, tetrasodium EDTA and disodium EDTA. have been screened out as insignificant, and so we agree that the applicant's proposed techniques are Best Available Techniques (BAT) for the installation.

National Air Pollution Control Programme

We have considered the National Air Pollution Control Programme as required by the National Emissions Ceilings Regulations 2018. By setting emission limit values and/or conditions in the permit in line with technical guidance we are minimising emissions to air. This will aid the delivery of national air quality targets. We do not consider that we need to include any additional conditions in this permit.

Raw materials

We have specified limits and controls on the use of fuels. Table S2.1 of the permit limits the operator to the use of ultra-low sulphur gas oil only.

Improvement programme

Based on the information on the application, we consider that we need to include an improvement programme.

Improvement condition IC1 is included to require the operator to implement improvements to the backup generators to achieve BAT standards within the shortest practicable timescale, in accordance with our guidance: Emergency backup diesel engines on installations: best available techniques (BAT).

IC2 and IC3 have been included because the assessment submitted with the application was based on an assumed composition. IC2 requires the operator to sample and test a representative sample of the discharge to sewer to fully characterise the effluent composition once the plant is operational.

IC3 requires twelve monthly samples of the discharge to sewer during the first year of operation to validate the assumptions made in the application regarding the concentrations and associated impacts of DTT, 4-Azaoctamethylenediamine and the two EDTA salts.

If additional hazardous chemicals or elements are identified following the completion of IC2, the operator is required to also monitor and assess those parameters in accordance with the requirements of IC3.

See the key issues section above for further explanation.

Emission Limits

We have decided that emission limits are not required in the permit.

With regard to the backup generators we did not require emission limits in accordance with the Medium Combustion Plant Directive because the generators will be operated for less than 500 hours per year.

The operator's H1 assessment demonstrated that the impacts from all other emissions to air and sewer are insignificant.

Monitoring

We have decided that monitoring should be carried out for the parameters listed in the permit, using the methods detailed and to the frequencies specified. In particular:

We have specified monitoring of emissions of carbon monoxide from emission points A4 to A9 (new medium combustion plant), with a minimum frequency of once every 1500 hours of operation or every five years (whichever comes first). This monitoring has been included in the permit in order to comply with the requirements of Medium Combustion Plant Directive, which specifies the minimum requirements for monitoring of carbon monoxide emissions, regardless of the reduced operating hours of the plant.

We have also specified monitoring of emissions of nitrogen oxides from emission points A4 to A9 (new medium combustion plant), with the same frequency specified for the monitoring of carbon monoxide emissions. In setting out this requirement, we have applied our regulatory discretion, as we consider that this limited monitoring, to happen in concurrence with the carbon monoxide monitoring, is proportionate to the risk associated with the emissions of NO_x from the installation.

Taking into account the limited hours of operation of the engines operating at the installation, and the fact that we are not setting emission limits for NO_x and carbon monoxide, we consider this monitoring can be carried out in line with web guide 'Monitoring stack emissions: low risk MCPs and specified generators' Published 16 February 2021 (formerly known as TGN M5).

We have set a requirement for the first monitoring to happen within 4 months of the issue date of the permit or the date when each new medium combustion plant is first put into operation, whichever is later.

Reporting

We have specified reporting in the permit to reflect the monitoring requirements.

The operator is required to report data on emissions to air from the generators within four of the issue date of the permit, or the date when each engine is first put into operation (whichever is later), and every 1500 hours of operation or every five years (whichever comes first) thereafter.

Management System

We are not aware of any reason to consider that the operator will not have the management system to enable it to comply with the permit conditions.

The decision was taken in accordance with the guidance on operator competence and how to develop a management system for environmental permits.

Previous performance

We have assessed operator competence. There is no known reason to consider the applicant will not comply with the permit conditions.

We have checked our systems to ensure that all relevant convictions have been declared. No relevant convictions were found. The operator satisfies the criteria in our guidance on operator competence.

Financial competence

There is no known reason to consider that the operator will not be financially able to comply with the permit conditions.

Growth duty

We have considered our duty to have regard to the desirability of promoting economic growth set out in section 108(1) of the Deregulation Act 2015 and the guidance issued under section 110 of that Act in deciding whether to grant this permit.

Paragraph 1.3 of the guidance says:

“The primary role of regulators, in delivering regulation, is to achieve the regulatory outcomes for which they are responsible. For a number of regulators, these regulatory outcomes include an explicit reference to development or growth. The growth duty establishes economic growth as a factor that all specified regulators should have regard to, alongside the delivery of the protections set out in the relevant legislation.”

We have addressed the legislative requirements and environmental standards to be set for this operation in the body of the decision document above. The guidance is clear at paragraph 1.5 that the growth duty does not legitimise non-compliance and its purpose is not to achieve or pursue economic growth at the expense of necessary protections.

We consider the requirements and standards we have set in this permit are reasonable and necessary to avoid a risk of an unacceptable level of pollution. This also promotes growth amongst legitimate operators because the standards applied to the operator are consistent across businesses in this sector and have been set to achieve the required legislative standards.

Consultation Responses

The following summarises the responses to consultation with other organisations, our notice on GOV.UK for the public and the way in which we have considered these in the determination process.

Responses from organisations listed in the consultation section:

Response received from Vale of White Horse District Council Environmental Protection Team

Brief summary of issues raised: the consultee recommended that a condition be included in the permit to ensure that no testing of the emergency generators shall take place other than between the hours of 0800 and 1800. No testing shall take place on Saturdays, Sundays or public holidays.

Summary of actions taken: we do not specify operating hours within our permit conditions. However during permit determination the operator confirmed that the generators will not be tested outside of the hours stated above. This operating technique has been included in Table 1.2 of the permit.

Representations from individual members of the public

Brief summary of issues raised:

One response was received. The consultee's concern related to potential ground contamination at the site.

Summary of actions taken:

The operator provided a description of the condition of the site before operations begin, see section above 'Site condition report'.

We have also assessed the operator's proposed surfacing, drainage and containment arrangements and operating techniques. We consider they are appropriate to avoid a pollution risk resulting from the operation of the installation.

We are satisfied that we have sufficient information to enable us to make a comparison, at permit surrender, of the condition of the site when permitted activities cease. Therefore, if deemed necessary, we can require the operator to return the site to a satisfactory state, having regard to the state of the condition of the site before the facility was put into operation, in accordance with the surrender test detailed in our [Regulatory Guidance Note, RGN 9: Surrender](#).