



**CHARNWOOD BOROUGH COUNCIL  
ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)  
REGULATIONS 2016, REGULATION 18**

**PERMIT REFERENCE NO: 115**

**VARIATION NOTICE**

To: **3M United Kingdom PLC**

Registered Office: **Charnwood Campus, 10 Bakewell Road, Loughborough  
Leicestershire LE11 5RB**

Charnwood Borough Council ('The Council'), in exercise of the powers conferred upon it by Regulation 18 of the Environmental Permitting (England and Wales) Regulations 2016 ("the 2016 Regulations") hereby gives you notice as follows:-

The Council has decided to vary and consolidate the conditions of Permit Reference 115 granted under regulation 13 (1) of the 2016 Regulations in respect of the following pharmaceutical formulation and finishing activity, following partial transfer of the activities

Operated by: **3M United Kingdom PLC,**

At: **Bishop Meadow Road, Loughborough, Leicestershire  
LE11 5RE**

The variation of the conditions of the permit are specified in Schedule 1 to this notice. A consolidated permit as varied by this notice is set out in Schedule 2. Unless otherwise stated, the variations made by this Notice will come into effect immediately.

Name	Date
Beverley Green	22 June 2020

Authorised on behalf of Charnwood Borough Council

Issued by:  
Regulatory Services, Environmental Protection Southfields, Southfields Road,  
Loughborough, Leicestershire LE11 2TX

**Schedule 1**

<b>Variations to the conditions of the permit</b>	<b>Date on which the variation is to take place</b>
Delete all wording and conditions highlighted in red in permit 115 dated 20 May 2019 (copied below in Schedule 1).	From the date of this Notice.
Delete the wording of the process description relating to Bulk Storage of Propellants and replace with the wording for Bulk Storage of Polymer (highlighted in green).	From the date of this Notice
Delete the wording in Table 1 highlighted in red and replace with wording highlighted in green.	From the date of this Notice
Replace existing site layout and location plan In Appendix 1 of Permit 115 dated 20 May 2019 with Drawing DIS12422 Rev A	From the date of this Notice

Name

Date

Beverley Green	22 June 2020
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Authorised on behalf of Charnwood Borough Council



**CHARNWOOD BOROUGH COUNCIL**

**POLLUTION PREVENTION AND CONTROL ACT 1999**

**ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)  
REGULATIONS 2016**

**PERMIT REF. NO. 115**

Charnwood Borough Council hereby permits, under regulation 13 of the of the Environmental Permitting (England and Wales) Regulations 2016

**3M United Kingdom PLC**

whose registered office is:

**Charnwood Campus, 10 Bakewell Road, Loughborough  
Leicestershire LE11 5RB**

To operate a pharmaceutical formulation and finishing activity at:

**3M United Kingdom PLC**

**Bishop Meadow Road, Loughborough, Leicestershire LE11  
5RE (National Grid Ref: SK 524 207)**

subject to the conditions outlined in this document. The conditions contained herein shall apply from the date of the Permit unless otherwise stated.

Name	Date
Beverley Green	20 May 2019

Authorised on behalf of Charnwood Borough Council

Permit issued by:

Regulatory Services, Environmental Protection Southfields, Southfields Road,  
Loughborough, Leicestershire LE11 2TX

## Introductory note

### *This introductory note does not form a part of the permit*

The following Permit is issued under Regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016 (SI 2016/1154), as amended, (“the EP Regulations”) to operate an installation carrying out one or more of the activities listed in Part 2 of Schedule 1 of the EP Regulations, to the extent authorised by the Permit:

“The ~~chemical synthesis, fermentation, extraction,~~ formulation and finishing of pharmaceutical products ~~and where carried out at the same site, the manufacture of intermediate products~~ with solvent consumption >50 tonnes”.

## Status Log

The status log of the permit sets out the permitting history, including any variations issued.

Detail	Date	Comments
Deemed Application 115	Received 9/11/05	Duly made
Extension to determination	8/3/06	
Permit determined	10 September 2007	
Variation Notice	1 June 2009	Varied permit issued
Variation Notice	24 September 2010	Permission for use of dichloromethane (R40) until 31 May 2011
Variation Notice	27 May 2011	Varied permit issued
Variation Notice	12 October 2011	Varied permit issued
Variation Notice	07 April 2014	Varied permit issued
Variation Notice	08 November 2016	Change of trading name, new aerosol filling line and incorporation of new packing lines
Variation Notice	20 May 2019	Legislation title change

## Origins of the conditions contained in the permit

The Secretary of State has issued various guidance notes to local authorities to assist with determining conditions. The conditions within this permit have been derived from the following guidance note;

PG 6/43 (11) Formulation and Finishing of Pharmaceutical Products

## Process Description

The main processes that are undertaken at the installation include:

## Storage

- ~~Bulk storage of propellants – propellants are stored in pressurised bulk storage tanks. These are filled by tankers using fuel hose connections. During filling displaced propellant emissions from the bulk storage tank are back-vented into~~

~~the tanker. All storage tanks are fitted with high-level alarms. These 2 tanks are not bunded because of the volatility of contents.~~

- Bulk storage of polymer – is within the raw materials store in a well ventilated and bunded cabinet.
- Raw Materials – ~~all powdered raw materials are kept on racks in the raw material store. Active ingredients are also kept in this area but are placed in locked cages due to the nature of the chemicals. Solvents not kept in the bulk holding tanks~~ are stored in drums in the flammable liquid store. All racks are bunded.

### Solid Dose Processes:

- ~~Dispensing / weighing;~~
- ~~sieving/milling of ingredients;~~
- ~~mixing and blending;~~
- ~~granulation;~~
- ~~drying;~~
- ~~Tablet/bead manufacture;~~

#### Sieving/milling of ingredients

~~Prior to use the raw materials may be sieved and or milled to aid the mixing and blending process.~~

#### Mixing and blending

~~The ingredients are weighed before being transferred to the mixing and blending operations. Mixing/blending is carried out using a variety of mixers, including propeller agitators, paddle mixers, Z blade mixers, ribbon blenders, tumbling mixers or high-speed mixers.~~

#### Granulation Process/Drying

~~The aim of granulation is to produce grains of the correct concentration of the active ingredient and the desired physical properties for compression and finishing.~~

~~Solvent and solids are dispensed in to a mixing vessel which is then sealed. The materials are then mixed and discharged in to a filter bowl prior to drying. Drying is carried out by two Calmic (fluid bed) dryers. The dry mixture is then vacuum transferred into a cube hopper for tablet and capsule compression, finishing and coating.~~

~~No solvents are used during the finishing process. Exhaust air from the granulation process is abated with bag and in line filters. VOC emissions are discharged to atmosphere from Calmic dryer 1; no solvents are used in the production of products dried on Calmic dryer 2.~~

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### Bead Manufacture

~~Solvent and solids are dispensed to a mixing vessel, which is then sealed. The materials are then mixed and discharged into a container from where they are extruded, spheronised and filtered prior to drying. The solution is sprayed into beads in an aeromatic spray dryer. VOC emissions occur during the drying process and are discharged to atmosphere; particulates are filtered out. The beads are then sieved and blended prior to being put into capsules. During bead filling and capsule finishing no solvents are used.~~

### Liquids & Creams Processes:

- Dispensing / weighing
- ~~Mixing~~
- Filling

~~Solvent for this process is pumped directly from the liquid store to the process vessels, to be mixed with solids. Once mixed the products are dispensed on a filling line. This is a closed system and the only emission is from the displacement of residual solvent saturated air in the vessel and pipe work.~~

Depending on the line, either empty plastic bottles, clean wipes (small sponges) or clean wands (swabs) are fed into ventilated filling machines where the correct amount of product polymer is dosed into /onto them from product housed within the ventilated 200 litre drum booths. Bottles are capped, whilst wipes and wands are heat sealed into laminated pouches. Any uncapped bottles or split /unsealed pouches are rejected into a ventilated waste collection bin whilst good products pass into the packaging area.

### Inhalation Processes:

- ~~Dispensing / weighing~~
- ~~Mixing~~
- ~~Filling~~

~~Metered Dose Inhalers (MDIs) are filled, capped, tested and weighed in specialised equipment. The cans are filled with the product and carrier gas, and then capped with valves in a single operation. The cans are then leak tested, weighed and the valve mechanism checked prior to packing. Any particulates emissions are captured by 3-wet-scrubbers~~

### Packing of Preparations

Packaging of the finished products may include the printing of labels and boxing of products, these operations may give rise to small releases of VOC and dust.

### Waste

Waste is stored on site in the waste compound. This area is bunded and waste is segregated into prescription only medicines/hazardous materials and general waste

and solvent divided into chlorinated and non-chlorinated waste. The waste is collected by an authorised waste handler and disposed of off-site.

**End of Introductory Note.**

The above named company is permitted to operate the activities and/or associated activities as specified in table 1 below: -

<b>Activity</b>	<b>Description of specified activity</b>	<b>Limits of specified activity</b>
Formulation and finishing of pharmaceuticals carried out with a solvent consumption of 50 tonnes or more.	Storage, <del>sieving, mixing, filling blending, granulation, drying and pressing of pharmaceuticals,</del> <b>production and packing</b> of liquid preparations, <del>production of aerosol preparations.</del>	From receipt of raw materials onto the site to the dispatch of finished products and handling storage and removal of waste. The installation boundary and key emission points mentioned in permit conditions are shown in Appendix 1 attached to this permit.

**Subject to compliance with the following conditions:**

## **Permit Conditions**

### **Emission Limits, monitoring and other provisions**

1. The non-VOC emission limits, methods and frequency of monitoring set out in Table 2 shall be complied with.

<b>Substance</b>	<b>Source</b>	<b>Emission Limit</b>	<b>Monitoring Method – (as recommended by the Source Testing Association)</b>	<b>Monitoring Frequency</b>
Particulate matter	All emission points listed in Table 4 below	50 mg/Nm <sup>3</sup> as 15 minute mean for contained sources	Manual extractive testing in accordance with BS EN 13284-1, or equivalent, with averages taken over operating periods excluding start-up and shutdown	Annually by 31 October 2014 and then biennially
<b>Notes:</b> 1.All periodic monitoring results shall be checked by the operator on receipt and sent to the Council on an annual basis. 2.The reference conditions for limits are: 273.1K, 101.3kPa, without correction for water vapour content, unless stated otherwise. 3.All periodic monitoring shall be representative, and shall use standard methods. 4.The emission limits do not apply during start-up and shut down. All emissions shall be kept to a minimum during these periods. 5. Compliance by dilution is not permitted.				

2. The VOC total emission limit value, calculation methods and monitoring, set out in Table 3 shall be complied with.



Table 3– Total Emission Limit			
VOC in waste gases	Total Emission Limit value/requirement	Total Emission	
		Fugitive releases	Contained releases
Existing Installations	15% of solvent input	Determined in accordance with Schedule A to this permit.	Determined from continuous monitoring and recording
<p><b>Compliance is achieved if:</b> the total emission from the activity expressed as a percentage of the organic solvent input into the activity is equal to or less than the total emission limit value:</p> <p>Where the total emission is equal to the mass of organic solvent released in the waste gases <b>PLUS</b> the fugitive releases.</p> <p>Total Emission = O<sub>1</sub> + Fugitive</p> <p><b>and</b> organic solvent input is equal to the quantity of organic solvents purchased and used in the process Plus the quantity of organic solvents recovered and reused as determined as part of the solvent management plan.</p> $\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100 \text{ is equal to or less than the total emission limit value}$ <p><b>NOTE</b> the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container</p>			

3. The following emission points shall be monitored to ensure compliance with the emission limits given in condition 1 above.

Table 4 – Emission Monitoring Points					
Ref	Emission Ref.	System Number	Application	Location	Monitoring
Wet Scrubbers					
01	Line 3	DR/55/09/11/WS0001	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
02	IVS packing	DR/55/09/11/WS0002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
03	Line 1	DR/55/09/12/ WS001	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
04	Function-Testers	DR/55/09/12/ WS002	Wet Scrubber	Plant Room 2 DR1.073	Manual extractive
05	Line 2	DR/55/09/18/WS001	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
06	Line 2	DR/55/09/18/WS002	Wet Scrubber	Plant Room 1 DR1.075	Manual extractive
Packaging Lines					
07	Selo Line	DR/55/09/13	Extract	Plant Room 3 DR1.064	Manual extractive
08	Wipes Line	DR/55/09/14	NSBF Extract	Plant Room 3 DR1.065	Manual extractive
09	Wands Line	DR/55/09/15	NSBF Extract	Plant Room 3 DR1.065	Manual extractive
Granulation Areas					
10	Aeromatic	DR/23/20/01	Aeromatic	Plant Room 1 DR1.075	Manual extractive
11	Calmic 1	DR/23/20/03	Dryer-	Plant Room 1 DR1.075	Manual extractive
12	Calmic 2	DR/23/20/04	Dryer-	Plant Room 1 DR1.075	Manual extractive

### Determination of Solvent Consumption

4. The operator shall determine the actual consumption of organic solvent (the total mass of organic solvent inputs minus any solvents sent for reuse/recovery off-site), at the installation on an annual basis. This shall be produced in the form of a mass balance and submitted to Charnwood Borough Council annually by 31 January.

$$\text{Where } C = I_1 - O_8$$

*Note: Further details on determining Solvent Consumption can be found in Schedule A of this permit*

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### Solvent Management Plan

5. A Solvent Management Plan (SMP) shall be produced annually by the operator and submitted to Charnwood Borough Council by 31 January. This shall be used to demonstrate compliance with the Total Emission Limit Value required by Condition 2. The SMP shall cover the period of 1 January to 31 December of the previous year.

*Further details on the definitions and calculations required are set out in Schedule A of this permit.*

### Designated Materials

6. Designated materials because of their halogenated VOC content with hazard statements H341 or H351 shall be controlled under contained conditions as far as is technically and economically feasible.

### Monitoring, investigation and recording

7. The operator shall keep written or computer records of all inspections, tests and emission monitoring, (including all non-continuous monitoring and visual assessments) of the permitted activity. Records shall be kept on site and retained by the operator for a minimum of two years.
8. Corrective action shall be taken immediately if any periodic monitoring result exceeds a limit in Table 2. Monitoring shall be undertaken or repeated as soon as possible thereafter and a brief record shall be kept of the main actions taken.

### Abnormal events

9. In the case of abnormal emissions, malfunction or breakdown leading to a significant escape of particulate matter, odour, fume or visible airborne emission, the operator shall investigate in accordance with company procedure **LBSOP-07- 000163** (available to an authorised officer of Charnwood Borough Council on request) to:
- Investigate and undertake remedial action;
  - Adjust the process or activity to minimise the emissions; **and**
  - Promptly record the events and actions taken.
10. Any emission likely to have an effect on the local community or failure of key arrestment plant (for example, bag filtration plant and scrubber units) shall be notified to Charnwood Borough Council without delay by telephone.
11. In cases where non-compliance is likely to cause an immediate danger to human health or threatens to cause an immediate significant adverse effect upon the environment, the operation of the activity must be suspended.

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**Standard Conditions**

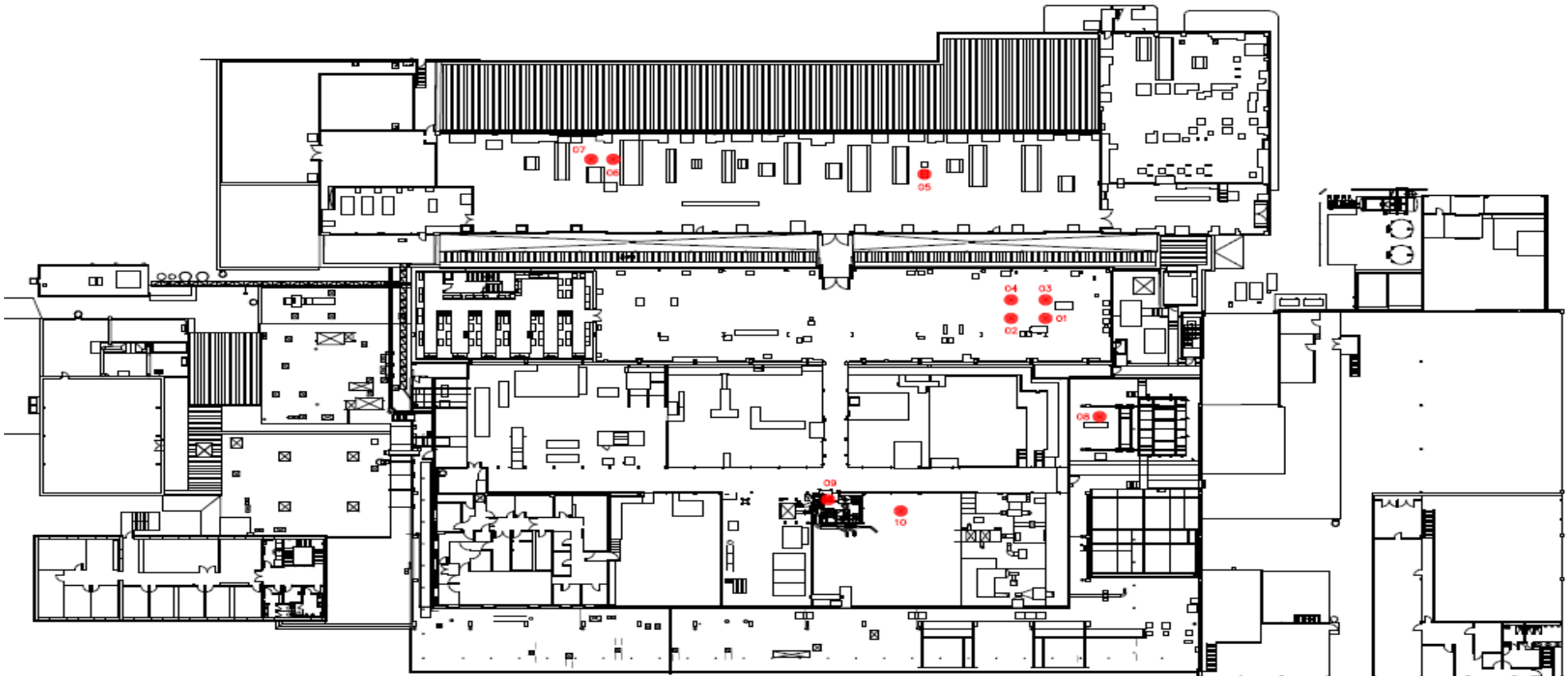
12. If the operator proposes to make a change in the operation of the installation, he shall, at least 14 days before making the change, notify Charnwood Borough Council in writing. The notification must contain a description of the proposed change. In this condition 'change of operation' means a change which may affect the substances or concentration of substances being emitted to air.

**End of Conditions**

**Appendix 1**

**Site Location and Layout**

REF	SYSTEM NUMBER	APPLICATION	LOCATION
01	DR/55/09/11	WET SCRUBBER WS0001	PLANT ROOM 2 DR1.07.
02	DR/55/09/11	WET SCRUBBER WS0002	PLANT ROOM 2 DR1.07.
03	DR/55/09/12	WET SCRUBBER WS0001	PLANT ROOM 2 DR1.07.
04	DR/55/09/12	WET SCRUBBER WS0002	PLANT ROOM 2 DR1.07.
05	DR/55/09/13	NSBF SELO LINE	PLANT ROOM 3 DR1.06.
06	DR/55/09/14	NSBF WIPES LINE	PLANT ROOM 3 DR1.06.
07	DR/55/09/15	NSBF WANDS LINE	PLANT ROOM 3 DR1.06.
08	DR/55/09/18	IVS LINE 2 WET SCRUBBER	PLANT ROOM 1 DR1.07.
09	DR/23/20/01	AEROMATIC	PLANT ROOM 1 DR1.07.
10	DR/23/20/03	CALMIC DRYER 1	PLANT ROOM 1 DR1.07.



**Schedule 2**

**Permit Reference 115 as varied by this Notice.**



**CHARNWOOD BOROUGH COUNCIL**

**POLLUTION PREVENTION AND CONTROL ACT 1999**

**ENVIRONMENTAL PERMITTING (ENGLAND AND WALES)  
REGULATIONS 2016**

**PERMIT REF. NO. 115**

Charnwood Borough Council hereby permits, under regulation 13 of the of the Environmental Permitting (England and Wales) Regulations 2016

**3M United Kingdom PLC**

whose registered office is:

**Charnwood Campus, 10 Bakewell Road, Loughborough  
Leicestershire LE11 5RB**

To operate a pharmaceutical formulation and finishing activity at:

**3M United Kingdom PLC**

**Bishop Meadow Road, Loughborough, Leicestershire LE11  
5RE (National Grid Ref: SK 524 207)**

subject to the conditions outlined in this document. The conditions contained herein shall apply from the date of the Permit unless otherwise stated.

Name	Date
Beverley Green	22 June 2020

Authorised on behalf of Charnwood Borough Council

Permit issued by:

Regulatory Services, Environmental Protection Southfields, Southfields Road,  
Loughborough, Leicestershire LE11 2TX

## Introductory note

### *This introductory note does not form a part of the permit*

The following Permit is issued under Regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016 (SI 2016/1154), as amended, (“the EP Regulations”) to operate an installation carrying out one or more of the activities listed in Part 2 of Schedule 1 of the EP Regulations, to the extent authorised by the Permit:

“The formulation and finishing of pharmaceutical products with solvent consumption >50 tonnes”.

### **Status Log**

The status log of the permit sets out the permitting history, including any variations issued.

<b>Detail</b>	<b>Date</b>	<b>Comments</b>
Deemed Application 115	Received 9/11/05	Duly made
Extension to determination	8/3/06	
Permit determined	10 September 2007	
Variation Notice	1 June 2009	Varied permit issued
Variation Notice	24 September 2010	Permission for use of dichloromethane (R40) until 31 May 2011
Variation Notice	27 May 2011	Varied permit issued
Variation Notice	12 October 2011	Varied permit issued
Variation Notice	07 April 2014	Varied permit issued
Variation Notice	08 November 2016	Change of trading name, new aerosol filling line and incorporation of new packing lines
Variation Notice	20 May 2019	Legislation title change
Partial Transfer Application	30 April 2020	Duly made
Variation Notice	22 June 2020	Variation and consolidated permit issued

### **Origins of the conditions contained in the permit**

The Secretary of State has issued various guidance notes to local authorities to assist with determining conditions. The conditions within this permit have been derived from the following guidance note;

PG 6/43 (11) Formulation and Finishing of Pharmaceutical Products

### **Process Description**

The main processes that are undertaken at the installation include:

### **Storage**

- 
- Bulk storage of polymer- is within raw materials store in a well ventilated and bunded area.
  - Raw Materials– Solvents are stored in drums in the flammable liquid store. All racks are bunded.

### **Liquids & Creams Processes:**

- Dispensing / weighing
- Filling

Depending on the line, either empty plastic bottles, clean wipes (small sponges) or clean wands (swabs) are fed into ventilated filling machines where the correct amount of product polymer is dosed into /onto them from product housed within the ventilated 200 litre drum booths. Bottles are capped, whilst wipes and wands are heat sealed into laminated pouches. Any uncapped bottles or split /unsealed pouches are rejected into a ventilated waste collection bin whilst good products pass into the packaging area.

Packaging of the finished products may include the printing of labels and boxing of products, these operations may give rise to small releases of VOC and dust.

### **Waste**

Waste is stored on site in the waste compound. This area is bunded and waste is segregated into prescription only medicines/hazardous materials and general waste and solvent divided into chlorinated and non-chlorinated waste. The waste is collected by an authorised waste handler and disposed of off-site.

**End of Introductory Note.**



The above named company is permitted to operate the activities and/or associated activities as specified in table 1 below: -

<b>Activity</b>	<b>Description of specified activity</b>	<b>Limits of specified activity</b>
Formulation and finishing of pharmaceuticals carried out with a solvent consumption of 50 tonnes or more.	Storage, filling and packing of liquid preparations.	From receipt of raw materials onto the site to the dispatch of finished products and handling storage and removal of waste. The installation boundary and key emission points mentioned in permit conditions are shown in Appendix 1 attached to this permit.

**Subject to compliance with the following conditions:**

### **Permit Conditions**

#### **Emission Limits, monitoring and other provisions**

1. The non-VOC emission limits, methods and frequency of monitoring set out in Table 2 shall be complied with.

<b>Substance</b>	<b>Source</b>	<b>Emission Limit</b>	<b>Monitoring Method – (as recommended by the Source Testing Association)</b>	<b>Monitoring Frequency</b>
Particulate matter	All emission points listed in Table 4 below	50 mg/Nm <sup>3</sup> as 15 minute mean for contained sources	Manual extractive testing in accordance with BS EN 13284-1, or equivalent, with averages taken over operating periods excluding start-up and shutdown	By 30 April 2021 and then biennially
<b>Notes:</b> 1.All periodic monitoring results shall be checked by the operator on receipt and sent to the Council within 8 weeks of completion of sampling. 2.The reference conditions for limits are: 273.1K, 101.3kPa, without correction for water vapour content, unless stated otherwise. 3.All periodic monitoring shall be representative, and shall use standard methods. 4.The emission limits do not apply during start-up and shut down. All emissions shall be kept to a minimum during these periods. 5. Compliance by dilution is not permitted.				

2. The VOC total emission limit value, calculation methods and monitoring, set out in Table 3 shall be complied with.

<b>Table 3– Total Emission Limit</b>			
VOC in waste gases	Total Emission Limit value/requirement	Total Emission	
		Fugitive releases	Contained releases
Existing Installations	15% of solvent input	Determined in accordance with Schedule A to this permit.	Determined from continuous monitoring and recording
<p><b>Compliance is achieved if:</b> the total emission from the activity expressed as a percentage of the organic solvent input into the activity is equal to or less than the total emission limit value:</p> <p>Where the total emission is equal to the mass of organic solvent released in the waste gases <b>PLUS</b> the fugitive releases.</p> <p>Total Emission = O<sub>1</sub> + Fugitive</p> <p><b>and</b> organic solvent input is equal to the quantity of organic solvents purchased and used in the process Plus the quantity of organic solvents recovered and reused as determined as part of the solvent management plan.</p> <p><math>\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100</math> is equal to or less than the total emission limit value</p>			
<p><b>NOTE</b> the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container</p>			

3. The following emission points shall be monitored to ensure compliance with the emission limits given in condition 1 above.

<b>Table 4 – Emission Monitoring Points</b>					
Ref	Emission Ref.	System Number	Application	Location	Monitoring
01	Selo Line	DR/55/09/13	Extract	Plant Room 3 DR1.064	Manual extractive
02	Wipes Line	DR/55/09/14	NSBF Extract	Plant Room 3 DR1.065	Manual extractive
03	Wands Line	DR/55/09/15	NSBF Extract	Plant Room 3 DR1.065	Manual extractive

### Determination of Solvent Consumption

4. The operator shall determine the actual consumption of organic solvent (the total mass of organic solvent inputs minus any solvents sent for reuse/recovery off-site), at the installation on an annual basis. This shall be produced in the form of a mass balance and submitted to Charnwood Borough Council annually by 31 January.

$$\text{Where } C = I_1 - O_8$$

*Note: Further details on determining Solvent Consumption can be found in Schedule A of this permit.*

### Solvent Management Plan

5. A Solvent Management Plan (SMP) shall be produced annually by the operator and submitted to Charnwood Borough Council by 31 January. This shall be used to demonstrate compliance with the Total Emission Limit Value required by Condition 2. The SMP shall cover the period of 1 January to 31 December of the previous year.

*Further details on the definitions and calculations required are set out in Schedule A of this permit*

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### Designated Materials

6. Designated materials because of their halogenated VOC content with hazard statements H341 or H351 shall be controlled under contained conditions as far as is technically and economically feasible.

### Monitoring, investigation and recording

7. The operator shall keep written or computer records of all inspections, tests and emission monitoring, (including all non-continuous monitoring and visual assessments) of the permitted activity. Records shall be kept on site and retained by the operator for a minimum of two years.
8. Corrective action shall be taken immediately if any periodic monitoring result exceeds a limit in Table 2. Monitoring shall be undertaken or repeated as soon as possible thereafter and a brief record shall be kept of the main actions taken.

### Abnormal events

9. In the case of abnormal emissions, malfunction or breakdown leading to a significant escape of particulate matter, odour, fume or visible airborne emission, the operator shall investigate in accordance with company procedure **LBSOP-07- 000163** (available to an authorised officer of Charnwood Borough Council on request) to:
  - Investigate and undertake remedial action;
  - Adjust the process or activity to minimise the emissions; **and**
  - Promptly record the events and actions taken.
10. Any emission likely to have an effect on the local community or failure of key arrestment plant (for example, bag filtration plant and scrubber units) shall be notified to Charnwood Borough Council without delay by telephone.
11. In cases where non-compliance is likely to cause an immediate danger to human health or threatens to cause an immediate significant adverse effect upon the environment, the operation of the activity must be suspended.

### Standard Conditions

12. If the operator proposes to make a change in the operation of the installation, he shall, at least 14 days before making the change, notify Charnwood Borough Council in writing. The notification must contain a description of the proposed change. In this condition 'change of operation' means a change which may affect the substances or concentration of substances being emitted to air.

### End of Conditions

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## **Schedule A** (reproduced from Process Guidance Note 6/43(11))

### **Compliance with the Total Emission Limit Values**

Compliance is achieved if the total emission from the activity expressed as a percentage of the organic solvent input to the activity is equal to or less than the total emission limit value:

Where the total emission is equal to the mass of organic solvent released in the waste gases **PLUS** the fugitive releases.

Total emission = O<sub>1</sub> + Fugitive

And organic solvent input is equal to the quantity of organic solvents purchased and used in the process **PLUS** the quantity of organic solvents recovered and reused as organic solvent into the process as determined as part of the Solvent Management Plan:

Organic solvent input (I) = I<sub>1</sub> + I<sub>2</sub>

Compliance with the total emission limit value is achieved if:

$$\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100 \text{ is equal to or less than the Total emission limit value}$$

### **Determination of Solvent Consumption**

A determination of the organic solvent consumption is the total mass of organic solvent Inputs minus any solvents sent for reuse/recovery off-site. This should be in the form of a mass balance in order to determine the annual actual consumption of organic solvent (C:)

Where  $C = I_1 - O_8$

The industrial emissions Directive provides guidance on what constitutes a solvent input and output. The definitions in Annex VII, Part 7 of the industrial emissions Directive are as follows:

**I<sub>1</sub>** Is the quantity of organic solvents, or their quantity in mixtures purchased which are used as input into the process/activity (including organic solvents used in the cleaning of equipment).

A calculation of the purchased organic solvent Input (I<sub>1</sub>) to the process/activity, is carried out by recording:

- (i) The mass of organic solvent contained in raw materials and preparations in the initial stock (IS) at the start of the accounting period; plus
- (ii) The mass of organic solvent contained in raw materials and preparations in the purchased stock (PS) during the accounting period.
- (iii) Minus the mass of organic solvent contained in raw materials and preparations in the final stock (FS) at the end of the accounting period.

Total Organic Solvent Input (I<sub>1</sub>) = IS + PS – FS

**O<sub>8</sub>** Is the quantity of organic solvents contained in mixtures recovered for reuse.

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## Solvent Management Plan

The definitions in Annex VII, Part 7 of the industrial emissions Directive are as follows and are shown diagrammatically below.

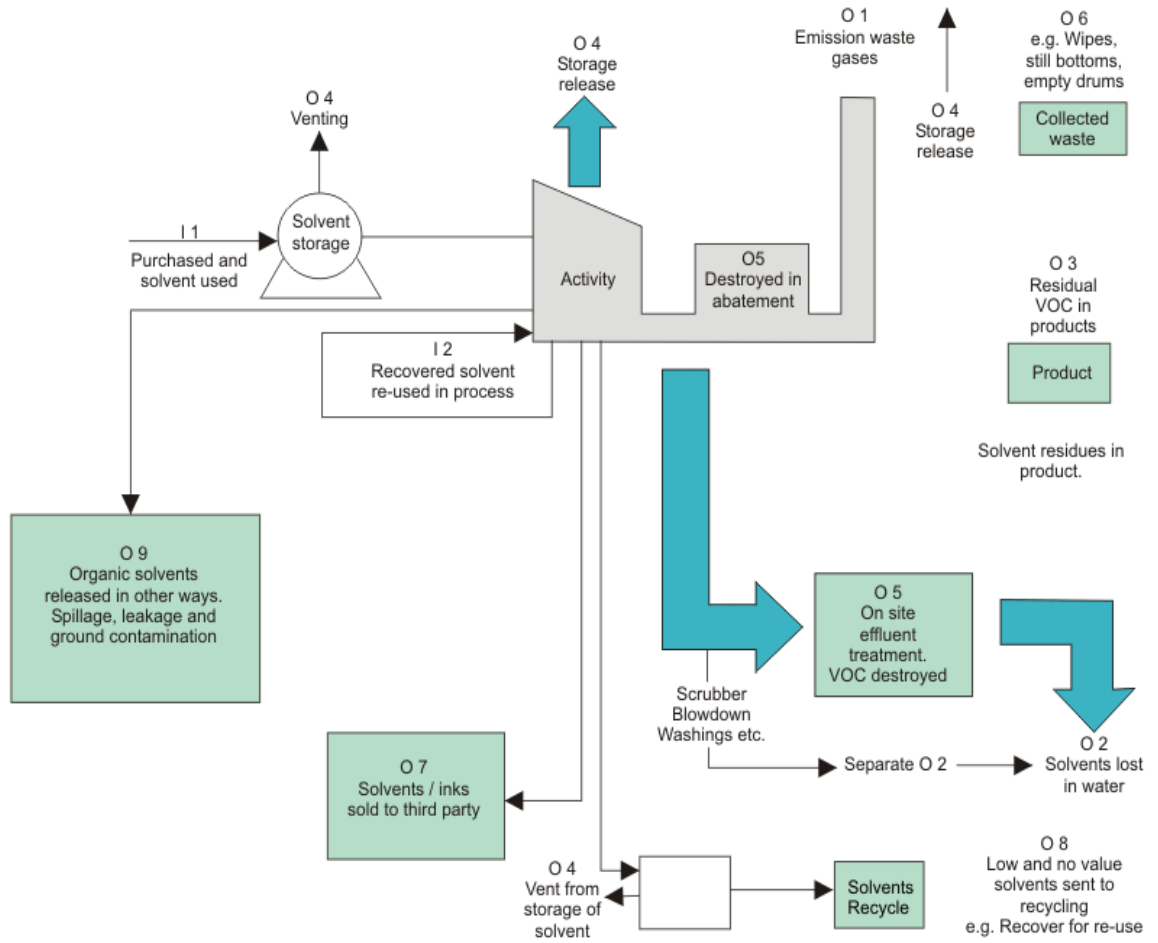
### Inputs of Organic Solvent in the time frame over which the mass balance is being calculated (I)

- I<sub>1</sub> The quantity of organic solvents or their quantity in mixtures purchased which are used as input into the process/activity (including organic solvents used in the cleaning of equipment, but not those used for the cleaning of the products).
- I<sub>2</sub> The quantity of organic solvents or their quantity in mixtures recovered and reused as solvent input into the process/activity. (The recycled solvent is counted every time it is used to carry out the activity).

### Outputs of Organic Solvents in the time frame over which the mass balance is being calculated (O)

- O<sub>1</sub> Emissions in waste gases.
- O<sub>2</sub> Organic solvents lost in water, if appropriate taking into account waste water treatment when calculating O<sub>5</sub>.
- O<sub>3</sub> The quantity of organic solvents which remains as contamination or residue in products output from the process/activity.
- O<sub>4</sub> Uncaptured emissions of organic solvents to air. This includes the general ventilation of rooms, where air is released to the outside environment via windows, doors, vents and similar openings.
- O<sub>5</sub> Organic solvents and/or organic compounds lost due to chemical or physical reactions (including for example those which are destroyed, e.g. by thermal oxidation or other waste gas or waste water treatments, or captured, e.g. by adsorption, as long as they are not counted under O<sub>6</sub>, O<sub>7</sub> or O<sub>8</sub>).
- O<sub>6</sub> Organic solvents contained in collected waste.
- O<sub>7</sub> Organic solvents, or organic solvents contained in mixtures, which are sold or are intended to be sold as a commercially valuable product.
- O<sub>8</sub> Organic solvents contained in mixtures recovered for reuse but not as input into the process/activity, as long as not counted under O<sub>7</sub>.
- O<sub>9</sub> Organic solvents released in other ways.

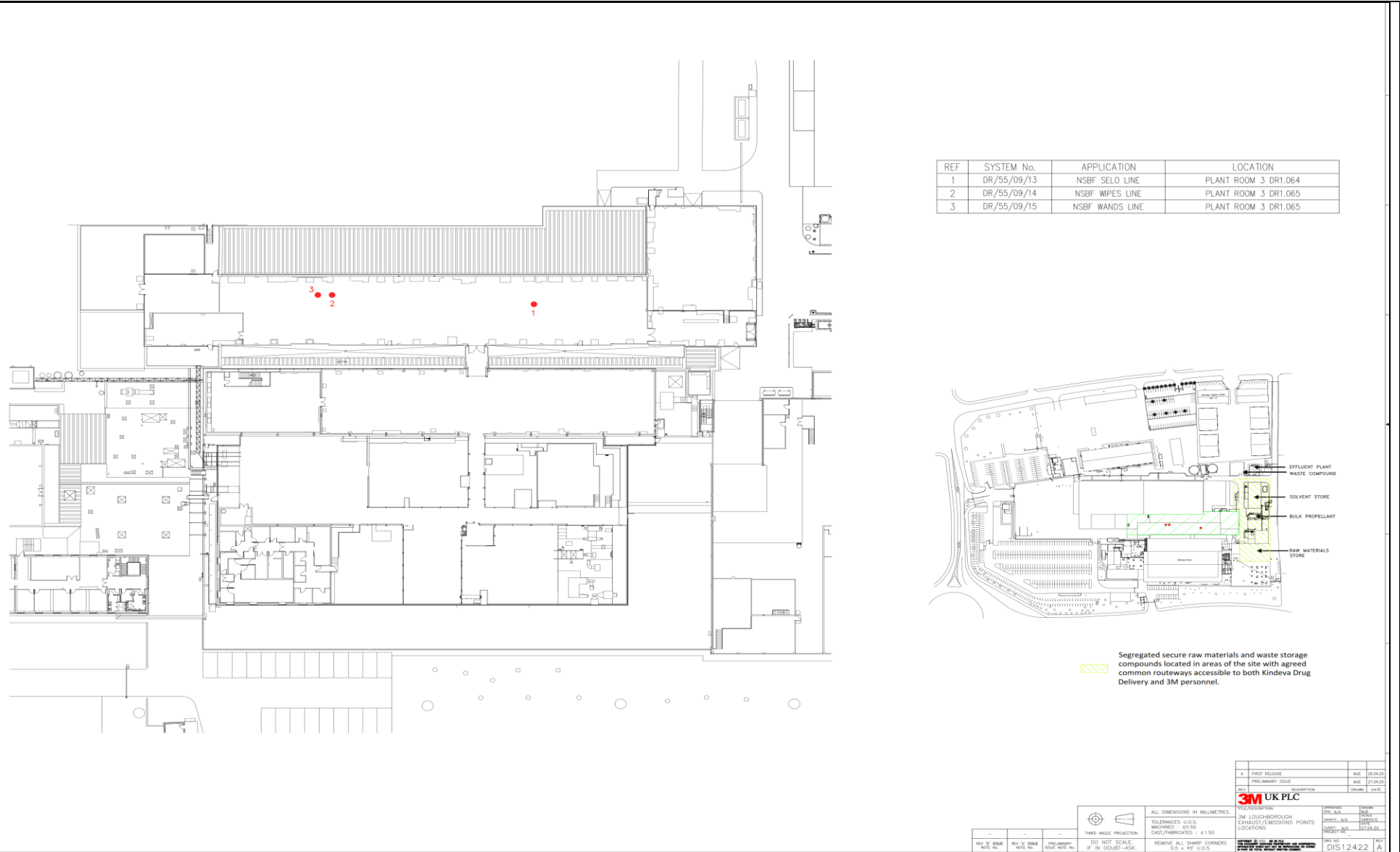
**Solvent Management Plan Inputs and Outputs**



<p>Solvent Management Plan</p> <p>Consumption = I 1 - O 8</p> <p>Actual solvent emission = I 1 - O 5 - O 6 - O 7 - O 8</p> <p>Fugitive emission (F) = I 1 - O 1 - O 5 - O 6 - O 7 - O 8</p> <p>OR</p> <p>Fugitive emission (F) = O 2 + O 3 + O 4 + O 9</p>	<p>Solvent Emissions Directive Activities</p> <p>Fugitive Emission Value =</p> $\frac{F}{I 1 + I 2} \times 100\%$ <p>Total emission = O 1 + Fugitive emission (F)</p>
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Appendix 1

Site Layout and Emission Points



## EXPLANATORY NOTES

### Notes

This notice varies the terms of the permit specified in the Notice by amending or deleting certain existing conditions and/or adding new conditions. The Schedule attached to the notice explain which conditions have been amended, added or deleted and the dates on which these have effect.

The Council have included a 'consolidated permit', which takes into account these and previous variations.

### Appeals

Under regulation 31 and Schedule 6 of the 2016 Regulations operators have the right of appeal against the conditions attached to their permit by a variation notice. The right to appeal does not apply in circumstances where the notice implements a direction of the Secretary of State/Welsh Ministers given under regulations 61 or 62 or a direction when determining an appeal.

Appeals against a Variation Notice do not have the effect of suspending the operation of the Notice. Appeals do not have the effect of suspending permit conditions, or any of the mentioned notices.

Notice of appeal against a Variation Notice must be given within **two months** of the date of the variation notification, which is the subject matter of the appeal. The Secretary of State/Welsh Ministers may in a particular case allow notice of appeal to be given after the expiry of this period, but would only do so in the most compelling circumstances.

### How to appeal

There are no forms or charges for appealing. However, for an appeal to be valid, appellants (the person/operator making the appeal) are legally required to provide the Secretary of State or Welsh Minister with the following (see paragraphs 2(1) and (2) of Schedule 6 of the 2016 Regulations):

- written notice of the appeal
- a statement of the grounds of appeal;
- a copy of any relevant application;
- a copy of any relevant environmental permit;
- a copy of any relevant correspondence between the appellant and the regulator;
- a copy of any decision or notice which is the subject matter of the appeal; and
- a statement indicating whether the appellant wishes the appeal to be in the form of a hearing or dealt with by way of written representations.

Appellants should state whether any of the information enclosed with the appeal has been the subject of a successful application for confidentiality under regulation 48 of the 2016 Regulations, and provide relevant details – see below. Unless such information is provided all documents submitted will be open to inspection.

### Where to send your appeal documents

Appeals should be despatched on the day they are dated, and addressed to:

The Planning Inspectorate  
Environment Team, Major and Specialist Casework  
Room 4/04 Kite Wing  
Temple Quay House  
2 The Square  
Temple Quay  
Bristol BS1 6PN

If an appeal is made, the main parties will be kept informed about the next steps, and will also normally be provided with additional copies of each other's representations.

To withdraw an appeal – which may be done at any time - the appellant must notify the Planning Inspectorate in writing and copy the notification to the local authority who must in turn notify anyone with an interest in the appeal.



## **Costs**

The operator and local authority will normally be expected to pay their own expenses during an appeal. Where a hearing or inquiry is held as part of the appeal process, by virtue of paragraph 5(6) of Schedule 6, either the appellant or the authority can apply for costs. Applications for costs are normally heard towards the end of the proceedings and will only be allowed if the party claiming them can show that the other side behaved unreasonably and put them to unnecessary expense. There is no provision for costs to be awarded where appeals are dealt with by written representatives.

## **Confidentiality**

An operator may request certain information to remain confidential, i.e. not be placed on the public register. The operator must request the exclusion from the public register of confidential information at the time of supply of the information requested by this notice or any other notice. The operator should provide clear justification for each item wishing to be kept from the register. The onus is on the operator to provide a clear justification for each item to be kept from the register. It will not simply be sufficient to say that the process is a trade secret.

## **National Security**

Information may be excluded from the public register on the grounds of National Security. If it is considered that the inclusion of information on a public register is contrary to the interests of national security, the operator may apply to the Secretary of State/Welsh Ministers, specifying the information and indicating the apparent nature of risk to national security. The operator must inform the local authority of such an application, who will not include the information on the public register until the Secretary of State/Welsh Ministers has decided the matter.

## **Advice**

If you do not understand the contents of this notice or would like to know more about it please contact the local authority. If you would like to receive independent advice about the contents of this notice, your rights and obligations then please contact a solicitor.

## **Warning**

Failure to comply with a Variation Notice is an offence under regulation 38(2) of the 2016 Regulations. A person guilty of an offence under this regulation could be liable to (i) a fine or imprisonment for a term not exceeding 12 months or both; or (ii) to a fine or imprisonment for a term not exceeding 5 years or both, depending on whether the matter is dealt with in the Magistrates or Crown Court.

## **Data Protection**

For information about how & why we may process your personal data, your data protection rights or how to contact our data protection officer, please view our Privacy Notice [www.charnwood.gov.uk/pages/privacynotice](http://www.charnwood.gov.uk/pages/privacynotice)