



Department
for Environment
Food & Rural Affairs

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Process Guidance Note 6/43(11)

Statutory guidance for formulation and finishing of pharmaceutical products

Revised: June 2014



Llywodraeth Cymru
Welsh Government



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Defra would like to acknowledge the work of the Environment Agency's Local Authority Unit in the drafting of this guidance note.



Revision of the guidance

The electronic version of this publication is updated from time to time with new or amended guidance. **Table 0.1** is an index to the latest changes (minor amendments are generally not listed).

Table 0.1 - Revision of the guidance		
Date of change	Section/ paragraph where change can be found	Nature of change - what paragraphs have been inserted, deleted or amended - what subject matter is covered by the change
June 2014	Fig 4.1	Error corrected in solvent management plan inputs and outputs diagram – in the text below the diagram, in the line ‘actual solvent emission’, O1 should not have been included
June 2013	SE Boxes 5,6 &7	Addition of colour coding to clarify requirements
June 2013	Table 7.1	Addition of colour coding to clarify requirements
March 2013	throughout	Replacement throughout the solvent PG notes of ‘Solvent Emissions Directive’ with ‘industrial emissions Directive’ or ‘the Directive’ as appropriate
	throughout	Replacement of the abbreviation ‘SED’ with ‘solvent emission’ ‘SE’ or ‘solvent emission activity(ies)’ as appropriate e.g. SED box will become SE box
	SE Box 1	No longer needed under the industrial emissions Directive
	SE Box 2	No longer needed under the industrial emissions Directive
	SE Box 3	Definition of substantial change has altered; both new definitions are taken from Directive and as the definitions relate to different classes of installations, the SE Box is split into two boxes to make the differences clear
	SE Box 4	To clarify the Directive basis for the provisions, three new notes have been added. They concern - report compliance, restore compliance if it is breached and for accidents and incidents, the Directive basis for the provisions is clarified
	SE Box 5	Monitoring of VOC emissions after abatement is no longer required to be annual – status of the monitoring column has changed from Directive to BAT with no shading to indicate non-Directive
	SE Box 6	Monitoring of VOC emissions after abatement is no longer required to be annual – so status of the monitoring column has changed from Directive to BAT with no shading to indicate non-Directive
	SE Box 7	Monitoring of VOC emissions after abatement is no longer required to be annual – so status of the monitoring column has changed from Directive to BAT with no shading to indicate non-Directive
	SE Box 8	The Directive adds ‘or threatens to cause an immediate significant adverse effect upon the environment’
SE Box 9	Monitoring of VOC emissions after abatement is no longer required to be annual ‘No compliance by dilution’ has been added to SE box to clarify the Directive basis for the provision	

	SE Box 10	Minimal change - updating of Article references
	SE Box 11	Minimal change - updating of Article references
	Para 1.17	Paragraph for England only – activities that are ‘Directive only’, are not subject to best available techniques, simply the requirements of the Directive. ‘Directive only’ means here - not caught by Part B of section 6.4-6.8 of Schedule 1, but subject to chapter V of the industrial emissions Directive
	Table 3.1	Links to new regulations updated

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1. Introduction

Legal basis

- 1.1 This note applies to the whole of the UK. It is issued by the Secretary of State, the Welsh Government, the Scottish Government and the Department of the Environment in Northern Ireland (DoE NI) to give guidance on the conditions appropriate for the control of emissions into the air from formulation and finishing of pharmaceutical products and tablet coating activities. It is published only in electronic form and can be found on the Defra website. It supersedes PG6/43(04) and NIPG6/43(04).
- 1.2 This guidance document is compliant with the [Code of Practice on Guidance on Regulation](#) page 6 of which contains the "golden rules of good guidance". If you feel this guidance breaches the code or you notice any inaccuracies within the guidance, please [contact us](#).
- 1.3 This is one of a series of statutory notes giving guidance on the Best Available Techniques (BAT). The notes are all aimed at providing a strong framework for consistent and transparent regulation of installations regulated under the statutory Local Air Pollution Prevention and Control (LAPPC) regime in [England and Wales](#), [Scotland](#) and [Northern Ireland](#). The note will be treated as one of the material considerations when determining any appeals against a decision made under this legislation. In certain cases in England, the appropriate conditions for solvent emissions activities differ from BAT, see paragraph 1.18. Further guidance on the meaning of BAT can be found for [England and Wales](#) (in chapter 12 of the General Guidance Manual), [Scotland](#), and [Northern Ireland](#), (in chapter 9).
- 1.4 In general terms, what are BAT for one installation in a sector are likely to be BAT for a comparable installation. Consistency is important where circumstances are the same. However, in each case it is, in practice, for regulators (subject to appeal) to decide what are BAT for each individual installation, taking into account variable factors such as the configuration, size and other individual characteristics of the installation, as well as the locality (e.g. proximity to particularly sensitive receptors).
- 1.5 The note also, where appropriate, gives details of any mandatory requirements affecting air emissions which are in force at the time of publication, such as those contained in Regulations or in Directions from the Government. In the case of this note, at the time of publication the mandatory requirements are those contained in the EU industrial emissions Directive. The Regulations referenced in paragraph 1.3 put the Directive requirements into UK law.

1.6 In **Section 4** and **Section 5**, arrows are used to indicate the matters which should be considered for inclusion as permit conditions. It is important to note, however, that this should not be taken as a short cut for regulators to a proper determination of BAT or to disregard the explanatory material which accompanies the arrows. In individual cases it may be justified to:

- include additional conditions;
- include different conditions;
- not include conditions relating to some of the matters indicated.

In addition, conditions will need to be derived from other parts of the note, in particular to specify emission limits, compliance deadlines and mandatory requirements arising from directions or other legislation.

Who is the guidance for?

1.7 This guidance is for:

Regulators

- local authorities in England and Wales, who must have regard to this statutory guidance when determining applications for permits and reviewing extant permits;
- the Scottish Environment Protection Agency (SEPA) in Scotland, and district councils or the Northern Ireland Environment Agency (NIEA), in Northern Ireland for whom this is statutory guidance;

Operators who are best advised also to have regard to it when making applications and in the subsequent operation of their installation;

Members of the public who may be interested to know what the Government considers, in accordance with the legislation, amounts to appropriate conditions for controlling air emissions for the generality of installations in this particular industry sector.

Updating the guidance

1.8 The guidance is based on the state of knowledge and understanding, at the time of writing, of what constitute BAT for this sector. The note may be amended from time to time to keep up with developments in BAT, including improvements in techniques, changes to the economic parameters, and new understanding of environmental impacts and risks. The updated version will replace the previous version on the [Defra](#) website and will include an index to the amendments.

- 1.9 Reasonable steps will be taken to keep the guidance up-to-date to ensure that those who need to know about changes to the guidance are informed of any published revisions. However, because there can be rapid changes to matters referred to in the guidance – for example to legislation – it should not be assumed that the most recent version of this note reflects the very latest legal requirements; these requirements apply.

Consultation

- 1.10 This note has been produced in consultation with relevant trade bodies, representatives of regulators including members of the Industrial Pollution Liaison Committee and other potentially-interested organisations.

Policy and procedures

- 1.11 General guidance explaining LAPPC and setting out the policy and procedures is contained in separate documents for [England and Wales](#), [Scotland](#) and [Northern Ireland](#).

EU industrial emissions Directive

- 1.12 Most of the activities covered by this note are solvent emission activities (SE) under the [industrial emissions Directive](#). To be a solvent emission activity, it must:
- a) be a formulation or finishing of pharmaceutical products activity listed as a solvent emission activity in the LAPPC Regulations (see **Table 3.1**); **and**
 - b) consume 50 tonnes or more of solvent in any 12 month period.

Which paragraphs of this note apply to solvent emission activities?

- 1.13 Everything in boxes labelled 'SE box' is mandatory, as is text which they invoke because it repeats what is required by the industrial emissions Directive. The rest of the note is guidance on Best Available Techniques for the sector.
- 1.14 The industrial emissions Directive requires replacement of certain solvents, as far as possible, in the shortest possible time. These are substances or mixtures which, because of their VOC content, are assigned or need to carry any of the following hazard statements H340, H350, H350i, H360D or H360F; there are further requirements which apply to the use of those materials, and to halogenated VOCs assigned hazard statements H341 or H351.

In June 2015, 'hazard statements' replace 'risk phrases'. Until then both categories are in use, and the preceding paragraph should be read with 'or risk phrases R45, R46, R49, R60, and R61' following H340, and read with 'or risk phrases R40 and R68' following H351. The [CLP Directive](#) implements the change from risk phrases to hazard statements. For further information on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), visit the [United Nations Economic Commission for Europe](#) website.

- 1.15 The industrial emissions Directive then offers two ways of compliance for pharmaceutical formulating or finishing activities:
- complying with the Directive emission limits for waste gases and fugitive emissions;
 - complying with the Directive total emission limits (with or without abatement).

1.16 The SE boxes in this note are:

1 - new VOC abatement plant (no longer needed under the industrial emissions Directive)

2 - new installations (no longer needed under the industrial emissions Directive)

3A - substantial change to all installations

3B - substantial change to existing installations

4 - VOC compliance

5 - waste gas and fugitive emission limits and requirements

6 - total emission limit values

7 - requirements for designated materials

8 - non-compliance causing immediate danger

9 - VOC monitoring

10 - installations with two or more activities

11 - start up and shut down

1.17 **Tables 1.1, 1.2 and 1.3** pick out the paragraphs and SE boxes that apply depending on which of these ways an operator chooses to comply:

- complying with the Directive emission limits and fugitive emission limits (see **Table 1.1**);
- complying with the Directive total emission limits (see **Table 1.2**);
- applying the Directive reduction scheme (see **Table 1.3**). This compliance option is not available for this activity.

Table 1.1 - Activities applying emission and fugitive limits	
Installation	Paragraphs of guidance note which apply
Single SE activity: Solvent consumption of the formulation and finishing activity more than 50 tonnes	All of sections except: SE Box 6 SE Box 10 Table 4.2
More than one SE activity: Solvent consumption of the formulation and finishing activity more than 50 tonnes plus another SE activity	All of sections except: SE Box 6 Table 4.2
No SE activity, but LAPPC activity: Solvent consumption of the tablet coating activity more than 5 tonnes	All of sections except: 1.12 – 1.16, 1.18, and 1.20 SE boxes 1-11
<p>A solvent emissions activity (SE) is an activity falling within the scope of the industrial emissions Directive (that is, an activity as defined in Annex VII, Part 1 and which exceeds the thresholds in Annex VII, Parts 2 & 3 of the Directive).</p> <p>Consumption is the organic solvent consumption of the activity (see Article 57(9) of the Directive). The determination of consumption is described in paragraph 4.7 of this note.</p> <p>Note: Tablet coating processes / activities with a solvent consumption of less than 5 tonnes are not covered by this note, unless they are technically connected and directly associated with a Directive pharmaceutical formulation/finishing activity.</p> <p>The formulation and finishing of pharmaceutical products with a solvent consumption of less than 50 tonnes is not covered by this note, where not directly associated and technically connected to a coating process with a solvent consumption of 5 tonnes or more.</p>	

Table 1.2 - Activities applying total emission limit

Installation	Paragraphs of guidance note which apply With or without VOC abatement
Single SE activity: Solvent consumption of the formulation and finishing activity more than 50 tonnes	All of Sections except: SE Box 5 Table 4.2 SE Box 10
More than one SE activity: Solvent consumption of the formulation and finishing activity more than 50 tonnes plus another SE activity	All of Sections except: SE Box 5 Table 4.2
No SE activity, but LAPPC activity: Solvent consumption of the tablet coating activity more than 5 tonnes	All of sections except: 1.12 - 1.16, 1.18, and 1.20 SE boxes 1-11

A solvent emissions activity (SE) is an activity falling within the scope of the industrial emissions Directive (that is, an activity as defined in Annex VII, Part 1 and which exceeds the thresholds in Annex VII, Part 2 of the Directive).

Consumption is the organic solvent consumption of the activity, (see Article 57(9) of the Directive). The determination of consumption is described in paragraph 4.7 of this note.

Note: Tablet coating processes / activities with a solvent consumption of less than 5 tonnes are **not** covered by this note, unless they are technically connected and directly associated with a Directive pharmaceutical formulation/finishing activity.

The formulation and finishing of pharmaceutical products with a solvent consumption of less than 50 tonnes is **not** covered by this note, where not directly associated and technically connected to a coating process with a solvent consumption of 5 tonnes or more.

Table 1.3 - Activities applying reduction scheme

This compliance option is not available for this activity.

England - solvent emission activities to which Chapter V of the Directive is applied but not BAT

1.18 In England, installations subject only to the industrial emissions Directive requirements are not subject to BAT other than in the very specific circumstances covered by Article 59(2) and (3) of the industrial emissions Directive. The 'Directive-only' installations are those which:

- carry on solvent emission activities in the Regulations (see **Table 3.1**);
- but do not also carry on activities listed in Part B of Sections 6.4, to 6.8 in the Regulations (see **Table 3.1**).

For these installations:

- the SE boxes apply, as does text which they invoke;
- the rest of the guidance in **Sections 4** and **5** does not apply;
- BAT does not apply; any mention of BAT in the guidance should be read simply as the requirements of the industrial emissions Directive.

(In practice, this paragraph applies to drycleaners, some surface cleaning operations and some boatyards and shipyards in England. It might apply to other installations in England, such as some pharmaceutical manufacturers.)

Which provisions in this note apply to non-Directive activities?

1.19 None of the SE boxes applies to non-Directive activities. All the remaining provisions are guidance on Best Available Techniques for the sector.

General guidance on industrial emissions Directive

1.20 The general guidance mentioned in paragraph 1.11 contains an outline of the industrial emissions Directive requirements, advice on derogations (that is, cases where, if specified criteria are met, an activity/activities can be excused from some requirements), the meaning of the 'shortest possible time' and other matters concerning industrial emissions Directive compliance.

Activities covered by this note

- 1.21 PG6/43(11) deals with formulation and finishing of pharmaceuticals **including the coating of tablets**. All ancillary processes such as filling and packaging are also covered by this note. More details can be found in **Section 3 (Activity description)**.
- 1.22 Directly associated and technically connected solvent processes/activities carried out within the same installation will form part of the activity and have to meet the provisions for that activity, unless defined as a separate activity within [industrial emissions Directive](#) (Appendix 1), in which case they should be regarded as an additional activity within a single installation and the provisions of SE Box 10 apply.
- 1.23 Formulation and finishing of pharmaceuticals which is carried out at the same site as the manufacture of pharmaceutical products are covered by more specific guidance:
 - [EPR 4.02 Speciality Organic Chemicals](#)

2. Timetable for compliance and reviews

Existing processes or activities

- 2.1 This note contains all the provisions from previous editions which have not been removed. Some have been amended. For installations in operation at the date this note is published, the regulator should have already issued or varied the permit having regard to the previous editions. If they have not done so, this should now be done.
- 2.2 The new provisions of this note and the dates by which compliance with these provisions is expected are listed in **Table 2.1**, together with the paragraph number where the provision is to be found. Compliance with the new provisions, which apply to both Directive and non-Directive activities, should normally be achieved by the dates shown. Permits should be varied as necessary, having regard to the changes and the timetable.

Table 2.1 - Compliance timetable		
Guidance	Relevant paragraph/ row in this note	Compliance date
Light coloured painting of outdoor tanks containing VOC*	Paragraph 5.6	By 31 December 2013
All other provisions		Normally within 12 months of the publication date of this note.
* Here and elsewhere in this note, this includes outdoor tanks containing any organic solvent and organic solvent-borne coating material, inks and adhesives		

- 2.3 Replacement plant should normally be designed to meet the appropriate standards specified for new installations/activities.
- 2.4 Where provisions in the preceding guidance note have been deleted or relaxed, permits should be varied as necessary as soon as reasonably practicable. **Section 6** provides a summary of all changes.
- 2.5 For new activities, the permit should have regard to the full standards of this guidance from the first day of operation.
- 2.6 For substantially changed activities, the permit should normally have regard to the full standards of this guidance with respect to the parts of the activity that have been substantially changed and any part of the activity affected by the change, from the first day of operation.

Permit reviews

- 2.7 Under LAPPC, the legislation requires permits to be reviewed periodically but does not specify a frequency. It is considered for this sector that a frequency of once every eight years ought normally to be sufficient for the purposes of the appropriate Regulations. Further guidance on permit reviews is contained in the appropriate Guidance Manual for [England and Wales](#), [Scotland, Practical guide](#) section 10 and Northern Ireland [Part B Guidance](#) page 9, Northern Ireland [Part C Guidance](#) chapter 17. Regulators should use any opportunities to determine the variations to permits necessitated by paragraph 2.2 above in conjunction with these reviews.
- 2.8 Conditions should also be reviewed where complaint is attributable to the operation of the process and is, in the opinion of the regulator, justified.

Specific industrial emissions Directive requirements

- 2.9 Since 31st October 2007 the full requirements of the solvent emissions Directive applied and have been continued in the industrial emissions Directive. All requirements, as set out in the SE boxes below and in **Section 4**, ought to have been complied with by that date.

SE Box 1 - New VOC abatement plant

No longer needed under the industrial emissions Directive.

SE Box 2 - New installations

No longer needed under the industrial emissions Directive.

SE Box 3A - Substantial change to all installations (Article 3(9) and 63)

'Substantial change' means a change in the nature or functioning, or an extension, of an installation which may have significant negative effects on human health or the environment.

Re-verify compliance: following a substantial change, compliance must be re-verified.

SE Box 3B - Substantial change to existing installations

'Existing installation' means an installation in operation on 29 March 1999 or which was granted a permit before 1 April 2001 or the operator of which submitted a complete application for a permit before 1 April 2001, provided that that installation was put in operation no later than 1 April 2002:

'Substantial change' additional meaning - a **change** of the maximum mass input of organic solvents by an **existing installation** averaged over 1 day, where the installation is operated at its design output under conditions other than start-up and shut-down operations and maintenance of equipment, shall be considered as **substantial** if it leads to an increase of emissions of volatile organic compounds of more than:

- 10 % for pharmaceutical manufacturing solvent emission installations.

Change of limits: where an **existing installation** undergoes a **substantial change**, or falls within the scope of this Directive for the first time following a substantial change, that part of the installation which undergoes the substantial change shall be treated either as a new installation or as an existing installation, provided that the total emissions of the whole installation do not exceed those that would have resulted had the substantially changed part been treated as a new installation.

3. Activity description

Regulations

- 3.1 This note applies to LAPPC installations for the formulation and finishing of pharmaceutical products and tablet coating. The activities for regulation are listed in **Table 3.1**.

Table 3.1 - Regulations listing activities				
LAPPC	Solvent consumption of activity	England and Wales	Scotland	Northern Ireland
		EPR reference	PPC reference	PPC reference
Part A	More than 150kg/hr or more than 200 tonnes in any 12-month period	Schedule 1 section 6.4 Part A2	Schedule 1 section 6.4 Part A	Schedule 1 section 6.4 Part A
Solvent emission activity	Formulating / finishing: 50 tonnes or more in any 12-month period	Reg 2 EPR as amended in 2013 refers to industrial emissions Directive Annex VII Parts 1 and 2	Schedule 2	n/a
Part B	Coating: 5 tonnes or more in any 12-month period	Schedule 1 section 6.4 Part B	Schedule 1 section 6.4, Part B	
Solvent emission activity	Formulating / finishing: 50 tonnes or more in any 12-month period	n/a	n/a	Schedule 1 section 7
Part C	Coating: 5 tonnes or more in any 12-month period			Section 6.4 Part C

The links are to the original version of the Regulations. A consolidated version is not available on www.legislation.gov.uk.

For England and Wales, an [unofficial consolidated version](#) is available, but read the first page of that document in order to understand its status and content

Installation

- 3.2 'Installation' means a stationary technical unit within which one or more activities listed in Part 1 of Annex VII are carried out, and any other directly associated activities on the same site which have a technical connection with the activities listed in those Annexes and which could have an effect on emissions and pollution.
- 3.3 The formulation and finishing of pharmaceuticals can be broken down into a number of stages:
- storage of ingredients;
 - sieving/milling of ingredients;
 - mixing and blending;
 - granulation (where required);
 - drying (where required);
 - tablet manufacture (pressing and coating);
 - production of liquid preparations ;
 - production of aerosol preparations;
 - packing of preparations.

Storage of ingredients

- 3.4 Raw materials are delivered in tankers, bags, drums, boxes or similar containers, on receipt of the raw materials are commonly transferred to standardised internal storage containers. Analysis of the raw materials is carried out on receipt.

Sieving/milling of ingredients

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

Mixing and blending

- 3.6 The ingredients are weighed in a dispensary before being transferred to the mixing and blending operations. Mixing/blending is carried out using propeller agitators for mobile liquids, turbine or paddle mixers for more viscous liquids and suspensions. Semi-solids are normally blended using 'Z' blade mixers, whilst powders are blended in ribbon blenders, tumbling mixers or high-speed mixers.

Granulation

- 3.7 Granulation is an agglomeration process and is a precursor to the majority of tablet compression processes and some encapsulation processes. The aim of granulation is to produce grains of the correct concentration of the active ingredient, and the desired physical properties for compression where required. Exhaust air from the granulation process is sometimes abated with scrubbers or other abatement plant.

Drying

- 3.8 Drying may be carried out using tray ovens, fluidized beds, vacuum driers, tumble driers, freeze driers or microwave or infrared techniques. Drying operations may give rise to large volume releases of solvents depending on the solvent involved and the operating conditions within the drier. Exhaust air from granulation process is sometimes abated with scrubbers, carbon adsorption with recovery or other abatement plant.

Tablet manufacture

- 3.9 Both pharmaceutical and non-pharmaceutical tablets are produced in a tablet press by direct compression of the blended materials or, the granulated dried mix. Tablet presses are a potential source of dust emission. However, normally a high degree of containment is used to prevent possible releases.
- 3.10 Press tablets may be coated with water or solvent based coatings to add physical strength, or delay the break-up of the tablet once consumed. Modern tablet coaters are closed rotating drums in which the tablets are suspended in a hot-air fluidized bed. The hot air dries the atomised coating as it is sprayed onto the tablet. Potential pollutants include dust and, where solvent-based coatings are used, VOC. Some solvent based coating operations use chlorinated organic solvents such as dichloromethane. Exhaust air from granulation processes is sometimes abated with scrubbers, carbon adsorption with recovery or other abatement plant.

Production of liquid preparations

- 3.11 Once the ingredients for a liquid product have been mixed they are dispensed into bottles etc. on a filling line. Emissions may occur during the filling process and the exhaust air is sometimes abated, with scrubbers or other abatement plant.

Production of aerosol preparations

- 3.12 Aerosols are filled, capped, tested and weighed in specialised equipment. The cans and O-rings are fed into the assembly unit through hoppers, and the rings are placed around the neck of the cans. 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.

Packing of preparations

- 3.13 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.

Figure 3.1 - VOC releases from a typical granulation process

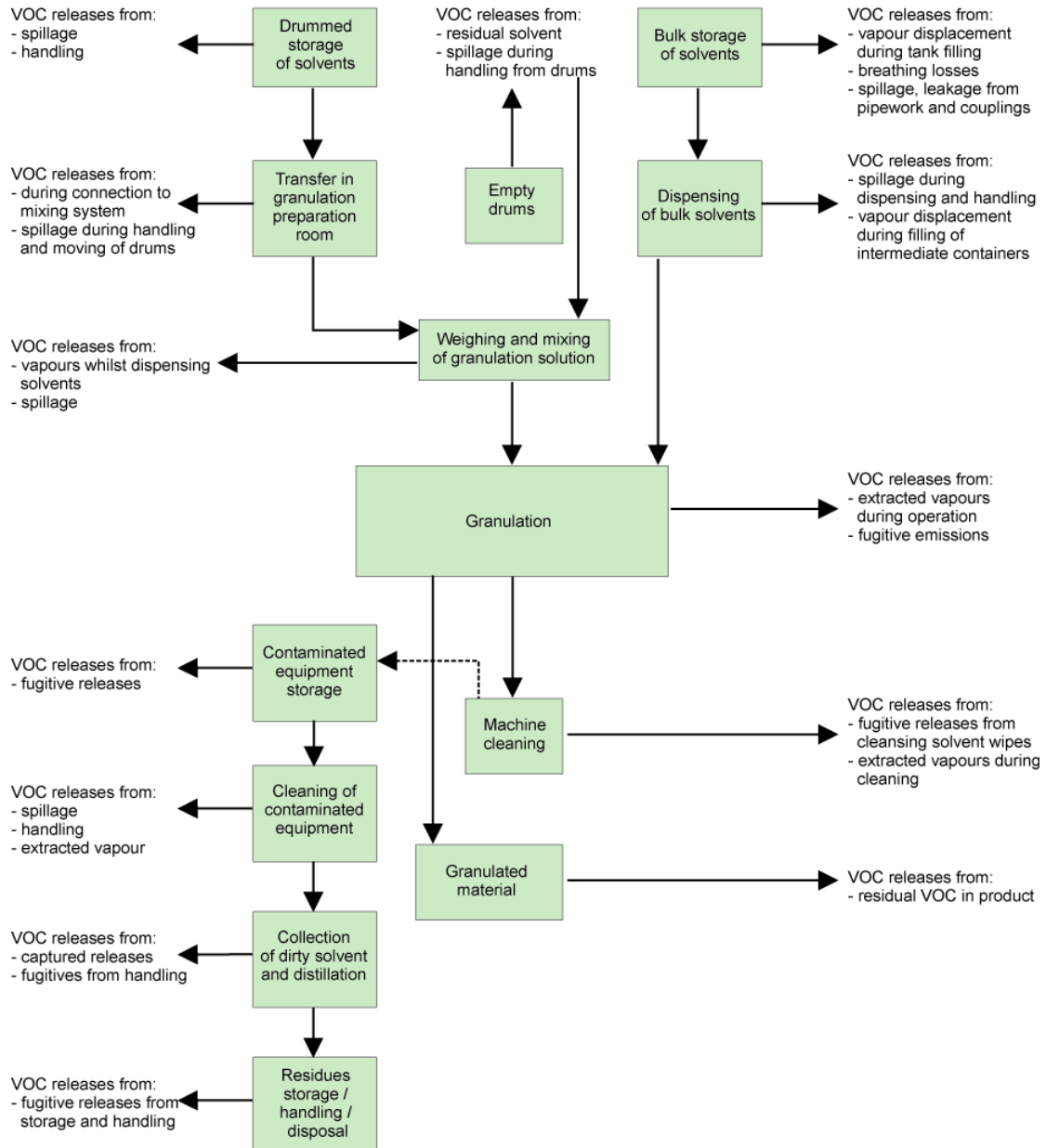


Figure 3.2 - VOC releases from a typical aerosol manufacturing process

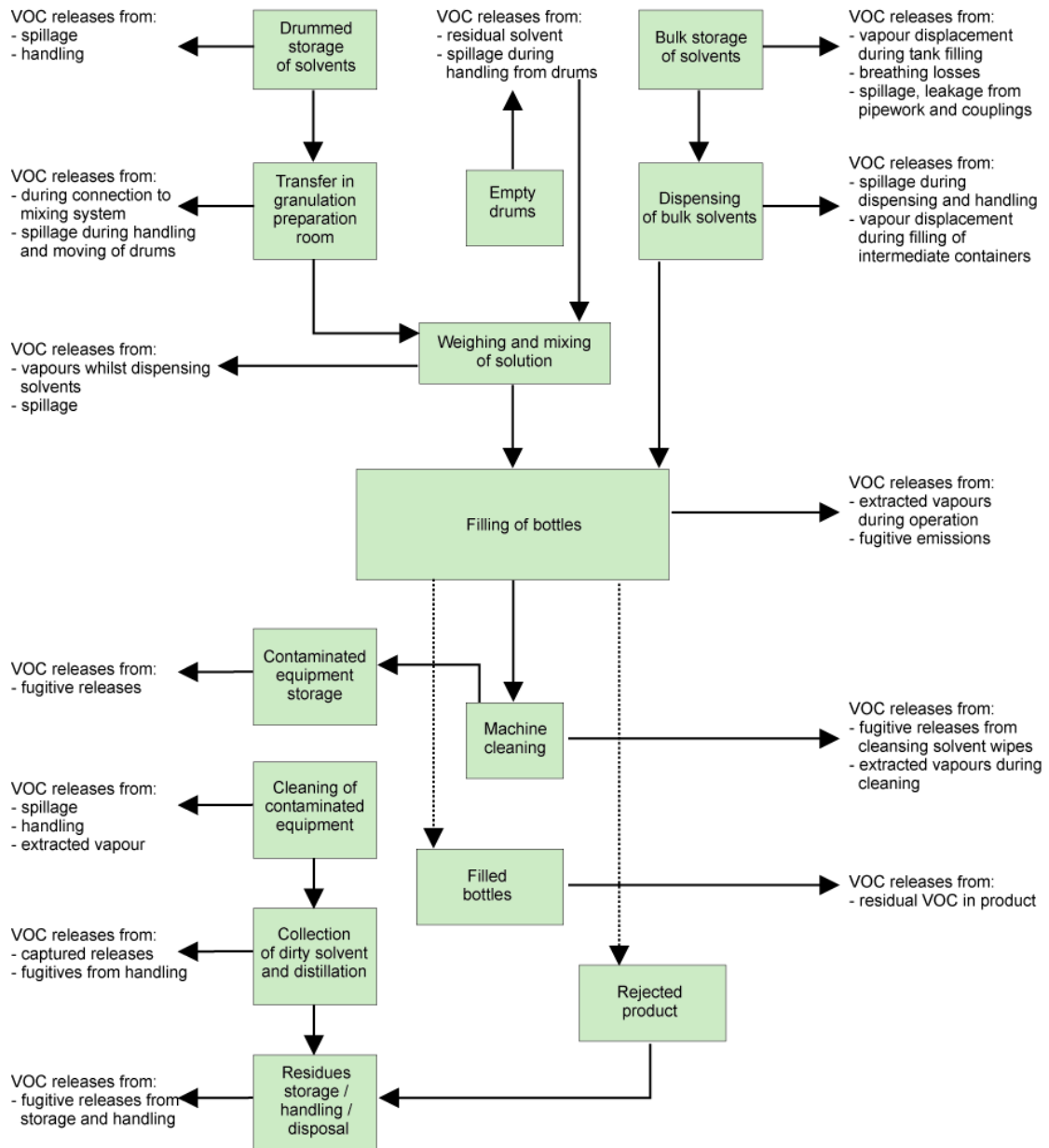


Figure 3.3 - VOC releases from a typical metered dose inhaler (MDI) manufacturing process

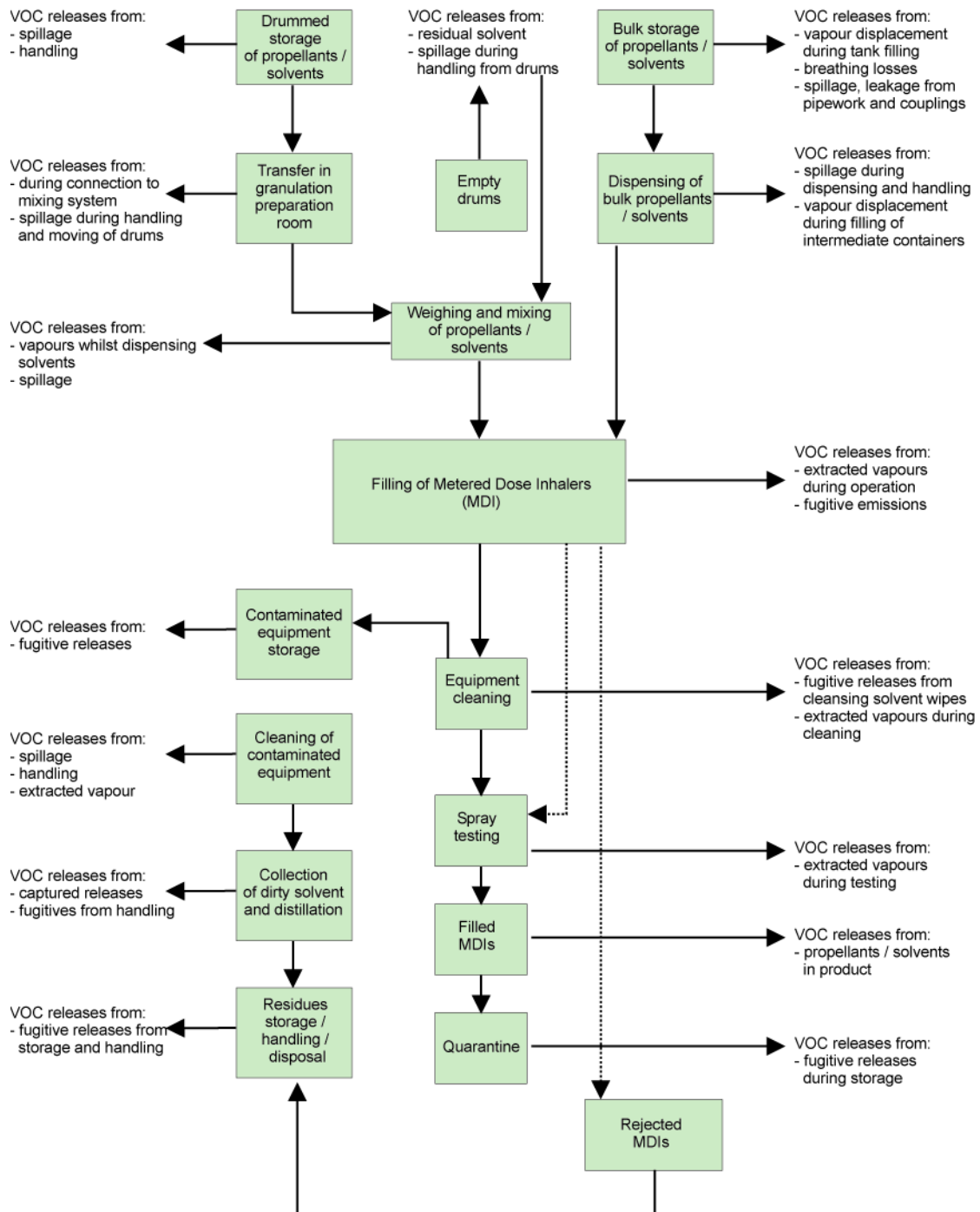
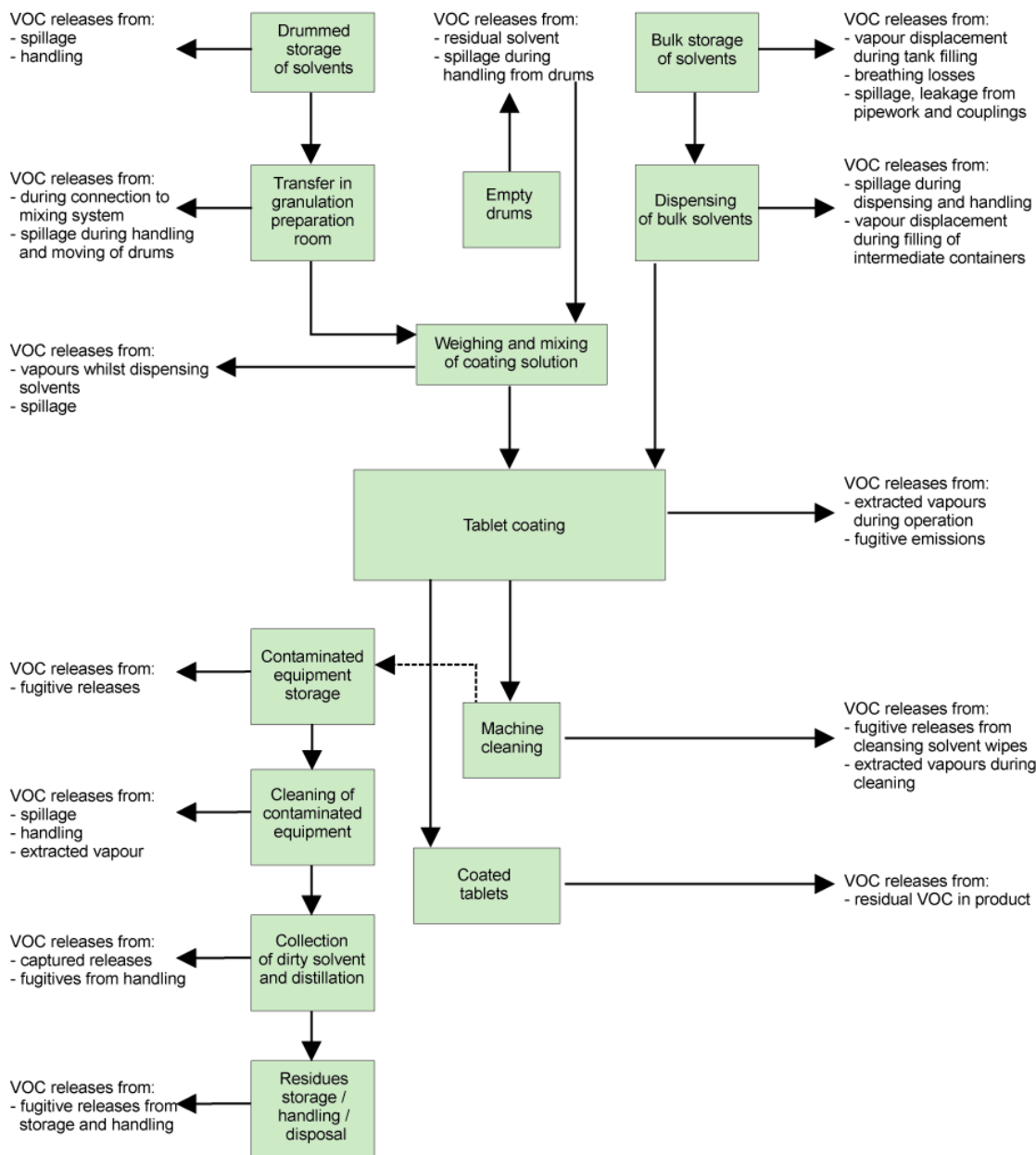


Figure 3.4 - VOC releases from a typical tablet manufacturing process



4. Emission limits, monitoring and other provisions

- 4.1 Emissions of the substances listed the Tables and SE boxes below should be controlled.
- 4.2 Guidance on techniques to achieve compliance with the industrial emissions Directive and BAT limit values and provisions is in **Section 5**. Monitoring of emissions should be carried out according to the method specified in this section or by an equivalent method agreed by the regulator. The latest information regarding the monitoring standards applicable can be found at the [Source Testing Association website](#). Further information on monitoring can be found in Environment Agency publications, [M1 and M2](#).
- 4.3 All activities should comply with the emission limits and provisions with regard to non-VOC releases in **Table 4.1**.

Table 4.1 and SE boxes 5 and 7 should be considered in conjunction with the monitoring paragraphs found later in this section.

The reference conditions for limits in **Section 4** are: 273.1K, 101.3kPa, without correction for water vapour content, unless stated otherwise.

Table 4.1 - Emission limits, monitoring and other provisions for non-VOC releases

	Substance	Source	Emission limits/provisions	Type of monitoring	Monitoring frequency
1	Carbon Monoxide	Oxidation plant	100 mg/Nm ³ as a 15-minute mean for contained sources	Catalytic oxidiser Monitoring and recording PLUS Manual extractive testing	Continuous PLUS Annual
		From turbines, reciprocating engines or boilers used as VOC abatement equipment.	500 mg/Nm ³ at 5% oxygen dry gas, as 15-minute mean for contained sources.	All other types of abatement: Manual extractive testing	Annual
2	Particulate matter	All processes / activities	50 mg/Nm ³ as 15-minute mean for contained sources	Manual extractive testing	Annual
3	Oxides of Nitrogen (measured as nitrogen dioxide)	Oxidation plant	100mg/Nm ³ as a 15-minute mean for contained sources.	Manual extractive testing	Annual
		From turbines, reciprocating engines or boilers used as VOC abatement equipment.	500 mg/Nm ³ as 15-minute mean for contained sources		
4	Sulphur dioxide	All activities using heavy fuel oil or other residual type /comparable Quality Protocol Processed Fuel Oil	1% wt/wt sulphur in fuel	Sulphur content of fuel is regulated under the Sulphur Content of Liquid Fuels Regulations	
		All activities using gas oil / comparable Quality Protocol Processed Fuel Oil	0.1% wt/wt sulphur in fuel		

Table 4.2 - Emission limits, monitoring and other provisions for non-Directive activity VOC releases

	VOC	Emission limits/provisions	Type of monitoring	Monitoring frequency
1	All processes/ activities Solvent consumption of 5 tonnes or more Where the mass emission of VOC from any individual source is greater than 1kg in any 8 hour period.	VOC expressed as total carbon excluding particulate matter	Abated releases: Monitoring and recording	Abated releases: Continuous
	Waste gases from oxidation plant	50 mg/Nm ³ as a 15-minute mean for contained sources	Plus Manual extractive testing	Plus Annual
	Any other waste gases	150 mg/Nm ³ as a 15-minute mean for contained sources		
2	All processes/ activities Solvent consumption of 15 tonnes or more Where the mass emission of VOC from any individual source is greater than 1kg in any 8 hour period	VOC expressed as total carbon excluding particulate matter	Non-abated releases: Manual extractive testing	Non-abated releases: Annual
	Waste gases from oxidation plant	50 mg/Nm ³ as a 15-minute mean for contained sources		
3	Non-methane VOC From turbines reciprocating engines or boilers used as VOC abatement equipment.	VOC expressed as total carbon excluding particulate matter. 150mg/Nm ³ as 15-minute mean for contained sources		

4	Total emission limit		
	All processes/activities The emission limits in Rows 1, 2 and 3 above, do not apply if the Total Emissions Limit requirements, below, are met.		
	VOC in waste gases	Total emission limit values/requirements	Monitoring
			Unabated releases Abated releases
Existing processes	15% of solvent input	manual extractive testing	Continuous monitoring and recording PLUS manual extractive testing
New and substantially changed processes	5% of solvent input		
<p>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 = O₁ + 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) = I₁ + I₂ Compliance with the total emission limit value is achieved if: $\frac{\text{Total emission}}{\text{Organic solvent input}} \times 100$ is equal to or less than the Total emission limit value</p>			
Note 1: The fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container.			

4.4 For VOC compliance, the Directive gives three compliance options (not all options are available to all activities and Option c (below) is **not** available to activities covered by this note).

SE Box 4 - VOC compliance (Articles 7, 8, 58, 59)

All activities

All installations must comply with the provisions of SE Box 7.

All installations must then comply with either:

- a) the emission limit in waste gases and the fugitive emission limit in SE Box 5; or
- b) the requirements of the total emission limit values in SE Box 6; or
- c) the requirements of the reduction scheme, paragraph 4.5.

All installations must report on compliance and the regulator requests the information needed. See paragraph 4.7 for consumption and for the solvent management plan, see paragraph 4.8.

For compliance with emission, fugitive and total limits, the regulator determines the frequency of monitoring. See the monitoring requirements alongside SE boxes 5, 6 & 7 and paragraph 4.25 on varying monitoring frequency.

If compliance is breached, it should be restored within the shortest possible time (see also paragraphs 4.11 and 4.15).

For accidents and incidents significantly affecting the environment, paragraphs 4.11 and 4.15 apply. In addition, further possible incidents or accidents should be prevented.

SE Box 5 - Waste gas and fugitive emission limits and requirements (Article 59 and Annex VII, Parts 2 & 3)			
For all activities using the waste gas and fugitive emission limits and requirements			
Row	VOC in waste gases	Emission limits / requirement	Fugitive emission values
	Pharmaceutical formulation and finishing installations Solvent consumption 50 tonnes or more in any 12 month period	VOC expressed as total mass of organic carbon	Existing activities: 15% of organic solvent input
	Waste gases from any techniques which allows the reuse of the recovered solvent	150mg C/Nm ³	New and substantially changed activities: 5% of organic solvent input
	Any other waste gases	20mg C/Nm ³	
<p>Note 1 - operators who were permitted to use an emission figure of 150mg/Nm³ until 1 April 2013 may find that using the total emission limit is the best way of achieving compliance thereafter.</p> <p>Note 2 – the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container.</p>			

Monitoring
<p>Abated releases: Continuous monitoring and recording</p> <p>PLUS Manual extractive testing</p> <p>Non-abated releases: Manual extractive testing</p>

SE Box 6 - All activities using the total emission limit values (Article 59, Annex VII, Parts 2, 3 & 4)

Row	VOC in waste gases	Total emission limit values / requirements
1	Existing installations	15% of organic solvent input
2	New and substantially changed installations	5% of organic solvent input

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

$$\text{Total emission} = O_1 + \text{Fugitive}$$

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 input into the process as determined as part of the solvent management plan.

$$\text{Organic solvent input (I)} = I_1 + I_2$$

Compliance with the total emission limit value is achieved if:

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

Note 1 - the fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container.

Monitoring

Abated releases:

Continuous monitoring and recording

PLUS

Manual extractive testing

Unabated releases:

Manual extractive testing

Solvent reduction scheme

- 4.5 Solvent reduction scheme is not a valid route to compliance for this sector.

Determination of solvent consumption

- 4.6 Construction of inventories of materials consumed and disposed of may involve the identification of individual organic solvents, or solids. This may give rise to an issue of commercial confidentiality. Information supplied must be placed on the public register, unless exclusion has been granted on the grounds of commercial confidentiality or national security. Further information can be found in the appropriate chapter of the relevant General Guidance Manual.
- 4.7 A determination of the organic solvent consumption, the total mass of organic solvent Inputs minus any solvents sent for reuse/recovery off-site, should be made and submitted to the regulator annually, preferably to coincide with the operators stocktaking requirements. This should be in the form of a mass balance in order to determine the annual actual consumption of organic solvent (C):

Where: $C = I_1 - O_8$ (See Definitions, paragraph 4.9).

Solvent management plan

- 4.8 Operators buy solvents to replace those lost during the process or included in the product. There are both environmental and cost savings from reducing the losses. The industrial emissions Directive requires a solvent management plan to demonstrate compliance with fugitive emission limits (SE Box 5), and give the public access to information about solvent consumption etc.
- 4.9 The industrial emissions Directive provides guidance on what constitutes a solvent input and an output. This can be described more simply as needing data on:

Inputs:

How much solvent is:

- bought, whether in pure form or contained in products;
- recycled back into the process.

Outputs:

How much solvent is:

- emitted to air, whether directly or via abatement equipment;
- discharged to water, whether directly or via water treatment;
- sent away in waste;
- lost by spills, leaks etc;
- leaving the installation in the product.

The definitions in Annex VII, Part 7 of the industrial emissions Directive are as follows and are shown diagrammatically in Figure 4.1.

Inputs of organic solvent in the time frame over which the mass balance is being calculated (**I**)

I₁ 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).

I₂ 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**)

O₁ Emissions in waste gases.

O₂ Organic solvents lost in water, if appropriate taking into account waste water treatment when calculating O₅.

O₃ The quantity of organic solvents which remains as contamination or residue in products output from the process/activity. The fugitive emission limit value does not include solvent sold as part of products or mixtures in a sealed container.

O₄ 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.

O5 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 O₆, O₇ or O₈).

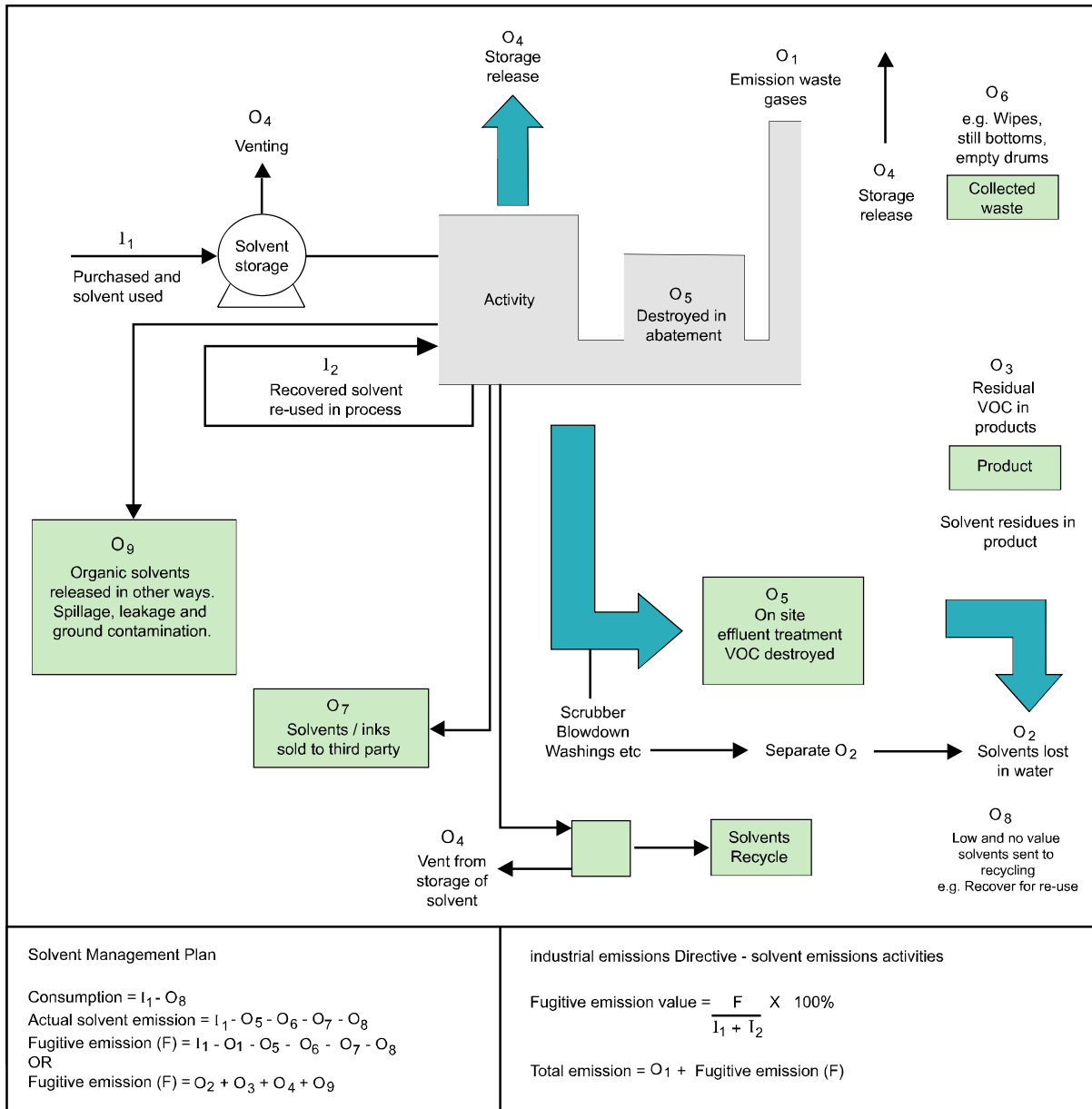
O6 Organic solvents contained in collected waste.

O7 Organic solvents, or organic solvents contained in mixtures, which are sold or are intended to be sold as a commercially valuable product.

O8 Organic solvents contained in mixtures recovered for reuse but not as input into the process/activity, as long as not counted under O₇.

O9 Organic solvents released in other ways.

Figure 4.1 - Solvent management plan inputs and outputs



SE Box 7 - industrial emissions Directive requirements for designated materials

(Articles 58, 59, 80(7))

All activities using designated materials

Designated materials used in industrial emissions Directive installations must be either replaced, or controlled contained and limited, as set out below.

All Directive installations

1. Materials designated because of their VOC content:

- hazard statement H340, H350, H350i, H360D, or H360F
- until 1 Jun 2015: risk phrases R45, R46, R49, R60, or R61

Requirements:

Replace as far as possible (Taking into account guidance under Article 64 of the industrial emissions Directive. See note 3 and Appendix 1) by less harmful substances or mixtures.

Timescale:

Installations must comply within the shortest possible time

Control under **contained** conditions as far as technically and economically feasible to safeguard public health and the environment, normally, in accordance with the guidance provided within Section 5 of the note.

Timescale:

Immediately (and see note 1 below)

Limit - where the sum of the mass flows of all the discharges of all the compounds causing the designated labelling is greater or equal to 10g/h, a limit value of 2mg/Nm³ for the mass sum of the individual compounds must apply.

Monitoring:

Manual extractive testing

2. Materials designated because of their halogenated VOC content:

- hazard statements H341 or H351
- until 1 Jun 2015 : risk phrases R40, or R68

Requirements:

Control under **contained** conditions as far as technically and economically feasible to safeguard public health and the environment, normally, in accordance with the guidance provided within Section 5 of the note.

Timescale:

Immediately (and see note 1 below)

Limit - where the sum of the mass flows of all the discharges of all the compounds causing the designated labelling is greater or equal to 100g/h, a limit value of 20mg/Nm³ for the mass sum of the individual compounds must apply.

Monitoring:

Manual extractive testing

Note 1 - substances or mixtures which are classified after the date of publication of this note as designated materials because of their VOC content, must apply the replace, control and limit requirements above within the shortest possible time from the date at which substances or mixtures became/become designated materials.

In determining the 'shortest possible time', the operator will need to justify their timetables taking account of the guidance in the relevant chapter of the appropriate Guidance Manual.

Note 2 - until 1 June 2015 'hazard statement' materials will, broadly, also be known as 'risk phrase' materials. After 1st June 2015, only the term 'hazard statement' materials will apply; see Section 7 for further details.

Note 3 - the European Commission have published information on [substituting and containing designated solvents](#)

Monitoring, investigating and reporting

4.10 The operator should monitor emissions, make tests and inspections of the activity. The need for and scope of testing (including the frequency and time of sampling) will depend on local circumstances.

- The operator should keep records of inspections, tests and monitoring, including all non-continuous monitoring, inspections and visual assessments. Records should be:
 - kept on site;
 - kept by the operator for at least two years; **and**
 - made available for the regulator to examine.
- If any records are kept off-site they should be made available for inspection within one working week of any request by the regulator.

Information required by the regulator

4.11 As well as being sent information to show compliance with solvent limits, the regulator needs to be informed of monitoring to be carried out and the results. The results should include process conditions at the time of monitoring.

- The operator should notify the regulator at least 7 days before any periodic monitoring exercise to determine compliance with emission limit values. The operator should state the provisional time and date of monitoring, pollutants to be tested and the methods to be used.
- The results of non-continuous emission testing should be forwarded to the regulator within 8 weeks of completion of the sampling.
- Adverse results from any monitoring activity (both continuous and non-continuous) should be investigated by the operator as soon as the monitoring data has been obtained. The operator should:
 - identify the cause and take corrective action;
 - clearly record as much detail as possible regarding the cause and extent of the problem, and the remedial action taken;
 - re-test to demonstrate compliance as soon as possible; **and** inform the regulator of the steps taken and the re-test results.

Visible emissions

- 4.12 The aim should be to prevent any visible airborne emission from any part of the process. This aim includes all sites regardless of location. Monitoring to identify the origin of a visible emission should be undertaken and a variety of indicative techniques are available.
- where ambient monitoring is carried out it may also be appropriate for the regulator to specify recording of wind direction and strength;
 - where combustion units are in use for dryers then the combustion process should be controlled and equipment maintained as appropriate.
- 4.13 Emissions from combustion processes in normal operation should be free from visible smoke. During start up and shut down the emissions should not exceed the equivalent of Ringelmann Shade 1 as described in British Standard BS 2742.
- All other releases to air, other than condensed water vapour, should be free from persistent visible emissions.
 - All emissions to air should be free from droplets.

Where there are problems that, in the opinion of the regulator, may be attributable to the installation, such as local complaints of visual emissions or where dust from the installation is being detected beyond the site boundary, the operator should investigate in order to find out which part of their operation(s) is the cause.

If this inspection does not lead to correction of the problem then the operator should inform the regulator who will determine whether ambient air monitoring is necessary. Ambient monitoring may either be by a British Standard method or by a method agreed with the regulator.

Whilst problems are ongoing, a visual check should also be made at least once per day/shift, by the operator, when an installation is being operated. The time, location and result of these checks, along with weather conditions such as indicative wind direction and strength, should be recorded. Once the source of the emission is known, corrective action should be taken without delay and where appropriate the regulator may want to vary the permit in order to add a condition requiring the particular measure(s) to be undertaken.

Emissions of odour

- 4.14 The overall aim should be that all emissions are free from offensive odour outside the site boundary, as perceived by the regulator. However, the location of the installation will influence the assessment of the potential for odour impact as local meteorological conditions may lead to poor dispersion conditions. Where the site has a low odour impact due to its remoteness from sensitive receptors, the escape of offensive odour beyond the installation would be unlikely to cause harm.

Where there are problems that, in the opinion of the regulator, may be attributable to the installation, such as local complaints of odour or where odour from the installation is being detected beyond the site boundary, the operator should investigate in order to find out which part of their operation(s) is the cause.

Whilst problems are ongoing, a boundary check should also be made at least once per day/shift, by the operator, when an installation is being operated. The time, location and result of these checks, along with weather conditions such as indicative wind direction and strength, should be recorded. Once the source of the emission is known, corrective action should be taken without delay and where appropriate the regulator may want to vary the permit in order to add a condition requiring the particular measure(s) to be undertaken.

Abnormal events

- 4.15 The operator should respond to problems which may have an adverse effect on emissions to air.
- In the case of abnormal emissions, malfunction or breakdown leading to abnormal emissions the operator should:
 - investigate and undertake remedial action immediately;
 - adjust the process or activity to minimise those emissions; **and**
 - promptly record the events and actions taken.
 - The regulator should be informed without delay, whether or not there is related monitoring showing an adverse result:
 - if there is an emission that is likely to have an effect on the local community; **or**
 - in the event of the failure of key arrestment plant, for example, bag filtration plant or scrubber units.
 - The operator should provide a list of key arrestment plant and should have a written procedure for dealing with its failure, in order to minimise any adverse effects.

SE Box 8 - Non-compliance causing immediate danger (Articles 7 and 8)

All activities

In cases of non-compliance causing immediate danger to human health, or threatening to cause an immediate significant adverse affect upon the environment, operation of the activity must be suspended.

All of following criteria should be taken into account:

- the toxicity of the substances being released;
- the amount released;
- the location of the installation; **and**
- the sensitivity of the receptors.

Continuous monitoring

4.16 Continuous monitoring can be either 'quantitative' or 'indicative'. With quantitative monitoring the discharge of the pollutant(s) of concern is measured and recorded numerically. For pollution control this measurement is normally expressed in milligrams per cubic metre of air (mg/m^3). Where discharge of the pollutant concerned is controlled by measuring an alternative parameter (the 'surrogate' measurement), this surrogate is also expressed numerically.

Continuous indicative monitoring is where a permanent device is fitted, for example, to detect leaks in a bag filter, but the output, whether expressed numerically or not, does not show the true value of the discharge. When connected to a continuous recorder it will show that emissions are gradually (or rapidly) increasing, and therefore maintenance is required. Alternatively it can trigger an alarm when there is a sudden increase in emissions, such as when arrestment plant has failed.

4.17 Where continuous indicative monitoring has been specified, the information provided should be used as a management tool. Where used, the monitor should be set up to provide a baseline output when the plant is known to be operating under the best possible conditions and emissions are complying with the requirements of the permit. Where used to trigger alarms, the instrument manufacturer should be able to set an output level which corresponds to around 75% of the emission limit. Thus the alarms are activated in response to this significant increase in pollutant loading above the baseline, so that warning of the changed state is given before an unacceptable emission occurs. The regulator may wish to agree the alarm trigger level.

4.18 Where continuous monitoring is required, it should be carried out as follows:

- All continuous monitoring readings should be on display to appropriately trained operating staff.
- Instruments should be fitted with audible and visual alarms, situated appropriately to warn the operator of arrestment plant failure or malfunction.
- The activation of alarms should be automatically recorded.
- All continuous monitors should be operated, maintained and calibrated (or referenced, in the case of indicative monitors) in accordance with the manufacturers' instructions, which should be made available for inspection by the regulator.
- The relevant maintenance and calibration (or referencing, in the case of indicative monitors) should be recorded.
- Emission concentrations may be reported as zero when the plant is off and there is no flow from the stack. If required a competent person should confirm that zero is more appropriate than the measured stack concentration if there is no flow.
- Any continuous monitor used should provide reliable data >95% of the operating time, (i.e. availability >95%). A manual or automatic procedure should be in place to detect instrument malfunction and to monitor instrument availability.

Calibration and compliance monitoring

4.19 Compliance monitoring can be carried out either by use of a continuous emissions monitor (CEM), or by a specific extractive test carried out at a frequency agreed with the regulator.

4.20 Where a CEM is used for compliance purposes it must be periodically checked, (calibrated), to ensure the readings being reported are correct. This calibration is normally done by carrying out a parallel stand-alone extractive test and comparing the results with those provided by the CEM.

4.21 For extractive testing the sampling should meet the following requirements:

- For batch processes, where the production operation is complete within, say, 2 hours, then the extractive sampling should take place over a complete cycle of the activity.

4.22 Should the activity either be continuous, or have a batch cycle that is not compatible with the time available for sampling, then the data required should be obtained over a minimum period of 2 hours in total.

- For demonstration of compliance where a CEM is used no daily mean of all 15-minute mean emission concentrations should exceed the specified emission concentration limits during normal operation (excluding start-up and shut-down); **and**
- No 15-minute mean emission concentration should exceed twice the specified emission concentration limits during normal operation (excluding start-up and shut-down).
- For extractive testing, no result of monitoring should exceed the emission limit concentrations specified.

4.23 Exhaust flow rates should be consistent with efficient capture of emissions, good operating practice and meeting the requirements of the legislation relating to the workplace environment.

- The introduction of dilution air to achieve emission concentration limits should not be permitted.

Dilution air may be added for waste gas cooling or improved dispersion where this is shown to be necessary because of the operational requirements of the plant, but this additional air should be discounted when determining the mass concentration of the pollutant in the waste gases.

Continuous monitoring of VOC abated releases

4.24 These paragraphs also apply where continuous monitoring and recording is required to demonstrate compliance with the VOC requirements of the note. For existing VOC abatement equipment surrogate measurements for VOC are acceptable. Where new VOC abatement equipment is installed, or existing VOC abatement equipment is modified or the operating conditions are changed, VOC monitoring should be carried out once more to demonstrate that the surrogate measurements are adequate to ensure compliance.

Thermal oxidisers must have continuous monitoring and recording for VOC expressed as total carbon excluding particulate matter. After sufficient monitoring data has been collected to clearly demonstrate adequate VOC destruction continuous monitoring of temperature may be used as a surrogate measurement.

Catalytic oxidisers must have continuous monitoring and recording for VOC expressed as total carbon excluding particulate matter. After sufficient monitoring data has been collected to clearly demonstrate adequate VOC destruction continuous monitoring of carbon monoxide and temperature may be used as a surrogate measurement. (It may be possible to waive the requirement for carbon monoxide monitoring, if the operator can demonstrate to the regulator that the catalytic oxidiser is designed in such a way that it cannot exceed the carbon monoxide limit (see Non VOC Emission Limits)).

Bio scrubbers and reactors must have continuous monitoring and recording for VOC expressed as total carbon excluding particulate matter. After sufficient monitoring data has been collected to clearly demonstrate adequate VOC destruction continuous monitoring of the flow and pH of the re-circulating water, fan suction, exhaust temperature and pressure drop across the packing, coupled with daily monitoring of the nutrient may be used as a surrogate measurement.

Turbines, reciprocating engines, boilers or any other form of VOC abatement equipment must have continuous monitoring and recording for VOC expressed as total carbon excluding particulate matter.

SE Box 9 - VOC monitoring (Articles 60 and 61)

All activities using

- **emission and fugitive limits; or**
- **total emission limit values with abatement**

For periodic measurements of VOC at least three readings must be obtained during each measurement exercise.

VOC emission limit values shall be considered to be complied with if, in one monitoring exercise:

- a) the average of all the readings does not exceed the emission limit values, and
- b) none of the hourly averages exceeds the emission limit value by more than a factor of 1.5*.

Where continuous monitoring is carried out to demonstrate compliance with VOC emission limits:

- c) none of the averages over 24 hours of normal operation exceeds the emission limit values, and
- d) none of the hourly averages exceeds the emission limit values by more than a factor of 1.5.*

*the hourly average of the 30-minute means value may be used to demonstrate compliance.

Where monitoring does not meet the requirements of a) or b), then no result should exceed the emission concentration limits specified.

Compliance by dilution is not permitted – see paragraph 4.23

Varying of monitoring frequency

- 4.25 Where non-continuous quantitative monitoring is required, the frequency may be varied. Where there is consistent compliance with emission limits, regulators may consider reducing the frequency. However, any significant process changes that might have affected the monitored emission should be taken into account in making the decision.
- 4.26 The following should be considered when deciding whether compliance is consistent:
- a) the variability of monitoring results, for example, results which range from 15 - 45 mg/m³, against an emission limit of 50 mg/m³ might not qualify for a reduction in monitoring.
 - b) the margin between the results and the emission limit, for example, results which range from 45 - 50 mg/m³ when the limit is 50 mg/m³ might not qualify for a reduction in monitoring.

Consistent compliance should be demonstrated using the results from at least;

- three or more consecutive annual monitoring campaigns; or
- two or more consecutive annual monitoring campaigns supported by continuous monitoring.

Where a new or substantially changed process is being commissioned, or where emission levels are near to or approach the emission concentration limits, regulators should consider increasing the frequency of testing.

- 4.27 A reduction in monitoring frequency should not be permitted where continuous quantitative or indicative monitoring is required. These types of monitoring are needed to demonstrate at all times when the plant is operating, that either the emission limits are being complied with or that the abatement equipment is functioning correctly.

Monitoring of unabated releases

- 4.28 Where emission limit values are consistently met without the use of abatement equipment, the monitoring requirement for those pollutants should be dispensed with subject to the 'Varying of monitoring frequency' paragraphs above.

Where monitoring is not in accordance with the main procedural requirements of the relevant standard, deviations should be reported.

Representative sampling

4.29 Whether sampling on a continuous or non-continuous basis, care is needed in the design and location of sampling systems, in order to obtain representative samples for all release points.

- Sampling points on new plant should be designed to comply with the British or equivalent standards (see paragraph 4.2).
- The operator should ensure that relevant stacks or ducts are fitted with facilities for sampling which allow compliance with the sampling standards.

SE Box 10 - All Installations with two or more activities (Article 59(6))

Installations with two or more activities

Installations where two or more of the activities in Annex VII, Part 1 of the industrial emissions Directive are carried out, each of which exceeds the threshold in Annex VII, Part 2 of the industrial emissions Directive, must:

- (1) as regards to designated hazard statement materials, meet the requirements specified in SE Box 7, for each activity individually;
- (2) as regards all other substances, either:
 - (i) meet the requirements for each activity individually; **or**
 - (ii) have total emissions not exceeding those that would have resulted had point (i) been applied.

When applying 2 (ii) above, the solvent management plan should be completed to determine total emissions from all activities concerned. That figure must then be compared with the total emissions from the installation that would have resulted had the requirements of Annex VII, Part 2 of the industrial emissions Directive been met for each activity separately.

Start up and shutdown

4.30 Higher emissions may occur during start-up and shut-down of a process. These emissions can be reduced, by minimising, where possible, the number of start-ups and shut-downs and having adequate procedures in place for start-up, shut-down and emergency shut-downs.

- The number of start-ups and shut downs should be kept to the minimum that is reasonably practicable.

SE Box 11 - Start-up and shut-down (Article 59(7))

All appropriate precautions shall be taken to minimise emissions during start-up and shut-down.

5. Control techniques

Summary of best available techniques

- 5.1 **Table 5.1** provides a summary of the best available techniques that can be used to control the process in order to meet the emission limits and provisions in **Section 4**. Provided that it is demonstrated to the satisfaction of the regulator that an equivalent level of control will be achieved, then other techniques may be used.

Table 5.1 - Summary of control techniques

Release source	Substance	Control techniques
Storage and handling of organic solvents and materials containing organic solvents	VOC	Use of low organic solvent materials
		Use of low volatility organic solvent materials
		Use of enclosed mixing and storage vessels
		Siting of storage tanks, Back venting deliveries if needed
		Capture; or Capture and disposal; or Capture and destruction
Handling and storage of dusty materials	Particulate matter	Particulate capture if required
Flue Gas	Sulphur oxides	Limit sulphur in fuel
	Nitrogen oxides	Low NOx burners

Non-VOC releases control techniques

Particulate matter

- 5.2 Emissions of particulate matter should be abated if necessary to meet the emission limit.

Sulphur dioxide

- 5.3 In combustion processes the most significant release of sulphur dioxide occurs as a result of the sulphur content of the fuel burnt and should be addressed by using low sulphur fuel as specified in **Table 4.1**.

Nitrogen oxides

- 5.4 In combustion processes nitrogen oxides can be formed as a result of the combustion of nitrogen in the fuel or the formation of thermal nitrogen oxides from nitrogen in the air used for combustion.
- Where necessary, the nitrogen content of the fuel and other material being burnt should be controlled.
 - Where necessary, low NO_x burners should be installed.

VOC control techniques

VOC and odour control storage

- 5.5 Odour may arise from the receipt, handling and storage of organic solvents and organic solvent containing liquids. Careful siting of storage and mixing tanks, particularly in relation to new and replacement tanks, and controlled handling of odorous liquids may help prevent offensive emissions off-site. In addition:
- Bulk storage tanks for organic solvents and organic solvent-containing liquids should wherever practicable be back vented to the delivery tank during filling. Where this is impracticable, displaced air vents should be sited in such a way as to prevent the arising of offensive odour beyond the site boundary.
 - All potentially odorous waste materials should be stored in suitable closed containers or bulk storage vessels, where appropriate vented to suitable abatement plant.
- 5.6 Breathing losses from bulk storage tanks can be minimised by fitting pressure vacuum relief valves. The vapour pressure within the bulk storage can also be minimised by reducing the solar absorbency of the storage tank.
- The exterior of outdoor bulk storage tanks for organic solvent storage should normally be light coloured.
 - If necessary, emissions from fixed organic solvent storage tanks should be vented to suitable arrestment equipment to meet the emission limits in **Section 4**.
 - All new static bulk organic solvent storage tanks containing organic solvent with a composite vapour pressure that is likely to exceed 0.4kPa at 20°C (293K) should be fitted with pressure vacuum relief valves. Pressure vacuum relief valves should be examined at regular intervals for signs of contamination, incorrect seating and be cleaned and/or corrected as required. The normal minimum examination frequency should be once every six months, but less frequent examination may be justified having regard for the tank contents and the potential emissions as a result of valve failure.

5.7 Both major and minor spillage of organic solvent from bulk storage tanks can arise as a result of a number of scenarios such as: overfilling of tanks, incorrect draining of filling lines, operator error or vandalism.

- Delivery connections to bulk storage tanks should be located within a bunded area.
- Where the operator can not demonstrate to the satisfaction of the regulation that suitable management controls and training with regard to bulk storage deliveries of organic solvents and organic solvent containing materials are in place, along with adequate on-site security, then connections to bulk storage tanks should be fixed and locked when not in use.
- All fixed storage tanks should be fitted with high-level alarms or volume indicators to warn of overfilling. Where practicable the filling systems should be interlocked to the alarm system to prevent overfilling.
- Bunding should:
 - completely surround the bulk liquid storage tanks;
 - be impervious and resistant to the liquids in storage; **and**
 - be capable of holding 110% of the capacity of the largest storage tank.

In certain circumstances, the specification of bunds may be controlled by other regulations. A code of practice on the use and storage of solvents is available at <http://archive.defra.gov.uk/environment/quality/water/waterquality/ground/solvents.htm>

VOC control handling

5.8 The receipt, handling, use and storage of organic solvents and organic solvent containing liquids will give rise to fugitive releases of VOC.

- Raw materials containing VOC should be stored in closed storage containers.
- All measures should be taken to minimise VOC emissions during mixing, i.e. the use of covered or closed mixing vessels.
- Emissions from the emptying of mixing vessels and transfer of materials should be adequately contained, preferably by the use of closed transfer systems. This may be achieved by the use of closed mobile containers, containers with close-fitting lids, or, preferably, closed containers with pipeline delivery.

VOC control cleaning

5.9 Cleaning operations will give rise to fugitive releases of VOC.

- Cleaning operations involving organic solvents should be periodically reviewed, normally at least once every two years, to identify opportunities for reducing VOC emissions (e.g. cleaning steps that can be eliminated or alternative cleaning methods). The regulator should be provided with a report on the conclusions of the review.
- Dispensing of cleaning solvents should be:
 - in the case of fixed manufacturing equipment from a contained device or automatic system when applied directly;
 - dispensed by piston type dispenser or similar contained device, when used on wipes.
- When organic solvent is used on wipes:
 - pre-impregnated wipes should be held within an enclosed container prior to use;
 - where practicable no organic solvent cleaning fluids or significantly less volatile organic solvents cleaning fluids should be used (with or without the addition of mechanical, chemical or thermal enhancements).
- Where practicable, fixed equipment should be cleaned in-situ and such equipment should, where practicable, be kept enclosed whilst cleaning is carried out.
- Where equipment is cleaned off-line cleaning should be carried out using enclosed cleaning systems, wherever possible. Enclosed cleaning systems should be sealed to prevent emissions whilst in operation, except during purging at the end of the cleaning cycle. If this is not practicable emissions should be contained and vented to abatement plant where necessary.
- Residual coating materials contained in parts of the application equipment should be removed prior to cleaning.

VOC control operational

5.10 Organic solvent losses can be identified and minimised by operational controls and good operational practice.

- Programmable scales should be used during the mixing and preparation of coatings to reduce organic solvent usage.

- A programme to monitor and record the consumption of coatings/ organic solvent against product produced should be used to minimise the amount of excess organic solvent / coating used.

VOC control waste

5.11 Waste contaminated with VOC may give rise to both odorous and fugitive emissions.

- All reasonably practicable efforts should be made to minimise the amount of residual organic solvent bearing material left in drums and other containers after use. All organic solvent contaminated waste should be stored in closed containers.
- Prior to disposal, empty drums and containers contaminated with organic solvent should be closed to minimise emissions from residues during storage prior to disposal and labelled, so that all personnel who handle them are aware of their contents and hazardous properties.
- Nominally empty drums or drums containing waste contaminated with VOC awaiting disposal should be stored in accordance with the requirements for full or new containers.

General control techniques

Dust and spillage control

5.12 Adequate provision to contain liquid and solid spillage is needed. Closed containers can prevent wind whipping of dusty, dry waste materials such as materials collected during combustion chamber cleaning or arising from particulate abatement plant:

- Dusty wastes should be stored in closed containers and handled in a manner that avoids emissions.
- Dry sweeping of dusty materials should not normally be permitted unless there are environmental or health and safety risks in using alternative techniques.
- Suitable organic solvent containment and spillage equipment should be readily available in all organic solvent handling areas.
- A high standard of housekeeping should be maintained.

Air quality

Dispersion & dilution

- 5.13 Pollutants that are emitted via a stack require sufficient dispersion and dilution in the atmosphere to ensure that they ground at concentrations that are deemed harmless. This is the basis upon which stack heights are calculated using HMIP Technical Guidance Note (Dispersion) D1.
- 5.14 The stack height so obtained is adjusted to take into account local meteorological data, local topography, nearby emissions and the influence of plant structure. The calculation procedure of D1 is usually used to calculate the required stack height but alternative dispersion models may be used in agreement with the regulator. An operator may choose to meet tighter emission limits in order to reduce the required stack height.
- 5.15 Where an emission consists purely of air and particulate matter, (i.e. no products of combustion or any other gaseous pollutants are emitted) the above provisions relating to stack height calculation for the purpose of dispersion and dilution should not normally be applied. Revised stack height calculations should not be required as a result of publication of this revision of the PG note, unless it is considered necessary because of a breach or serious risk of breach of an EC Directive limit value or because it is clear from the detailed review and assessment work that the permitted process itself is a significant contributor to the problem.

Ambient air quality management

- 5.16 In areas where air quality standards or objectives are being breached or are in serious risk of breach and it is clear from the detailed review and assessment work under Local Air Quality Management that the permitted process itself is a significant contributor to the problem, it may be necessary to impose tighter emission limits. If the standard that is in danger of being exceeded is not an EC Directive requirement, then industry is not expected to go beyond BAT to meet it. Decisions should be taken in the context of a local authority's Local Air Quality Management action plan. For example, where a permitted process is only responsible to a very small extent for an air quality problem, the authority should not unduly penalise the operator of the process by requiring disproportionate emissions reductions. Paragraph 59 of the [Air Quality Strategy 2007 \[Volume 1\]](#) gives the following advice:

“...In drawing up action plans, local authority environmental health/pollution teams are expected to engage local authority officers across different departments, particularly, land-use and transport planners to ensure the actions are supported by all parts of the authority. In addition, engagement with the wider panorama of relevant stakeholders, including the public, is required to ensure action plans are fit-for-purpose in addressing air quality issues. It is vital that all those organisations, groups and individuals that have an impact upon local air quality, buy-in and work towards objectives of an adopted action plan.”

Stacks, vents and process exhausts

- 5.17 Liquid condensation on internal surfaces of stacks and exhaust ducts might lead to corrosion and ductwork failure or to droplet emission. Adequate insulation will minimise the cooling of waste gases and prevent liquid condensation by keeping the temperature of the exhaust gases above the dewpoint. A leak in a stack/vent and the associated ductwork, or a build up of material on the internal surfaces may affect dispersion:

Flues and ductwork should be cleaned to prevent accumulation of materials, as part of the routine maintenance programme.

When dispersion of pollutants discharged from the stack (or vent) is necessary, the target exit velocity should be 15m/s under normal operating conditions, however, lower velocities than 15m/s are acceptable provided adequate dispersion and dilution is achieved (see also the paragraph below regarding wet plumes). In order to ensure dispersion is not impaired by either low exit velocity at the point of discharge, or deflection of the discharge, a cap, or other restriction, should not be used at the stack exit. However, a cone may sometimes be useful to increase the exit velocity to achieve greater dispersion.

An exception to the previous paragraph is where wet arrestment is used as the abatement. Unacceptable emissions of droplets could occur from such plant where the linear velocity in the stack exceeds 9m/s.

To reduce the potential of droplet emissions a mist eliminator should be used. Where a linear velocity of 9m/s is exceeded in existing plant consideration should be given to reducing this velocity as far as practicable to ensure such droplet entrainment and fall out does not happen.

Management

Management techniques

- 5.18 Important elements for effective control of emissions include:
- proper management, supervision and training for process operations;
 - proper use of equipment;
 - effective preventative maintenance on all plant and equipment concerned with the control of emissions to the air; **and**
 - ensuring that spares and consumables - in particular, those subject to continual wear – are held on site, or available at short notice from guaranteed local suppliers, so that plant breakdowns can be rectified rapidly. This is important with respect to arrestment plant and other necessary environmental controls. It is useful to have an audited list of essential items.

Appropriate management systems

- 5.19 Effective management is central to environmental performance; it is an important component of BAT and of achieving compliance with permit conditions. It requires a commitment to establishing objectives, setting targets, measuring progress and revising the objectives according to results. This includes managing risks under normal operating conditions and in accidents and emergencies.

It is therefore desirable that installations put in place some form of structured environmental management approach, whether by adopting published standards (ISO 14001 or the EU Eco Management and Audit Scheme [EMAS]) or by setting up an environmental management system (EMS) tailored to the nature and size of the particular process. Operators may also find that an EMS will help identify business savings.

- 5.20 Regulators should use their discretion, in consultation with individual operators, in agreeing the appropriate level of environmental management. Simple systems which ensure that LAPPC considerations are taken account of in the day-to-day running of a process may well suffice, especially for small and medium-sized enterprises. Regulators are urged to encourage operators to have an EMS for all their activities, but it is outside the legal scope of an LAPPC permit to require an EMS for purposes other than LAPPC compliance. For further information/advice refer to the appropriate chapter of the appropriate Guidance Manual for [England and Wales](#), [Scotland](#) and [Northern Ireland](#).

Training

- 5.21 Staff at all levels need the necessary training and instruction in their duties relating to control of the process and emissions to air. In order to minimise risk of emissions, particular emphasis should be given to control procedures during start-up, shut down and abnormal conditions. Training may often sensibly be addressed in the EMS referred to above.
- All staff whose functions could impact on air emissions from the activity should receive appropriate training on those functions. This should include:
 - awareness of their responsibilities under the permit;
 - steps that are necessary to minimise emissions during start-up and shutdown;
 - actions to take when there are abnormal conditions, or accidents or spillages that could, if not controlled, result in emissions.
 - The operator should maintain a statement of training requirements for each post with the above mentioned functions and keep a record of the training received by each person. These documents should be made available to the regulator on request.

Maintenance

5.22 Effective preventative maintenance plays a key part in achieving compliance with emission limits and other provisions. All aspects of the process including all plant, buildings and the equipment concerned with the control of emissions to air should be properly maintained. In particular:

- The operator should have the following available for inspection by the regulator:
 - a written maintenance programme for all pollution control equipment;
and
 - a record of maintenance that has been undertaken.

6. Summary of changes

The main changes to this note, with the reasons for the change, are summarised in **Table 6.1**. Minor changes that will not impact on the permit conditions e.g. slight alterations to the Process Description have not been recorded.

Table 6.1 - Summary of changes			
Section/paragraph/row	Change	Reason	Comment
Introduction			
	Simplification of text	Make note clearer	
	Addition of links	Change to electronic format	Removes need for extensive footnotes /references
Emission limits, monitoring and other provisions			
	Removal of redundant paragraphs	The solvent emissions Directive is fully in force (and is now replaced by the industrial emissions Directive.)	
	Used to be Section 5 in previous note	Section 4 in previous note deleted	
Control techniques			
Air Quality	Clarification of exhaust velocity requirements	Make note clearer	
	Used to be Section 6 in previous note	Section 4 in previous note deleted leading to renumbering of sections	
Para 4.12 Visible Emissions	Revised text describing approach to take to visible and odorous emissions. Removal of arrowed condition suggesting inclusion of an odour boundary condition.	Allows more flexibility in managing visible/odorous emissions	Conditions requiring boundary checks will normally only be appropriate where potential odour is particularly offensive (see chapter 17 of the GGM).
Para 4.14 - Emissions of odour			

7. Further information

Sustainable consumption and production (SCP)

Both business and the environment can benefit from adopting sustainable consumption and production practices. Estimates of potential business savings include:

- £6.4 billion a year UK business savings from resource efficiency measures that cost little or nothing;
- 2% of annual profit lost through inefficient management of energy, water and waste;
- 4% of turnover is spent on waste.

When making arrangement to comply with permit conditions, operators are strongly advised to use the opportunity to look into what other steps they may be able to take, for example, having regard to the efficient use of auxiliary fuels, such as gas and electricity. Regulators may be willing to provide assistance and ideas, although cannot be expected to act as unpaid consultants.

Health and safety

Operators of installations must protect people at work as well as the environment:

- requirements of a permit should not put at risk the health, safety or welfare of people at work or those who may be harmed by the work activity;
- equally, the permit must not contain conditions whose only purpose is to secure the health of people at work. That is the job of the health and safety enforcing authorities.

Where emission limits quoted in this guidance conflict with health and safety limits, the tighter limit should prevail because:

- emission limits under the relevant environmental legislation relate to the concentration of pollutant released into the air from prescribed activities;
- exposure limits under health and safety legislation relate to the concentration of pollutant in the air breathed by workers;
- these limits may differ since they are set according to different criteria. It will normally be quite appropriate to have different standards for the same pollutant, but in some cases they may be in conflict (for example, where air discharged from a process is breathed by workers). In such cases, the tighter limit should be applied to prevent a relaxation of control.

Further advice on responding to incidents

The UK Environment Agencies have published [guidance](#) on producing an incident response plan to deal with environmental incidents. Only those aspects relating to air emissions can be subject to regulation via a Part B (Part C in NI) permit, but regulators may nonetheless wish to informally draw the attention of all appropriate operators to the guidance.

It is not envisaged that regulators will often want to include conditions, in addition to those advised in this PG note, specifying particular incident response arrangements aimed at minimising air emissions. Regulators should decide this on a case-by-case basis. In accordance with BAT, any such conditions should be proportionate to the risk, including the potential for harm from air emissions if an incident were to occur. Account should therefore be taken of matters such as the amount and type of materials held on site which might be affected by an incident, the likelihood of an incident occurring, the sensitivity of the location of the installation, and the cost of producing any plans and taking any additional measures.

Hazard statement classifications

Until 1 June 2015 'hazard statement' materials might also be known as 'risk phrase' materials. From 1 June 2015, only the term 'hazard statement' materials will apply. This change is incorporated in the industrial emissions Directive, and all requirements regarding hazard statement materials still apply to risk phrase materials. Table 7.1 has been included to allow comparison between the two ways of labelling hazardous materials.

Fluorinated Gas (F-gas) Regulations and Ozone Depleting Substances

Certain key obligations apply to the use of fluorinated (F-gas) and Ozone Depleting Substances (ODS) used as cleaning solvents. Designated Materials used in SED installations must either be replaced, controlled or limited and care should be taken to ensure that operators comply with the requirements of the F-gas and ODS Regulations for any replacement solvents that may contain F-gases or ODS.

At the time of publication of this guidance, further information was available at: <http://www.defra.gov.uk/environment/quality/air/fgas/>

or by contacting F Gas Support at fgas-support@enviros.com

Table 7.1 - Classification of hazardous materials

	The industrial emissions Directive catches materials which, because of their VOC content, are designated with the phrases/statements in these columns		Halogenated VOC is the trigger for the Directive in this column
Risk Phrases	class 1 'known to'	class 2 'treat as'	class 3 'cause concern'
Hazard statements categories They are NOT exact equivalents	category 1a known from human evidence	category 1b presumed from animal evidence	category 2 suspected human carcinogens
	H340, H350, H350i, H360D or H360F		H341 H351
Carcinogens	R45 May cause cancer H350 May cause cancer	R45 May cause cancer H350 May cause cancer	R40 Limited evidence of a carcinogenic effect H351 Suspected of causing cancer
Mutagens	R46 May cause heritable genetic damage H340 May cause genetic defects	R46 May cause heritable genetic damage H340 May cause genetic defects	R68 possible risk of irreversible effects H341 Suspected of causing genetic defects
Carcinogen by inhalation	R49 May cause cancer by inhalation H350i May cause cancer by inhalation	R49 May cause cancer by inhalation H350i May cause cancer by inhalation	R40 Limited evidence of a carcinogenic effect H351 Suspected of causing cancer
Toxic to reproduction	R60 May impair fertility - and R61 May cause harm to the unborn child H360D or H360F May damage fertility or the unborn child	R60 May impair fertility - and R61 May cause harm to the unborn child H360D or H360F May damage fertility or the unborn child	Outside the Directive - R62 and R63 for the suspected R phrases say "possible risk to".

Appendix 1: Industrial emissions Directive

The [industrial emissions Directive 2010/75](#) recasts 7 Directives including the solvent emissions Directive, which is minimally changed.

In the industrial emissions Directive, Chapters I and V, and Annex VII, Parts 1 to 8 are most directly related to the solvent emissions Directive and this guidance note.

The Directive chapters are:

Chapter I - common provisions

Chapter II - provisions for activities listed in Annex I

Chapter III - special provisions for combustion plants

Chapter IV - special provisions for waste incineration plants and waste co-incineration plants

Chapter V - special provisions for installations and activities using organic solvents

Chapter VI - special provisions for installations producing titanium dioxide

Chapter VII - committee, transitional and final provisions

In the Directive, the Parts of Annex VII are:

Part 1 - activities

Part 2 - thresholds and emission limit values

Part 3 - emission limit values for installations of the vehicle coating industry

Part 4 - emission limit values relating to volatile organic compounds with specific risk phrases

Part 5 - reduction scheme

Part 6 - emission monitoring

Part 7 - solvent management plan

Part 8 - assessment of compliance with emission limit values in waste gases