

Compliance Assessment Report CAR_NRW0041942

Permit being assessed: SP3030LZ.

For: Wrexham Pharmaceutical Works, held by Ipsen Biopharm Ltd

At: Unit 9 Ash Road North , Wrexham Industrial Estate, Wrexham, WREXHAM, Clwyd, LL13 9UF.

Type of assessment carried out: Site Inspection, Reason: Routine.

On 08/06/2023 between 10:00 and 12:15.

Parts of permit assessed: SEE NOTES (Section 4)

NRW Lead Officer: Victoria Griffin.

Report sent to: Christine Dillon , Environmental Health & Safety Manager on 16/06/2023.

1. Summary of our findings (full details in section 4)

Part of permitted activity assessed (criteria)	Assessment result	Permit condition
A1 - Specified by permit	Assessed (A)	
C2 - General Management - Management system and operating procedures	Action only (X)	
C2 - General Management - Management system and operating procedures	Action only (X)	
C2 - General Management - Management system and operating procedures	Action only (X)	

Result types are explained in more detail in the 'Important Information' section below.

Total number of non-compliances recorded	Total non-compliance score
0	0

How we use the non-compliance score to calculate your annual fee is explained in the 'Important Information' section below.

2. What action is required?

Criteria	Action needed	Complete by
C2	Operator to provide the most recent site plan with updated building nomenclature	07/07/2023
C2	Operator to provide a summary table of all combustion plant (including generators) to NRW	07/07/2023
C2	Operator to provide a revised site plan, including updated drainage arrangements, which incorporates the recent and ongoing development /changes at the Installation	29/12/2023

Action criteria codes are listed in the 'Important information' section below.

3. What will happen next?

Any non-compliance we have identified and recorded on this form is an offence. It can result in criminal prosecution and/or suspension or revocation of your permit.

At this time, we do not intend to take any further action.

This statement does not stop us from taking additional enforcement action if further relevant information comes to light or offences continue.

4. Details of our assessment

This was a pre-arranged Installation visit by the Natural Resources Wales (NRW) regulating Officer which included a meeting and high-level tour of the Installation.

A meeting was held with Christine Dillion and Ana Szabo, the purpose of which was to provide an overview of the recent, ongoing and proposed changes to the Installation. The salient points of the meeting are summarised below:

- The construction and fitting of Building Five is almost complete, it is expected to be fully operational the end of 2023 /early 2024. Building Five includes a boiler room which comprises four gas powered domestic style boilers. The relevant infrastructure within Building Five is vented via stacks on the roof of the building. The drainage from Building Five has been connected to the existing drainage system and connects via Building Two.
- Building Four (DPL) has been repurposed. It now includes a fume hood and safety cabinet, which generate minor emissions to air.
- The boilers in Building Three were replaced with newer lower energy boilers as part of the energy reduction programme at the Installation.
- Combustion plant at the Installation was discussed and there was uncertainty regarding the applicability of the Medium Combustion Plant (MCP) Regulations and or the Specified Generator Regulations. NRW to review combustion plant information when provided (see actions below) and discuss with Operator to determine the need for a permit variation and expected timescales.
- The extension to Building Ten is being progressed and is expected to be complete and operational by 2025. The existing section of Building Ten will be progressively decommissioned and the use of formaldehyde phased out and replaced with hydrogen peroxide as the equipment is replaced /modernised.
- NRW requested that the Operator provided documentation clarifying the recent changes at the installation, in particular with regard to installation layout, combustion plant, and drainage arrangements.
- The last external environmental and health and safety audit (ISO14001 & 45001) was undertaken in October 2022. The Operator advised that no non-conformances or issues were raised during the audit.

- The pond and surface water discharge point were observed. The Operator stated the pond had recently been assessed by North Wales Wildlife Trust, who reported it to be in a good ecological state.

The meeting was followed by a high-level tour of the Installation led by Tony Philips (Health and Safety Contractor) and Ben Grey (Project Manager). The focus of the tour was on Building Five (excluding the "clean" process level), the external area of Building Two and the Pond area.

At the time of the tour a significant amount of maintenance and improvement was being undertaken. Nevertheless, whilst a detailed inspection was not undertaken, the Installation was clean and tidy and high-level observations did not identify any apparent permit breaches.

ACTIONS AND RECOMMENDATIONS

ACTION Operator to provide the most recent site plan with updated building nomenclature by **7 July 2023**.

ACTION Operator to provide a summary table of all combustion plant (including generators) to NRW by **7 July 2023**. Information to be included as follows:

Item Ref	Type	Fuel	Rated Thermal Input (MWth)	Date Commissioned	Purpose	Location
example	generator	gas	1.5MW	April 2018	standby generator	outside Building 2

ACTION Operator to provide a revised site plan, including updated drainage arrangements, which incorporates the recent and ongoing development /changes at the Installation by **29 December 2023**.

It is recommended that the Operator reviews the online guidance with respect to MCP. Links are provided below.

<https://www.gov.uk/government/collections/medium-combustion-plant-and-specified-generator-regulations>

If you have any queries about this report, or to discuss completion of any actions, please contact the NRW Officer named above.

Important information

Legal status of this report

Your permit is issued to you under the Environmental Permitting Regulations. You have a responsibility to comply with the conditions of your permit and prevent pollution/harm of the environment. You must also ensure that you comply with any other relevant legislation that may apply to your site's operations.

This report explains the findings of our assessment and any action you are required to take. We categorise non-compliance using our guidance for assessing non-compliance at regulated sites.

When we find potential non-compliance/s we will normally give you advice on how to maintain compliance.

To correct non-compliance, we may:

- require you to take specific actions
- issue a notice
- review the conditions of your permit.

Any advice and guidance we give will be without prejudice to any other enforcement response that we consider may be required.

Assessment results and non-compliance categories (used in section 1):

Assessment result	Description
Assessed (A)	Assessed or assessed in part, no evidence of non-compliance found
Action only (X)	Action only relating to the activity assessment
Ongoing (O)	Ongoing non-compliance, not scored

Non-compliance category	Description	Score
C1 Major	Potential to have a major, serious, persistent and/or extensive impact or effect on the environment, people and/or property	60
C2 Significant	Potential to have a significant impact or effect on the environment, people and/or property	31
C3 Minor	Potential to have a minor or minimal impact or effect on the environment, people and/or property	4
C4 No environmental impact	Non-compliance at a regulated site that cannot foreseeably have any impact on the environment, people and/or property	0.1

How we use assessment scores

The number and severity of non-compliances recorded in a year will affect your annual subsistence fee the following year. A non-compliance factor is added to your site's Operator

Performance Risk Appraisal (OPRA) score when we calculate your fee to reflect the additional resource we use to assess permit compliance.

What are suspended scores?

In line with our guidance, we may suspend scores for up to six months to allow time for remedial action to be taken. Suspended scores will be re-instated if the action is not completed.

Full list of Industry and Waste action criteria (used in section 1 and 2):

A: Permitted activities

- A1 Specified by permit

B: Infrastructure

- B1 Infrastructure – Engineering for prevention and control of emissions
- B2 Infrastructure – Closure and decommissioning
- B3 Infrastructure – Site drainage engineering (clean and foul)
- B4 Infrastructure – Containment of stored materials
- B5 Infrastructure – Plant and equipment

C: General management

- C1 General management – Staff competency/training
- C2 General management – Management system and operating procedures
- C3 General management – Materials acceptance
- C4 General management – Storage, handling, labelling and segregation

D: Incident management

- D1 Incident management – Site security
- D2 Incident management – Accidents, emergency and incident planning

E: Emissions

- E1 Emissions – Air
- E2 Emissions – Land and groundwater
- E3 Emissions – Surface water
- E4 Emissions – Sewer
- E5 Emissions – Waste

F: Amenity

- F1 Amenity – Odour
- F2 Amenity – Noise
- F3 Amenity – Dust/fibres/particulates and litter
- F4 Amenity – Pests/birds and scavengers
- F5 Amenity – Deposits on road

G: Monitoring and records, maintenance and reporting

- G1 Monitoring and records, maintenance and reporting – Monitoring of emissions and environment
- G2 Monitoring and records, maintenance and reporting – Records of activity, site diary/journal/events
- G3 Monitoring and records, maintenance and reporting – Maintenance records
- G4 Monitoring and records, maintenance and reporting – Reporting and notification to Natural Resources Wales

H: Resources efficiency

- H1 Resource efficiency – Efficient use of raw materials
- H2 Resource efficiency – Energy efficiency

Enforcement response

Any permit condition non-compliance is an offence and we may take legal action against you. Action we take can include prosecution, serving a notice on you and/or suspension or revocation of your permit. See our Enforcement and Sanctions Guidance for further information.

Data protection notice

You should make sure that anyone named in this report knows that the information it contains will be processed by Natural Resources Wales to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s).

We may also use and/or disclose the report in connection with:

- offering or providing you with our literature or services relating to environmental matters
- consulting with the public, public bodies and other organisations (e.g. Health and Safety Executive, local authorities) on environmental issues
- carrying out statistical analysis, research and development on environmental issues
- providing public register information to enquirers
- investigating possible breaches of environmental law
- assessing customer service satisfaction and improving our service
- Freedom of Information Act or Environmental Information Regulations requests.

We may also pass it on to our agents or representatives to do these things on our behalf.

Disclosure of information – this report will be available to view on-line

If you think this report contains commercially confidential information that should not be placed on our public register, you must contact your local Natural Resources Wales office within **fifteen working days** of receiving this report, using the contact details in the accompanying email or letter. You must give a full explanation of why it should not be added to our public register, including specifying which information is commercially confidential. We will assess your request and respond to you within 20 working days to let you know if we agree to your request.

What do I do if I disagree with the report or have a complaint?

If you disagree with this compliance assessment report, you should contact the lead officer without delay to discuss your concerns.

If you are unable to resolve the issue with the lead officer or their line manager you should contact our Customer Contact team on 0300 065 3000 (Monday to Friday 08:00 – 18:00), or email enquiries@naturalresourceswales.gov.uk for details of how to raise your dispute further through our Complaints and Commendations procedure.

If you are dissatisfied with our response, you can contact the Public Services Ombudsman for Wales by phone on 0300 7900203 or by email at ask@ombudsman.wales

Welsh Language Standards

We are committed to establishing Natural Resources Wales as a naturally bilingual organisation. We will provide compliance reports in your preferred language.