Variation notice with introductory note

Environmental Permitting (England & Wales) Regulations 2010

Gaskill Road, Speke Vaccines

Novartis Vaccines and Diagnostics Limited
Gaskill Road
Speke Liverpool
L24 9GR

Variation notice number
EPR/BS5401IK/V003

Permit number

EPR/BS5401IK

Gaskill Road, Speke Vaccines
Permit number EPR/BS5401IK

Introductory note

This introductory note does not form a part of the permit

The following notice, which is issued pursuant to regulation 20 and Part 1 of Schedule 5 of the Environmental Permitting (England and Wales) Regulations 2010 S.I.2010 No. 675 (the Regulations), gives notice of the variation of an environmental permit to operate a regulated facility

A non-technical description of the Variation is given in the Application but the main features of the Variation include the following:

- Adding and removing Emission points to Atmosphere;
- Amendment of Activities to allow update of Directly associated activities;
- Amendment to Operating Procedures for the Installation with particular emphasis of Environmental improvements to Odour abatement for emission point A37.

Schedule 1 of this notice lists any deleted conditions, Schedule 2 lists any amended conditions, Schedule 3 lists any conditions that have been added and Schedule 4 shows any changes to the plan.

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 Addendum 1		05/03/10
Oxides of nitrogen A38 emission monitoring data		05/03/10
OMP addendum II Parts 1,2 and 3		23/03/10
Interim acid scrubber process flow		23/03/10
A38 oxides of nitrogen monitoring plan		23/03/10
OMP addendum III		29/03/10
Variation Notice EPR/BS5401IK/V003 determined		09/04/10

End of Introductory Note.

Notice of variation

Environmental Permitting
(England and Wales) Regulations 2010

Permit number

EPR/BS5401IK

The Environment Agency in exercise of its powers under Regulation 20 of the Environmental Permitting (England and Wales) Regulations 2010 (SI 2010 No 675) varies the permit as set out below.

Novartis Vaccines and Diagnostics Limited ("the operator"),

whose registered office/or principal office is

Frimley Business Park

Frimley

Camberley

Surrey

GU16 7SR.

Company registration number **3970089**

holds a permit to operate a regulated facility at

Gaskill Road

Speke

Liverpool L24 9GR.

and that permit is varied to the extent set out in Schedules 1 to 4 of this notice.

The notice shall take effect from 09/04/2010

Name	Date
	09/04/2010

Mark Taylor

Authorised on behalf of the Environment Agency.

Schedule 1 – conditions to be deleted

None.

Schedule 2 – conditions to be amended

The following conditions are amended as follows:

Table S1.1 as referenced in condition 2.1.1 is amended to update the directly associated activities as follows:

Table S1.1 activities		
Activity listed in Schedule 1 of the PPC Regulations	**Description of specified activity**	**Limits of specified activity**
Section 4.5 Part A (1) (a) – Producing pharmaceutical products using a chemical or biological process.	The manufacture of seasonal/pandemic influenza.	From the receipt of raw materials to the manufacture, storage and despatch of finished product (including the cleaning and fumigation of process plant, and storage and handling of waste/wastewater arising from the process).
Section 5.3 Part A (1) (c) (ii) – Disposal of non-hazardous waste in a facility with a capacity of more than 50 tonnes per day by physico-chemical treatment, not being treatment specified in any paragraph other than paragraph D9 in Annex IIA to Council Directive 75/442/EEC, which results in final compounds or mixtures which are discarded by means of any of operations numbered D1 to D12 in that Annex.	Treatment of process effluent from Site 4.	Physical treatment (pH and temperature control) prior to discharge into the public sewer.
Section 6.8 Part A(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 though to filtration, drying and collection prior to off site disposal.
Directly Associated Activity		
Steam Supply	Operation of the following combustion plant for heating, sanitisation and sterilisation purposes: • Site 1 - 1.4MW & 2.1MW gas-fired boilers; • Site 2 - two 5.0 MW fuel oil-fired boilers; • Site 3 – 1.4MW gas-fired boiler; and • Site 4 - two 5.4MW gas-fired boilers and one 4.4 MW gas fired boiler.	From the receipt, handling and combustion of fuel to steam generation (including the storage of heavy fuel oil).
Heating Ventilation & Cooling	Maintenance of workplace environment and air quality.	Operation of Heating Ventilation & Cooling (HVAC) systems.
Refrigeration	The operation of Blast Chillers.	The cooling of eggs following incubation.
Odour Abatement System	Site 4 Effluent Treatment Area (A37).	Odour abatement via combination of acid scrubbing, carbon adsorption and caustic bleach scrubbing.
Water Purification.	The production of Purified Water (PW) and Water for Injection (WFI).	Water purification using softeners, reverse osmosis, electro-deionisation and distillation techniques.

Table S1.2 as referenced in condition 2.3.1 is amended to add the following rows:

Table S1.2 Operating techniques		
Description	**Parts**	**Date Received**
Variation application	Response to questions 2a and 2b of the Part C application form. Supporting Application Document11.12.09: • 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), (13) and (14)	22/12/2009
Additional Information	Email clarification additional information on minor operational changes points (7) and (14)	20/01/10
Odour Management Plan	All	28/02/10
Initial Odour Management Plan additional information	All	05/03/10
OMP addendum II Parts 1,2 and 3		23/03/10
Interim acid scrubber process flow		23/03/10
Oxides of Nitrogen Monitoring actions (A38)	All	23/03/10
OMP addendum III		29/03/10

Table S4.1 a) Point source emissions to air as referenced in condition 3.6.1 is amended as follows:

Table S4.1a (Site 1) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A1, A12, A13	No parameters set	Inoculation, Incubation & Harvest suites	No limit set	-	-	-
A2	No parameters set	Intermediate Bulk Fluid following inactivation with β-propiolactone.	No limit set	-	-	-
A3, A4	Oxides of Nitrogen (expressed as NO_2) (mg/m^3)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	BS EN 14792

Note 1: Permanent sampling access not required.

Table S4.1b) Point source emissions to air as referenced in condition 3.6.1 is amended as follows:

Table S4.1b (Site 2) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A5, A14, A15, A16, A17, A18	No parameters set	Centrifugation suite, Formulation suite, Media suite, Technical Development Lab & Centrifugation suite.	No limit set	-	-	-
A6	No parameters set	Centrifugation suite zone YB	No limit set	-	-	-
A7, A8	Oxides of Nitrogen (expressed as NO_2) (mg/m^3)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	BS EN 14792
A7, A8	Sulphur Dioxide (expressed as SO_2) (mg/m^3)	Boiler 1, Boiler 2	No limit set	Hourly average	As requested by the Agency	BS EN 14791

Note 1: Permanent sampling access not required

Table S4.1c) Point source emissions to air as referenced in condition 3.6.1 is amended as follows:

Table S4.1c (Site 3) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, received 29/03/06)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A9	No parameters set	VPL suite	No limit set	-	-	-
A10	No parameters set	RSL suite	No limit set	-	-	-
A11	Oxides of Nitrogen (expressed as NO_2) (mg/m^3)	Boiler 1	No limit set	Hourly average	As requested by the Agency	BS EN 14792
A36	Propan-2-ol	HVAC	No limit set	-	Annual	Mass Balance

Note 1: Permanent sampling access not required.

Table S4.1d) Point source emissions to air as referenced in condition 3.6.1 is amended as follows:

Table S4.1d (Site 4) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (including unit)**	**Reference Period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A19, A28 (Points A1 & A10 on Figure 3, received 03/11/05)	No parameters set	zone 1, zone 2 (including vacuum system exhaust)	No limit set	-	-	-

Table S4.1d (Site 4) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (including unit)**	**Reference Period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A20 (Point A2 Figure 3, received 03/11/05)	No parameter set	β-propiolactone vent header: zone 1	No limit set	-	-	-
A21 (Point A3 on Figure 3, received 03/11/05)	No parameter set	Brine tank	No limit set	-	-	-
A22 (Point A4 on Figure 3, received 03/11/05)	No parameter set	Hotwell stack	No limit set	-	-	-
A23 (Point A5 on Figure 3, received 03/11/05)	Oxides of Nitrogen (expressed as NO_2)	Boiler 1, 2	150 mg/m^3	Hourly average	As requested by the Agency	BS EN 14792
A24, A25 (Points A6 & A7 on Figure 3, received 03/11/05)	No parameter set	Bulk waste tanks (TK417004 & TK417005)	No limit set	-	-	-
A27 (Point A9 on Figure 3 received 03/11/05)	No parameter set	Egg waste tank	No limit set			
A29, A31, A32, A34, A35 (Points A11, A13, A14, A15 & A16 on Figure 3, received 03/11/05)	No parameter set	Zone 1, 3, 4, 5, 6 Heating Ventilation and Cooling (HVAC) systems.	No limit set	-	-	-
A37 (Point A37 on Fig 3-1 2007 received 10/09/07)	Odour unit per cubic metre (oue/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)	Oxides of Nitrogen (expressed as NO_2)	Boiler 3	150 mg/m^3	Hourly average	As requested by the 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 as stated in approved Odour Management Plan.

The condition 3.4.1 is amended to:

3.4.1 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 Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in an approved odour management plan, to prevent or where that is not practicable to minimise the odour.

Table S5.1 as referenced by condition is amended with addition of an emission point to air as follows:

Table S5.1 Reporting of monitoring data			
Parameter	**Emission or monitoring point/reference**	**Reporting period**	**Period begins**
Emissions to air Parameters as required by condition 3.6.1.	A3, A4, A7, A8, A11, A23, A37 & A38	Every 12 months	01/01/10
Emissions to sewer .Parameters as required by condition 3.6.1.	S1, S2, S3, S4, S5 & S7.	Monthly	01/01/10

Schedule 3 – conditions to be added

The following conditions are added to the permit.

Table S1.3 as specified in condition 2.5.1 as follows is amended to add the following:

Table S1.3 Improvement programme requirements		
Reference	**Requirement**	**Date**
IP10	The Operator shall, having regard to Agency Guidance Note IPPC H4 Odour Part 2 – Assessment and Control provide a written report outlining the features of the new odour abatement system for Site 4 emission Point A37 to minimise potentially odorous emissions from the Permitted Installation. A written summary shall be submitted to the Agency which shall include, but not be limited to the following: • Overall description of the final abatement system design; • Process parameters and their control for effective odour abatement; • Abatement system solid and liquor annual usages, liquor containment, waste handling and waste minimisation; • Actions in the event of system failure and corrective actions to ensure odour control; • Contingency facilities and procedures in the event of complete system abatement failure (including having regarded to permit condition 4.3.1).	30/06/10
IP11	The Operator shall, having regard to Agency Guidance Note IPPC H4 Odour Part 2 – Assessment and Control outline the commissioning protocol for the new A37 odour abatement system. A written summary shall be submitted to the Agency which shall but not be limited to the following: • Inspection Testing – provision of details of actions under this phase; • Functional Testing – provision of actions under this phase; • Performance Monitoring – provision of actions to undergo odour monitoring for confirmation that targets for minimisation of potentially odorous emissions from the Permitted Installation have been achieved. Monitoring shall have regard to Agency Guidance Note M2: Monitoring of Stack Emissions to Air. • Procedures for corrective action completion to ensure optimum design for odour control. The Environment Agency is to provide written approval on receipt of this report to allow actioning of this protocol.	31/07/10
IP12	The Operator shall undertake the approved commissioning protocol for A37 new odour abatement system as detailed in improvement condition IP11. A report summarising the results with monitoring data, including details of the methodology used and interpretation of the results plus any remedial actions, shall be submitted to the Agency.	Within 3 months of the commencement of the operation of new A37 emission point odour abatement system at Site 4

The condition 3.4.2 is added as follows:

3.4.2 (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 Agency.

(b) If notified by the Agency that the activities are giving rise to pollution, the operator shall submit to the Agency for approval within the period specified, a revision of any plan specified in schedule 1, Table S1.2 or otherwise required under this permit, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Agency.

Schedule 4 – amended plan

None.

END OF NOTICE