

Surrender notice with introductory note

The Environmental Permitting (England & Wales) Regulations 2010

Novartis Vaccines and Diagnostics Limited

Gaskill Road, Speke Vaccines
Gaskill Road
Speke
Liverpool
L24 9GR

Surrender application number
EPR/BS5401IK/S007

Permit number
EPR/BS5401IK

Gaskill Road, Speke Vaccines

Permit number EPR/BS5401IK

Introductory note

This introductory note does not form a part of the notice

The following notice gives notice of the surrender in part and variation of an environmental permit.

The Operator manufactures vaccines and this represents the principal listed activity falling under Section 4.5 A (1) (a) of the EPR regulations.

This is part surrender for the installation. The remaining activities consist of site 4 plus limited site 3 facilities including materials warehouse, banded drum storage area and warehouse area heating facilities plus diesel fuelled standby electrical generator; sites 1 and 2 having already been surrendered under permit EPR/BS5401IK/S005.

There is no change to the installation boundary and there are no other changes beyond the part surrender to the remaining installation facilities.

The permit includes modern conditions to ensure compliance with latest legislation.

Any changes made as a result of the part surrender are set out in the schedules.

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

| Status Log of the permit | | |
|---|-----------------------|----------------------|
| Detail | Date | Response Date |
| Application BS5401IK (EPR/BS5401IK/A001) | Duly made 29/03/06 | |
| Response to request for further information | 16/11/06 | 11/12/06 |
| Permit determined BS5401IK (EPR/BS5401IK/A001) | 21/12/06 | |
| Application for Variation YP3531UV (EPR/BS5401IK/V002) | Duly Made 28/09/07 | |
| Variation YP3531UV determined (EPR/BS5401IK/V002) | 20/12/07 | |
| Application for Variation EPR/BS5401IK/V003 | Duly Made 31/12/09 | |
| Additional Information e-mail on minor operational changes | 20/01/10 | |
| Odour Management Plan (OMP) | 28/02/10 | |
| Initial OMP amendment | | 03/03/10 |
| Oxides of nitrogen A38 emission monitoring data | | 05/03/10 |
| Final OMP amendment | | 12/03/10 |
| A38 oxides of nitrogen monitoring plan | | 15/03/10 |
| Variation Notice EPR/BS5401IK/V003 determined | 09/04/10 | |
| Application for Variation EPR/BS5401IK/V004 | Duly made 13/09/10 | |
| Application for Partial Surrender EPR/BS5401IK/S005 | Duly Made 03/02/11 | |
| Revision of site plan | | 15/03/11 |
| Confirmation of cessation of site 2 development work and drainage flushed – site returned to satisfactory state | | 05/05/11 |
| Partial Surrender Notice EPR/BS5401IK/S005 determined | 05/05/11 | |
| Application for Variation EPR/BS5401IK/V006 | Duly made 15/08/11 | |
| Schedule 5 dated 23/08/11 | | 01/09/11 |
| Formaldehyde monitoring technique information | | 02/09/11 |
| Draft consent to discharge | | 21/10/11 |
| Variation EPR/BS5401IK/V006 determined | 21/10/11 | |
| Application for Part Surrender EPR/BS5401IK/S007 | Duly made 22/01/14 | |
| Part Surrender determination EPR/BS5401IK/S007 | 10/02/14 | |

End of Introductory note

Notice of surrender

The Environmental Permitting (England and Wales) Regulations 2010

The Environment Agency in exercise of its powers under regulation 20 and 25 of the Environmental Permitting (England and Wales) Regulations 2010 accepts the surrender in part and varies

Permit number
EPR/BS5401IK

issued to

Novartis Vaccines and Diagnostics Limited ("the operator")

whose registered office is

Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR

company registration number **3970089**

to operate a regulated facility at

Gaskill Road
Speke
Liverpool
L24 9GR

to the extent set out in the schedules.

The notice shall take effect from 10/02/14

| Name | Date |
|-------------------------|-------------------|
| Anne Nightingale | 10/02/2014 |

Authorised on behalf of the Environment Agency

Schedule 1 – changes to the permit

Note: The conditions numbers used in this schedule refer to those in the consolidated permit.

All conditions have been varied by the consolidated permit as a result of the application made by the operator.

Schedule 2 – consolidated permit

Consolidated permit issued as a separate document.

Permit

The Environmental Permitting (England and Wales) Regulations 2010

Permit number

EPR/BS540IK

This is the consolidated permit referred to in the surrender notice for application EPR/BS5401IK/S007 authorising

Novartis Vaccines and Diagnostics Limited (“the operator”),

whose registered office is

Frimley Business Park

Frimley

Camberley

Surrey

GU16 7SR

company registration number **3970089**

to operate an installation at

Gaskill Road

Speke

Liverpool

L24 9GR

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

| Name | Date |
|-------------------------|-------------------|
| Anne Nightingale | 10/02/2014 |

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General Management

1.1.1 The operator shall manage and operate the activities:

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

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3

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

1.2 Energy efficiency

1.2.1 The operator shall:

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

1.3 Efficient use of raw materials

1.3.1 The operator shall:

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

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

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.4.2 Review and record at least every four years whether changes to those measures should be made; and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

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

2.2 The site

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

2.3 Operating techniques

- 2.3.1 (a) The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.
- (b) If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation (“plan”) specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 2.3.2 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.3 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and
 - (e) the waste code of the waste.
- 2.3.4 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

3 Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 Periodic monitoring shall be carried out at least every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

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

3.3 Odour

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

3.4 Noise and vibration

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

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

3.5 Monitoring

- 3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:
- (a) point source emissions specified in tables S3.1 and S3.2;
- 3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.
- 3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.3.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.
- 3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1 and S3.3 unless otherwise agreed in writing by the Environment Agency.

4 Information

4.1 Records

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

4.2 Reporting

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

- 4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment Agency) each year. The report(s) shall include as a minimum:
- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;
 - (b) the performance parameters set out in schedule 4 table S4.2 using the forms specified in table S4.3 of that schedule.
- 4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:
- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
 - (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.3; and
 - (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.3 Notifications

- 4.3.1 (a) In the event that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
- (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
- (b) in the event of a breach of any permit condition the operator must immediately—
- (i) inform the Environment Agency, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
- (c) in the event of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.
- 4.3.2 Any information provided under condition 4.3.1 (a)(i), or 4.3.1 (b)(i) where the information relates to the breach of a limit specified in the permit, shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.

- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:

Where the operator is a registered company:

- (a) any change in the operator's trading name, registered name or registered office address; and
- (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

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

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

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

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

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

- 4.3.7 Where the operator has entered into a climate change agreement with the Government, the Environment Agency shall be notified within one month of:

- (a) a decision by the Secretary of State not to re-certify the agreement;
- (b) a decision by either the operator or the Secretary of State to terminate the agreement; and
- (c) any subsequent decision by the Secretary of State to re-certify such an agreement.

4.4 Interpretation

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

- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made "without delay", in which case it may be provided by telephone.

Schedule 1 – Operations

| Activity listed in Schedule 1 of the EPR Regulations / Associated Activity | Description of specified activity | Limits of specified activity |
|--|--|---|
| Section 4.5 A (1) (a) Pharmaceutical production. | The manufacture of seasonal/pandemic influenza vaccine. | From the receipt of raw materials to the manufacture, storage and despatch of finished bulk product (including the cleaning and fumigation of process plant and storage and handling of waste/waste water arising from the process). This includes mercury laden aqueous waste segregation, collection and off site transfer. |
| Section 5.4A (1) (a) (ii) Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day. | Treatment of process effluent from Site 4. | Physical treatment (pH and temperature control) prior to discharge into the public sewer. |
| Section 6.8A (1)(c) –disposing of or recycling animal carcasses or animal waste, other than by rendering, at a plant with a treatment capacity exceeding 10 tonnes per day of animal carcasses or animal waste or, in aggregate of both. | Treatment of egg waste from site 4. | Collection of egg waste through to filtration, drying and collection prior to off-site disposal. |
| Directly Associated activities | | |
| Steam Supply | Operation of the following combustion plant for process heating and sanitisation purposes: Site 4 – two gas fired thermal input 5.4 MW boilers and one gas boiler with thermal input of 4.4 MW. | From receipt, handling and combustion of fuel to steam generation. |
| Heating Ventilation & Cooling | Maintenance of workplace environment and air on sites 3 and 4. | Operation of Heating Ventilation and Cooling (HVAC) systems. |
| Refrigeration | Operation of Blast Chillers. | The cooling of eggs following incubation. |
| Odour Abatement System | Site 4 Effluent Treatment Area. | Odour abatement via a combination of acid scrubbing, carbon adsorption and caustic (sodium hydroxide) scrubbing. |
| Water Purification | The production of Purified Water and Water for Injection. | Water purification using softeners, reverse osmosis, electro-deionisation and distillation techniques. |

| Table S1.2 Operating techniques | | |
|---|--|-----------------------|
| Description | Parts | Date Received |
| Application BS5401IK (EPR/BS5401IK/A001) | The response to section 2.1 and 2.2 in the application plus air emissions stack locations plan. | 29/03/06 |
| Response to request for additional information | <ul style="list-style-type: none"> a) Revised drainage plan (Figure 6) and effluent discharge locations (Table 1) b) Details of boiler specification and operation (Table 3) c) Revised installation layout plan (Figure 3) d) Revised H1 assessment | 11/12/06 |
| Application for variation YP3531UV (EPR/BS5401IK/V002) | The response to section 2 in the Application for the variation | 28/09/07 |
| Additional information | Two letters clarifying aspects of the variation | 15/10/07 12 /12/07 |
| Application for variation EPR/BS5401IK/V003 | <p>Response to questions 2a and 2b of the Part C application form. Supporting Application Document 11.12.09:</p> <ul style="list-style-type: none"> • Section 1 Solid Waste Dewatering Plant Effluent Treatment Area Site 4 Optimisation. • Section 2 Nano-filtration Equipment Site 4 Effluent Treatment Area: Operational Information. • Section 3 Odour Abatement Optimisation for Effluent Treatment Area Site 4. • Additional Boiler for Site 4 Effluent Treatment Area operation details under Document 11.12.09 point (1) • Various minor operational changes listed in Supporting Application Document 11.12.09 under points (5), (7) (8), (10), (11) plus (13) and (14). | Duly made 31/12/09 |
| Additional information | Additional Information Email clarification additional information on minor operational changes points (7) and (14) | 20/01/10 |
| Initial Odour Management Plan (OMP) | All | 28/02/10 |
| OMP additional information Part 1 | All | 05/03/10 |
| OMP additional information Part 2 including acid scrubber process flow | All | 23/03/10 |
| Oxides of Nitrogen Monitoring actions (A38) | All | 23/03/10 |
| OMP additional information Part 3 | All | 29/03/10 |
| Variation application EPR/BS540IK/V004 | Application form C3 response to question 3 titled Operating techniques and associated supplementary information reference MT082010 sections 3, 4, 5, 6, 7, 8 and 9. Plus duly making responses on raw material usage. | Duly made 13/09/10 |
| Additional information on operating procedure summary, spill containment and spill receiving sump volumes | Responses 2, 3, 4 and 5 | 24/09/10 |
| Partial surrender EPR/BS5401IK/S005 Report 49308339/MARP0003 Detailing Operating Techniques, Monitoring and Resource efficiency changes | All | Duly made 03/02/11 |
| Variation EPR/BS5401IK/V006 Report AG060211 Detailing Operating Techniques in Section 1 for the new products process and Section 2 for the new waste storage facilities | All | Duly made 15/08/11 |
| Schedule 5 dated 23/08/11 | All | 01/09/11 |
| Formaldehyde monitoring technique information | All | 02/09/11 |

Table S1.2 Operating techniques

| Description | Parts | Date Received |
|---|---|-----------------------|
| Draft Consent to discharge related to formaldehyde for effluent discharge | All | 21/10/11 |
| Variation EPR/BS54011K/S007 | Application supplementary information report and duly making responses (clarifying remaining atmospheric emissions and surface water discharges). | Duly made 22/01/14 |

Schedule 2 - Waste types, raw materials and fuels

Table S2.1 Raw materials

| Raw materials and fuel description | Specification |
|------------------------------------|-----------------------------|
| Heavy Fuel Oil | Less than 1 % Sulphur (w/w) |

Schedule 3 – Emissions and monitoring

| Table S3.1 Point source emissions to air – emission limits | | | | | | |
|--|---|--|-----------------------|------------------|--|-------------------------------|
| Emission point ref. & location | Parameter | Source | Limit (incl. unit) | Reference period | Monitoring frequency | Monitoring standard or method |
| A11 (A11 on Figure 5 in EPR/BS5401IK/A001 application). | No parameters set | Site 3 warehouse space heating boilers (5 off with total thermal input capacity 0.675 MW). | No limit | - | - | - |
| A19 (A1 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Zone 1 (including vacuum system exhaust) | No limit | - | - | - |
| A20 (A2 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | β-propiolactone /Formaldehyde Fume cabinet: Zone 1 | No limit | - | - | - |
| A21 (A3 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Brine tank | No limit | - | - | - |
| A22 (A4 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Hot well stack | No limit | - | - | - |
| A23 (A5 on Figure 3 in EPR/BS5401IK/A001 application). Note 1. | Oxides of Nitrogen (expressed as NO ₂) | Boilers 1 and 2 | 150 mg/m ³ | Hourly average | As requested by the Environment Agency | BS EN 14792 |
| A24, A25 (Points A6 and A7 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Bulk waste tanks (TK417004 and TK417005) | No limit | - | - | - |
| A27 (A9 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Egg waste tank | No limit | - | - | - |
| A28 (A10 on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Zone 2 (including vacuum system exhaust) | No limit | - | - | - |
| A29, A31, A32, A34, A35 (Points A11, A13, A14, A15 & A16 respectively on Figure 3 in EPR/BS5401IK/A001 application). | No parameters set | Zone 1,3,4,5,6 Heating Ventilation and Cooling (HVAC) systems | No limit | - | - | - |
| A37 (A37 on Fig 3-1-2007 as received 10/09/07) | Odour unit per cubic metre (ou _e /m ³) | Odour scrubber (Effluent Treatment Area) | Note 2 | Note 3 | Annual | BS EN 13725 |
| A38 (Original point A36 on Fig 3-1-2007 as received 10/09/07). Note 1 | Oxides of Nitrogen (expressed as NO ₂) | Boiler 3 | 150 mg/m ³ | Hourly average | As requested by the Environment Agency | BS EN 14792 |

Note 1: Permanent sampling access not required.

Note 2: Limit as stated in approved Odour Management Plan.

Note 3: Sampling reference period as stated in approved Odour Management Plan.

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

| Emission point ref. & location | Parameter | Source | Limit (incl. unit) | Reference Period | Monitoring frequency | Monitoring standard or method |
|--------------------------------|-----------|--------|--------------------|------------------|----------------------|-------------------------------|
| - | - | - | - | - | - | - |

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

| Emission point ref. & location | Parameter | Source | Limit (incl. Unit) | Reference period | Monitoring frequency | Monitoring standard or method |
|--|------------------------|---|--------------------|--|----------------------|---|
| S5 (Point W9 on Figure 6 received 11/12/06) to Speke Boulevard sewer | No parameters set | Surface water from site 3 remaining installation facilities; final discharge to sewer | No limit set | - | - | - |
| S6 (Point S1 on Figure 4, received 03/11/05) to Shaw Road sewer | No parameters set | Process Effluent ¹ from S7 & Surface Water run-off ² . | No limit set | - | - | - |
| S7 (Point S2 on Figure 4, received 03/11/05) | Formaldehyde | The discharge of process effluent ¹ from sump 2. | No limit | Weekly flow proportional composite sample. | (3) | Spectrophotometric method. UKAS accredited Sample measured at 412 nm on a spectrophotometer. |
| S7 (Point S2 on Figure 4, received 03/11/05) | Total Mercury | The discharge of process effluent ¹ from sump 2. | 10 µg/l | Weekly flow proportional composite sample. | Weekly (4) | Cold vapour atomic absorption technique. |
| S7 (Point S2 on Figure 4, received 03/11/05) | Total Mercury | The discharge of process effluent ¹ from sump 2. | No limit set | | Monthly (4) | UKAS accredited |
| S7 (Point S2 on Figure 4, received 03/11/05) | Nonylphenol ethoxylate | The discharge of process effluent ¹ from sump 2. | No limit set | Weekly flow proportional composite sample. | Monthly (4) | UKAS accredited |

Note 1: Excluding segregated sources of effluent potentially contaminated with mercury and nonylphenol ethoxylate and process effluent from zones 4 & 5.

Note 2: Discharge via on oil interceptor.

Note 3: Monitoring frequency weekly solely during specific product operation with formaldehyde usage once. After final review of IC13 operator submission Environment Agency to confirm in writing any changes to monitoring frequency.

Note 4: Monitoring frequency applies only when process utilising mercury and nonylphenol ethoxylate in operation.

Schedule 4 Reporting

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

Table S4.1 Reporting of monitoring data

| Parameter | Emission or monitoring point/reference | Reporting period | Period begins |
|--------------------|--|------------------|---------------|
| Emissions to air | A23, A37 and A38 | Every 12 months | Xx/02/14 |
| Emissions to sewer | S7 | Monthly | Xx/02/14 |

Table S4.2 Performance parameters

| Parameter | Frequency of assessment | Units |
|---|-------------------------|-------|
| Nonylphenol ethoxylate content of sewer discharge | Annual | Kg |
| Mercury content of contaminated liquid waste (excluding discharge to sewer) | Annual | Kg |
| Mercury content of the discharge to sewer | Annual | g |

Table S4.3 Reporting forms

| Media/parameter | Reporting format | Date of form |
|------------------------|-------------------|--------------|
| Air | Form Air1 | 12/02/14 |
| Water | Form Sewer1 | 12/02/14 |
| Performance Indicators | Form Performance1 | 12/02/14 |

Schedule 5 - Notification

These pages outline the information that the operator must provide.

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

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

Part A

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

| | |
|--|--|
| (a) Notification requirements for any activity that gives rise to an incident or accident which significantly affects or may significantly affect the environment | |
| To be notified Immediately | |
| Date and time of the event | |
| Reference or description of the location of the event | |
| Description of where any release into the environment took place | |
| Substances(s) potentially released | |
| Best estimate of the quantity or rate of release of substances | |
| Measures taken, or intended to be taken, to stop any emission | |
| Description of the failure or accident. | |

| | |
|---|--|
| (b) Notification requirements for the breach of a permit condition | |
| To be notified immediately | |
| Emission point reference/ source | |
| Parameter(s) | |
| Limit | |
| Measured value and uncertainty | |
| Date and time of monitoring | |
| Measures taken, or intended to be taken, to stop the emission | |

| Time periods for notification following detection of a breach of a limit | |
|---|---------------------|
| Parameter | Notification period |
| | |
| | |
| In the event of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment: | |
| Description of where the effect on the environment was detected | |
| Substances(s) detected | |
| Concentrations of substances detected | |
| Date of monitoring/sampling | |

Part B - to be submitted as soon as practicable

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

| | |
|------------------|--|
| Name* | |
| Post | |
| Signature | |
| Date | |

* authorised to sign on behalf of the operator.

Schedule 6 - Interpretation

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

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

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

“emissions to land” includes emissions to groundwater.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2010 No. 675 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

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

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

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

“quarter” means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

“recovery” means any of the operations provided for in Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste.

“Waste code” means the six digit code referable to a type of waste in accordance with the List of Wastes (England) Regulations 2005, or List of Wastes (Wales) Regulations 2005, as appropriate, and in relation to hazardous waste, includes the asterisk.

“Waste Framework Directive” or *“WFD”* means Waste Framework Directive 2008/98/EC of the European Parliament and of the Council on waste.

“year” means calendar year ending 31 December.

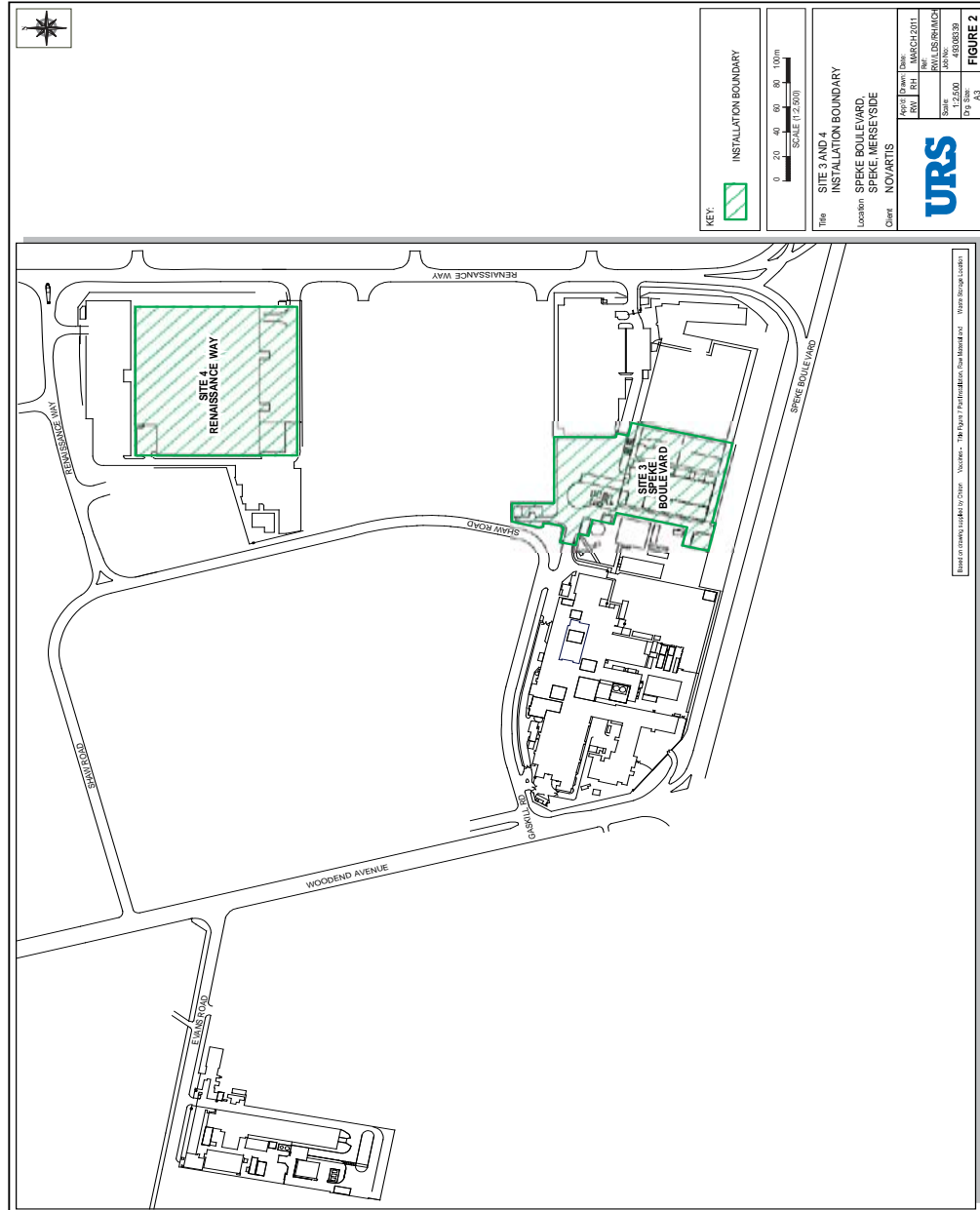
Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or

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

Schedule 7 Site Plan

The installation site plan is as below:



END OF NOTICE

Permit Number: EPR/BS5401IK Operator: Novartis Vaccines and Diagnostics Limited

Facility: Gaskill Road, Speke Vaccines Form Number: Air1

Reporting of emissions to air for the period from

| Emission Point | Substance / Parameter | Emission Limit value (mg/m ³) | Reference Period | Result ^[1] | Test Method ^[2] | Sample Date and Times ^[3] |
|----------------|--|---|------------------|-----------------------|----------------------------|--------------------------------------|
| A23 | Oxides of Nitrogen (as NO ₂) | 150 | Hourly Average | | BS EN 14792 | |
| A37 | Odour units (oue/m ³) | (5) | (6) | | BS EN 13725 | |
| A38 | Oxides of Nitrogen (as NO ₂) | 150 | Hourly Average | | BS EN 14792 | |

Notes

(1)The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value.

(2)Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values. Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Environment Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, for example gas chromatography.

(3)For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.

(4)The uncertainty associated with the quoted result at the 95% confidence interval, unless otherwise stated.

(5) Limit as stated in approved Odour Management Plan.

(6) Sampling reference period as stated in approved Odour Management Plan.

Signed

Date.....

(Authorised to sign as representative of Operator)

Permit Number: EPR/BS5401IK

Operator: Novartis Vaccines and Diagnostics Limited

Facility: Gaskill Road, Speke Vaccines

Form Number: Sewer 1

Reporting of emissions to water for the quarterly period

| Emission Point | Substance / Parameter | Emission | | Reference Period | Result ^[2] | | Test Method ^[3] | Sample Date and Times ^[4] | Uncertainty ^[5] |
|----------------|------------------------|-------------|--------------------------------------|--|-----------------------|------------------------|---|--------------------------------------|----------------------------|
| | | Limit Value | | | | | | | |
| S7 | Formaldehyde | No limit | | Weekly flow proportional composite sample. | | | Spectrophotometric method. UKAS accredited. Sample measured at 412 nm on a spectrophotometer. | | |
| S7 | Nonylphenol ethoxylate | No limit | | Weekly proportional composite sample | | | UKAS accredited method | | |
| S7 | Mercury | No limit | | Spot sample | | | UKAS accredited method | | |
| S7 | Mercury | 10 µg/l | Weekly proportional composite sample | Maximum weekly result | | Cold vapour absorption | | | |
| | | | | Average of weekly results | | | | | |

Notes

- (1) Maximum values to be no greater than double 95 % percentile limit for these parameters.
- (2) The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value. Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values.
- (3) Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Environment Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, for example gas chromatography.
- (4) For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.
- (5) The uncertainty associated with the quoted result at the 95% confidence

Signed

Date.....

(Authorised to sign as representative of Operator)

Permit Number: EPR/BS5401IK

Operator: Novartis Vaccines and Diagnostics Limited

Facility: Gaskill Road, Speke Vaccines

Form Number: P1

| Parameter | Units | Results |
|---|-------|---------|
| Nonylphenol ethoxylate content of sewer discharge | Kg | |
| Mercury content of contaminated liquid waste (excluding discharge to sewer) | Kg | |
| Mercury content of the discharge to sewer | g | |

Signed

Date.....

(Authorised to sign as representative of Operator)