# Attachment I.8

Thermal Oxidiser Technology Assessment IE0311237-41-RP-0001

BAT Reviews including Applicable Assessment Tables





# Thermal Oxidiser Technology Assessment

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**Customer Project Number:** Customer Document Number:



# **Document Sign Off**

Thermal Oxidiser Technology Assessment

AbbVie NL B.V Manorhamilton Rd VOC Abatement IE0311237-41-RP-0001, Issue A

#### File No: IE0311237.41.040

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# Contents

1	Introduction	4
2	Abbreviations	4
3	Summary of Conclusions and Recommendations	5
4	Legislative Requirements	7
5	Implications for Technology Choice for AbbVie	11





### 1 Introduction

This report by PM Group addresses the key legislative requirements in relation to the design of thermal oxidisers and the resulting available technology choices. This will therefore aid in the technology selection for the proposed thermal oxidiser for AbbVie, Sligo, which forms part of the VOC abatement project.

### 2 Abbreviations

Abbreviation	Description
BAT	Best Available Techniques
BREF	Best Available Techniques Reference Document
ННС	Halogenated Hydrocarbons
IED	Industrial Emissions Directive (2010/75/EC)
IPPC	Integrated Pollution Prevention and Control (Directive 1996/61/EC)
NOx	Nitrogen Oxides
PCDD/F	Polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran
RTO	Regenerative Thermal Oxidise
SCR	Selective Catalytic Reduction
SNCR	Selective Non-Catalytic Reduction
TA Luft	The German technical regulations on control of air pollution. First published in 1986 and then updated in 2002.
VOC	Volatile Organic Compound
	Consent of Con



### 3 Summary of Conclusions and Recommendations

The system of emissions permitting in Ireland and the EU is currently in a transition phase between the older Integrated Pollution Prevention and Control (IPPC) regime, originating from 1996, and the new Industrial Emissions Directive, which became applicable in Ireland in mid-2013. However, the cornerstone of this legislation, that emission limits and equivalent control parameters should be based on the principles of Best Available Techniques (BAT) remained the same. The difference now being that the BAT conclusions in the EU guidance documents would become mandatory, instead of as previous where they were solely for guidance. As a result, these Best Available Techniques Reference Documents (BREFs) produced by the EU's IPPC Bureau in Seville are currently in a process of upgrade and revision, which as the documents are complex and run to some several hundred pages, is a process which will take considerable time to complete.

With regard to the BREF for "Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector", this is currently in December 2013 at the final meeting review stage and should therefore be formally adopted by the EU Commission in mid-2014. It is important to note that the BREFs differentiate between thermal oxidation, which is a term applied strictly to the combustion of the gas phase on its own, and the co-treatment of liquid or solid waste streams, which is deemed as incineration technology. Therefore the stringent emission limits associated with incineration do not directly apply to thermal oxidation. However, BAT Conclusion 48 of the final draft of the above revised BREF is clear in relation to thermal oxidation of waste gas streams from chemical combustion that:

When halogenated VOCs are present, to suppress the generation of dioxins/furans (PCDD/F), oxidation conditions should be as follows:

oxidation conditions should be as follows:
 Residence time > 2 seconds, temperature > 1100 °C (850 °C when incinerating with less than 1 % of halogenated organic substances) and an oxygen content of > 3%. Some waste gas pre-treatment can be necessary, such as condensing the water vapour from a wet waste gas.

The above is a position which also tons through the associated BREF on the Organic Fine Chemical sector, which dates to 2006 and is yet to undergo the start of its lengthy review process. While one cannot say with absolutely surety, until the draft updated BREF is formally adopted in mid-2014 that for the position of the combustion of halogenated methylene chloride vapours, as will occur at AbbVie, Sligo, that the technology must meet 1,100°C for two seconds. However, there is an extremely high likelihood that this will indeed become a mandatory BAT conclusion. As such therefore, the choice of technology should meet this condition, which while it can be fulfilled by direct fired thermal oxidisers, cannot be fulfilled by the regenerative based systems. Therefore, the direct fired model, with its operating temperature of greater than 1,100°C and combustion chamber sized to give a two second residence time, is the preferred technology choice.

From the technical perspective, the above parameters can be easily met by multiple suppliers of direct fired thermal oxidisers, but the consequence of the higher operating temperature not only requires more fuel input, but also leads to an increased oxidation of the nitrogen in the combustion air. As a result, the so called thermal nitrogen oxides (NOx) increase and it becomes more difficult to meet a 200 mg/m<sup>3</sup> emission level for NOx. Additional flue gas treatment, the so called DeNOx systems, using either Selective Non-Catalytic Reduction (SNCR) or Selective Catalytic Reduction (SCR) technologies, can be successfully applied, but this comes at an extra cost. Again reflecting the fact that a thermal oxidiser does not have to meet the 200 mg/m<sup>3</sup> limit for NOx set for incineration plants, the draft BREF refers to "Abatement efficiencies and emission levels associated with straight thermal oxidation", where NOx levels of 346 mg/m<sup>3</sup> are being achieved at a large German plant.

While the technical paper on the above, submitted to the working group at the IPPC bureau by the German Federal Environment Agency, could not be released as it was confidential to the group, the German authorities did put PM Group in contact with the expert in this area. Discussions were held with this expert, who is responsible for licensing of industrial plants in the Nord Rhein Westfalen province, which is the most densely populated area of Germany including the Ruhr industrialised conurbation. As was pointed out, TA Luft the German air pollution regulations of



2002, which are also used by the Irish authorities in permitting decisions, does not specify a NOx limit for thermal oxidisers and flares associated with the burning of gases, which do not arise from waste handling plants. As such the authorities come to an individual judgement, based on the impact assessment (dispersion modelling), the cost of the technology and its availability, As a result, it is quite in common in German permits that a NOx emission limit of 350 mg/m<sup>3</sup> is applied to such technology.

Based on the above, it is clear for the circumstances at AbbVie, Sligo that preference should be given to direct fired thermal oxidation technology, operating during production process involving halogenated methylene chloride, at a temperature of greater than 1,100°C for two seconds. As regards NOx limits, if the existing 200 mg/m<sup>3</sup> limit can no longer be achieved at the higher operating temperature, then either the scope of the project can include DeNOx technology or consideration be given to seeking a higher emission limit for NOx of 350 mg/m<sup>3</sup>. Note: This is based on the fact that it is unlikely that NOx levels at the 1,100°C operating temperature can be maintained at the lower limit by primary measures alone, i.e. control of combustion characteristics.

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## 4 Legislative Requirements

Currently pollution control of larger industrial sites is achieved by means of the Industrial Emissions Directive, which replaced in 2013 the previous regime based on the 1996 Integrated Pollution Prevention and Control (IPPC) Directive. For both Directives, the basis for setting the relevant emission limits and other appropriate pollution control measures was through the principles of Best Available Techniques (BAT). The IPPC Directive established a European Integrated Pollution Prevention and Control Bureau in Seville, which through an exchange of information between industry, regulators and other interested parties has produced a range of Best Available Techniques Reference Documents (BREFs) for the various industry sectors. Note: These documents are very comprehensive and run to several hundred pages. Under the previous IPPC regime the BREFs were non-binding and were to provide guidance, e.g. emission limits associated with Best Available Techniques. With the advent of the new Industrial Emissions Directive, the BAT conclusions in these updated documents will become a mandatory part of licensing.

Currently the Reference Document on the "Best Available Techniques in Common Waste Water and Waste Gas Treatment Management Systems in the Chemical Sector", which dated to 2003, is in an advanced stage of drafting to a new second edition<sup>1</sup>, which will contain the BAT conclusions for implementation of the Industrial Emissions Directive. Note: The final meeting for the review of this BREF occurred in Seville on the 10<sup>th</sup> to 13<sup>th</sup> December 2013, so its adoption by the EU in its final form should occur in early to mid-2014. There is also a first edition of a Best Available Techniques reference document for the Organic Fine Chemicals sector<sup>2</sup>, dated to 2006, which will in time be updated by the Bureau in Seville to a second edition containing the new BAT conclusions, although the process of updating this second BREF has yet to begin.

As regards pharmaceutical manufacturing, the two documents above would form the core information input to the determination of BAT for the licensing process. It is therefore instructive to evaluate both the content of; (a) the final draft of the new BREF on common waste water and waste gas treatment management systems in the chemical sector and; (b) the existing BREF on organic fine chemicals, in order to come to a position on what are the most likely the BAT conclusions, which will be applied to thermal oxidisers.

As Section 2.3.7 of the Organic Fine Chemicals BREF clarifies on "Recovery/abatement of exhaust gases":

 Thermal oxidisers and incinerators: In this document, the term "thermal oxidation" is used where applied to the gas phase, however, where co-treatment of gas, liquids and/or solids is carried out, then "incineration" is used.

This is important, as when the combustion system, as at AbbVie, Sligo, is being used for the treatment of waste gas only, without the co-combustion of waste streams comprising liquid and / or solids, then the technology does not fall under the more demanding requirements of the waste incineration Directive (2000/76/EC). Note: These incineration requirements have now been incorporated directly into a specific section of the new Industrial Emissions Directive. However, the thermal oxidiser still has to operate to the standards recognised as BAT and this has to be evaluated from the relevant BREFs, which are currently available.

The Combined Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector BREF, in its second draft of its updated version, states in Section 3.2.5.2.5 on Common Techniques to Consider in the Determination in Applied Individual Technology Techniques for thermal oxidation:

When halogenated VOC are present, special conditions might be needed to suppress the generation (or de nova synthesis) of dioxins / furans (PCDD/F), though normally there is only a negligible dioxin formation with the combustion of waste gas streams. These special conditions

<sup>&</sup>lt;sup>1</sup> <u>http://eippcb.jrc.ec.europa.eu/reference/BREF/CWW\_D2\_07\_2011.pdf</u>

<sup>&</sup>lt;sup>2</sup> http://eippcb.jrc.ec.europa.eu/reference/BREF/ofc\_bref\_0806.pdf



(which are indicated in several EU regulations on incineration, e.g. Directive 2010/75/EU on industrial emissions) include:

- Temperature > 1,100°C (850°C when incinerating waste with less than 1% of halogenated, organic substances)
- Residence time > 2 s
- Oxygen content of > 3%

The key issue therefore is whether or not more than 1% halogenated VOCs are present, as this necessitates a requirement for a higher operating temperature. Furthermore BAT Conclusion 48 (on page 684) on reducing emissions of VOCs in waste gas streams from chemical production states in relation to thermal oxidation:

When halogenated VOCs are present, to suppress the generation of dioxins/furans (PCDD/F), oxidation conditions should be as follows:

Residence time > 2 seconds, temperature > 1100 °C (850 °C when incinerating with less than 1 % of halogenated organic substances) and an oxygen content of > 3%. Some waste gas pre-treatment can be necessary, such as condensing the water vapour from a wet waste gas.

In addition, while it will take a few years for the existing BREF for the Organic Fine Chemicals sector to be updated and become mandatory, as this process has not yet started for this particular BREF, it is instructive to review some key features of the current BREF. In particular, the two sections, namely 4.3.2.5 and 4.3.2.9, which provide specific guidance on the combustion of halogenated hydrocarbons (HHCs):

- The exhaust gases contain HX, X2, N2 and XOC/HHC. A high percentage of the halogen (80 % in the case of chlorine) can be removed in a scrubbing tower (e.g. a bubble column) containing an easily halogenatable compound, preferably a raw material used in the halogenation process, and a catalyst (see also Section 4.3.5.5). The waste gas is then burned at temperatures of about 1,100°C and dwell times of 1 2 seconds in order to remove HHCs. If the waste gas does not contain HHCs, oxidisers are operated at lower temperatures in order to reduce the formation of NO<sub>X</sub> (about 800°C with a dwell time of 0.75 second).
- Exhaust gas. If halogenated solvents are used, the VOC load of the exhaust gas is passed through a condenser for recovery and subsequently destroyed by thermal oxidation (temperatures of about 1,100°C and dwell times of 1 – 2 s) followed by treatment of the fluegas.

The important issue to note here is that while it is not yet absolutely mandatory to operate above 1,100°C for two seconds, it is currently expected that one would achieve at least something similar, so as to avoid the formation of dioxins. Furthermore, it is clearly indicated that this minimum of 1,100°C for two seconds, as a specified operating condition, will become mandatory for thermal oxidation with more than 1% halogenated compounds, once the BAT Conclusions are finalised in the BREF for the Common Waste Water and Waste Gas Treatment / Management Systems for the Chemical Sector.

It is also necessary to consider the implications of operating at 1,100°C in relation to increased fuel requirements and increased generation of nitrogen oxides (NOx). NOx can be formed from the combustion of nitrogenous compounds in the inlet fuel / inlet waste gas, the so called 'chemical NOx', and also from the oxidation of the nitrogen component in the combustion air. The latter being called 'thermal NOx'. Thermal NOx increases with increasing combustion temperature, although other factors such as flame stability and characteristics also play a role.



In Table 3.225 of the draft BREF for Common Waste Water and Waste Gas Treatment / Management Systems relating to "Abatement efficiencies and emission levels associated with straight thermal oxidation", it is stated:

For NOx as NO<sub>2</sub>: 346 mg/m<sup>3</sup>. At a German incineration plant treating waste gases from three installations for a total of about 68,000 Nm<sup>3</sup>/h. The heat generated in the process is used for energy generation (combined heat and power).

Note: It is also clarified that: "The emission levels reported are indicative of what is being achieved at some industrial installations under normal operating conditions; because emission levels strongly depend on the specific plant configuration and operating conditions, the values given have to be used with extreme caution for permitting".

The source for the above NOx emission levels is a report submitted by the German Umweltbundesamt (Federal Environment Agency). When the Umweltbundesamt was contacted as to possible release of this document, it was found that they could not do so, as according to them, the information was confidential to the relevant industrial sites and had been provided in this manner to the European IPPC Bureau working group only. However, some discussions were also had with the German authorities and their TA Luft air pollution regulations of 2002<sup>3</sup> and the permitting of thermal oxidisers. Note: TA Luft is also often used by the Irish authorities for the setting of air emission limits.

In Section 5.2.4 of TA Luft on Inorganic Gaseous Substances the limit for nitrogen oxides (nitrogen monoxide and nitrogen dioxide), to be indicated as nitrogen dioxide is:

- Mass flow per substance 1.8 kg/h or;
- Mass concentration per substance 0:35 g/m<sup>3</sup>.

In waste gas generated by thermal or catalytic post-combustion facilities, nitrogen monoxide and nitrogen dioxide emissions, to be indicated as nitrogen dioxide, may not exceed a mass concentration of 0.20 g/m<sup>3</sup>; simultaneously, carbon monoxide emissions may not exceed a mass concentration of 0.10 g/m<sup>3</sup>. Insofar as the gases fed into the post-combustion system contain concentrations of nitrogen oxides or other nitrogen compounds which are not low, case-to-case requirements shall be established; in this context, nitrogen monoxide and nitrogen dioxide emissions, to be indicated as nitrogen dioxide, may not exceed a mass flow of 1.8 kg/h or a mass concentration of 0.35 g/m<sup>3</sup>.

Note: The terminology used above in the translation on the Federal Ministry for the Environment, namely 'thermal post-combustion facility', derives from a literal translation of the German 'Nachverbrennungsanlage', which is actually what we refer to in English as a 'thermal oxidiser'.

While the Umweltbundesamt were not in a position to assist on providing the information submitted to the IPPC working group in Seville, they recommended that contact be made with Franz-Willi Iven of the emissions licensing authority based in Köln. Note: In Germany the Federal administration is responsible for overarching regulatory issues, while it is at the Länder (Provincial) level that its actual implementation occurs. As Franz-Willi pointed out, Section 5.4.8.1a.2.2 of TA Luft relates to "Installations for Flaring Combustible Gaseous Substances that are not derived from Waste Treatment Facilities". This specifically states in relation to sulphurous oxides, nitrogen oxides and carbon monoxide that:

"The requirements under 5.2.4 shall not apply"

Therefore in practice with flares and thermal oxidisers, which are not connected to the combustion of waste related facilities, the NOx limit which is applied is based on the impact assessment using the relevant dispersion modelling techniques and an appropriate choice of technology selection, based on an assessment of costs and availability, i.e. BAT. It is in this regard well recognised in Germany that a NOx limit of 200 mg/m<sup>3</sup> imposes additional technology and cost considerations, so

<sup>&</sup>lt;sup>3</sup> <u>http://www.bmu.de/fileadmin/bmu-import/files/pdfs/allgemein/application/pdf/taluft\_engl.pdf</u>



in practice it is common to apply that of 350 mg/m<sup>3</sup>. Note: As previously highlighted, the Sligo, AbbVie thermal oxidiser is not connected to waste incineration, so the above is highly relevant.

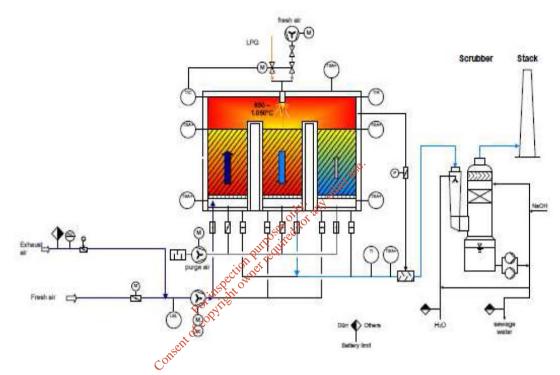
Finally, it is worth nothing that the same section of TA Luft, namely 5.4.8.1a.2.2 requires for organic material, that a minimum emissions reduction rate of 99.9%, expressed as total hydrocarbons, is achieved. Note: This is an emissions reduction rate which is readily achievable with direct fired thermal oxidisers, but less so with regenerative thermal oxidiser technology.

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## 5 Implications for Technology Choice for AbbVie

Clearly given the direction in the BREFs it would be unwise for AbbVie, Sligo, not to proceed without ensuring for the times when methylene chloride is in use, that the thermal oxidiser can meet the conditions of a minimum of 1,100°C for two seconds. In this case if we consider a regenerative thermal oxidiser, see diagram below, it operates by alternating chambers full of ceramic heat transfer medium from one side to another, thereby achieving a heat recover function by pre-heating the gas stream to the central combustion chamber.

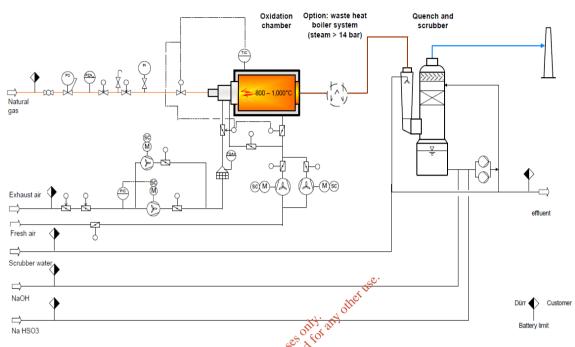


#### Flowsheet from Dürr of Regenerative Thermal Oxidiser operating with halogenated solvents

This technology was originally developed for treating large volumes of 'dilute' waste gas, such as from spray painting, with the limitation of an inlet concentration of less than 25% of the Lower Explosion Limit applying. While Dürr has adapted this technology to the treatment of halogenated solvents, see full system above complete with quench and scrubber section, it comes with additional cost and complexity. Namely, a scrubber has to be added to remove the hydrochloric acid generated by combustion of chlorinated compounds and the oxidiser itself has to be made out of corrosion resistant alloys, such as hastelloy. However, there are also practical limitations to the temperatures this system can reach, as it is a metal structure with quite rapidly cycling inlet and outlet valves to each chamber. It appears that this temperature limitation is currently around 1,050°C. Furthermore, there is no post combustion chamber in which combustion gas is actually held at an elevated temperature for a specified residence time. Instead, the gas once combusted is directly routed through to the heat recovery section.

As a consequence, a regenerative thermal oxidiser, even if it does meet the necessary emissions limits when burning relatively clean solvent emissions, such as at AbbVie, Sligo, will not meet the required BAT specification of a minimum of 1,100°C for two seconds. It is therefore necessary to consider instead direct fired technology, a schematic of which, see overleaf is provided from Dürr.

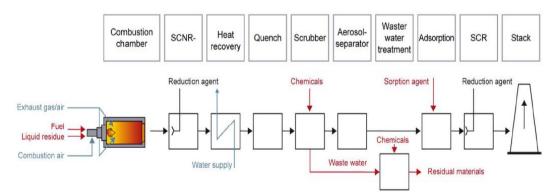




#### Direct fired thermal oxidiser, schematic from Durr

The principle of direct fired technology is relatively straight forward; the gases are fired into a combustion chamber and then held at the required temperature for the specified period of time, the size / volume of the chamber being directly proportional to the required operating temperature and residence time. As the chamber can be lined with a refractory brick or similar refractory coating, there are no technical limitations to achieving operating temperatures greater than 1,100°C. Given this energy input, it is desirable to recover useful heat as steam through the use of a waste heat boiler. The final cooling stage, being completed in a quench system, before scrubbing of the flue gas, at close to ambient temperatures, to remove the hydrochloric acid. Note: The exit temperature of the flue gas leaving the waste heat boiler is still hot enough, to prevent dew point corrosion on the carbon steel surfaces, which are used to manufacture the boiler components.

However, the issue of NOx may also need to be addressed when operating at higher temperatures. To the direct fired combustion chamber, heat recovery, quench and scrubber identified above, it may be necessary to add additional flue gas treatment sections, such as is documented in the expanded process flow sheet below from Dürr.



#### Expanded process flow sheet from Dürr for thermal oxidation / waste incineration



The principle of deNOx can first be explained by reference to the simplified chemical formula below:

-  $NH_3 + NO / NO_2 \rightarrow N_2 + H_2O$ 

Ammonia under the right temperature and operating conditions will react with the NOx to produce nitrogen and water vapour. There are two methods of doing this; the first is called Selective Non-Catalytic Reduction (SNCR). The flue gas leaving the combustion chamber at 1,100°C is dropped in temperature to the range 950-1,100°C by the addition of cooling air. In a second chamber at this lower temperature, urea solution is sprayed in, which at the elevated temperature dissociates to ammonia and completes the necessary reduction reaction. While the reaction does not go the whole way to completion, NOx removal rated to 60-70% are achievable with this SNCR technology approach.

In the second DeNOx technology approach, namely Selective Catalytic Reduction (SCR), a catalyst is used which enables a higher NOx removal rate to be achieved, 80-90% being readily achievable. However, the flue gas must first be scrubbed to remove the corrosive gases and then reheated to circa 300°C before being passed over the catalyst to which ammonia solution has been injected. Note: The direct addition of urea solution is generally not possible with SCR, as it has to be converted to ammonia first. Heat recuperation can also be applied, in that the heat input to reach 300°C can be partly recovered on the discharge side of the SCR system.

Both SNCR and SCR technologies are large investments and while it is only necessary to apply one or the other, it would not be unrealistic that DeNOx requirements could lead to a 15 to 20% increase in the capital cost of a standard thermal oxidiser package. It is also worth mentioning that primary DeNOx control can be achieved by more advanced burner technologies, in particular the uniformity and maximum temperature within the tame. For instance, with natural gas burners lower NOx levels can be achieved than with oil tire burners, as the flame temperature with natural gas is lower. However, it remains to be seen if the thermal oxidiser vendors can achieved the currently specified NOx levels of 200 mg/Nm3 given that the new thermal oxidiser will have a temperature increase from the existing unit at 850%C to the halogenated requirement of 1,100°C. If this is not currently technically possible with primary DeNOx controls alone, then consideration should be given to seeking a new NOx level of 350 mg/m3, which as has been highlighted in the previous section is reflective of BAT under these operating circumstances

BREF on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector, Draft 2 (2011)

(2011)	1					
BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation			
BAT conclusions for environmental management systems						
1. BAT is to implement and adhere to an environmental management systems (EMS) that incorporates all of the following features:(I-IX)	3.1.1	Applicable.	EMS in place that incorporates features I-X of BAT conclusion. AbbVie have implemented and adhere to an EMS which is a condition of their EIA licence. The system is accredited to ISO14001. The new T.O will be incorporated into the EMS.			
BAT conclusions for environmental management at chemical s	sites					
<ol><li>BAT is to reduce the environmental risks and impacts by applying all of the following management techniques:(I-VI)</li></ol>	3.1.2	Applicable	AbbVie have emergency plans, pollution control procedures, waste plant management plans and fire water retention facilities.			
3. BAT is to prevent soil and groundwater contamination by applying a combination of the following operational techniques:(I-XI)	3.1.2.2	Applicable	Testing and maintenance programs in place in compliance with the conditions of the IEA licence .Piping, valves and bund inspections & testing, material movement strategy			
BAT conclusions for energy management at chemical sites			e vi <sup>se.</sup>			
4. BAT is to reduce energy consumption by applying one or more of the following techniques: (I-III)	3.7.2	Applicable.	BAT is achieved by technique (II) recovery of exothermic reaction heat through the generation of low-pressure steam. A new steam boiler will be installed to recover heat from the exhaust gas stream from the new thermal oxidiser and used to generate steam for use on site. The new TO is more energy efficient model than the previous TO.			
<ol> <li>BAT is to reduce energy consumption at central waste water pre-treatment and/or treatment plants by adopting an energy management plan.</li> </ol>	3.7.3	Not Applicable	N/A			
BAT conclusions for waste management at chemical sites		at insplit on				
6. BAT is to prevent, or where that is not practicable, to reduce waste generation by adopting a waste management plan that, in order of priority, ensures that waste is prepared for reuse, recycling, recovery or disposal for all the identified waste fractions.	3.6	to of Applicable	AbbVie implement a waste management plan that ensures that the appropriate disposal method for waste materials generated on site is used.			
<ul> <li>7. BAT is to prevent, or where that is not practicable, to reduce waste generation by using one or more of the following waste reuse/recycle techniques:</li> <li>(i) recycling and reuse of used containers/drums</li> <li>(ii) recycling of used soft packaging materials</li> <li>(iii) recycling and reuse of solvents and by-products</li> </ul>	3.6	Applicable	Recycling plan in place			
BAT Treatment of sludge at central waste water pre-treatment and treatment plants at chemical site						
8. BAT is to reduce energy, chemical and handling capacity requirements of sludge for its subsequent treatment by reducing its water content by applying sludge thickening techniques.	3.2.4.1	Not Applicable	N/A			
9. BAT is to reduce the pathogenic content, to eliminate offensive odours and to reduce the putrescibility of sludge by applying one of the following sludge stabilisation techniques:	3.2.4.2	Not Applicable	N/A			

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation					
10. BAT is to reduce the water content of the sludge before its final disposal in order to render it odourless and non-putrescible, to reduce its potential to produce leachate at the final disposal site, to increase its energy content if it is to be incinerated and to reduce the cost of sludge transport to the final disposal site by applying one of the following sludge dewatering techniques:	3.2.4.1	Not Applicable	N/A					
11. BAT is to prevent pollutant discharges from sludge treatment facilities to the environment by recirculating the liquid effluent resulting from the treatment of sludge by any of the techniques cited in BAT 8, 9 and 10 back to the central waste water treatment plant.	3.2.4.1	Not Applicable	N/A					
BAT conclusions for the prevention/reduction of diffuse VOC e	missions fron	n chemical plants at ch	emical sites					
<ul> <li>12.BAT is to prevent, or where that is not practicable, to reduce diffuse VOC emissions during the plant design phase by applying a combination of the following techniques:</li> <li>I. limiting the number of potential emission sources</li> <li>II. maximising inherent process containment features</li> <li>III. selecting appropriate materials for equipment</li> <li>IV. selecting appropriate materials for equipment</li> <li>V. facilitating monitoring and maintenance activities by ensuring good access to</li> <li>components that have the potential to leak</li> <li>VI. collecting and treating diffuse VOC emissions.</li> <li>13. BAT is to prevent, or where that is not practicable, to reduce diffuse VOC emissions related to plant installation and commissioning by applying all of the following techniques:</li> </ul>	3.4.1	Applicable. only applicable on the second se	BAT is achieved by (I) Imiting the number of potential emission sources, (III) selecting active high integrity equipment, (III) selecting appropriate materials for equipment, (V) facilitating monitoring and maintenance activities by ensuring good access to components that have the potential to leak, (VI) collecting and treating diffuse VOC emissions (e.g. storage tank vents)					
<ul> <li>I. having strict and well-defined procedures for construction and assembly</li> <li>II. ensuring that gaskets are installed correctly, and that the highest possible gasket stress is used during the installation of flanged joints.</li> <li>III. having robust commissioning and hand-over procedures to ensure that the plant is installed in line with the design requirements.</li> </ul>		Applicable.	in Thermal Oxidiser technology and construction will design and construct a plant in accordance with all latest practices for eliminating diffuse emissions. Common areas for diffuse emissions include valve stems & flanges. Strict and well defined procedures for construction and assembly will be in place, (II) having robust commissioning and hand- over procedures to ensure that the plant is installed in line with the design requirements. Commissioning will be carried out by a third party to the relevant standards.					
14. BAT is to prevent, or where that is not practicable, to reduce fugitive VOC emissions related to plant operation by adopting a leak detection and repair (LDAR) programme in order to identify leaking components, and to repair these leaks to minimise losses.	3.4.3	Applicable.	This will be implemented by regular plant inspection procedures.					
BAT conclusions for prevention/reduction of odour emissions	BAT conclusions for prevention/reduction of odour emissions at chemical sites							
<ul> <li>15. BAT is to prevent, or where that is not practicable, to reduce odour emissions by applying I and II below:</li> <li>(I) Odour management plan as part of EMS</li> <li>(II) Management techniques</li> </ul>	3.5	Applicable	(I) BAT is achieved through an odour management strategy and monitoring program at the AbbVie site. This program is part of the EMS (II) Staff expertise is available within the AbbVie EHS dept. to manage and implement odour plan. New T.O will be included in update to EMS.					

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
16. BAT is to prevent, or where that is not practicable, to reduce odour emissions from waste water collection systems, central waste water pre-treatment and/or treatment plants and sludge treatment facilities by applying a combination of the following techniques.	3.5.5.1	Not Applicable	N/A
17. BAT is to reduce odour emissions by using one of the following end-of-pipe odour treatment techniques:	3.2.5.2, 3.5.5.2.1	Applicable	BAT is achieved through end-of-pipe odour treatment by (IV) Thermal Oxidation. Thermal oxidisers of this design have an odour abatement efficiency > 99.9%. Measures taken to prevent fugitive/diffuse gaseous will also help with respect to odour problems.
BAT conclusions for prevention/reduction of noise emissions a	at chemical si	tes	
18. BAT is to prevent, or where that is not practicable, to reduce noise emissions from central waste water pre-treatment and/or treatment plants and sludge treatment facilities by enclosing noisy equipment such as pumps and compressors.	-	Not Applicable	N/A
<ol> <li>BAT is to reduce noise emissions from flaring by applying a combination of techniques.</li> </ol>	-	Not Applicable	N/A
BAT conclusions for waste water and waste gas collection sys	tems at chem	ical sites	N. NOT
A) Waste water collection and segregation at chemical sites		er a	to.
20. BAT is to reduce the volume of waste water to be treated and to increase possible material recycling and/or reuse by installing waste water collection and segregation systems designed based on the results of the stream inventory/register (see BAT 2(V)).	3.1.5.2.5.1	Applicable requires	The new T.O and associated plant will be contained in its own bund. Bund inspections and testing will be carried out as part of routine inspections. Details contained in the AbbVie EMS.
<ul> <li>21. BAT is to avoid the contamination of rainwater from production-related activities by applying a combination of the following techniques:</li> <li>I. installing roofs over production areas</li> <li>II. installing roofs over storage areas</li> <li>III. avoiding overpressure/safety venting discharges (e.g. from relief valves of tanks) to roofed areas and protecting the discharge port of the venting devices from rainwater.</li> </ul>	3.2.3.4.5 <mark>0</mark> 0	For index on the formation of the format	High risk areas and storage areas will be covered as required to prevent the generation of contaminated rainwater. Vents will be protected from rainwater ingress.
22. BAT is to prevent uncontrolled discharge of potentially contaminated rainwater from production areas and fire-fighting water from a chemical site by collecting them in a storage tank for their further control, treatment and/or disposal. The parameters to be monitored and the frequency of monitoring need to be adopted to the frequency and duration of the expected rainfall episodes, the size of the chemical site, the activities carried out at the site and their potential impact to the receiving water body. If the monitoring results demonstrate that the rainwater is not contaminated, BAT is to apply one or more of the following techniques:(I-III)	3.2.3.4.5	Applicable	BAT is achieved by technique (II) direct discharge to the municipal sewerage system. Any potentially contaminated surface water or fire-fighting water will be held in the fire water retention pond which has been sized based on a fire water risk assessment. Monitoring of any water will be carried out in line with the EMS strategy for emissions to sewer/surface water.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
23. BAT is to remove the pollutants from the contaminated rainwater collected at chemical sites by a combination of physical, chemical and/or biological treatment techniques. The following techniques can be applied for the treatment of contaminated rainwater:	3.2.3.4.5	Not Applicable	N/A
B) Waste gas collection at chemical sites			
24. BAT is to reduce the volume of waste gas to be treated by minimising the gas flow rate to the control unit by enclosing the emission sources as much as possible by means of separating the sources of emission from their surroundings.	3.1.5.2.5.2	Applicable	BAT is achieved through the control of the concentration of VOCs in the collection system. An assessment has been carried out on the current vent header system. For VOC collecting systems, the most important issues are personnel safety and prevention of cross contamination. Flame arresters will be installed to minimise the propagation of any potential explosion.
BAT conclusions for waste water management and treatment a	t chemical sit	es	
25. BAT is to reduce the consumption of fresh water, to reduce the volume and/or load of waste water streams, to enhance the reuse of waste water within the production processes and/or to recover and reuse raw materials by applying one or more of the following process-integrated techniques:	3.2.3.1	Not Applicable	N/A N/A
26. BAT is to remove the pollutants from waste waters generated at chemical sites before their discharge to a receiving water body by applying one of the following techniques.(I-II)	3.2.3.1	Not Applicable different	N/A
A) Central pre-treatment of tributary waste water streams at ch	emical sites	Dection nert	
27. BAT is to reduce the amount of pollutants in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying all techniques.	-	NotApplicable	N/A
28. BAT is to reduce the amount of organic load in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one of the following techniques:	3.2.3.4.4. <mark>}</mark> ð	Not Applicable	N/A
29. BAT is to reduce the amount of heavy metals in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one or more of the following techniques: (I-VII)	3.2.3.4.3.1	Not Applicable	N/A
30. BAT is to avoid any subsequent risk to the environment upon the removal of heavy metals when applying any of the techniques cited in BAT 29 by recovering of the removed heavy metals and/or safely disposing of any residue formed containing heavy metals.	-	Not Applicable	N/A
31. BAT is to reduce the cyanide concentration in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one of the following techniques:(I-II)	3.2.3.4.3.7	Not Applicable	N/A
32. BAT is to break emulsions and avoid their release to the environment by use of emulsion-breaking chemicals prior to their discharge to a downstream biological waste water treatment plant.	3.2.3.4.2.7	Not Applicable	N/A

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
33. BAT is to remove free oil, grease, de-emulsified oil (from BAT 32) and other non-soluble light liquids that tend to build up on top of the waste waters prior to their discharge to a downstream biological waste water treatment plant by applying techniques.	3.2.3.4.2.7	Not Applicable	N/A
<ul><li>34. BAT is to avoid any subsequent risk to the receiving environment by recovering and reusing the skimmed oil (from BAT 33) in the process units and/or safely disposing of the skimmed oil.</li></ul>	3.2.3.4.2.7	Not Applicable	N/A
35. BAT is to reduce the inorganic salts (mainly chlorides and sulphates) in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one of the following techniques: (I-II)	3.2.3.4.3.8	Not Applicable	N/A
36. BAT is to reduce the low- and/or non-biodegradable organic pollutants (refractory organics) and/or toxic substances in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one or more of the following techniques:	-	Not Applicable	N/A
37. BAT is to reduce the phenols in the tributary waste water streams prior to their discharge to a downstream biological waste water treatment plant by applying one technique.	-	~~~ \ \	N/A
38. BAT is to reduce the adsorbable organically bound halogens (AOX) prior to their discharge to a downstream biological waste water treatment plant by using one of the following techniques: (I-IV)	-	Not Applicable	N/A
B) Central waste water treatment at chemical sites		FOLUTION	
39. BAT is to prevent fluctuations in the effluent waste water quality and to lower effluent emissions by balancing of flows and pollution loads/concentrations at the inlet to the central waste water treatment plant by using an equalisation tank.	3.2.3.2	For propriet or the second sec	N/A
40. BAT is to reduce the emission of pollutants to the receiving environment due to operational failures, equipment leakages and any accidental spills by having a buffer storage capacity available in order to store waste waters for their further recovery, treatment and/or disposal.	3.2.3.3	Not Applicable	N/A
41. BAT is to reduce the emission of total suspended solids (TSS) from central waste water treatment plants by applying I and II	-	Not Applicable	N/A
42. BAT is to reduce the emission of biodegradable components from central waste water treatment plants by applying one or more of the following techniques:(I-III)	3.3.2, 3.4.3.4.4.3	Not Applicable	N/A
43. BAT is to reduce the emission of total nitrogen from central waste water treatment plants by applying biological nitrification/denitrification	3.2.3.4.4.4	Not Applicable	N/A

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation				
SAT conclusions for waste gas management and treatment at chemical sites							
<ul> <li>44. BAT is to recycle/reuse in the original or other production processes at least the following pollutants from waste gas streams of chemical production processes:</li> <li>I. volatile organic compounds (VOCs), recovered from solvent vapours or vapours of low boiling products</li> <li>II. VOCs used as an energy carrier in incinerators/oxidisers or boilers</li> <li>III. hydrogen chloride to produce hydrochloric acid</li> <li>IV. ammonia to recycle into the production process</li> <li>V. sulphur dioxide transferred into sulphuric acid, sulphur or gypsum</li> <li>VI. dust that contains high amounts of solid raw products or end-products</li> </ul>	3.2.5	Not Applicable	N/A				
45. BAT is to reduce the emissions of particulate matter (dust, heavy metals and their compounds, aerosols, mist and soot) in waste gas streams from chemical production processes by applying one or a combination of the techniques listed in table.	3.2.5.3	50 g	or any other N/A				
46. BAT is to recover hydrogen chloride and sulphur dioxide in waste gas streams from chemical production processes by applying one of the following techniques:	3.2.5.1.4, 3.2.5.4.1	Applicable, require	BAT is achieved through technique (I) - Wet Gas Scrubbing with water. Flue gas from T.O will be cooled in a quench system, before scrubbing of the flue gas to remove HCI.				
47. BAT is to recover VOCs and inorganic compounds in waste gas streams from chemical production processes and reduce their emissions by applying one of the following techniques: (I-IV)	3.2.5.1.1, 3.2.5.1.2, 3.2.5.1.3, 3.2.5.1.4	For instantion to the second	(IV) Wet gas scrubbing				
48. BAT is to reduce emissions of VOCs in waste gas streams from chemical production processes by applying one of the following techniques listed in table, section 48.	3.2.5.2	Applicable.	BAT is achieved by Technique (V) Thermal Oxidation will be employed. New T.O will suppress the formation of dioxins/furan (PCDD/F) from the combustion of halogenated VOCs by reaching a temp >1100°C for the specified time >2 secs.				
49. BAT is to reduce emissions of nitrogen oxides in waste gas streams from chemical production processes by applying Primary and Secondary techniques in table, section 49.	3.2.5.4.3	Applicable.	BAT is achieved by Primary technique (c) burner control and by secondary technique (b) Selective non-catalytic reduction (SNCR). With SNCR, a reducing agent, commonly an aqueous solution of urea is added to the flue gas which has been cooled to between 950°C-1100°C leading to a reduction in NOx through chemical reaction. This technology can reduce NOx levels by approximately 60-70%.				
50. BAT is to minimise the need for flaring by correct plant design (e.g. using high integrity relief valves, having a gas recovery system) and good plant management (e.g. having advanced process control).	3.2.5.5	Not Applicable	N/A				
51. BAT is to dispose only of excess combustible gases that cannot otherwise be recovered from non-routine operational conditions (e.g. start-ups, shutdowns), emergency situations and/or upset conditions by use of flaring.	3.2.5.5	Not Applicable	N/A				

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
52. BAT is to maximise the combustion efficiency of flares by appropriate selection and design of the flare system and closely monitoring the heat content of the flare fuel mixture, the ratio of fuel gas to assist gas (air or steam) and burner tip velocity and the crosswind velocity.	3.2.5.5	Not Applicable	N/A
BAT conclusions on monitoring of final effluent discharge from	n <mark>central was</mark> t	e water treatment plant	S
53. BAT is to measure all relevant parameters to adjust and optimise continuously the waste water treatment and to ensure stable and smooth operation of the waste water treatment plant. The parameters to be monitored as well as the frequency of monitoring is site-specific and depend in particular on the type of chemical production, the type and amount of pollutants in the waste waters, and the nature of the recipient water body.	-	Not Applicable	N/A
54. BAT is to continuously monitor at least waste water flow, pH and temperature in the effluents discharged from central waste water treatment plants.	-	Not Applicable	N/A N/A
55. BAT is to monitor chemical oxygen demand (COD) (or total organic carbon, TOC), biochemical oxygen demand (BOD5), total suspended solids (TSS), total nitrogen and ammoniacal nitrogen in the effluent of the treatment plant by using flow-proportional 24-hour composite samples collected at the same well-defined point at the outlet of the central waste water treatment plant. These samples are the basis for reporting yearly average emission values.	-	Not Applicable	N/A
56. When one or more of the following pollutants are likely to be emitted in significant quantities, BAT is to measure these pollutants periodically (the monitoring frequency is site-specific):		S	N/A
57. BAT is to minimise the ecotoxic impact of waste water effluents by biomonitoring of the effluents and taking measures based on the biomonitoring results.	3.1.5.2.2.2	Not Applicable	N/A
58. BAT is to assess and to minimise the release of hazardous substances by discharge of waste water effluents containing chemicals which are persistent, liable to bioaccumulate and/or toxic by using the whole effluent assessment (WEA) technique.	3.1.5.2.2.3	Not Applicable	N/A

# BREF on Manufacture of Organic Fine Chemicals, August 2006

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation					
Prevention of Environmental impact – Integration	Prevention of Environmental impact – Integration of environmental, health and safety considerations into process development							
BAT is to provide an auditable trail for the integration of environmental, health and safety considerations into process development (see Section 4.1.2)	5.1.1.1	Applicable	Environmental, health and safety considerations have been incorporated into the design process through specific EHS design reviews, ATEX reviews, HAZOPS etc. This ensures that the process is designed to best industry practices.					
BAT is to develop new processes as follows (see Section 4.1.1):	5.1.1.1							
a) to improve process design to maximise the incorporation of all the input materials used into the final product (see, e.g. Sections 4.1.4.3 and 4.1.4.8)		Applicable	This is addressed by AbbVie corporate development of new product end processing. Waste minimisation is an integral feature of operations at the Sligo site.					
b) to use substances that possess little or no toxicity to human health and the environment. Substances should be chosen in order to minimise the potential for accidents, releases, explosions and fires (e.g. for solvent selection, see Section 4.1.3).		Applicable	Solvents are used in the production process. Halogenated and non-halogenated VOCs will be treated in the new TO.					
c) to avoid the use of auxiliary substances (e.g. solvents, separation agents, etc. see e.g. Section 4.1.4.2)		Applicable လျှိ	The use of solvents is unavoidable in the production process for active pharmaceutical compounds.					
d) to minimise energy requirements in recognition of the associated environmental and economic impacts. Reactions at ambient temperatures and pressures should be preferred		Applicable of the second	The new TO will reach a temperature of 1100°C for 2 seconds to suppress the formation of dioxins/furans when burning halogenated VOCs.					
e) to use renewable feedstock rather than depleting, wherever technically and economically practicable		Not Applicable	N/A					
f) to avoid unnecessary derivatisation (e.g. blocking or protection groups)		Not Applicable	N/A					
g) to apply catalytic reagents, which are typically superior to stoichiometric reagents (see, e.g. Sections 4.1.4.4 and 4.1.4.5)		Not Applicable	N/A					
Prevention of Environmental impact – Process sa	fety and pre	vention of runaway	y reaction					
BAT is to carry out a structured safety assessment for normal operation and to take into account effects due to deviations of the chemical process and deviations in the operation of the plant (see Section 4.1.6)	5.1.1.2.1	Applicable	The vent header has been subject to a Hazard and Operability Study (HAZOP) (HAZOP Report IE0311237-23-RP-0002, issued February 2014).HAZOPs study the design with regards to deviations from the design intent from a safety and operability perspective.					
In order to ensure that a process can be controlled adequately, BAT is to apply one or a combination of the following techniques (without ranking, see Section 4.1.6.1): a) organisational measures b) concepts involving control engineering techniques c) reaction stoppers (e.g. neutralisation, quenching) d) emergency cooling e) pressure resistant construction f) pressure relief.	5.1.1.2.1	Applicable	As outlined above the entire process has undergone the HAZOP process which ensures that the relevant control measures are in place to avoid any hazards and plant operability issues which may or may not lead to environmental impact. Therefore the techniques outlined in the BREF and other techniques have all been considered in order to ensure process safety and the prevention of runaway reactions					
BAT is to establish and implement procedures and technical measures to limit risks from the handling and storage of hazardous substances	5.1.1.2.2	Applicable	Training and SOPs are in place at the AbbVie facility and will be extended to include any new procedures associated with new TO ensuring proper handling and storage of hazardous materials.					

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT is to provide sufficient and adequate training for operators who handle hazardous substances	5.1.1.2.2	Applicable	Training and SOPs are in place at the AbbVie facility and will be extended to include any new procedures associated with new TO ensuring proper handling and storage of hazardous materials.
Minimisation of Environmental Impact – Plant Design			
BAT is to design new plants in such a way that emissions are minimised by applying techniques including the following (see Sections 4.2.1, 4.2.3, 4.2.15, 4.2.21):4.2.14,	5.1.2.1		26 <sup>0</sup> .
a) using closed and sealed equipment		Applicable	which is sealed.
<ul> <li>b) closing the production building and ventilating it mechanically</li> </ul>		Applicable	The production building is fully closed and is serviced by mechanical ventilation throughout
<ul> <li>c) using inert gas blanketing for process equipment where VOCs are handled</li> </ul>		Applicable	Nitrogen blanking used in vent header collection system. Vent header system to be altered for new TO installation
d) connecting reactors to one or more condensers for solvent recovery		Applicable	Condensation is used on process vents prior to routing to the TO for final abatement.
e) connecting condensers to the recovery/abatement system		Applicable	Condensation is used on process vents prior to routing to the TO for final abatement.
<ul> <li>f) using gravity flow instead of pumps (pumps can be an important source of fugitive emissions)</li> </ul>		A coApplicable	Gravity flow and pressure transfers are utilised while pumps are minimised.
g) enabling the segregation and selective treatment of waste water streams	CON	Not Applicable	N/A
h) enabling a high degree of automation by application of a modern process control system in order to ensure a stable and efficient operation.		Applicable	The process equipment will be controlled by a Process Control System (PCS).
Minimisation of Environmental Impact – Ground protection a	ind water retent	ion options	
BAT is to design, build, operate and maintain facilities, where substances (usually liquids) which represent a potential risk of contamination of ground and groundwater are handled, in such a way that spill potential is minimised. Facilities have to be sealed, stable and sufficiently resistant against possible mechanical, thermal or chemical stress (see Section 4.2.27).	5.1.2.2	Applicable	The transport and storage of materials at the AbbVie site has been designed in accordance with EPA guidance and is in compliance with conditions set out in the Industrial Emissions Licence which relate to material storage.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT is to enable leakages to be quickly and reliably recognised (see Section 4.2.27).	5.1.2.2	Applicable	1) The Process Control System, and 2) designing to ensure good access to components that have the potential to leak for regular inspection. These areas will be made part of an updated inspection and maintenance program.
BAT is to provide sufficient retention volumes to safely retain spills and leaking substances in order to enable treatment or disposal (see Section 4.2.27).	5.1.2.2	Applicable	The new TO and associated equipment will be positioned in a bund/ bunds in accordance with EPA guidance.
BAT is to provide sufficient retention volume to safely retain firefighting water and contaminated surface water (see Section 4.2.28).	5.1.2.2	Applicable	As part of existing site infrastructure for firewater retention.
BAT is to apply all the following techniques (see also Section 4.2.27):	5.1.2.2		
a) carrying out loading and unloading only in designated areas protected against leakage run-off		Applicable	All loading and unloading in vicinity of TO will be carried out in areas that are either bunded locally or remotely.
b) storing and collecting materials awaiting disposal in designated areas protected against leakage run-off		Applicable	Existing site infrastructure
c) fitting all pump sumps or other treatment plant chambers from which spillage might occur with high liquid level alarms or regularly supervising pump sumps by personnel instead		Not Applicable	N/Aother to
d) establishing programmes for testing and inspecting tanks and pipelines including flanges and valves		Applicable	Visual checks will be carried out periodically on-site. Testing and inspection of tanks and pipelines will be carried out in accordance with the Industrial Emissions Licence.
e) providing spill control equipment, such as containment booms and suitable absorbent material		Applicable	Spill kits are provided throughout the site
f) testing and demonstrating the integrity of bunds		Applicable	Any bunds installed will be initially tested for use and tested thereafter in accordance with the requirements of the Industrial Emissions Licence.
g) equipping tanks with overfill prevention. Minimisation of VOC emissions – Enclosure of sources		FOT VITE	Overfill protection on new scrubber to existing site waste water system.
BAT is to contain and enclose sources and to close any openings in order to minimise uncontrolled emissions (see Section 4.2.14).	5.1.2.3.1	Not Applicable	All pipes and flanges at tie in points shall be provided in accordance with ASME B31.3 – Process Piping & ASME B16.5 – Pipe Flanges and Flanged Fittings.
Minimisation of VOC emissions – Drying in closed circuits			
BAT is to carry out drying by using closed circuits; including condensers for solvent recovery (see Section 4.2.14).	5.1.2.3.2	Applicable	A part of the process plant design upstream of the TO.
Minimisation of VOC emissions – Equipment cleaning using BAT is to keep equipment closed for rinsing and cleaning with			
solvents (see Section 4.2.14).	5.1.2.3.3	Not Applicable	A part of the process plant design upstream of the TO.
Minimisation of exhaust gas volume flows and loads - Closu	ire of openings		
BAT is to use recirculation of process vapours where purity requirements allow this (see Section 4.2.14).	5.1.2.3.4	Not Applicable	Purity Requirements (GMP) do not allow this.
BAT is to close any unnecessary openings in order to prevent air being sucked to the gas collection system via the process equipment (see Sections 4.2.14 and 4.3.5.17).	5.1.2.4.1	Applicable	The vent header collection system will be a closed system with vacuum pumps in sub headers.
Minimisation of exhaust gas volumes and loads – Testing th	e air tightness o	of process equipment	
BAT is to ensure the air tightness of process equipment, especially of vessels (see section 4.2.16)	5.12.4.2	Applicable	Process equipment is regularly leak tested as part of inerting procedures. Much of the process equipment is designed to operate under vacuum and leak tightness is important.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation		
Minimisation of exhaust gas volume flows and loads - Inertis	sation				
BAT is to apply shock inertisation instead of continuous inertisation (see Section 4.2.17).	5.1.2.4.3	Applicable	Continuous inerting is used but sweep flows are small due to tightness of equipment		
Minimisation of exhaust gas volume flows and loads - Minimi	isation of exhau	ist gas volume flows f	rom distillations		
BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser (see Section 4.2.20).	5.1.2.4.4	Applicable	Distillation is completed with controlled heat input and adequate condensation		
Liquid additions into vessels					
BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg, unless reaction chemistry and/or safety considerations make it impractical (see Sections 4.2.15, 4.2.18). In such cases, the addition of liquid as top feed with a pipe directed to the wall reduces splashing and hence, the organic load in the displaced gas.	5.1.2.4.5	Applicable	Liquid additions are controlled and splashing avoided		
If both solids and an organic liquid are added to a vessel, BAT is to use solids as a blanket in circumstances where the density difference promotes the reduction of the organic load in the displaced gas, unless reaction chemistry and/or safety considerations make it impractical (see Section 4.2.18).	5.1.2.4.5	Not Applicable	This does not apply		
Minimisation of peak emission concentrations		and and			
BAT is to minimise the accumulation of peak loads and flows and related emission concentration peaks by, e.g. a) optimisation of the production matrix (see Section 4.3.5.17) b) application of smoothing filters (see Section 4.3.5.16 and also Section 4.3.5.13).	5.1.2.4.6	Applicable	The process control system minimises peak loads such as simultaneous pressure transfer and venting.		
Minimisation of volume and load of waste water streams - Mo	other liquors wit	th high salt content			
<ul> <li>BAT is to avoid mother liquors with high salt content or to enable the work-up of mother liquors by the application of alternative separation techniques (see Section 4.2.24), e.g.</li> <li>a) membrane processes</li> <li>b) solvent-based processes</li> <li>c) reactive extraction</li> <li>d) or to omit intermediate isolation.</li> </ul>	میں 5.1.2.5.1	Not Applicable	N/A		
Minimisation of volume and load of waste water streams - Countercurrent product washing					
BAT is to apply countercurrent product washing where the production scale justifies the introduction of the technique (see Section 4.2.22).	5.1.2.5.2	Not Applicable	N/A		
Minimisation of volume and load of waste water streams - Wa	ater-free vacuur	n generation			
BAT is to apply water-free vacuum generation (see Sections 4.2.5, 4.2.6 and 4.2.7). Minimisation of volume and load of waste water streams - De	5.1.2.5.3	Applicable	Dry running vacuum pumps are used.		

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
For batch processes, BAT is to establish clear procedures for the determination of the desired end point of the reaction (for an example, see Section 4.2.23). Minimisation of volume and load of waste water streams - In	5.1.2.5.4	Not Applicable	N/A
		Not Ann Kookla	N/A
BAT is to apply indirect cooling (see Section 4.2.9).	5.1.2.5.5	Not Applicable	N/A
Minimisation of volume and load of waste water streams – C	leaning		
BAT is to apply a pre-rinsing step prior to rinsing/cleaning of equipment to minimise organic loads in wash-waters (see Section 4.2.12).	5.1.2.5.6	Not Applicable	N/A
Minimisation of energy consumption			
BAT is to assess the options and to optimise the energy consumption (for examples, see Sections 4.2.11 and 4.2.20).	5.1.2.6	Applicable	New TO is designed to be more energy efficient than previous TO. e.g. a new steam boiler will be installed to recover heat from the exhaust gas stream from the new TO and used to generate steam for use on site.
Mass balances and process waste stream analysis - Mass ba	alances	a di seconda di s	1. and
BAT is to establish mass balances for VOCs (including CHCs), TOC or COD, AOX or EOX and heavy metals on a yearly basis (see Sections 4.3.1.4, 4.3.1.5 and 4.3.1.6).	5.2.1.1.1	Applicable of the second	<sup>55</sup> The process raw materials and waste streams generated are constantly reviewed in a bid to minimise waste stream volumes.
Mass balances and process waste stream analysis - Waste s	tream analysis	ion stre	
BAT is to carry out a detailed waste stream analysis in order to identify the origin of the waste stream and a basic data set to enable management and suitable treatment of exhaust gases, waste water streams and solid residues (see Section 4.3.1.1).	5.2.1.1.2	For Applicable	Waste stream characterisation was carried out to identify waste streams and their sources. The nature of the processes leads to significant halogenated and non-halogenated VOC exhaust gases and these will be treated in the new TO.
Mass balances and process waste stream analysis - Assess	ment of waste w	ater streams	
BAT is to assess at least the parameters given in Table 5.1 for waste water streams, unless the parameter can be seen as irrelevant from a scientific point of view (see Section 4.3.1.2).	5.2.1.1.3	Not Applicable	N/A
Mass balances and process waste stream analysis - Monitor	ing of emission	s to air	
For emissions to air, BAT is to monitor the emission profile which reflects the operational mode of the production process (see Section 4.3.1.8).	5.2.1.1.4	Applicable	A new CEMS (Continuous Emissions Monitoring) system will be installed as part of the new TO package. The flow rate to the TO will also be monitored
In the case of a non-oxidative abatement/recovery system, BAT is to apply a continuous monitoring system (e.g. FID), where exhaust gases from various processes are treated in a central recovery/abatement system (see Section 4.3.1.8).	5.2.1.1.4	Applicable	CEMS
BAT is to individually monitor substances with eco-toxicological potential if such substances are released (see Section 4.3.1.8).	5.2.1.1.4	Not Applicable	Monitoring programme to be put in place for any eco-toxicological substances that may be released
Mass balances and process waste stream analysis - Assess	ment of individu	al volume flows	
BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems (see Section 4.3.1.7).	5.2.1.1.5	Applicable	Completed as part of the vent header design system.
Re-use of solvents			

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<ul> <li>BAT is to re-use solvents as far as purity requirements (e.g. requirements according to cGMP) allow, by:</li> <li>a) using the solvent from previous batches of a production campaign for future batches as far as purity requirements allow (see Section 4.3.4)</li> <li>b) collecting spent solvents for on-site or off-site purification and re-use (for an example, see Section 4.3.3)</li> <li>c) collecting spent solvents for on-site or off-site utilisation of the calorific value (see Section 4.3.5.7).</li> </ul>	5.2.2	Not Applicable	N/A
Selection of VOC recovery/abatement techniques and achieved	able emission	evels - Selection of VC	OC and recovery abatement techniques
BAT is to select VOC recovery and abatement techniques according to the flow scheme in Figure 5.1.	5.2.3.1.1	Applicable	Thermal Oxidation is the chosen technique according to the flow chart in figure 5.1.
Selection of VOC recovery/abatement techniques and achieved	able emission	evels - Non-oxidative	VOC recovery and abatement techniques
BAT is to reduce emissions to the levels given in Table 5.2 where non-oxidative VOC recovery or abatement techniques are applied (see Sections 4.3.5.6, 4.3.5.11, 4.3.5.14, 4.3.5.17, 4.3.5.18).	5.2.3.1.2	Not Applicable	N/A
Selection of VOC recovery/abatement techniques and achieved	vable emission	evels - VOC abatemen	thermal oxidation/incineration and catalytic oxidation
BAT is to reduce VOC emissions to the levels given in Table 5.3 where thermal oxidation/incineration or catalytic oxidation are applied (see Sections 4.3.5.7, 4.3.5.8, 4.3.5.18).	5.2.3.1.3	Applicable of the applicable o	The new TO will reduce both halogenated and no-halogenated VOC emissions. The TO will be capable of reaching 1100°C for 2 seconds to deal with the halogenated VOC.
Recovery/abatement of NOX - NOX from thermal oxidation/in	ncineration or ca		
For thermal oxidation/incineration or catalytic oxidation, BAT is to achieve the NOX emission levels given in Table 5.5 and, where necessary, to apply a DeNOX system (e.g. SCR or SNCR) or two stage combustion to achieve such levels (see Sections 4.3.5.7 and 4.3.5.19).		to Applicable	The higher temperatures relating to the abatement of the halogenated VOC emissions leads to an increase in nitrogen oxides (NOx) for which there are emissions limits. To ensure compliance Selective Non-Catalytic reduction (SNCR) technology will be employed as part of the abatement system.
Recovery/abatement of NOX - NOX from chemical processes			
For exhaust gases from chemical production processes, BAT is to achieve the NOx emission levels given in Table 5.5 and, where necessary to apply treatment techniques such as scrubbing or scrubber cascades with scrubber media such as $H_2O$ and/or $H_2O_2$ to achieve such levels (see Section 4.3.5.1).	5.2.3.2.2	Not Applicable	N/A
Recovery/abatement of HCI, Cl2 and HBr/Br2	1		
BAT is to achieve HCl emission levels of $0.2 - 7.5 \text{ mg/m}^3$ or $0.001 - 0.08 \text{ kg/hour}$ and, where necessary, to apply of one or more scrubbers using scrubbing media such as H <sub>2</sub> O or NaOH in order to achieve such levels (see Section 4.3.5.3).	5.2.3.3	Applicable	The flue gas will be cooled in a quench to approximately saturation temperature to dissolve and neutralise the HCI.
BAT is to achieve $CI_2$ emission levels of $0.1 - 1 \text{ mg/m}^3$ and, where necessary, to apply techniques such as absorption of the excess chlorine (see Section 4.3.5.5) and/or scrubbing with scrubbing media such as NaHSO <sub>3</sub> in order to achieve such levels (see Section 4.3.5.2).	5.2.3.3	Applicable	The scrubbing will include an additive such as NaHSO $_3$ to ensure CL $_2$ emission levels are reached.

BAT Statement	BAT Reference	Applicability	State technique and whether it is in place or state schedule for
BATOLACIA	Number	Assessment	implementation
BAT is to achieve HBr emission levels <1 mg/m <sup>3</sup> and, where necessary, to apply scrubbing with scrubbing media such as H2O or NaOH in order to achieve such levels (see Sections 1.1.1, 4.3.5.4).	5.2.3.3	Not Applicable	Bromine compounds are not used in the production process. If they were to be used in the future, this BAT would be complied with.
NH3 emission levels - Removal of NH <sub>3</sub> from exhaust gases			
BAT is to achieve $NH_3$ emission levels of $0.1 - 10 \text{ mg/m}^3$ or $0.001 - 0.1 \text{ kg/hour}$ and, where necessary, to apply scrubbing with scrubbing media such as $H_2O$ or acid in order to achieve such levels (see Section 4.3.5.20).	5.2.3.4.1	Applicable	Urea injection to the SNCR will be controlled to prevent 'ammonia slippage'.
NH3 emission levels - NH <sub>3</sub> slip from DeNOX			
BAT is to achieve $NH_3$ slip levels from SCR or SNCR of <2 mg/m <sup>3</sup> or <0.02 kg/hour (see Section 4.3.5.7).	5.2.3.4.2	Applicable	Urea injection to the SNCR will be controlled to prevent 'ammonia slippage'.
NH3 emission levels - Removal of SOx from exhaust gases			e de la companya de la compa
BAT is to achieve SOx emission levels of $1 - 15 \text{ mg/m}^3$ or $0.001 - 0.1 \text{ kg/hour}$ and, where necessary, to apply scrubbing with scrubbing media such as H <sub>2</sub> O or NaOH in order to achieve such levels (see Section 4.3.5.21).	5.2.3.4.3	Not Applicable of	o <sup>v</sup> A There should be no SO₂ in the stack gas, as there are no sulphurous compounds in the exhaust gas, however NaOH scrubbing is utilised.
Removal of particulates from exhaust gases		pureque	
BAT is to achieve particulate emission levels of 0.05 – 5 mg/m <sup>3</sup> or 0.001 – 0.1 kg/hour and, where necessary, to apply techniques such as bag filters, fabric filters, cyclones, scrubbing, or wet electrostatic precipitation (WESP) in order to achieve such levels (see Section 4.3.5.22).	5.2.3.6	Not Applicable	N/A
Removal of free cyanides from exhaust gases		at	
BAT is to remove free cyanides from exhaust gases, and to achieve a waste gas emission level of 1 mg/m <sup>3</sup> or 3 g/hour as HCN (see Section 4.3.6.2).	5.2.3.7 Con	Not Applicable	N/A
Typical waste water streams for segregation, pre-treatment of	or disposal - Mo	ther liquors from halo	genation and sulphochlorination
BAT is to segregate and pretreat or dispose of mother liquors from halogenations and sulphochlorinations (see Sections 4.3.2.5, 4.3.2.10).	5.2.4.1.1	Not Applicable	N/A
Typical waste water streams for segregation, pretreatment o	r disposal - Was	ste water streams con	taining biologically active substances
BAT is to pretreat waste water streams containing biologically active substances at levels which could pose a risk either to a subsequent waste water treatment or to the receiving environment after discharge (see Sections 4.3.2.6, 4.3.7.5, 4.3.7.9, 4.3.8.13 and 4.3.8.18).	5.2.4.1.2	Not Applicable	N/A
Typical waste water streams for segregation, pretreatment o	r disposal - Spe	nt acids from sulphon	ations or nitrations
BAT is to segregate and collect separately spent acids, e.g. from sulphonations or nitrations for on-site or off-site recovery or to apply BAT given in 5.2.4.2 (see Sections 4.3.2.6, 4.3.2.8)	5.2.4.1.3	Not Applicable	N/A

BAT Statement	BAT Reference	Applicability Assessment	State technique and whether it is in place or state schedule for implementation			
Treatment of waste water streams with relevant refractory organic load - Relevant refractory organic loading						
For the purposes of pretreatment, BAT is to classify organic	ganic load - Rei	evant refractory organ	lic loading			
loading as follows: Refractory organic loading is not relevant if the waste water stream shows a bioeliminability of greater than about $80 - 90$ % (see Sections 4.3.7.6, 4.3.7.7, 4.3.7.8). In cases with lower bioeliminability, the refractory organic loading is not relevant if it is lower than the range of about 7.5 – 40 kg TOC per batch or per day (see Sections 4.3.7.10, 4.3.7.12 and 4.3.7.13).	5.2.4.2.1	Not Applicable	N/A			
Treatment of waste water streams with relevant refractory or	ganic load - Se	pregation and pretreat	ment			
BAT is to segregate and pretreat waste water streams containing relevant refractory organic loadings according to the criteria given in Section 5.2.4.2.1.	5.2.4.2.2	Not Applicable	N/A			
Treatment of waste water streams with relevant refractory or	ganic load - Ov	erall COD elimination				
For the segregated waste water streams carrying a relevant refractory organic load according to Section 5.2.4.2.1, BAT is to achieve overall COD elimination rates for the combination of pretreatment and biological treatment of >95 % (see Section 4.3.8.9).	5.2.4.2.3	Not Applicable	N/A N/A			
Removal of solvents from waste water streams		1005 11ed				
BAT is to recover solvents from waste water streams for on-site or off-site reuse, using techniques such as stripping, distillation/rectification, extraction or combinations of such techniques, where the costs for biological treatment and purchase of fresh solvents are higher than the costs for recovery and purification (see Section 4.3.7.18).		Not Applicable	N/A			
BAT is to recover solvents from waste water streams in order to use the calorific value if the energy balance shows that overall natural fuel can be substituted (see Section 4.3.5.7).	0.2.4.0 Con	ent Or Applicable	N/A			
Removal of halogenated compounds from waste water strea	ms - Removal o	f purgeable chlorinate	d hydrocarbons			
BAT is to remove purgeable CHCs from waste water streams, e.g. by stripping, rectification or extraction and to achieve sum concentrations <1 mg/l in the outlet from pretreatment or to achieve sum concentrations of <0.1 mg/l in the inlet to the on- site biological WWTP or in the inlet to the municipal sewerage system (see Sections 4.3.7.18, 4.3.7.19, 4.3.7.20).	5.2.4.4.1	Not Applicable	N/A			
Removal of halogenated compounds from waste water streams - Pretreatment of waste water streams containing AOX						
BAT is to pretreat waste water streams with significant AOX loads and to achieve the AOX levels given in Table 5.6 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.14).	5.2.4.4.2	Not Applicable	N/A			
Pre-treatment of waste water streams containing heavy meta	ls					

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT is to pretreat waste water streams containing significant levels of heavy metals or heavy metal compounds from processes where they are used deliberately and to achieve the heavy metal concentrations given in Table 5.7 in the inlet to the on-site biological WWTP or in the inlet to the municipal sewerage system (see Section 4.3.7.22).	5.2.4.5	Not Applicable	N/A
Destruction of free cyanides			office and the second
BAT is to recondition waste water streams containing free cyanides in order to substitute raw materials where technically possible (see Section 4.3.6.2). BAT is to: a) pretreat waste water streams containing significant loads of cyanides and to achieve a cyanide level of 1 mg/l or lower in the treated waste water stream (see Section 4.3.6.2) or to b) enable safe degradation in a biological WWTP (see Section 4.3.6.2 under Applicability).	Å	Not Applicable	N/A
Biological waste water treatment	C <sub>0</sub> ,		
After the application of BAT given in Sections 5.2.4.1, 5.2.4.2, 5.2.4.3, 5.2.4.4 and 5.2.4.5 (management and treatment of waste water streams), BAT is to treat effluents containing a relevant organic load, such as waste water streams from production processes, rinsing and cleaning water, in a biological WWTP (see Sections 4.3.8.6 and 4.3.8.10).	5.2.4.7	Not Applicable	N/A
Biological waste water treatment - On-site and joint treatmer	t		
BAT is to ensure that the elimination in a joint waste water treatment is overall not poorer than in the case of on-site treatment. This is realised by regular degradability/bioeliminability testing (see Section 4.3.8.5). Biological waste water treatment - Elimination rates and emi	5.2.4.7.1	Not Applicable	N/A

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT is to take full advantage of the biological degradation potential of the total effluent and to achieve BOD elimination rates above 99 % and yearly average BOD emission levels of 1 – 18 mg/l. The levels relate to the effluent after biological treatment without dilution, e.g. by mixing with cooling water (see Section 4.3.8.11).	5.2.4.7.2	Not Applicable	N/A
BAT is to achieve the emission levels given in Table 5.8.	5.2.4.7.2	Not Applicable	N/A
Monitoring of the total effluent			
BAT is to regularly monitor the total effluent to and from the biological WWTP measuring at least the parameters given in Table 5.1. (see Section 4.3.8.21).	5.2.4.8	Not Applicable	N/A
Monitoring of the total effluent – Biomonitoring			
BAT is to carry out regular biomonitoring of the total effluent after the biological WWTP where substances with ecotoxicological potential are handled or produced with or without intention (for examples, see Sections 4.3.8.18 and 4.3.8.19).	5.2.4.8.1	Not Applicable	N/A N/A
Monitoring of the total effluent - Online toxicity monitoring		005 JEC	
BAT is to apply online toxicity monitoring in combination with online TOC measurement if residual acute toxicity is identified as a concern, for examples see Sections 4.3.8.7 and 4.3.8.20.	5.2.4.8.2	Not Applicable	N/A
Environmental management		insolut	
<ul> <li>BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates, as appropriate to individual circumstances, the following features: (see Chapter 4)</li> <li>definition of an environmental policy for the installation by top management (commitment of the top management is regarded as a precondition for a successful application of other features of the EMS)</li> <li>planning and establishing the necessary procedures</li> <li>implementation of the procedures, paying particular attention</li> </ul>	5.3 CON	Applicable	An EMS is in place in compliance of the conditions of the IEA Licence and as such will be developed to include the procedures and operations related to the new TO.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
to - structure and responsibility - training, awareness and competence - communication - employee involvement - documentation - efficient process control - maintenance programme - emergency preparedness and response - safeguarding compliance with environmental legislation. • checking performance and taking corrective action, paying particular attention to - monitoring and measurement (see also the Reference document on Monitoring of Emissions) - corrective and preventive action - maintenance of records - independent (where practicable) internal auditing in order to determine whether or not the environmental management system conforms to planned arrangements and has been properly implemented and maintained. • review by top management.	5.3 Con	Applicable Applicable	An EMS is in place in compliance of the conditions of the IEA Licence and as such will be developed to include the procedures and operations related to the new TO.

# BREF on the General Principles of Monitoring, July 2003

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
General Principles of Monitoring BREF 2003 Clarity about the relationship between the ELVs and the monitorin is good practice to take into account the following points: (p18 of Make it clear in the permit that monitoring is an inherent and legally enforceable requirement and that it is as necessary to comply with the monitoring obligation as with the limit value/equivalent parameter Specify clearly and unambiguously the pollutant or parameter being limited as detailed in Section 2.7	ng programme is o	essential. The specific 7) Applicable Applicable	ed monitoring requirements should cover all relevant aspects of the ELV. To this end it All site emissions will be monitored and compared to the limits set under the site IEA Licence. It is a legal requirement of site to comply with these requirements. Air Dispersion Modelling exercise has been carried out to ensure emissions from new To will meet the requirements of the licence and AQS. The pollutant parameters and limits are set out in schedule B of the IEA licence. It is proposed that no increases will be required due the new VOC abatement project.
State clearly the location where samples and measurements are to be taken. These should match the positions where the limits are applied. It is necessary to have suitable sampling measurement sections and/or measurement sites available. To this end, relevant requirements for space and technical facilities, such as safe measurement platforms and sampling ports, should also be stated in the permit	2.7	Applicable	The locations of monitoring and sampling points have been outlined in the Industrial Emissions Licence Application. The new TO emission monitoring point will replace the existing emission point but no increase in emission will be required.
Specify the monitoring timing requirements (time, averaging time, frequency, etc.) of sampling and measurements, as explained in Section 2.5. Consider the feasibility of limits with regard to available measurement methods. Limits must be set so that the monitoring required in order to determine compliance is within the capability of available measurement methods. For example, in order to obtain detectable quantities of dioxins from stack emissions it is usually necessary to sample over several hours. In this case the averaging time should correspond to this practical sampling duration. The limit setting process must therefore take into account the technical limitations of the relevant monitoring methods which will include consideration of detection limits, response times, sampling times, possible interferences, general availability of the methods and possible use of surrogates.	2.7 Consent 2.7	Applicable For instead owner of convingition Applicable	<ul> <li>Schedule B of the IEA licence sets out the monitoring timing periods in relation to the thermal oxidiser and cryogenic condenser.</li> <li>All measurement methods will comply with guidelines as prescribed in EPA Guidance Note on the Implementation of I.S. EN 14181 (AG3).</li> <li>A new CEMS (Continuous Emissions Monitoring) system will be installed as part of the new TO package. The existing CEM's installation associated with the original TO is no longer suitable for purpose and is to be de-commissioned in parallel with the original TO. It is proposed the existing cryogenic abatement unit will also be integrated into this new CEM's system also.</li> <li>The new CEM's units will be expected to conform to all relevant practices and international standards, including: <ul> <li>I.S. EN14181</li> <li>EN14181 (Data Acquisition)</li> <li>40 CFR (Protection of the Environment) part 60</li> <li>40 CFR (Protection of the Environment) part 75</li> </ul> </li> <li>The CEM's unit (assuming a "Talas" or "Durag" data acquisition platform) will be expected to relay pre-nominated critical emission values to the Delta-V DCS from monitoring and alarm generation protocols.</li> </ul>

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
Consider the general approach to the monitoring available for relevant needs (e.g. the scale). It is useful if the monitoring programme for a limit first describes the general type of monitoring required, before giving details of specific methods. The general approach will suit the considerations of location, timing, time-scale and feasibility, and take into account the options of direct measurement, surrogate parameters, mass balances, other calculations, and the use of emission factors. These general approaches are described in Chapter 5.	2.7	Applicable	A new CEMS (Continuous Emissions Monitoring) system will be installed and set up appropriate to comply with regulatory requirements.
Specify the technical details of particular measurement methods, i.e. the associated standard (or alternative) measurement method, and the units of measurement. Choosing measurement methods in accordance with the following priorities will lead to better reliability and comparability, provided they are reasonably practicable as detailed in section 2.7	2.7	Applicable	All measurement methods will comply with guidelines as prescribed in EPA Guidance Note on the Implementation of I.S. EN 14181 (AG3). Site EMS procedures and staff training will ensure all onsite monitoring is conducted by appropriately qualified and certified third party contractors in line with the required EPA standards. These SOPs will also ensure all laboratory testing shall be conducted by accredited laboratories as per the EPA requirements and the required records are retained.
In cases of self-monitoring, either performed by the operator or by a contractor, clearly state the procedure for periodically checking the traceability of the self-monitoring. An accredited third party testing laboratory should be used for this work	2.7	Applicable se off	Site EMS procedures and staff training will ensure all onsite monitoring is conducted by appropriately qualified and certified third party contractors in line with the required EPA standards. These SOP's will also ensure all laboratory testing shall be conducted by accredited laboratories as per the EPA requirements and the required records are retained. The checking of self-monitoring will be carried out by the accredited third party in line with IS 14181 (AG3).
State the operational conditions (e.g. production load) under which the monitoring is to be performed. If normal or maximum production at the facility is required, this should be quantitatively defined	2.7	For Applicable	TO emissions monitoring shall be conducted continuously via the CEMS.
Clearly state the compliance assessment procedures, i.e. how will the monitoring data be interpreted to assess compliance with the relevant limit (as shown in Chapter 6), also taking into account the uncertainty of the monitoring result as explained in Section 2.6.	2.7 Consent	0	Site EMS procedures, staff training and role competency will ensure the correct interpretation of monitoring results. On-site monitoring shall be conducted by appropriately qualified and certified third party contractors to minimise the risk of uncertainty in monitoring results.
Specify the reporting requirements, e.g. what results and other information are to be reported; when, how, and to whom. Reporting aspects of compliance monitoring are considered further in Chapter 7.	2.7	Applicable	Site EMS SOPs will detail the required roles and responsibilities and the required internal communication structures for emission monitoring onsite. The site Emergency Response Procedure (ERP) will provide for the notification of the relevant authorities as required. The facility Annual Environmental Report (AER) and PRTR Annual Returns will outline compliance with limits and will be reported to the EPA as per the conditions of the AbbVie IEA licence.
Include appropriate quality assurance and control requirements, so that the measurements are reliable, comparable, consistent and auditable. The main quality considerations may include those detailed in Section 2.7	2.7	Applicable	Site EMS procedures and staff training will ensure all onsite monitoring is conducted by appropriately qualified and certified third party contractors in line with the required EPA standards. These SOPs will also ensure all laboratory testing shall be conducted by accredited laboratories as per the EPA requirements and the required records are retained.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
Make arrangements for the assessment and reporting of exceptional emissions, both foreseeable (e.g. shutdowns, stoppages, maintenance) and unforeseeable (e.g. disturbances in the process input, or in abatement technique). The approach to these emissions is discussed in Section 3.2	2.7	Applicable	The site Process Control System (PCS), site Building Management System (BMS) and site EMS Emergency Response Procedure (ERP) will provide warning of any failures and malfunctions throughout facility. The site ERP will detail the requirements of sampling during exceptional emissions as identified. This procedure will ensure any exceptional releases are recorded and quantified. Any exceptional emissions will be report to the EPA and such incidents will be summarised and included in the facility AER.

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## BREF on Energy Efficiency, February 2009

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation		
Energy efficiency management					
BAT is to implement and adhere to an energy efficiency management system (ENEMS) that incorporates, as appropriate to the local circumstances, all of the following features (see section 2.1)	4.2.1	Applicable	There is an Energy Efficiency Management System in place for the site which is adhered to in all aspects of operation.		
Planning and establishing objectives and targets - Continuous environmental improvement					
BAT is to continuously minimise the environmental impact of an installation by planning actions and investments on an integrated basis and for the short, medium and long term, considering the cost-benefits and cross-media effects.	4.2.2.1	Applicable	Energy Audits are carried out annually to assess the opportunity for greater energy efficiency across the site. There is a dedicated Energy and Utilities Leader at the facility who works to incorporate the energy efficiency policies outlined in the EMS throughout the facility.		
Planning and establishing objectives and targets – Identification of energy efficiency aspects of an installation and opportunities for energy					
savings	1		AND I DECEMBER OF A DECEMBER O		
BAT is to identify the aspects of an installation that influence energy efficiency by carrying out an audit. It is important that an audit is coherent with a systems approach (see BAT 7).	4.2.2.2	Applicable	Schergy Audits are carried out annually. The recommendations from these audits are incorporated into the company's EMS.		
When carrying out an audit, BAT is to ensure that the audit identifies the following aspects (see Section 2.11):	4.2.2.2	Applicable unice	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>a) energy use and type in the installation and its component systems and processes</li> </ul>		Applicable	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>energy-using equipment, and the type and quantity of energy used in the installation</li> </ul>			All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>c) possibilities to minimise energy use, such as: controlling/reducing operating times, e.g. switching off when not in use (e.g. see Sections 3.6, 3.7, 3.8, 3.9, 3.11) ensuring insulation is optimised, e.g. see sections 3.1.7, 3.2.11 and 3.11.3.7 optimising utilities, associated systems, processes and equipment (see Chapter 3)</li> </ul>	Consent	Applicable	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>d) possibilities to use alternative sources or use of energy that is more efficient, in particular energy surplus from other processes and/or systems, see Section 3.3</li> </ul>		Applicable	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>e) possibilities to apply energy surplus to other processes and/or systems, see Section 3.3</li> </ul>		Applicable	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		
<ul> <li>f) possibilities to upgrade heat quality (see Section 3.3.2).</li> </ul>		Applicable	All listed aspects are identified in the Energy Audit and implemented on a continuous basis throughout the site.		

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<ul> <li>BAT is to use appropriate tools or methodologies to assist with identifying and quantifying energy optimisation, such as: <ul> <li>energy models, databases and balances (see Section 2.15)</li> <li>a technique such as pinch methodology (see Section 2.12) exergy or enthalpy analysis (see Section 2.13), or thermoeconomics (see Section 2.14)</li> <li>estimates and calculations (see Sections 1.5 and 2.10.2).</li> </ul> </li> </ul>	4.2.2.2	Applicable	Energy models are used in identifying energy use across the facility and also used as a tool in optimising, where possible, the energy efficiency of operations and processes on site.
BAT is to identify opportunities to optimise energy recovery within the installation, between systems within the installation (see BAT 7) and/or with a third party (or parties), such as those described in Sections 3.2, 3.3 and 3.4.	4.2.2.2	Applicable	Energy recovery systems are in place across all process areas of the facility. A new steam boiler has been installed to recover heat from the exhaust gas stream from the new thermal oxidiser and used to generate steam for use on site.
Planning and establishing objectives and targets	- A systems a	approach to ener	gy management
BAT is to optimise energy efficiency by taking a systems approach to energy management in the installation. Systems to be considered for optimising as a whole are, for example: - process units (see sector BREFs) - heating systems such as: - steam (see Section 3.2) - hot water - cooling and vacuum (see the ICS BREF) - motor driven systems such as: - compressed air (see Section 3.7) - pumping (see Section 3.8) - lighting (see Section 3.10) - drying, separation and concentration (see Section3.11).	4.2.2.3	For inpection purposes on For inpection purposes include to copyright include	Energy efficient technologies will be employed throughout the new thermal oxidiser package, including high efficiency motors on pumps and fans, minimum IE2 and IE3 standard. Motors will be Variable Speed Drive (VSD) controlled.
Planning and establishing objectives and targets	- Establishing	g and reviewing o	energy efficiency objectives and indicators
BAT is to establish energy efficiency indicators by carrying out all of the following:	4.2.2.4		
<ul> <li>a) identifying suitable energy efficiency indicators for the installation, and where necessary, individual processes, systems and/or units, and measure their change over time or after the implementation of energy efficiency measures (see Sections 1.3 and 1.3.4)</li> </ul>		Applicable	The new TO features indicators for its fuel consumption and energy recovery using standard methods of measuring heat energy coming from the exhaust gas and subsequent heat recovered by the new steam boiler. Annual Energy Audits will serve to supplement this.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<ul> <li>b) identifying and recording appropriate boundaries associated with the indicators (see Sections 1.3.5 and 1.5.1)</li> </ul>		Not Applicable	N/A
<ul> <li>c) identifying and recording factors that can cause variation in the energy efficiency of the relevant process, systems and/or units (see Sections 1.3.6 and 1.5.2).</li> </ul>		Not Applicable	N/A
Planning and establishing objectives and targets	– Benchmark	ing	
BAT is to carry out systematic and regular comparisons with sector, national or regional benchmarks, where validated data are available.	4.2.2.5	Applicable	AbbVie is committed to maintaining its membership with the Sustainable Energy Authority of Ireland (SEAI). As per the company's energy policy, this will be achieved by ensuring a continuous improvement philosophy to promote on-going energy efficiency and energy performance improvements.
Energy efficient design (EED)			d'any diffe
BAT is to optimise energy efficiency when planning a new installation, unit or system or a significant upgrade (see Section 2.3) by considering all of the following:	4.2.3	Applicatile and a clicon the test	The new TO is offers greater energy efficiency than the existing TO on-site and as such, the installation will improve the energy efficiency of the facility. The most energy efficient technology that can also meet the operating conditions required was chosen during the design phase. Each of the points listed was considered during this process.
<ul> <li>a) the energy efficient design (EED) should be initiated at the early stages of the conceptual design/basic design phase, even though the planned investments may not be well-defined. The EED should also be taken into account in the tendering process</li> </ul>	CORSER ON SERVICE	G <sup>copytett</sup> ow Applicable	See 4.2.3
<li>b) the development and/or selection of energy efficient technologies (see Sections 2.1(k) and 2.3.1)</li>	U U	Applicable	See 4.2.3
<ul> <li>additional data collection may need to be carried out as part of the design project or separately to supplement existing data or fill gaps in knowledge</li> </ul>		Applicable	See 4.2.3
<ul> <li>d) the EED work should be carried out by an energy expert</li> </ul>		Applicable	See 4.2.3

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<ul> <li>e) the initial mapping of energy consumption should also address which parties in the project organisations influence the future energy consumption, and should optimise the energy efficiency design of the future plant with them. For example, the staff in the (existing) installation who may be responsible for specifying design parameters.</li> </ul>		Applicable	See 4.2.3
Increased process integration			
BAT is to seek to optimise the use of energy between more than one process or system (see Section 2.4), within the installation or with a third party.	4.2.4	Applicable	The new TO is designed to handle both halogenated and non-halogenated VOC streams. Before this the existing TO and cryogenic condenser were both used in order to deal with these streams. The introduction of the new TO will limit the use of the cryogenic condenser and create a more energy efficient system.
Maintaining the impetus of energy efficiency initia	atives		and the second sec
BAT is to maintain the impetus of the energy efficiency programme by using a variety of techniques, such as:	4.2.5	For intering the second	A. BIA Office
a) implementing a specific energy efficiency management system (see Section 2.1 and BAT 1)		Fo <sup>t</sup> in Applicable	There is an Energy Efficiency Management System in place for the site which is adhered to in all aspects of operation.
<ul> <li>b) accounting for energy usage based on real (metered) values, which places both the obligation and credit for energy efficiency on the user/bill payer (see Sections 2.5, 2.10.3 and 2.15.2)</li> </ul>	Consent	Applicable	Appropriate metering is implemented through the company's EMS in accordance with the ISO 50001 licence. The facility also submits and Annual Environmental Report to the EPA in accordance with its IEA licence with details on energy use at the site.
<ul> <li>c) the creation of financial profit centres for energy efficiency (see Section 2.5)</li> </ul>		Not Applicable	N/A
d) benchmarking (see Section 2.16 and BAT 9)		Not Applicable	N/A
e) a fresh look at existing management systems, such as using operational excellence (see Section 2.5)		Not Applicable	N/A

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation		
<li>f) using change management techniques (also a feature of operational excellence, see Section 2.5).</li>		Not Applicable	N/A		
Maintaining expertise					
BAT is to maintain expertise in energy efficiency and energy- using systems by using techniques such as:	4.2.6				
<ul> <li>a) recruitment of skilled staff and/or training of staff. Training can be delivered by in-house staff, by external experts, by formal courses or by self- study/development (see Section 2.6)</li> </ul>		Applicable	A dedicated Energy and Utilities Leader is available to deliver energy expertise to all projects on site.		
<ul> <li>b) taking staff off-line periodically to perform fixed term/specific investigations (in their original installation or in others, see Section 2.5)</li> </ul>			projects on site.		
<ul> <li>c) sharing in-house resources between sites (see Section 2.5)</li> </ul>		Nocapplicable	N/A		
<ul> <li>d) use of appropriately skilled consultants for fixed term investigations (e.g. see Section 2.11)</li> </ul>	Consent	ð.	N/A		
<ul> <li>e) outsourcing specialist systems and/or functions (e.g. see Annex 7.12)</li> </ul>		Not Applicable	N/A		
Effective control of processes					
BAT is to ensure that the effective control of processes is implemented by techniques such as:	4.2.7				

	BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
a)	having systems in place to ensure that procedures are known, understood and complied with (see Sections 2.1(d)(vi) and 2.5)		Applicable	The effective control of processes is implemented by the company's comprehensive EMS which is supplemented by annual energy audits carried out on site.
b)	ensuring that the key performance parameters are identified, optimised for energy efficiency and monitored (see Sections 2.8 and 2.10)		Applicable	The effective control of processes is implemented by the company's comprehensive EMS which is supplemented by annual energy audits carried out on site.
c)	documenting or recording these parameters (see Sections 2.1(d)(vi), 2.5, 2.10 and 2.15).		Applicable	Energy Audit Reports and Annual Environmental Reports are produced to ensure no deviations from regular energy efficiency.
Maint	enance			
	o carry out maintenance at installations to optimise efficiency by applying all of the following:	4.2.8		
a)	clearly allocating responsibility for the planning and execution of maintenance		Applicable	Maintenance at all installations is carried out on a regular basis by trained personnel.
b)	establishing a structured programme for maintenance based on technical descriptions of the equipment, norms, etc. as well as any equipment failures and consequences. Some maintenance activities may be best scheduled for plant shutdown periods		Applicable set of	of the second structured programme of maintenance schedules and techniques detailed within the company's EMS.
c)	c. supporting the maintenance programme by appropriate record keeping systems and diagnostic testing		Applicable	Records are kept on site of maintenance operations.
d)	identifying from routine maintenance, breakdowns and/or abnormalities possible losses in energy efficiency, or where energy efficiency could be improved	Consent	Applicable	Energy efficiency deviations are recorded and incorporated into the EMS in order to be rectified and continuously improved.
e)	identifying leaks, broken equipment, worn bearings, etc. that affect or control energy usage, and rectifying them at the earliest opportunity.	0	Applicable	There are safeguards and corrective measure in place for incidents of installation malfunction.
Monit	oring and measurement			
monitor charact significa	o establish and maintain documented procedures to and measure, on a regular basis, the key eristics of operations and activities that can have a int impact on energy efficiency. Some suitable ues are given in Section 2.10.	4.2.9	Applicable	Energy Audit Reports and Annual Environmental Reports are produced to ensure no deviations from regular energy efficiency. Emissions of CO, NO <sub>x</sub> and O <sub>2</sub> are continuously monitored to ensure a high level of energy efficiency is achieved.
Comb	ustion			
BAT is t relevan - -	o optimise the energy efficiency of combustion by techniques such as: those specific to sectors given in vertical BREFs those given in Table 4.1.	4.3.1	Applicable	Energy efficiency of the new TO is optimised using a number of the techniques listed in Table 4.1. These include a preheater for the combustion air stream and a heat recovery system whereby steam is generated in a boiler using the waste stream from the exhaust.
Steam	l systems			

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT for steam systems is to optimise the energy efficiency by using techniques such as: - those specific to sectors given in vertical BREFs - those given in Table 4.2	4.3.2	Applicable	Equipment shall be insulated to retain thermal energy where possible.
Heat recovery			
<ul> <li>BAT is to maintain the efficiency of heat exchangers by both:</li> <li>a) monitoring the efficiency periodically, and</li> <li>b) preventing or removing fouling</li> <li>See Section 3.3.1.1.</li> </ul>	4.3.3	Applicable	Continuous temperature monitoring and regular cleaning procedures are carried out to ensure the energy efficiency of the equipment is maintained.
Cogeneration			
BAT is to seek possibilities for cogeneration, inside and/or outside the installation (with a third party).	4.3.4	Not Applicable	N/A
Electrical power supply			ى.
BAT is to increase the power factor according to the requirements of the local electricity distributor by using techniques such as those in Table 4.3, according to applicability (see Section 3.5.1).	4.3.5	Not Applicable	N/A N/A
BAT is to check the power supply for harmonics and apply filters if required (see Section 3.5.2).	4.3.5	Not Applicable rec	N/A
BAT is to optimise the power supply efficiency by using techniques such as those in Table 4.4 according to applicability.	4.3.5	Applicable	BATs are reviewed annually and implemented within the company's energy policy and EMS.
Electric motor driven sub-systems		Forming	
BAT is to optimise electric motors in the following order (see Section 3.6):	4.3.6	S.C.	
<ol> <li>optimise the entire system the motor(s) is part of (e.g. cooling system, see Section 1.5.1)</li> </ol>	Collec	Applicable	Motors are minimum IE2 or IE3 standard.
<ol> <li>then optimise the motor(s) in the system according to the newly-determined load requirements, by applying one or more of the techniques in Table 4.5, according to applicability</li> </ol>		Not Applicable	N/A
<ul> <li>3. when the energy-using systems have been optimised, then optimise the remaining (nonoptimised) motors according to Table 4.5 and criteria such as: <ol> <li>prioritising the remaining motors running more than 2000 hrs per year for replacement with EEMs</li> <li>ii. electric motors driving a variable load operating at less than 50 % of capacity more than 20 % of their operating time, and operating for more than 2000 hours a year should be considered for equipping with variable speed drives.</li> </ol> </li> </ul>		Applicable	Fan motors are equipped with VSDs to optimise efficiency.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation		
Compressed air systems (CAS)					
BAT is to optimise compressed air systems (CAS) using the techniques such as those in Table 4.6 according to applicablility.	4.3.7	Applicable	The techniques listed in Table 4.5 are utilised across the facility to optimise compressed air system efficiency.		
Pumping systems					
BAT is to optimise pumping systems by using the techniques in Table 4.7 according to applicability. (see Section 3.8)	4.3.8	Applicable	Pumps are designed to operate at the highest efficiency achievable. Regular maintenance on these systems is carried out on site in order to sustain the high performance level of the pumps.		
Heating, ventilation and air conditioning (HVAC) s	systems				
<ul> <li>BAT is to optimise heating, ventilation and air conditioning systems by using techniques such as:</li> <li>for ventilation, space heating and cooling, techniques in Table 4.8 according to applicability</li> <li>for heating, see Sections 3.2 and 3.3.1, and BAT 18 and 19</li> <li>for pumping, see Section 3.8 and BAT 26</li> <li>for cooling, chilling and heat exchangers, see the ICS BREF, as well as Section 3.3 and BAT 19</li> </ul>	4.3.9	Applicable	Techniques for optimising the efficiency of the HVAC systems on site are implemented and continuously improved by the company's EMS. There are no HVAC systems in place on the TO as this is an external piece of equipment.		
Lighting		on purequi			
BAT is to optimise artificial lighting systems by using the techniques such as those in Table 4.9 according to applicability. (see Section 3.10)	4.3.10	in Applicable	Energy efficient lighting is used across the site.		
Drying, separation and concentration processes					
BAT is to optimise drying, separation and concentration processes by using techniques such as those in Table 4.10 according to applicability, and to seek opportunities to use mechanical separation in conjunction with thermal processes:	4.3.11_015eth	Applicable	Drying and cooling processes within the production plant are carried out using efficient mechanical and thermal processes.		

# BREF on Emissions from Storage, July 2006

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
Tank Design			
<ul> <li>BAT for a proper design is to take into account at least the following: <ul> <li>the physico-chemical properties of the substance being stored</li> <li>how the storage is operated, what level of instrumentation is needed, how many operators</li> <li>are required, and what their workload will be</li> <li>how the operators are informed of deviations from normal process conditions (alarms)</li> <li>how the storage is protected against deviations from normal process conditions (safety</li> <li>instructions, interlock systems, pressure relief devices, leak detection and containment, etc.)</li> <li>what equipment has to be installed, largely taking account of past experiences of the</li> <li>product (construction materials, valve quality, etc.)</li> <li>which maintenance and inspection plan needs to be implemented and how to ease the</li> <li>maintenance and inspection work (access, layout, etc.)</li> <li>how to deal with emergency situations (distances to other tanks, facilities and to the</li> <li>boundary, fire protection, access for emergency services such as the fire brigade, etc.).</li> </ul> </li> </ul>	5.1.1.1	Applicable Applicable	Detailed design, risk assessment, and HAZOPs are carried out prior to the selection and installation of any tanks on site. All stakeholders including designers, vendors, engineers & operators are consulted during the process.
Inspection and Maintenance	C		
BAT is to apply a tool to determine proactive maintenance plans and to develop risk-based inspection plans such as the risk and reliability based maintenance approach	4.1.2.2.1	Applicable	Preventative maintenance system is in place. Includes visual operational inspections, routine maintenance as per manufacturer's instructions and plant shutdown inspections.
Location and layout			
BAT is to locate a tank operating at, or close to, atmospheric pressure aboveground. However, for storing flammable liquids on a site with restricted space, underground tanks can also be considered. For liquefied gases, underground, mounded storage or spheres can be considered, depending on the storage volume.	4.1.2.3	Applicable	Tanks are located and positioned as per best industrial practice (e.g. HSG 176).

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
Tank Colour			
BAT is to apply either a tank colour with a reflectivity of thermal or light radiation of at least 70 %, or a solar shield on aboveground tanks which contain volatile substances	4.1.3.6, 4.1.3.7	Applicable	All tanks containing VOCs are of stainless steel construction and finish and hence meet the reflectivity requirements.
Emissions minimisation principle in tank storage			
BAT is to abate emissions from tank storage, transfer and handling that have a significant negative environmental effect	4.1.3.1	Applicable	All tanks in tank farm with the potential for fugitive emissions which could have a significant environmental effect are abated into the new vent header design which directs the emission to the ne thermal oxidiser or treatment.
Monitoring of VOC			N <sup>Se.</sup>
On sites where significant VOC emissions are to be expected, BAT includes calculating the VOC emissions regularly. The calculation model may occasionally need to be validated by applying a measurement method.	4.1.2.2.3	Applicable of	Abby ie annually report the solvent mass balance for the installation and compares the
Dedicated Systems		etion put coor	
BAT is apply dedicated systems	4.1.4.4	For Applicable	There are dedicated systems for particular materials on site. Due the changing products and manufacturing methods, some systems have been design to accept multiple materials.
Tank Specific Considerations	Consen	°	
BAT is to apply a vapour treatment installation.	4.1.3.15	Applicable	Vapour Treatment in the form of; New thermal oxidiser will treat all atmospheric and fugitive emissions from solvent storage tanks via the vent header collection system
Preventing Incidents and Major Accidents		•	
Safety and Risk Management BAT in preventing incidents and accidents is to apply a safety management system	4.1.6.1.	Applicable	Safety and emergency procedures in place. See Emergency Response Plan submitted as Part J of Review Application

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<b>Operational procedures and training</b> BAT is to implement and follow adequate organisational measures and to enable training and instruction of employees for safe and responsible operation of the installation.	4.1.6.1.1.	Applicable	Training and SOPs are in place at the AbbVie facility and will be extended to include any new procedures associated with new TO.
<ul> <li>Leakage due to corrosion and/or erosion</li> <li>Corrosion is one of the main causes of equipment failure and can occur both internally and externally on any metal surface.</li> <li>BAT is to prevent corrosion by:</li> <li>selecting construction material that is resistant to the product stored</li> <li>applying proper construction methods</li> <li>preventing rainwater or groundwater entering the tank and if necessary, removing water that has accumulated in the tank</li> <li>applying preventive maintenance, and</li> <li>where applicable, adding corrosion inhibitors, or applying cathodic protection on the inside of the tank.</li> <li>Additionally for an underground tank, BAT is to apply to the outside of the tank:</li> <li>a corrosion-resistant coating</li> <li>plating, and/or</li> <li>a cathodic protection system.</li> </ul>	4.1.6.1.4.	Applicable only of the province of the provinc	Betailed design, risk assessment, and material compatibility are carried out prior to the selection and installation of any tanks/ pipes on site. Maintenance and treatment of materials is carried out as per manufacturer's instructions.
Stress corrosion cracking (SCC) is a specific problem for spheres, semi-refrigerated tanks and some fully refrigerated tanks containing ammonia. BAT is to prevent SCC by: • stress relieving by post-weld heat treatment • applying a risk based inspection	4.1.6.1.4, 4.1.2.2.1.	Applicable	All refrigeration equipment and tanks installed to the relevant standards by trained individuals.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
Operational procedures and instrumentation to prevent overfill BAT is to implement and maintain operational procedures – e.g. by means of a management system –to ensure that: • high level or high pressure instrumentation with alarm settings and/or auto closing of valves is installed • proper operating instructions are applied to prevent overfill during a tank filling operation, and • sufficient ullage is available to receive a batch filling.	4.1.6.1.5	Applicable	Training, SOPs and instrumentation are in place at the AbbVie facility. Alarms on tanks are sent to the building management system and flagged for immediate investigation.
<b>Instrumentation and automation to detect leakage</b> BAT is to apply leak detection on storage tanks containing liquids that can potentially cause soil pollution. The applicability of the different techniques depends on the tank type.	4.1.6.1.7	Applicable For instruct	Leak detection installed on high risk tanks. All tanks are bunded.
<b>Risk-based approach to emissions to soil below tanks</b> BAT is to achieve a 'negligible risk level' of soil pollution from bottom and bottom-wall connections of aboveground storage tanks. However, on a case-by-case basis, situations might be identified where an 'acceptable risk level' is sufficient.	_ Consent	O <sup>7</sup>	Tanks situated on bund on legs. Visual inspections possible. Leak detection on tanks.
Soil protection around tanks – containment			
BAT for aboveground tanks containing flammable liquids or liquids that pose a risk for significant soil pollution or a significant pollution of adjacent watercourses is to provide Secondary containment.	4.1.6.1.10	Applicable	All tanks are bunded in line with EPA guidance and as per industrial Emissions Licence Conditions.
For building new single walled tanks containing liquids that pose a risk for significant soil pollution or a significant pollution of adjacent watercourses, BAT is to apply a full, impervious, barrier in the bund.			

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
For <b>existing tanks within a bund</b> , BAT is to apply a risk- based approach, considering the significance of risk from product spillage to the soil, to determine if and which barrier is best applicable.	-	Applicable	Risk assessments carried out for all spillage scenarios. All tanks are bunded.
For <b>chlorinated hydrocarbon solvents</b> (CHC) in single walled tanks, BAT is to apply CHC proof laminates to concrete barriers (and containments), based on phenolic or furan resins. One form of epoxy resin is also CHC-proof.	4.1.6.1.12	Not Applicable	No
<ul> <li>BAT for underground and mounded tanks containing products that can potentially cause soil pollution is to:</li> <li>apply a double walled tank with leak detection</li> <li>to apply a single walled tank with secondary containment and leak detection</li> </ul>	4.1.6.1.16, 4.1.6.1.17.	Not Applicable	No
Flammable areas and ignition sources See ATEX Directive 1999/92/EC.	4.1.6.2.1	Applicableses of	ATEX zoned areas have been identified on site and the necessary operational and equipment measures are in place in accordance with both ATEX Directives.
Fire protection The necessity for implementing fire protection measures has to be decided on a case-by-case basis. Fire protection measures can be provided by applying, e.g., • fire resistant claddings or coatings • firewalls (only for smaller tanks), and/or • water cooling systems. Fire-fighting equipment The necessity for implementing fire-fighting equipment and the decision on which equipment to apply has to be taken on a case-by-case basis in agreement with the local fire brigade.	4.1.6.2.2	For inspection Percet Applicable	Fire protection measures are in place in the tank farm. The fire protection strategy and equipment was based on detail design and risk assessments
<b>Containment of contaminated extinguishant</b> For toxic, carcinogenic or other hazardous substances, BAT is to apply full containment.	4.1.6.2.4.	Applicable	All tanks are bunded. There is a firewater retention pond also which will contain all firewater on site. This will then be tested to decide its fate – release to environment or taken off site by waste specialist.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation	
Storage of Packaged Dangerous Substances				
Safety and risk management BAT in preventing incidents and accidents is to apply a safety management system as described in Sections 4.1.6.1. The minimum level of BAT is to assess the risks of accidents and incidents on the site using the five steps.	4.1.6.1	Applicable	Safety and emergency procedures in place. See Emergency Response Plan submitted as Part J of Review Application. All risk assessments carried out to one of the established methods contained in BS EN 31010:2010	
<b>Training and responsibility</b> BAT is to appoint a person or persons who is or are responsible for the operation of the store. BAT is to provide the responsible person(s) with specific training and retraining in emergency procedures.	4.1.7.1	Applicable	The drum store building is managed by an area manager who is trained in the relevant SOPs and emergency procedures.	
<b>Storage area</b> BAT is to apply a storage building and/or an outdoor storage area covered with a roof. For storing quantities of less than 2500 litres or kilograms dangerous substances, applying a storage cell as described in Section is also BAT.	4.1.7.2	For interior purposes of the policable	The drum store is roofed with separate external chemical stores for segregation of certain materials.	
Separation and segregation BAT is to separate the storage area or building of packaged dangerous substances from other storage, from ignition sources and from other buildings on- and off-site by applying a sufficient distance, sometimes in combination with fire-resistant walls. BAT is to separate and/or segregate incompatible substances.	- Consent	Applicable	Drums store is ATEX rated and segregation strategies are in place.	
<ul> <li>Containment of leakage and contaminated extinguishant BAT is to install a liquid-tight reservoir according to Section 4.1.7.5, that can contain all or a part of the dangerous liquids stored above such a reservoir.</li> <li>BAT is to install a liquid-tight extinguishant collecting provision in storage buildings and storage areas.</li> </ul>	4.1.7.5	Applicable	Drum Store is bunded.	

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<b>Fire-fighting equipment</b> BAT is to apply a suitable protection level of fire prevention and fire-fighting measures as described in Section	4.1.7.6.	Applicable	Fire fighting equipment and procedures are in place for the drum store.
<b>Preventing ignition</b> BAT is to prevent ignition at source.	4.1.7.6.1	Applicable	Ignition control measures in place. No smoking, ATEX Zone, SOPs, Permit to Work System
Basins & Lagoons, Atmospheric mined Caverns,	Pressurised N	Ained Caverns, F	Floating Storage
Not Applicable	4.1.3 -5.1.7	Not Applicable	No No
Transfer and Handling of Liquids and Liquefied G	ases – Gener	al Principles ൣര്	
<b>Inspection and maintenance</b> BAT is to apply a tool to determine proactive maintenance plans and to develop risk-based inspection plans such as, the risk and reliability based maintenance approach; see Section.	4.1.2.2.1	Applicable Inger owned	Preventative maintenance system is in place. Includes visual operational inspections, routine maintenance as per manufacturer's instructions and plant shutdown inspections.
Leak detection and repair programme For large storage facilities, according to the properties of the products stored, BAT is to apply a leak detection and repair programme. Focus needs to be on those situations most likely to cause emissions (such as gas/light liquid, under high pressure and/or temperature duties).	4.2.1.3 Consent	Applicable	Preventative maintenance system is in place. Includes visual operational inspections of pipelines, routine maintenance as per manufacturer's instructions and plant shutdown inspections. LPG tank and transfer pipelines inspected and maintained as per Gas installer Instructions.
<b>Emissions minimisation principle in tank storage</b> BAT is to abate emissions from tank storage, transfer and handling that have a significant negative environmental effect	4.1.3.1	Applicable	Fugitive emissions from tank storage and transfer pipework collected in vent header system and directed to new thermal oxidiser for treatment.
Safety and risk management BAT in preventing incidents and accidents is to apply a safety management system.	4.1.6.1	Applicable	Safety and emergency procedures in place. See Emergency Response Plan submitted as Part J of Review Application. SOPs in place for safe use of all equipment including transfer procedures.
<b>Operational procedures and training</b> BAT is to implement and follow adequate organisational measures and to enable the training and instruction of employees for safe and responsible operation of the installation.	4.1.6.1.1	Applicable	AbbVie training and procedures in place for all operatives.
Considerations on transfer and handling techniq	ues		

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<b>Piping</b> BAT is to apply aboveground closed piping in new situations. For existing underground piping it is BAT to apply a risk and reliability based maintenance approach.	4.2.4.1	Applicable	All processing liquid and gas piping is overhead between the tank farm and the production cells.
<b>Bolted flanges and gasket-sealed joints</b> are an important source of fugitive emissions. BAT is to minimise the number of flanges by replacing them with welded connections, within the limitation of operational requirements for equipment maintenance or transfer system flexibility, see Section	4.2.2.1.	Applicable	All pipes and flanges at tie in points are provided in accordance with ASME B31.3 – Process Piping & ASME B16.5 – Pipe Flanges and Flanged Fittings.
BAT for <b>bolted flange connections</b> include: • fitting blind flanges to infrequently used fittings to prevent accidental opening • using end caps or plugs on open-ended lines and not valves • ensuring gaskets are selected appropriate to the process application • ensuring the gasket is installed correctly • ensuring the flange joint is assembled and loaded correctly • where toxic, carcinogenic or other hazardous substances are transferred, fitting high integrity gaskets, such as spiral wound, kammprofile or ring joints. Internal corrosion may be caused by the corrosive nature of the product being transferred.	4.2.2.2, 4.2.3.1.	Applicablesesed	A and other use. All pipes and flanges at tie in points are provided in accordance with ASME B31.3 – Process Piping & ASME B16.5 – Pipe Flanges and Flanged Fittings.
BAT is to <b>prevent corrosion</b> by: • selecting construction material that is resistant to the product • applying proper construction methods • applying preventive maintenance, and • where applicable, applying an internal coating or adding corrosion inhibitors.	-	Applicable	Detailed design, risk assessment, and material compatibility are carried out prior to the selection and installation of any tanks/ pipes on site. Maintenance and treatment of materials is carried out as per manufacturer's instructions.
Vapour treatment BAT is to apply vapour balancing or treatment on significant emissions from the loading and unloading of volatile substances to (or from) trucks, barges and ships.	-	Not Applicable	No. No significant emissions from loading or unloading activities.

BAT Statement	BAT Reference Number	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
<ul> <li>Valves</li> <li>BAT for valves include:</li> <li>correct selection of the packing material and construction for the process application</li> <li>with monitoring, focus on those valves most at risk (such as rising stem control valves in continual operation)</li> <li>applying rotating control valves or variable speed pumps instead of rising stem control valves</li> <li>where toxic, carcinogenic or other hazardous substances are involved, fit diaphragm, bellows, or double walled valves</li> <li>route relief valves back into the transfer or storage system or to a vapour treatment system.</li> </ul>	3.2.2.6 and 4.2.9.	Applicable	The plant is constructed in accordance with all latest practices for eliminating diffuse emissions. Common areas for diffuse emissions include valve stems & flanges. Strict and well defined procedures for construction and assembly are in place and robust inspection/maintenance procedures exist to ensure that plant is installed/maintained in line with design requirements.
Pumps and compressorsInstallation and maintenance of pumps and compressorsSealing systems in compressorsBAT for compressors transferring non-toxic gases is to apply gas lubricated mechanical seals.BAT for compressors, transferring toxic gases is to apply double seals with a liquid or gas barrier and to purge the process side of the containment seal with an inert buffer gas. In very high pressure services, BAT is to apply a triple tandem seal system.	3.2.2.2, 3.2.4.1 and 4.2.9, 3.2.3 and 4.2.9.13.	Applicable so only of the second seco	A whether use and compressors including seals and couplings are installed, maintained and inspected in line with the manufacturer's instructions. Preventative maintenance systems in place to ensure
<b>Sampling connections</b> BAT, for sample points for volatile products, is to apply a ram type sampling valve or a needle valve and a block valve. Where sampling lines require purging, BAT is to apply closed- loop sampling lines. See Section	4.2.9.14. conset	Applicable	Sampling ports installed win line with EPA Guidance.
Storage and transfer of Solids			
BAT is to apply enclosed storage by using, for example, silos, bunkers, hoppers and containers, to eliminate the influence of wind and to prevent the formation of dust by wind as far as possible by primary measures.	-	Not Applicable	No external bulk storage of solids.
BAT is to apply enclosed storage by using, for example, silos, bunkers, hoppers and containers. Where silos are not applicable, storage in sheds can be an alternative. This is, e.g. the case if apart from storage, the mixing of batches is needed.	-	Applicable	All solids are contained within sealed containers and stored indoors.

# Attachment J

AbbVie Emergency Response Plan

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# AbbVie Ireland NL B.V. Manorhamilton Road Sligo

# Emergency Preparedness & Response Procedure





Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 1 of 67

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# Contents

1	Introduction and Objectives	
2	Abbreviations	
3	Facility Description, Infrastructure and Utilities	6
4	Emergency Organisation	7
	4.1 Crisis Management Team	
	4.2 Role of Incident Commander	
	4.3 Role of Emergency Team Leader	9
	4.4 Role of Emergency Team Members	
	4.5 Role of Fire Wardens / Roll Callers	10
5	Emergency Response Centre	10
6	8 v	
	6.1 External & Management Contacts	11
	6.2 Employee Emergency Contacts	11
7	Emergency Response Procedures	12
	7.1 Fire / Explosion	12
	Emergency Response Procedures	13
	7.1.2 Developed developed a final $(D_{14}, A_{14}, \dots, D_{14}, A_{14}, \dots, A_{14})$	1 /
	7.2 O2 / LEL	15
	7.2.1 O2 / LEL Alarm	16
	7.3 Ammonia Release	17
	7.3.1 Ammonia Release	18
	7.4 Chemical Spill	19
	<ul> <li>7.1.2 Procedure for Full Site Alarm (Double Knock)</li> <li>7.2 O2 / LEL.</li> <li>7.2.1 O2 / LEL Alarm</li> <li>7.3 Ammonia Release</li> <li>7.3.1 Ammonia Release</li> <li>7.4 Chemical Spill</li> <li>7.4.1 Chemical Spill Procedure</li> </ul>	20
	7.5 Utility Loss	21
	7.5 Utility Loss	22
	7.6 Transportation Incident	23
	7.6.1 Transportation Incident	24
	7.7 Medical Emergency / Mass Causalities	25
	7.7.1 Medical Emergency / Mass Causality	
	7.8 Civil Disturbances / Strikes / Protestors	27
	7.8.1 Civil Disturbances / Strikes / Protestors	28
	7.9 Workplace Violence	29
	7.9.1 Workplace Violence	30
	7.10 Suspicious Parcel and Letter	31
	7.10.1 Suspicious Parcel and Letter	
	7.11 Kidnap / Extortion / Threats	33
	7.12 Cyber Attack	34
	7.13 Sabotage	35
	7.14 Bomb Threat	
	7.15 Chemical Threat	
	7.15.1 Chemical Threat	
	7.16 Nuclear Threat	
	7.16.1 Nuclear Threat	42
	7.17 Biological Threat	43

Approved Date: 15-Oct-2014 Version 8.0, Effective

Effective By Date: 14-Nov-2014 Page 2 of 67

7.18	Biological Threat	
7.19	Lone Working	
7.20	Other	
7.21	Severe Weather	
8 Mee	dia Relations	
9 Inci	ident Reporting	

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Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 3 of 67

## 1 Introduction and Objectives

This Emergency Preparedness and Response Procedure which applies to Abbvie Ireland NL B.V. Sligo describe the actions to be taken in the event of an emergency situation arising at its facility.

The objective is to assure responsible leadership during emergencies to minimise or eliminate loss of life, injuries to personnel or damage to either property or the environment.

This procedure establishes the responsibilities and procedures for anticipated emergency situations, the training requirements for responsible parties and an inventory of emergency response equipment.

The Emergency Preparedness and Response Procedure will be maintained by the EHS department and will be reviewed no less than annually for updating as required.

The emergency contact telephone numbers will be checked quarterly by the EHS Department through an audit set up on the audit module of enviroManager.  $\aleph^{1}$ 

The procedure will be reviewed and amended as required for any of the following;

- Changes to the emergency system. <sup>1</sup>
   <sup>1</sup>
- Changes in applicable regulations
- Facility changes in design, construction, operation or maintenance that might increase the risk of fire/explosion or the risk of hazardous materials release or spill.

## 2 Abbreviations

Emergency Response Team	ERT
ERT Team Lead	ERT TL
Team Lead	TL
Incident commander	IC
Emergency Coordinator	EC
Plant Emergency Coordinator	PEC
Crisis Management Team	CMT
Break Glass Unit	BGU
Plant Support Engineer	PSE
Breathing Apparatus	BA
Liquefied Petroleum Gas	LPG

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 5 of 67

#### 3 **Facility Description, Infrastructure and Utilities**

The facility is located on a green-field site of 47ha (116 acres) on the north side of Sligo town.

The facility occupies an area of approximately 12.5ha (31 acres) in the eastern part of the site.

The facility address is: Abbvie Ireland NL B.V. Manorhamilton Road, Sligo.

The site consists of four main buildings and a number of ancillary facilities.

The buildings and facilities are set out in four parallel rows, each row aligned on an approximately east-west orientation.

The rows are arranged on a north-south axis.

The main buildings are as follows:

- Building 70 Utilities building •
- Building 40 Bulk pharmaceutical facility •
- Building 20 Drug formulation facility •
- Building 10 Administration and laboratory building • FOT INSPECTION PUTPOR
- Sycamore offices .

The ancillary facilities are follows:

- Tank farm •
- Tank loading Bay
- Fire water storage tank •
- Emergency generator •
- Air emissions abatement systems •
- Aqueous waste treatment system •
- Drum store •
- LPG gas compound •
- Security building

Refer to:

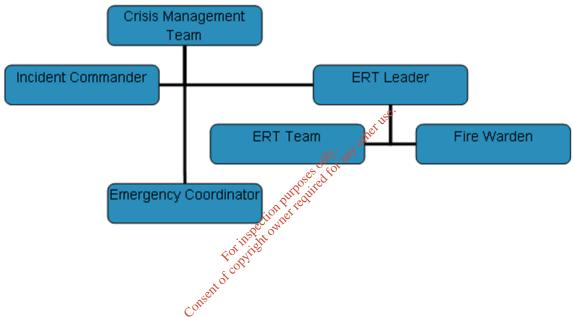
Appendix 1: Emergency Equipment / Utilities Appendix 2: Description of Main Buildings Facilities and utilities

# 4 Emergency Organisation

The facility's primary emergency response organisation is the Emergency Response Team (ERT).

The ERT is responsible for:

- Coordinating all operations during an emergency,
- Resolving the emergency situation if safe and practical; and
- Coordinating the efforts of emergency services / local officials, if necessary.



# 4.1 Crisis Management Team

The sites crisis management team is made up of the senior management team. The roles and responsibilities of the crisis management team are out lined in the Plants Business Continuity Plan.

In the event of an escalation of an emergency this will be coordinated with the crisis management team through the emergency coordinator and/or Incident Commander.

The Site Director is also a members of the Country Crisis Communication Team which co-ordinate on a national basis all communication relating to Abbvie. The team includes members from Abbvie Dublin and Abbvie Cork.

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Effective By Date: 14-Nov-2014 Page 7 of 67

# 4.2 Role of Incident Commander

Assess each situation with Emergency Team Leader as it arises and decide on appropriate action such as:

- Should the emergency team go into action?
- What is the risk to employees, product, property or environment?
- Who is required from an advisory role to deal with the incident?
- Should the plant be evacuated partially/completely if not already evacuated?

To take direct charge of all aspects of an emergency incident which may arise this includes giving managerial updates and support to the ERT TL and direct other members of the team in an emergency.

To liaise with external emergency services during an emergency.

Once satisfied that an emergency is over and the plant is safe, give direction for all employees to return to their normal duties in the event of an evacuation.

Ensuring that all services and utilities have been restored to normal where there has been no impact. E.g. Fire water retention value reopened, HVAC systems running in each building etc.

Ensure that all reports regarding the medent are written up in a timely and efficient manner as soon as possible after the medent.

Ensure that in their absence while on incident duty their own reports are safe and accounted for.

Contact members of the Crisis Management Team as necessary alongside the Emergency Coordinator and update them on progress as the incident develops.

In the event of a partial evacuation, it is the responsibility of the IC, after liaising with the ERT TL to update the CMT.

It is then the responsibility of the CMT to advise/inform their direct department supervisors, who will then be responsible to co-ordinate and/or communicate to the applicable departments that are required to be evacuated if not already evacuated.

Effective By Date: 14-Nov-2014 Page 8 of 67

## 4.3 Role of Emergency Team Leader

To provide leadership to the ERT members during an emergency ensuring members of their team are safe and take directions from them during emergencies. Assign emergency team members roles and responsibilities throughout the emergency ensuring that all critical steps throughout an emergency are completed in a controlled and safe manner.

To liaise with the IC during an emergency incident to ensure that correct decisions are being made throughout the incident.

To ensure that all equipment available to the emergency team is available to fulfil its duties is properly stored and maintained.

To partake in frequent emergency drills to evaluate the response of the ERT and to ensure that all lessons learnt as a result are implemented into revised training.

Write formal reports to the IC and EHS on any emergency that has arisen with recommendations for future improvements.

To motivate and encourage active involvement of all ERT members.

Report any issues/recommendations on behalf of the team to the EHS Dept.

To direct the other members of the team in an emergency.

In the absence of the ERTETL this duty will be delegated to the Plant Support Engineer on site and/or on call or the IC.

Following the emergency alongside the IC Ensure that all services and utilities have been restored to normal where there has been no impact. E.g. Fire water retention valve reopened, HVAC systems running in each building etc.

## 4.4 Role of Emergency Team Members

In the event of an emergency incident occurring, ERT members carry out emergency procedures under the directions of the ERT TL or delegate.

To locate and use emergency equipment in a trained manner on an "IF safe to do so" basis.

To partake in all training and emergency drills as directed by the ERT TL

Effective By Date: 14-Nov-2014 Page 9 of 67

## 4.5 Role of Fire Wardens / Roll Callers

Assure that all employees in your area know the evacuation routes for their area and the designated assembly Point.

At the designated assembly point account for all employees and report immediately to Emergency Coordinator/ IC on any unaccounted for personnel.

Ensure that employees under your control remain at the designated assembly point until authorised to return to the facility by the ERT TL IC.

## 5 Emergency Response Centre

The primary on-site emergency response centre is located in Security.

This Procedure and all supporting materials shall be kept in the Emergency Response Center.

The emergency response center serves the following purposes:

- Provides a central base of operations for ERT members and local authorities.
- Functions as the main clearinghouse for information about the incident for employees, media, and the public.

If an emergency at the facility is severe, it may be necessary for the ERT to manage the incident from an off-site location or an alternate on-site location.

An off-site emergency response centre is located at the Abbvie Ballytivnan facility.

(Refer to PH- 1174 for the drawing number for route to secondary emergency center)

Effective By Date: 14-Nov-2014 Page 10 of 67

#### 6 **Emergency Contacts**

#### 6.1 **External & Management Contacts**

(Refer to PH -1173 for a full listing of all emergency numbers).

A copy of all contact details are held in security.

This includes a full listing of all managers' mobile numbers outside of business hours for use in the event of an emergency.

An internal emergency telephone number is 555 which are highlighted on all telephones with an express call button highlighted which calls a dedicated emergency telephone at security to summons help or raise an emergency.

Numbers are reviewed on a quarterly basis by the EHS Department and updated where any changes impact on these numbers.

This is set up as an audit on the enviroMANAGER system.

#### 6.2 **Employee Emergency Contacts**

required for Employee emergency contact details are held on SAP MYHR portal. Employees can update any changes to their emergency contact details on their own MYHR portal or by contacting the MYHR team directly as needed.

In the event of an emergency HR will work with the MYHR team or the employee's leader/manager to access this information from the SAP MYHR Portal.

Calls of this nature to alert next of kin of an incident/emergency will only be fulfilled by the HR Manager or their designee or under their direction.

Out of normal office hours the HR manager and senior manager is to be contacted by the IC to inform them of an incident involving an injury/fatality to an employee.

In the event of a fatality the HR Manager will work with the Gardai to provide next of kin information and follow the direction of the Gardai leading the investigation.

In the event of a contractor being involved in an incident/fatality while carrying out activities at the facility HR or their designee will contact the contractors manager and inform them of the incident who are then responsible for contacting the contractors family.

A full listing of contacts for contractor companies employed at the facility is maintained with contractor dashboard.

Contractors are requested to inform EHS department of any changes to their management structure within their companies as they happen.

#### 7 **Emergency Response Procedures**

#### 7.1 **Fire / Explosion**

Emergency preparedness and response procedure in case of a fire /explosion at the facility including any incident, which involves a fire, explosion or smouldering of material that is likely to ignite.

Fire/ Explosion Hazard Identification:

A catastrophic fire or explosion, leading to human exposure to a chemical fire and negative environmental effects.

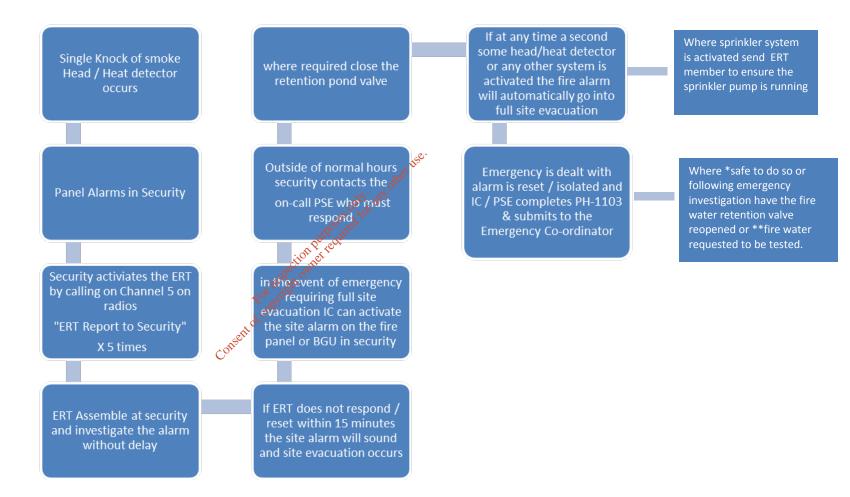
Fire/Explosion Scenarios:

- Liquid / Dust /Gas /Solids Fires & Explosions
- Fire and explosion hazards that can arise from the way a substance or chemical is • handled or processed - chemical reactivity in process manufacturing tion.
- •
- •
- Incorrect storage of chemical stronger Build-up of material Build-up of materials with a low auto ignition temperature
- Tanker loading/unloading pooled or flash fire / explosion Consent
- Electrical fire
- Fuel fire

Fire alarm detection system:

- Smoke detectors •
- Heat detectors .
- Sprinkler and deluge System

# 7.1.1 Procedure for Single Knock Alarm



\*Safe to do so: No contamination of fire water has occurred either from activation of sprinkler system or chemical spill. \*\*Where risk that fire water has been contaminated request EHS to test the water and don't open the Fire Water retention valve

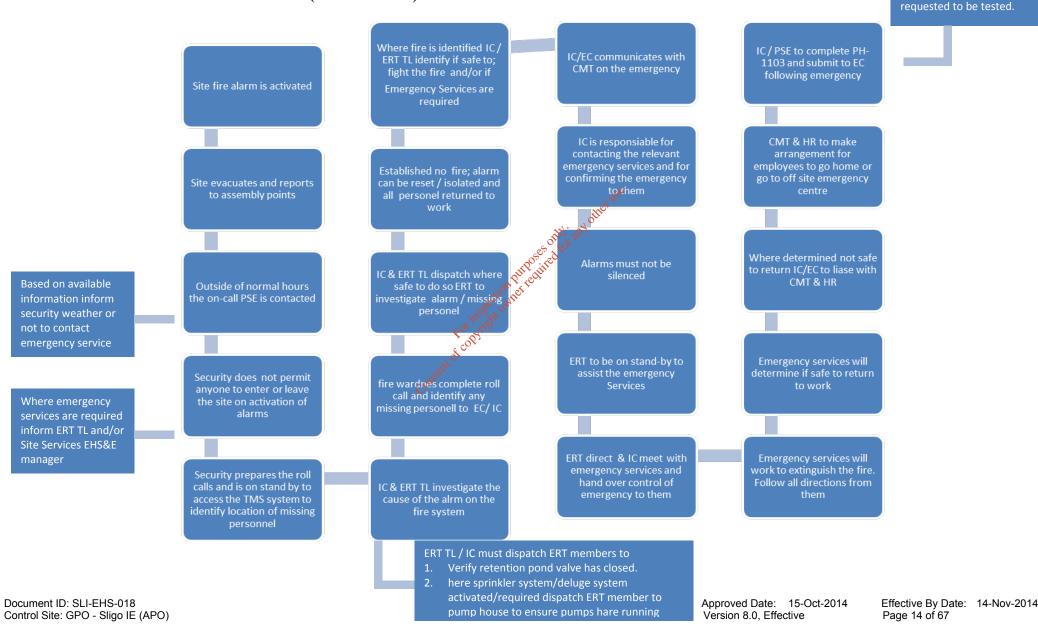
Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 13 of 67

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AbbVie

### Title: Emergency Preparedness and Response Procedure

### 7.1.2 Procedure for Full Site Alarm (Double Knock)



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Where \*safe to do so or following emergency

investigation have the fire water retention valve reopened or \*\*fire water

7.2 **O2 / LEL** 

> Emergency preparedness and response procedure in case of an O2/LEL alarm at the facility including any incident, which involves Gas and Solvents.

> O2/LEL Hazard Identification: A leak or rupture of equipment leading to human exposure to an oxygen deficient or flammable atmosphere with potential of fire and damage to plant, equipment and the environment.

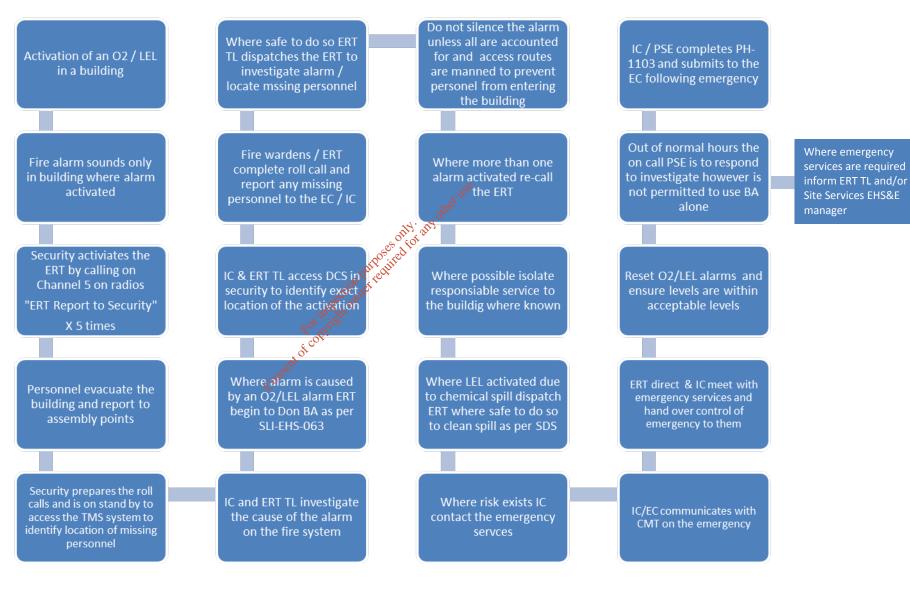
**O2/LEL Scenarios:** 

- Nitrogen Leak •
- **Chemical Spill**
- **Damaged** Lines •
- Leaks and or rupture of plant and equipment •

O2/LEL Detection System:

- O2 Analysers (B10, B20, B40)
- LEL Analysers (B40) ٠
- Connected to the BMS to ramp up the AHU in building where alarm has been • activated and DCS system to allow access to identify the exact location of the alarm activation.
- Fire Alarm Activation in building where alarm was activated. ٠
- , n .1SO.aV For inspection purposition For inspection net required O2/LEL Hand Held meters are also available for other works such as Confined Space Entry, Hot Works etc.

# 7.2.1 O2 / LEL Alarm



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 I Version 8.0, Effective

Effective By Date: 14-Nov-2014 Page 16 of 67

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#### **Ammonia Release** 7.3

Emergency preparedness and response procedure in case of an ammonia release from the site chillers.

Mass inventory of material to discharge is 75Kg.

Ammonia is used in the process chillers as a refrigerant.

The system comprises of two water cooled chillers in parallel and a glycol storage tank.

Ammonia Hazard Identification:

Ammonia is very corrosive to body tissues, reacting with body moisture on contact. At concentrations between 1000 and 3500ppm increasing chest tightness and severe eye and skin irritation will result.

Delayed effects such as chemical pneumonitis and pulmonary edema may develop several hours after exposure.

At concentrations above 3500ppm may result in rapid asphyxia.

Effects may be more pronounced at lower concentrations in children, the elderly, and persons with impaired lung function.

Ammonia is slightly flammable in the presence of open flames and sparks.

Ammonia Release Scenarios

- Ammonia Release Scenarios Ammonia liquid release due to a leak on the condenser's pipe outlet;
- Ammonia liquid release due to a catastrophic rupture on the condenser's pipe • FOL outlet;
- Ammonia vapour release ave to the relief from the safety valve.

# Ammonia Release Detection system

Ammonia leak detection system is present in the process chiller room with a central ammonia leak detection and alarm system.

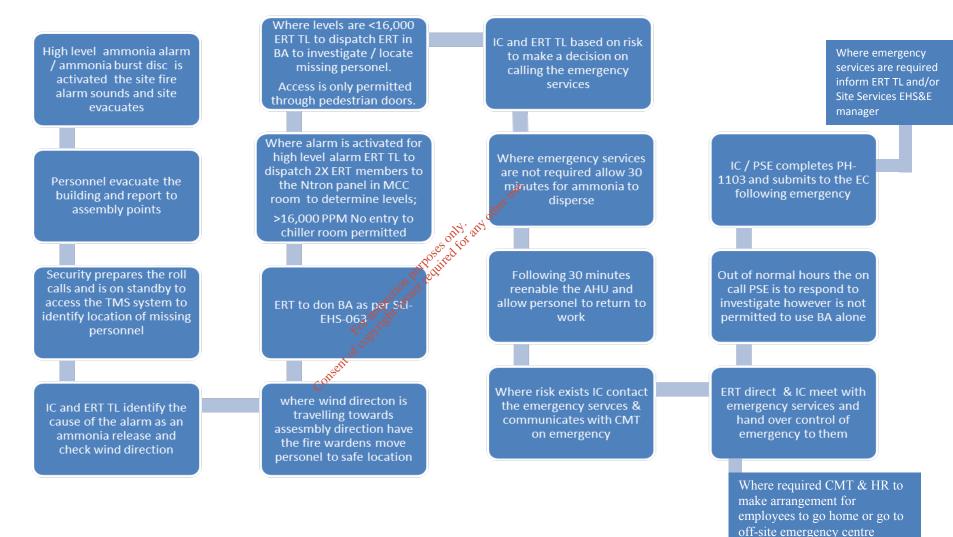
Ammonia vapour release due to the relief from the safety valve is detected by vent relief bursting discs located in the vent valves.

The burst discs are connected back to the Autronica fire and security system.

The Burst disc in the ammonia vent will be displayed on the Autronica system at security.

Effective By Date: 14-Nov-2014 Page 17 of 67

# 7.3.1 Ammonia Release



Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 18 of 67

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO)

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# 7.4 Chemical Spill

Emergency preparedness and response procedure in the response of a chemical material spill leak or release.

Chemical Hazard Identification: A spill, leak or release of any hazardous or toxic material whether in liquid, solid or gaseous form.

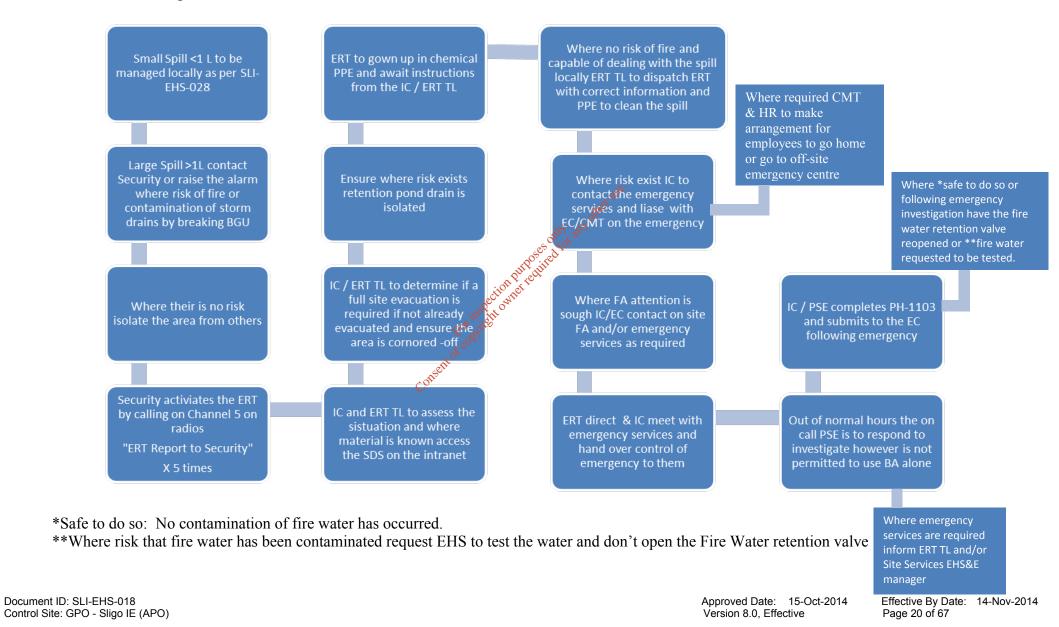
Chemical Release/Spill Sanarios:

Transportation chemical spill Chemical Spill during charging activities Chemical spill due to failure of equipment during loading & unloading activities Leak from bulk storage Damaged Lines Leaks and or rupture of plant and equipment Spillage of chemicals onto personnel

Chemicals Detection System:

- Secondary containment on all tanks
- Level Switch high alarms to DCS on critical bunds (utilities sump, scrubber • bund, tanker loading sump, TK-902 & 903 tank bund, retention pond) only an
- Weekly Bund Inspections
- •
- LEL Analysers (B40) Fire Alarm Activation automatic shat off of fire water retention pond outlet valve
- Continuous monitoring of TOC and PH at fire water retention pond- alarmed to the DCS
- LEL Hand Held meters are also available for other works Consent

# 7.4.1 Chemical Spill Procedure



Title: Emergency Preparedness and Response Procedure

## 7.5 Utility Loss

This emergency action item provides the actions to take in response to:

- Loss of power to the site or
- In the event of the failure of backup emergency equipment

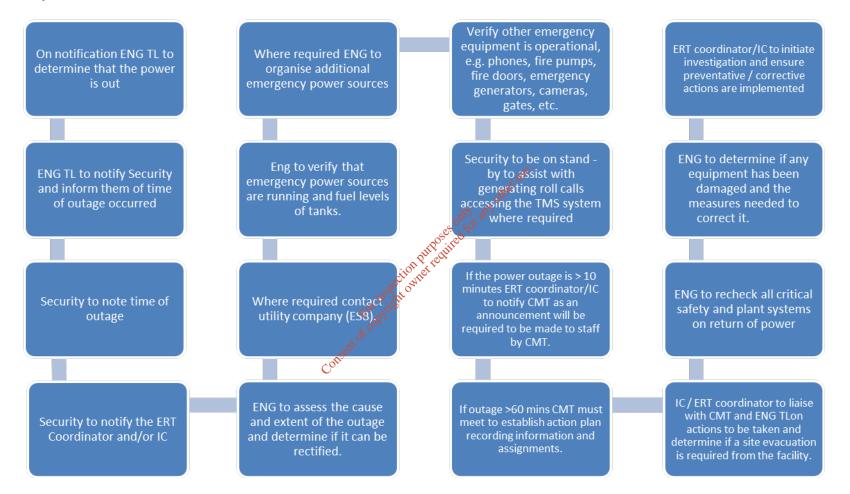
## General

On discovering a utility loss contacts the engineering team leader and notify of what has been affected.

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 21 of 67

## 7.5.1 Utility Loss



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 22 of 67

Title: Emergency Preparedness and Response Procedure

# 7.6 Transportation Incident

Emergency preparedness & response procedures for dealing with an incident during the transportation of products or hazardous materials, which have originated at the site.

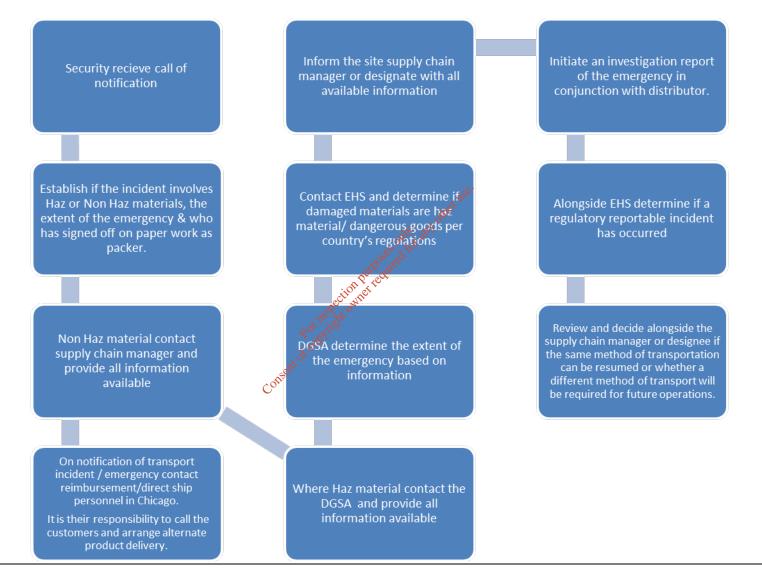
Transportation emergency is any incident, which may result in the release of or damage to products or hazardous materials which have originated at the facility.

General

In the event of receiving a call in relation to transportation incident / emergency refer the person to Security at extension 6603.

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# 7.6.1 Transportation Incident



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 24 of 67

# 7.7 Medical Emergency / Mass Causalities

This emergency procedure provides the actions to take in response to a medical emergency or casualties at the site.

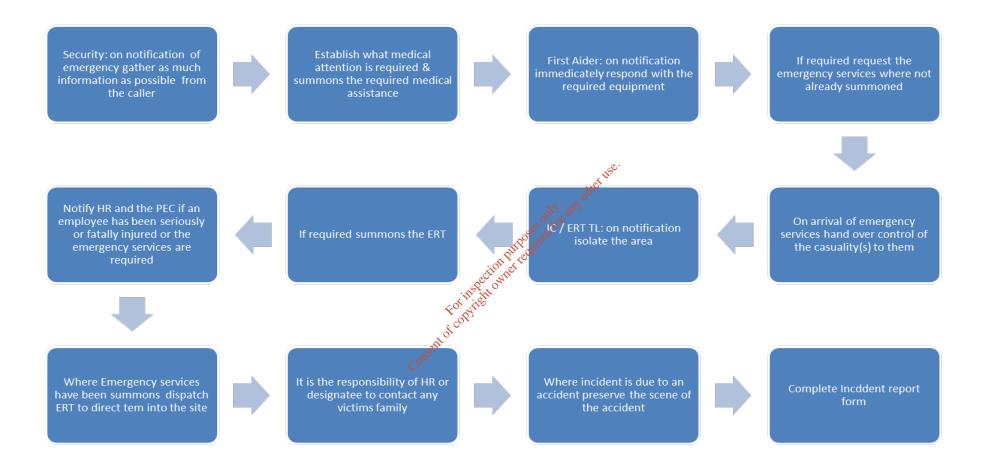
General

In the event of an emergency arising contact a first aider and / or security who can summons a first aider / emergency services for you.

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# 7.7.1 Medical Emergency / Mass Causality



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 26 of 67

# 7.8 Civil Disturbances / Strikes / Protestors

<u>Purpose:</u> This procedure outlines the response procedures for dealing with a civil disturbance, site strike or protestors.

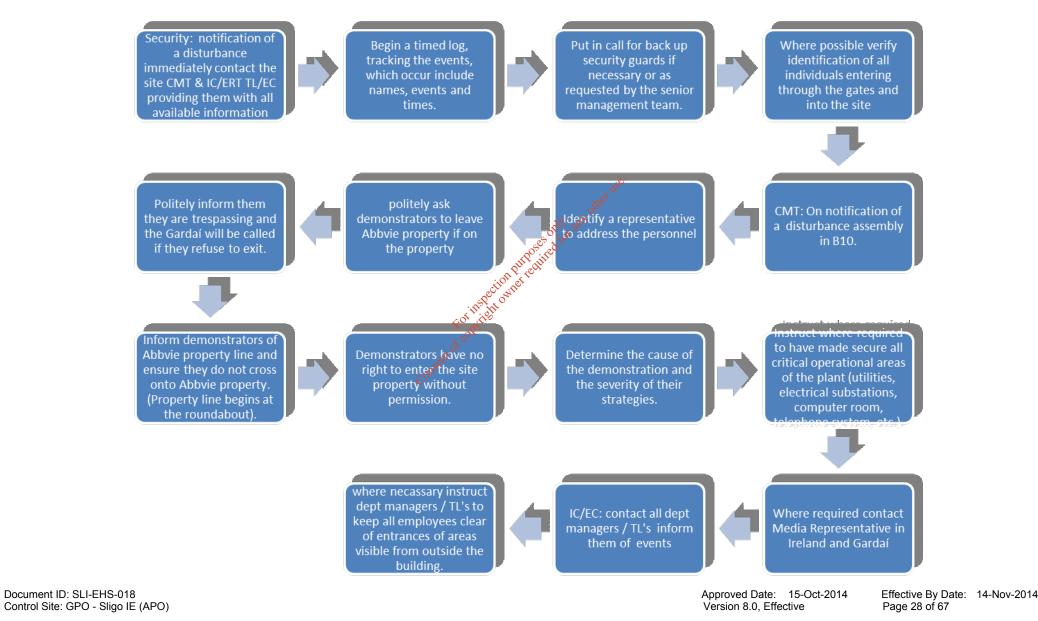
A civil disturbance/ site strikes / protestors are the presence on Abbvie Ireland NL B.V. site of unauthorized persons.

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#### Title: Emergency Preparedness and Response Procedure

# 7.8.1 Civil Disturbances / Strikes / Protestors



## 7.9 Workplace Violence

<u>Purpose</u>: To provide a procedure to deal with situations where anyone, directly or indirectly associated with Abbvie is involved in threatening or violent behaviour.

General:

•

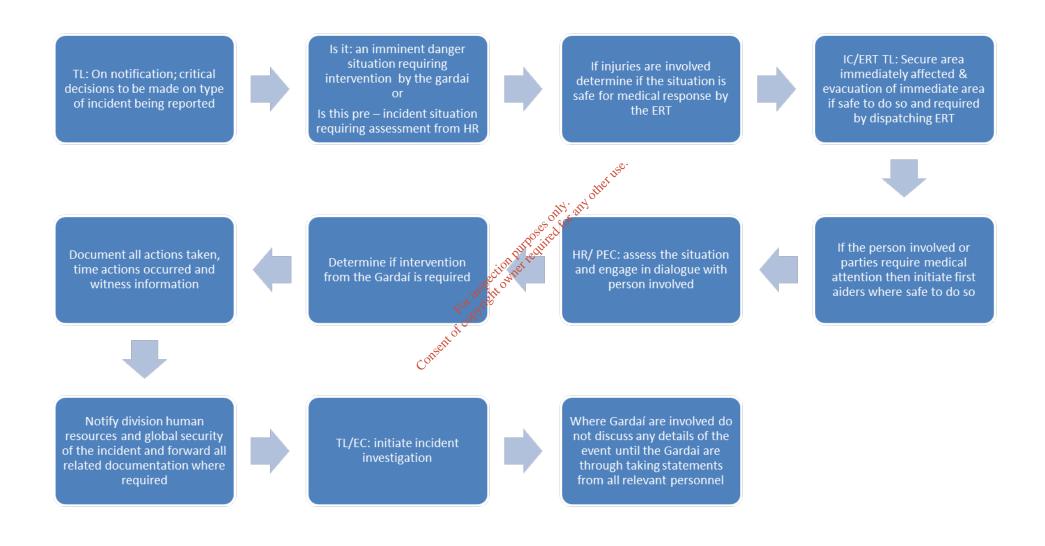
Report any incident or event that involved threatening or violent behaviour to your team leader.

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#### Title: Emergency Preparedness and Response Procedure

## 7.9.1 Workplace Violence



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 30 of 67

# 7.10 Suspicious Parcel and Letter

Purpose: This emergency procedure provides the actions to take in response to a suspect parcel or letter being delivered to the site.

# General

On discovering a suspicious letter and/or package notify security

Incident commander/ ERT Team Lead / Emergency Coordinator

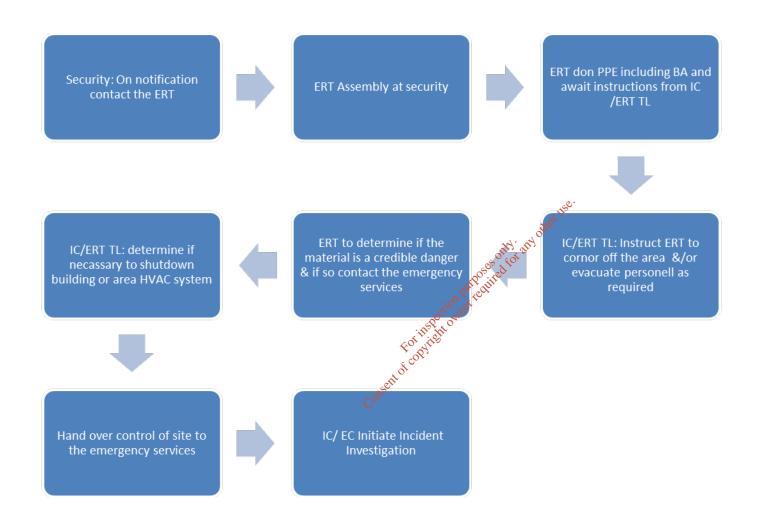
Hand over site to the emergency services •

# ERT

- Assembly at security and Only emergency personnel are allowed into the area. • Potentially contaminated personnel are not allowed to leave the area.
- Screener should not open, shake, sniff, or taste the package or its contents.
- Assist any potentially exposed personnel by keeping them calm and in the area. •
- If the material is a credible danger inform the ERT Team lead and have them contact • the emergency services
- Provide any medical attention required •
- Provide any medical attention required Assist the emergency services upon arrival on site. one use conservice on the provided of the provided •

#### Title: Emergency Preparedness and Response Procedure

## 7.10.1 Suspicious Parcel and Letter



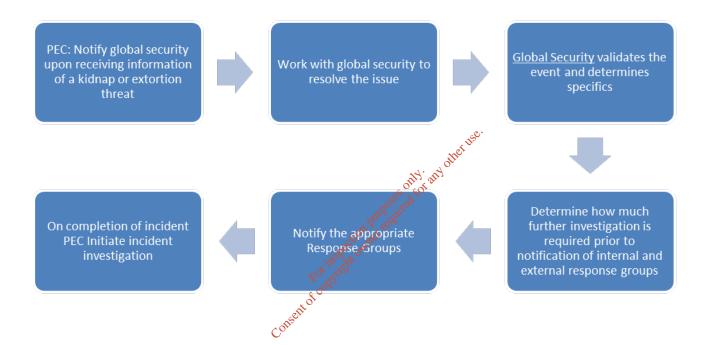
Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 32 of 67

# 7.11 Kidnap / Extortion / Threats

<u>Purpose</u>: This emergency action item provides the actions to take in response to the kidnapping or attempted extortion threat to a member of Abbvie staff in connection with company business.

General:

• Individual receiving or hearing about a kidnapping or extortion threat notify the plant emergency controller.



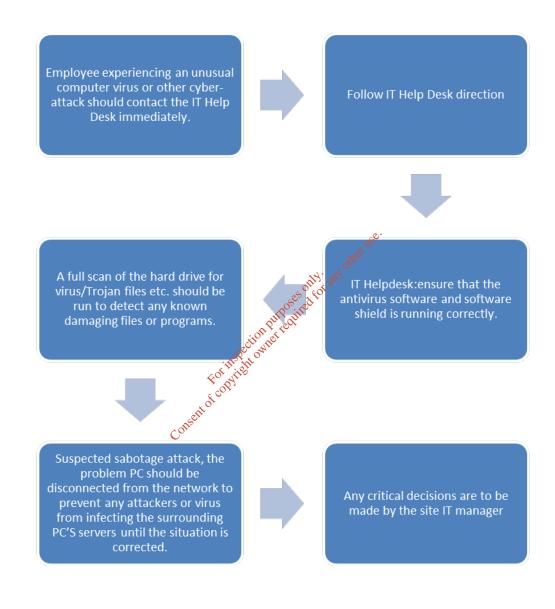
Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 33 of 67

# Title: Emergency Preparedness and Response Procedure 7.12 Cyber Attack

<u>Purpose:</u> This emergency procedure provides the actions to take in response to a cyber attack.

# General

• IT may inform others of the presence of the Virus



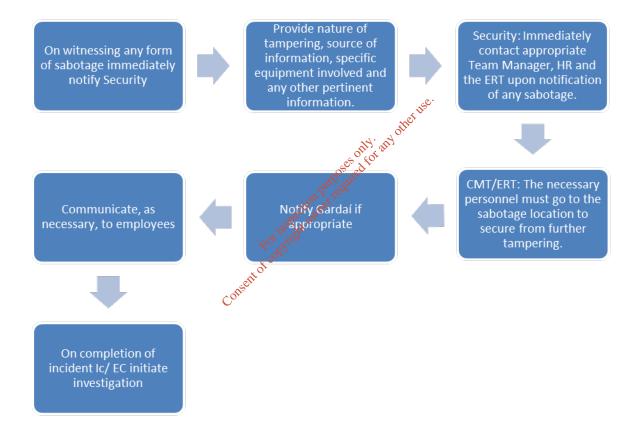
Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 34 of 67

# 7.13 Sabotage

<u>Purpose</u>: This emergency procedure provides the actions to take in response to a specific sabotage threat within the facility that could result in on-site or off-site injuries.

General:

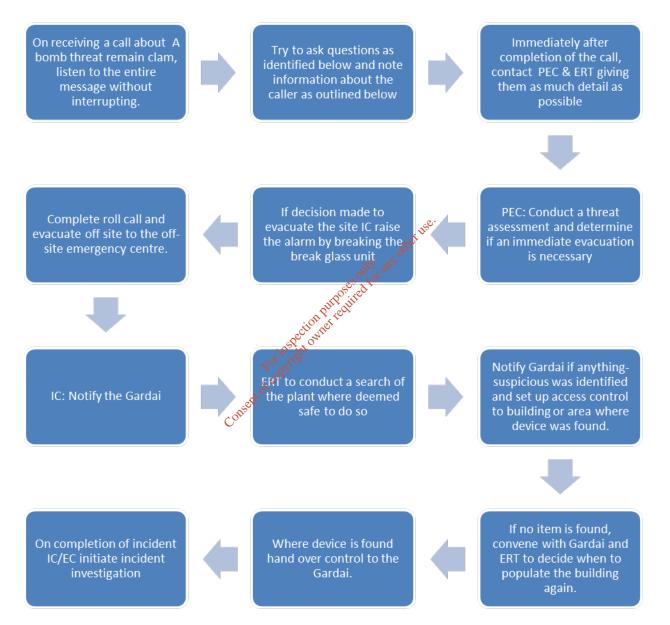
- Reportable sabotage events/incidents include:
  - Violation of plant property/procedures/product
  - o Unusual/abnormal or unexplained performance
  - o Unexplained shutdown
  - Unexplained occurrence of a repetitive problem
  - o Any other deemed actual or attempted sabotage



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 35 of 67

# 7.14 Bomb Threat

<u>Purpose</u>: The purpose of this procedure is to ensure that any Bomb Threats that are received are dealt with speed and efficiency. The Person answering the Bomb Threat Call is usually the only link with the bomber/hoaxer. The amount of information this person can extract from the caller and the speed and accuracy in reporting such information to Management will determine whether the premises should be evacuated or not.



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 36 of 67

Questions for the Caller:		
Where at the facility is the l	omb located?	
What does the bomb look li	ke?	
What type of bomb is it?		
How big is the bomb?		
What is going to cause the l	iton purperint	
When will the bomb go off		
Did you place the Bomb?		
Why are you doing this?		
Are you aware that the plan	t is occupied?	

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO)

Effective By Date: 14-Nov-2014 Page 37 of 67

# Title: Emergency Preparedness and Response Procedure

Note the following information about the caller:

Male: Adult:	Female: Child:	Approx age:	
Did the caller soun	d drunk, which may suggest a	hoax?	
Was there laughing	or music in the background,	suggesting a hoax?	
Wag it a investila w	siss with low shine and misses	ning in the healteneus do	

Was it a juvenile voice with laughing and sniggering in the background?	
Was the caller calm and precise suggesting the call may be legitimate?	

<u>Origin</u>	Male Femal Adult Juveni			<u>Speech</u>	Fast Slow Distinct Blurred Stutter	
<u>Voice</u>	Loud Soft Rough Educa High I Deep Disgu	ted Pitch	Consent of C	Language	Obscene Coarse Normal Educated Local Regional Foreign	
A R Ir C In D H	alm ngry ational rational oherent coherent eliberate ysterical ggrieved		Background No	oises Factor	y Traffic 	

TIME OF CALL

Humorous

Drunken

DATE	

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective

Effective By Date: 14-Nov-2014 Page 38 of 67

Title: Emergency Preparedness and Response Procedure

# 7.15 Chemical Threat

This emergency action item provides the actions to take in response to a specific chemical threat targeted toward the facility or the surrounding community.

General

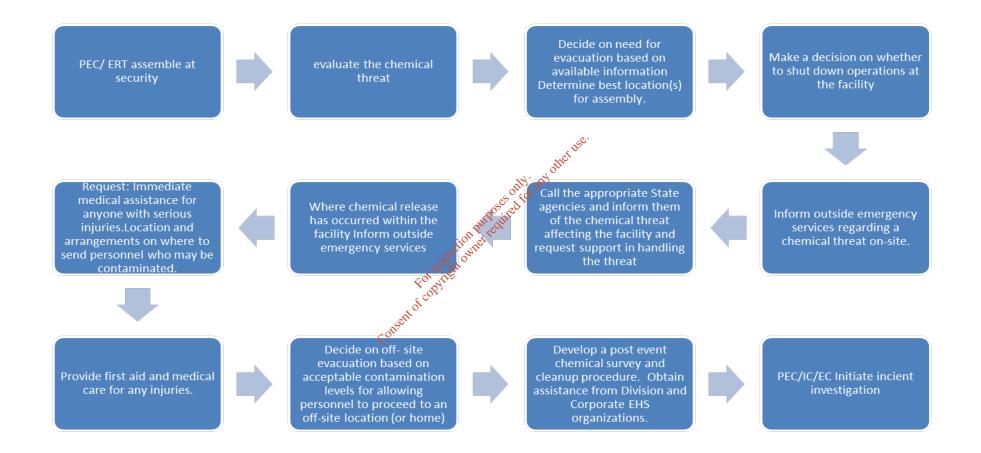
• On receiving or hearing about a chemical threat, notify security and provide information on the nature of the chemical threat.

Security:

- Record all information from the caller as outlined below
- Contact the PEC and the ERT

Time the information was received?
Location for the threat target and proximity to the facility?
When did/will the chemical agents be released?
ally and other
Bhei description of the threat (terrorist act, etc)?
What is the specific chemical or compound that is or will be released?
Caller's Name?
Other pertinent information offered by the caller?

# 7.15.1 Chemical Threat



Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 40 of 67

# 7.16 Nuclear Threat

This emergency procedure provides the actions to take in response to a specific nuclear threat targeted toward the facility or surrounding community.

General:

An event-in-progress involving the detonation of a radiological dispersion device or "dirty bomb" at the facility or within the nearby community.

A "dirty bomb" is a conventional explosive device that incorporates radioactive material. The facility will receive minimal to no radioactivity from a "dirty bomb" that explodes several miles away.

An event-in-progress involving a nuclear bomb that explodes at sufficient distance from the facility that the primary impact, post shockwave, is from radioactive debris and fallout. Expect nuclear fallout to arrive approximately 20 minutes after the blast.

• On notification of hearing about a nuclear threat notify security

# **Security**

• On receiving a call re nuclear threat record the following information and try to verify that the information is factual:

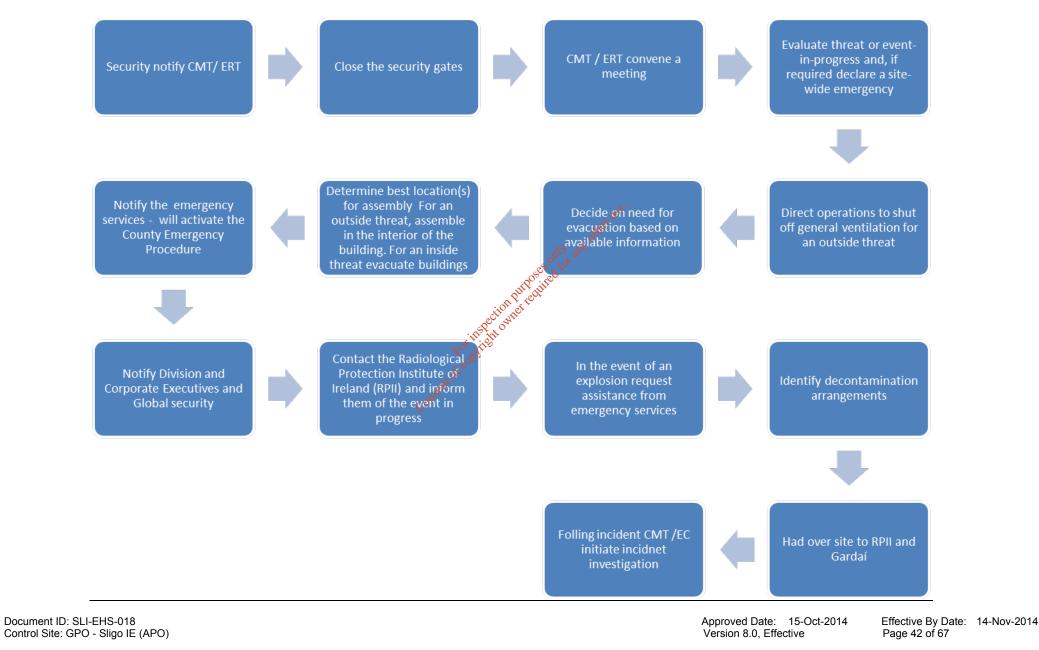
Location for the threat target or event-in-progress and proximity to the facility?
ntro sites
When did/will the device/bomb explode?
instan o
For stills
Where is the device/bomb located (be specific as possible)?
est of
const
Brief description of the threat (nuclear bomb; dirty bomb - what radioactive isotopes does it contain and
how much)?
now inden):
Caller's Name and/ or news source?
Other pertinent information offered by the caller or contained in the news report?
The time the information was received?

• Close the gates to the facility and man with a security guard

Effective By Date: 14-Nov-2014 Page 41 of 67

#### Title: Emergency Preparedness and Response Procedure

## 7.16.1 Nuclear Threat



# 7.17 Biological Threat

<u>Purpose</u>: This emergency action item provides the actions to take in response to a specific biological threat targeted toward the facility, surrounding or community.

General

An event-in-progress involving the release of biological agents from an act of terrorism, or accident involving the transport of bio agents, near the facility

On receiving notification of a biological threat try to verify information is factual and notifies security

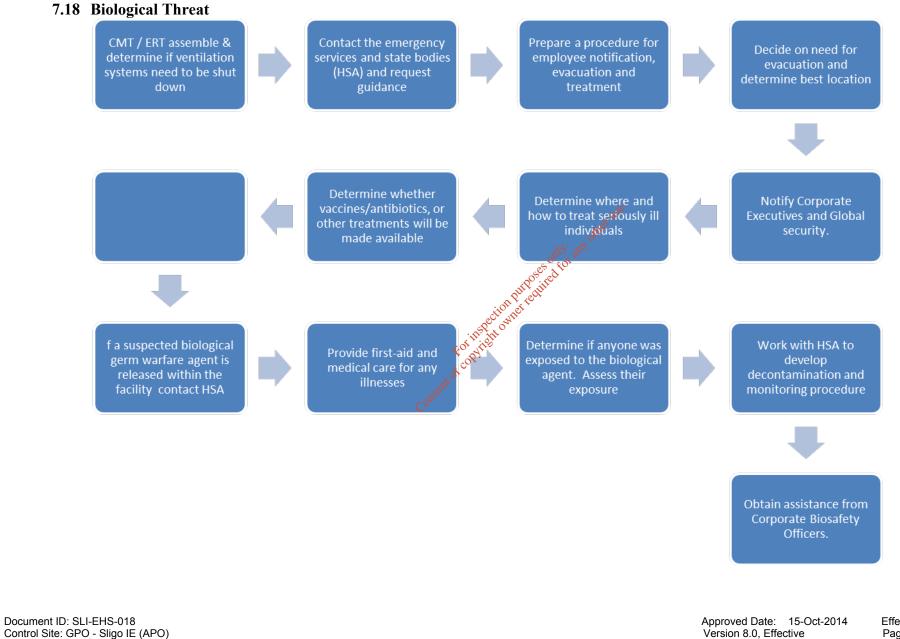
Security

• On receiving a call re biological threat record the following information

Location for the threat target and proximity to the facility?
What is biological agent: (Assume Aerosol Transmission)?
and the
Brief description of the threat?
Caller's Name or news source?
Other pertinent information offered by the caller or contained in the news report?
Wind Direction and Speed?
Record the time the information was received?

- Continually monitor Local Radio.
- Notify the Plant Emergency controller and the ERT

## Title: Emergency Preparedness and Response Procedure



Effective By Date: 14-Nov-2014 Page 44 of 67

# 7.19 Lone Working

A response of the ERT to a lone working alarm as per SII-EHS-071 Lone working procedure is another means of activation of the ERT team

# 7.20 Other

There are other requirements on site to which the ERT maybe summonsed. These include but are not limited to: Confined space rescue (SLI-EHS-031), Work at heights/fall from heights rescue (SLI-EHS-064), First Aid (SLI-EHS-050).

# 7.21 Severe Weather

To ensure there is a procedure in place to deal with severe weather conditions such as Storms, Heavy Rainfall, Leakages, Severe Snow or Low Temperatures etc.

## General

If employees at home feel they cannot attend work due to severe weather conditions, they • must inform their Team Leader Manager.

Senior Management Team

- 150. Every effort will be made to keep the plant open during extreme weather to provide work
- Update the plant employee notification system with plant opening/closure information or • work status information
- Determine if closure is necessary. Decision is based on severity of weather conditions •
- Consideration should be given to the fact that closing the facility will cause many • employees to enter the severe weather conditions.
- Notify local radio stations of status of plant. ٠ ofcor

Effective By Date: 14-Nov-2014 Page 45 of 67

# 8 Media Relations

General

- Members of the News Media are not allowed on site without the approval of a member of the Plant Staff and accompanied by a Public Affairs member
- If a member of the media somehow gains access to the facility, politely ask them to leave, escorting them from the location, and advise them to contact the PEC
- If the media refuse to leave the facility contact the PEC immediately.
- Only the PEC is authorised to release any information
- The PEC or designate contacts division and/or corporate public affairs.
- All media communications are to be conducted as per media guidelines in Abbvie crisis communications procedure.



## 9 Incident Reporting

In the event of an emergency response incident, the emergency evacuation report (PH-1103) must be completed and forwarded to the EC within 24 hours of the event by the IC or on call plant support engineer responding to the emergency.

The EC will determine whether it is necessary to report the incident to the appropriate corporate personnel and or government agency (refer to Significant EHS Incident Reporting, EHS Global Technical Standard, No. 15) and will initiate the investigation procedure.

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 47 of 67

# **Appendix 1: Emergency Detection Systems**

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 48 of 67

#### **Fire Alarm System** A.

# Ref: SLI-ENG-031 Fire Alarm Procedure

- Autronica fire system is implemented at the site.
- There are 5 fire alarm panels.
- One alarm is located in each building and one in security.
- All 5 panels are identical.
- Any one of the 5 fire alarm panels can control the whole site.
- The fire alarm system on the sycamore offices is a standalone system. •

There are six main types of device used on the fire alarm system.

# Break glass units / Manual call point

They are used to allow building occupants to signal that a fire or other emergency exists within the building. They are used to initiate an alarm signal

# **Smoke detectors**

Smoke detectors are located in the ceiling and ceiling voids. They are designed to detect smoke from a fire and sound the alarm.

# Aspirating smoke detector (ASD)

Aspirating smoke detector (ASD) Air samples are captured and filtered and then processed by a centralized, highly sensitive laser detection unit. If smoke is detected, the systems alarm is triggered, and signals then are processed through centralised monitoring stations within a few seconds.

0

# Heat detectors

Heat detectors are located in the ceilings. They work by detecting a change in heat, when activated they operate the same as a smoke detector.

# Relay units sprinkler system pressure switches

Relay switches are on the sprinkler system when the sprinklers have been activated the relay will switch telling the fire alarm panel which sprinkler has been activated

# **Sounders**

When a fire has been detected the sounders will sound the alarm all over the site so people can leave the workstations and go to a safe designated area for a roll call.

# Title: Emergency Preparedness and Response Procedure

# B. Sprinkler & Deluge System

	ENG-030 Sprinkler Deluge Procedure
Sprinkler System	A fire sprinkler system is an active fire protection measure, consisting of a water supply system, providing adequate pressure and flow rate to a water distribution piping system, onto which fire sprinklers are connected.
	Each closed-head sprinkler is held closed by a heat-sensitive glass bulb.
	The glass bulb applies pressure to a pipe cap which acts as a plug which prevents water from flowing until the ambient temperature around the sprinkler reaches the design activation temperature of the individual sprinkler head.
	In a standard wet-pipe sprinkler system, each sprinkler activates independently when the predetermined heat level is reached.
	Because of this, the number of sprinklers that operate is limited to only those near the fire, thereby maximizing the available water pressure over the point of fire origin. This also minimizes the water damage to the building.
Deluge Valve	The tank farm and all solvent storage tanks on site are protected by deluge systems.
Sprinkler Systems	The Deluge system is designed to protect high hazard areas containing a severe fuel hazard with a high heat release rate by bringing a large number of open sprayers into action simultaneously in the event of a fire.
	The detecting of a fire is by the use of a sprinkler detection line permanently charged by air.
	In the event of a fire, the sprinkler detector heat-sensitive glass bulb heads directly affected by the fire will operate.
	The immediate drop in air pressure within the detector line releases the pressure against the Deluge valve diaphragm unit causing the Deluge Valve to open and discharge water through all the open water spray nozzles to rapidly control and extinguish the fire.
	There is a manual release valve on each of the deluge system valves
Pre- Action	Building 70 switch room has a double knock pre-action system.
Sprinkler Systems	These systems require that both a "preceding" fire detection event, the activation of a smoke detector, and an automatic sprinkler operation take place prior to the "action" of water introduction into the system's piping.
	Activation of either the fire detectors alone, or sprinklers alone, without the concurrent operation of the other, will not allow water to discharge from the piping.
	(A double knock is required of both a smoke head and the temperature sensitive glass bulb in the sprinkler system before activation of sprinklers will occur)

Effective By Date: 14-Nov-2014 Page 50 of 67

# C. O2/LEL Analysers

02	Oxygen (O2) analysers are an electronic device that measure oxygen			
analysers	concentrations in the atmosphere.			
	This measurement is a percentage by volume reading and is unaffected by barometric pressure changes.			
	A display on the monitor identifies the oxygen concentration at any given time.			
	O2 analysers are set to alarm when O2 levels drop below 19%.			
	When the O2 alarms are activated they will trigger the fire alarm sounders in the building that is affected.			
	There are O2 alarms in buildings 10 (QC Lab), 20 40, and 70.			
LEL	Lower Explosion Limit Analyser (LEL)			
Analysers	There are 12 LEL clarmes in building 40			
	There are 12 LEL alarms in building 40.			
	When the LEL alarms are activated they will trigger the fire alarm sounders in the			
	building.			
	LEL detectors are set up to react to the highest flammable solvent Lower			
	Explosion Limit.			
	ant of COP?			
	Carrent			

# **D.** Ammonia Detection

Central ammonia leak	The process chiller system is equipped with a central ammonia leak detection and alarm system.
detection	This comprises of a central controller, one low level sensor, one high level sensor, two extract fans and combined alarm sounder / beacon.
	In the event of an ammonia leak, the low level sensor will activate at approx. 0.05% concentration.
	This will activate extract fan No 1 and also the warning beacon, located outside the process chiller room.
	If the ammonia concentration continues to rise, the high level sensor will activate at a concentration of approx. 3%.
	This will activate extract fan No 2, and the alafm sounder, and will also activate the shunt trip on each of the electrical panels / MCCs, disconnecting power to the chillers.
Vent relief bursting	Bursting discs are fitted to the ventrelief of the process chiller.
disc's	These are activated in the event of an over pressurisation of the chillers and will burst when a vent out of the vet relief valve occurs.
	nonia leak detection and bursting discs system are linked to the fire alarm vill evacuate the site and cause a complete shutdown of Building 10,20 and 40's

Effective By Date: 14-Nov-2014 Page 52 of 67

# E. FM – 200 Fire extinguishing media

FM- 200 is an extinguishant and will not sustain combustion.

Primary method of action is achieved through cooling the fire and absorbing heat energy so that the combustion reaction cannot be sustained.

The agent does not suppress fire by displacing oxygen.

FM-200 gas suppression systems are implemented on site in;

- B10; IT server room
- B20; Switch room
- B40; Switch room & Control room

All 4 systems are linked to the main autronica fire alarm system.

The autronica system shows fire activation (agent released) on the system on the activation of FM-200 system.

A first stage warning that a smoke detector has activated;

• Sounders are switched on in the affected room.

If second smoke detector activates in the room concerned;

- A second sounder is activated, after 30 seconds the agent is then released into the room.
- The initial discharge is noisy and looks like steam.
- Visibility is obscured for about 15 seconds. After this the room visibility is normal again.
- It is preferred that personnel leave the room prior to agent release as opening the doors with the agent already discharged lets it out the door and reduces the hold time of the agent.
- It is required that the room has a 10 minute holding time at sufficient agent concentration to suppress fire.
- There is no clean up required open the doors and it disperses.

# F. Fire Extinguishers

An extinguisher is an active fire protection device used to extinguish or control small fires, often in emergency situations.

It is not intended for use on an out-of-control fire, such as one which has reached the ceiling, endangers the user (i.e. no escape route, smoke, explosion hazard, etc.), or otherwise requires the expertise of emergency services.

Extinguishers are strategically placed around the site.

They undergo monthly inspections and annual testing.

Fire Classification	Fire Risk	Water	Foam	CO2	Powder	Wet Chemical
Class A	Wood, Paper, Textiles and Fabrics	$\checkmark$	$\checkmark$		$\checkmark$	
Class B	Flammable Liquids - Petrol, Oil, Paints		√	$\checkmark$	$\checkmark$	
Class C	Flammable Gases		of USC.		$\checkmark$	
Class D	Metal Fires	1. 4	<u>Gr</u>		Special Powder Only	
Class E	Electrical Fires	mily any		$\checkmark$	$\checkmark$	
Class F	Cooking Oils and Fats	0				$\checkmark$
	Cooking Oils and Fats					

Title: Emergency Preparedness and Response Procedure



# G. Fire hydrants

Fire Hydrants at the facility enable the emergency services to tap into the municipal water supply to assist ior in extinguishing a fire.

A hose is attached to the fire hydrant, then the value is opened to provide a powerful flow of water, on the order of 11.5 Bar PA.

This hose can be further attached to a fire engine, which can then use a powerful pump to boost the water pressure and possibly split it into multiple streams.

The hose may be connected with an instantaneous "quick" connector.

Care should be taken not to open or close a fire hydrant too quickly, as this can create a water hammer which can damage nearby pipes and equipment.

The water inside a charged hoseline causes it to be very heavy and high water pressure causes it to be stiff and unable to make a tight turn while pressurized.

Monthly hydrant release testing is completed.

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0. Effective

Effective By Date: 14-Nov-2014 Page 55 of 67

Title: Emergency Preparedness and Response Procedure

## H. Fire water storage tank

The site has a mains and firewater storage tank with a capacity of 1136m3.

About 900 m3 of this will be permanently in reserve for the fire sprinkler system and ring main.

The water/fire water supply storage tank is located to the north of the utilities building.

## I. Fire water retention pond

A firewater retention pond is located at the south-western part of the site.

Upon activation of the fire alarm, sprinklers etc the outlet of the firewater pond closes automatically.

Any firewater used to fight fires will be contained in the firewater retention pond, thus preventing any contaminated water leaving the site.

In the event of a chemical spill the valve can be shut manually at the retention pond or by breaking a break glass unit and raising the fire alarm which will contain the spill and prevent contaminated water leaving the site.

**J. Liquefied Petroleum Gas (LPG)** Jurge Live A 30 Tonne Tank is located to the north west of the facility.

This vessel is the property of Calor Teorenta who is responsible for its maintenance and for carrying out corê the necessary inspections.

The vaporisers have safety pressure switches set at low pressure (3bar) and high pressure (10bar) this is to ensure the safety of the vaporiser in case of a fault occurring.

Each vessel is fitted with relief valves set to 210p.s.i.g (14.48bar) to prevent internal pressure rising above the vessel design pressure.

Alarm Conditions on the LPG System:

- If the boiler fails to begin heating within 10 minutes = Alarm. The system continues to run (but the boiler may be in lock-out)
- If the water pressure is too low = Alarm, The boiler will automatically shut down.
- If the Gas pressure continues to fall it will be picked up by the LOW pressure switch and if below 3 bar = Alarm, but the boiler stays ON.
- If gas pressure becomes excessive, monitored by Excess pressure switch = ALARM AND EVERYTHING SHUTS DOWN.

Effective By Date: 14-Nov-2014 Page 56 of 67

#### Title: Emergency Preparedness and Response Procedure

All alarms feed back to the BMS and engineering investigate.

02 alarms are present in the boiler room in B70 where LPG enters the building.

In the event of a gas leak in the boiler room the O2 alarm will sound locally and the O2/LEL alarm procedure is followed.

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 57 of 67 Title: Emergency Preparedness and Response Procedure

**Appendix 2 Site Utilities** 

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Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 58 of 67

This information is confidential to AbbVie. The user is responsible for using the appropriate version of this document.

Unit Operations	Purpose	Process Control
Boilers	There are three kerosene fired steam-	Key Control Parameters
	generating boilers located in the utilities	The boilers are integrated with
	building. They normally operate on a	instrumentation, control and
	duty-standby basis but can operate	safeguarding systems which provide
	together if exceptional demand arises.	the controls and monitoring for safe
		operation. The systems are linked and
		alarmed to the site Building
		Management System (BMS). External
		contractors conduct boiler efficiency
		tests routinely on the boilers.
Cooling Systems	There are 3 cooling towers. The cooling	Key Control Parameters
	towers service the process chillers for	The cooling towers are instrumentation,
	chilled ethyele glycol, which is supplied	control and safeguarding systems
	to the HVAC systems. Cooled water route	which provide the controls and
	from the towers is also supplied to the air	monitoring for safe operation. The
	compressors and the Solvent Stripper	systems are linked and alarmed to the
	CL-803	site Building Management System
		(BMS).
Heating, Ventilation & Air	There are 13 Air Handing Units currently	Key Control Parameters
Conditioning System	in operation for production, offices and	The air handling units are integrated
(HVAC)	occupied spaces onsite. The HVAC	units with required instrumentation and
	chilled water supply is provided by two	control systems, which are linked and
	Trane gear driven water cooled	alarmed to the BMS. The AHU and
	centrifugal chillers.	HVAC chillers.

Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 59 of 67

Purified Water	Purified water is used in production and the laboratories onsite. Purified water is produced in an integrated system providing water for consumption.	Key Control Parameters The purified water system is an integrated unit with required instrumentation and control systems, which are linked and alarmed to the site DCS system.
Nitrogen, Argon, Oxygen Gases	The gases are used in production as part of the process, as a carrier gas and in equipment (nitrogen). They are also used in the QC analytical lab in B20.	Key Control Parameters The gas storage and pipeline systems are fitted with pressure relief which are linked and alarmed to the site Building Management System (BMS).
Instrument Air	The instrument air for the plant is supplied using two compressors one and used cooled and one water cooled which are located in the utility building. Recommendation Compressed air is used primarily in production for instrument aux and breathing air.	

Approved Date: 15-Oct-2014 Version 8.0, Effective

Nitrogen	Gaseous nitrogen (GAN) and LIN Liquid	Key Control Parameters
	nitrogen are used on site. Nitrogen is	The gas storage and pipeline systems
	distributed throughout the site at various	are fitted with pressure relief which are
	pressures between 5.5 Barg and 16	linked and alarmed to the site Building
	mBarg	Management System (BMS).
	where it is used for all vessel blanketing,	Areas where Nitrogen is provided is
	equipment inertion and line purging	supplied with O2 monitors which are
	processes.	connected to the fire alarm system
	Gaseous nitrogen is generated by two	
	systems as described below.	NSC.
	System 1:	ther
	Liquid nitrogen is supplied to the site in	St. and
	bulk form and is stored in pressure vessel	KOT
	70-	
	TK-771. The liquid nitrogen is then the second	
	70- TK-771. The liquid nitrogen is then required to GAN using the evaporative	
	process	
	before entering the site distribution	
	system liquid nitrogen is also distributed	
	to the site cryogenic abatement system.	
	System 2:	
	Pre-treated compressed air passes	
	through three pressure swing absorption	
	(PSA)	
	Nitrogen generation to produce a	
	continuous stream of high quality	
	gaseous	
	nitrogen. The GAN then passes to a bulk	
	storage pressure vessel, 70-TK-772	
	where it	
	remains until the site requires it. The	
	GAN is filtered and quality is monitored	

Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 61 of 67

D CI :11		<b>T</b> 1 1 11 1 4
Process Chillers	The system comprises of two water	Each chiller is controlled by the grasso
(cold)	cooled chillers in parallel and a glycol	system controller. The primary control
	storage tank. Ammonia is being used as a	parameter is the Dwocal outlet
	refrigerant. The operation of each chiller	temperature, which is to be maintained
	is totally automatic, once switched on the	at an adjustable set point, depending on
	chillers will also automatically adjust	requirements.
	cooling capacity to cope with changes in	Ammonia detection system located in
	the process load.	the process chiller room connected to
		Autronica Fire and safety system. Each
		chiller contains 75kg ammonia.
		Vent relief bursting discs are fitted to
	a de la companya de la	the vent relief lines and connected to
	٠٠ ۵. <sup>ش</sup> هر	the Autronica Fire and safety system.
	on Purposes	
	Propylene Glycol solution's heated in a	Propylene Glycol system(temperate
Propylene Glycol	heat exchanger unit located in the Bulk	and hot) is an integrated unit with
system(temperate and hot)	Manufacturing Facility, using steam from	required instrumentation and control
	the boiler. The hot propylene glycol	systems, which are linked and alarmed
	solution is supplied to the jackets on	to the site DCS system.
	vessels such as the reactors and the filter	
	dryers and is used to heat the filter dryer	
	agitator.	
Electrical Supply	2 electrical supplies PR1 and PR2	All key utility alarms will be alerted to
		the BMS system in event of power
		failure.

Approved Date: 15-Oct-2014 Version 8.0, Effective

-		
Emergency Generator	800KW – The emergency generator is	The emergency generator is an
	located to the north of the utilities	integrated unit with required
	building. It will be used in the event of	instrumentation and control systems,
	the main generator malfunction, power	which are linked and alarmed to the site
	failure or during routine testing and	BMS system.
	serving of the main generator. It will be	
	powered by Kerosene from the main	
	Kerosene tank. The generator operates in	
	•	
	take over from the ESB supply of key	
	utilities including Boilers, compressor,	of USE
	chiller and associated pumps.	offic
	onnier and associated pumps.	St. all
	Server and the server	
	stand by mode and where necessary will take over from the ESB supply of key utilities including Boilers, compressor, chiller and associated pumps.	
	tonstre	
	- Per own	
	and the second sec	
Process Water	0	, <u> </u>
	Farm stores 120,000 litres of incoming	pumps (Pu-01/02), which can add
	mains water. 2 pumps which operated on	Sodium Hypochlorite as required. The
	duty stand by which supply water	pumps are controlled via a chlorine
	throughout the site. Process water is	monitor in the return pipe
	used for all water systems on site.	to (TK-741) the process water tank.
	Process water is dosed with chlorine	This monitors the town water chlorine
	through a The dosing system is designed	content and can increase it up to the
	to maintain a constant reserve of between	level as necessary. The chlorine pumps
	1 and 2 ppm of free Chlorine in the	are supplied from TK-01, the Sodium
	process water system.	Hypochlorite tank which can contain
	process water system.	1000 litres.
		1000 11005.

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 63 of 67

I DIIW/	Steam meduced by the bailons is symplical	The LDIW systems are symplical with
LPHW	Steam produced by the boilers is supplied	The LPHW systems are supplied with
	to a heat exchanger in each building.	instrumentation, controls and
	This heat exchanger heats the water.	safeguarding systems which provide
	This is used in HVAC system for heating	the controls and monitoring for safe
		operation which alarm to the BMS
		system
Chilled Water	HVAC Chillers chill the water which is	The chilled water systems are supplied
	supplied by pumps in utilities to all	with instrumentation, controls and
	buildings HVAC systems. Water can	safeguarding systems which provide
	also be chilled using a heat exchanger in	the controls and monitoring for safe
	the Process chiller room. 2Chilled water	operation which alarm to the BMS
	is used in the HVAC system for cooling.	system
Dust Extract System	There is a dust extract system in Drug Product building. All the dust from production activities within the	The system comprises of a FIKE
	Product building. All the dust from an area	explosion suppression system.
	production activities within the	If the FIKE system is not operating all
	equipment is captured by the system to	production will shut down and alarms
	dust collection units in the Drug Product	will be displayed on equipment.
	Plant room area. There is an aspirator for	
	the CFM and TP rooms in DP which also	Where aspirators are not running or are
	collects dust into a water system	in fault there is an alarm to the CFM or
	Cot	TP and the equipment is unable to
	In API & DP there is a local dust extract	operate.
	system in all production rooms. This	1
	extracts any dusts in the room into a	
	HEPA filter unit.	
		HEPA Filters are safe change. Where
		HEPA filter fan fails these alarm to the
		BMS system.

Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 64 of 67

Air Emission Abatement	The air abatement equipment is located	The air emission abatement equipment
Equipment	between the tank farm and the utility	is integrated with instrumentation,
	building. It contains	control and safeguarding systems
	a thermal oxidizer, a scrubber and a	which provide the controls and
	cryogenic system.	monitoring for safe operation. The
		systems are linked and alarmed to the
		site Delta V control system (DCS) and
		the Thermal Oxidser and Cryogenic
		condenser have continuous emissions
		monitor linked to the DCS system and
		alarms to the on- call mobile phone.
		Any malfunctions or high level alarms
	ి రోగా సి	cause an automatic shut down of
	att <sup>05</sup> tit <sup>20</sup>	production activities
Aqueous waste treatment	Aqueous Waste Solvent Stripper The	This is currently redundant
system	aqueous waste solvent stripper is located	
	between the tank farm and the utility	
	building. Its	
	main purpose is to remove solvent	
	contaminants from the aqueous waste	
	streams.	

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO) Approved Date: 15-Oct-2014 Version 8.0, Effective Effective By Date: 14-Nov-2014 Page 65 of 67

### Title: Emergency Preparedness and Response Procedure

Appendix 3

ERT Critical checks

ERT Assemble at security

## ERT to evaluate

- Should the ERT go into action?
- What are the risks' to Employees/Property/Environmental?
- Who is required from an advisory role?
- Evacuation is it required? Partial or full site?

## What has activated?

Fire:

- Ensure Fire water pumps are running
- Ensure Fire Water Retention Pond outlet has activated and have ERT verify it is closed
- Where an alarm has activated in building 40 a check of the solvent transfers into the building to be completed and evaluation if transfer is required to be stopped due to emergency situation.
- Post emergency –Have ERT reopen retention pond valve where no contamination has occurred, where potential or know contamination bas occurred notify EHS and leave valve closed
- Stop the fire pumps post emergency, put

Chemical Spill:

- Is the area cornered off from employees
- Is there any possibility of the chemical catching fire
- Ensure fire water retention pond valve is closed where likelihood of chemical entering external drains have ert verify it has closed.
- Ensure spill kit implemented to protect drains
- Is there adequate BA team members available
- Locate SDS for material
- Where required ensure First Aider available
- Post emergency –Have ERT reopen retention pond valve where no contamination has occurred, where potential or know contamination has occurred notify EHS and leave valve closed

Title: Emergency Preparedness and Response Procedure

Ammonia Release:

- Wind direction remove employees from wind direction to alternative assembly point
- Confirm HVAC has shut down on all buildings to prevent ammonia entering buildings To check the HVAC has shut down will require someone to look at the BMS in building 70 office close to the suspected gas cloud, this should only be completed where deemed safe by ERR IC and ERT TL based on wind direction and/or use of BA
- Ensure BA is utilised and adequate BA team members available
- Take reading on Ntron Panel in MCC room ensure <16,000PPM prior to permitting any entry into the process chiller room
- Ensure access is only via the pedestrian door roller doors cannot be opened
- Access should only be granted in event of missing person, otherwise time must be allowed to allow ammonia to dissipate
- Post emergency- ensure all HVAC is enabled for the site where safe to do so.
- Have ERT reopen retention pond valve where no contamination has occurred, where potential or know contamination has occurred notify EHS and leave valve closed

O2/LEL

- Ensure all personnel have evacuated the building and are accounted for
- Where an alarm has activated in building 40 a check of the solvent transfers into the building to be completed and evaluation if transfer is required to be stopped due to emergency situation.
- Ensure BA is used and adequate BA team members available
- A personal gas monitor should be used when investigating the cause of the activation.
- Where there is an chemical or nitrogen leak isolate the supply immediately
- Ensure doors of building are manned where required to isolate fire alarm
- Where O2 or LEL has activated and cause isolated ensure HVAC is running to elevate vapours from area
- Ensure that all levels have returned to normal and issue rectified prior to permitting personnel to return to the area/building

Lone working

- Identify from the lone working log book location of worker and hazards associated with the activity
- Ensure First Aider is available, call for first aider where none has responded with the ERT

Effective By Date: 14-Nov-2014 Page 67 of 67

### Abbott - Global Pharmaceutical Operations Document Properties

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO)

	Info
Checked Out By:	
Document ID:	SLI-EHS-018
Title:	Emergency Preparedness and Response Procedure
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Action Required:	Create New / Revise
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Departments/Areas Affected:	Corr
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	Update to SLI-EHS-018 version 7 redline: Section 4.2 include requirement of Incident
	commander to ensure service and utilities have been restored. Section 4.3 include role of ERT team lead to assign Emergency team members roles and responsibilities throughout emergency, ensuring that all emergencies are completed in a controlled and safe manner. Included a check following emergency that all services and utilities are restored. Section 7.1 updated to include sprinkler and deluge to fire detection system. 7.1.1 updated flow chart for a single knock activation 7.1.2 updated flow chart for double knock activation 7.4.1 updated flow chart for chemical spill Included section 7.19 for lone working and 7.20 for other means of activating the emergency response team. Included appendix 3 for critical checks for the ERT in an emergency.
Legacy CR Numbers:	
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Legacy SME:	
Legacy SME Functional Areas:	
Legacy User Site Effective Dates:	
Legacy User Sites:	

#### Abbott - Global Pharmaceutical Operations Document Properties

Document ID: SLI-EHS-018 Control Site: GPO - Sligo IE (APO)

#### Post Approval

Business Type: Engineering, Safety Governing Document: IPPC License No. 755, T13, Emergency Response Plan Reference Document: N/A Legacy Doc ID:

#### **Periodic Review**

Periodic Review State: Enabled Last Review Date: 12-Aug-2013 Review Interval: 36 months Next Review Date: 12-Aug-2016 Subject Matter Expert: Taylor\_Barbara\_K SME Functional Area: EH&S

Site Effectivity

< No Site Effectivity Data to Display >

END OF DOCUMENT

#### Abbott - Global Pharmaceutical Operations Change Request Properties

#### CR Number: CR-GPSLI-14-00000440 Control Site: GPO - Sligo IE (APO)

## Initiator CR Initiator: Taylor\_Barbara\_K Initiator Phone Number: 0719136648 Initiator Location: Abbvie Sligo Initiator Division: Global Pharmaceutical Operations (GPO) CR Info CR Number: CR-GPSLI-14-00000440 CR Submitted Date: 10-Sep-2014 CR Control Site: GPO - Sligo IE (APO) **CR Division:** Global Pharmaceutical Operations CR Status: Closed CR Status Date: 15-Oct-2014 CR Approved Date: 15-Oct-2014 anyotherus Change Info Application Context: GPSLI Change Document Title Change Document / Document ID SLI-EHS-018 Emergency Prepardness and responce procedure Description of Change: Update to SLI-EHS-018 version 7 redline: Section 4.2 include requirement of Incident commander to ensure service and utilities have been restored. Section 4.3 include role of ERT team lead to assign Emergency team members roles and responsibilities throughout emergency, ensuring that all emergencies are completed in a controlled and safe manner. Included a check following emergency that all services and utilities are restored. Section 7.1 updated to include sprinkler and deluge to fire detection system. 7.1.1 updated flow chart for a single knock activation 7.1.2 updated flow chart for double knock activation 7.4.1 updated flow chart for chemical spill Included section 7.19 for lone working and 7.20 for other means of activating the emergency response team. Included appendix 3 for critical checks for the ERT in an emergency. Reason for Change: Update of procedure following an audit review Justification for Change: Update to include requirements following audit

#### Effectivity

Effective Date Type: Effective By Date Implementation Period: Default Implementation Justification:

### Abbott - Global Pharmaceutical Operations Change Request Properties

CR Number: CR-GPSLI-14-00000440 Control Site: GPO - Sligo IE (APO)

		Change Docume	ents	
Document ID	Title	Control S	Site	<u>Abbott Document</u> <u>Type</u>
SLI-EHS-018	Emergency Prepared and Response Procee		igo IE (APO)	Standard Operating Procedure
	Inter	nal Supporting Do	ocuments	
	< No Internal S	upporting Docume	nt Data to Display >	
	Exter	nal Supporting De	ocuments	
Name				
Change history AIPO-E	EHS-018.pdf			
Change history for SLI-	-EHS-018.pdf			
EHS-018 Change histo	pry.pdf			
Imapct assessment SL	I-EHS-018.pdf			
PH-953.pdf			A USE.	
SLI-EHS-018 redlined.			other	
SLI-EHS-018 redlined.		only	, and	
cr-gpsli-14-00000440 c	compliance review.pdf	100° ited to		
		Approvals		
		Meaning of	Approver Functional	
User Name	<u>User OS Name / Domain <sub>v</sub>o</u>	Signature	Area	Date of Signature
Taylor_Barbara_K	taylobk2 / oneabbott	, <sup>s</sup> ∕ Approver	CR Initiator	15-Sep-2014 15:12:43
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Change Document				
	mpletion Date:			
Change D	ocument Title:			

### END OF DOCUMENT

# Attachment K

Closure Plan and ELRA IE0311237-22-RP-0007

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# abbvie

# Closure Plan and Environmental Liabilities Risk Assessment

AbbVie Ireland NL B.V Manorhamilton Rd VOC Abatement System IE0311237-22-RP-0007, Issue: A



# Document Sign Off

Closure Plan and Environmental Liabilities Risk Assessment

AbbVie Ireland NL B.V Manorhamilton Rd VOC Abatement System IE0311237-22-RP-0007, Issue A

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CURRENT ISSUE					
2/09/15 Reason fo	or issue: For Informa	0			
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### PREVIOUS ISSUES

lssue No	Date	Originator	Checker	Reviewer	Approver	Customer	Reason for issue



# Contents

Exe	cutive	Summary	5
Sun	nmary -	- Closure Plan	6
Sun	nmary -	- Environmental Liabilities Risk Assessment	7
1	Intro	duction	8
	1.1	General	8
	1.2	Facility and Licence Details	8
	1.3	Scope of Closure Plan and Environmental Liabilities Risk Assessm	ient 9
2	Site	Evaluation	11
	2.1	Facility Description and History Operator Performance	11
	2.2	Operator Performance	11
	2.3	Overview of Existing Pollution Sources and Sensitive Receptors	11
	2.4	Facility Infrastructure, and Processes and Activities	14
3	Clos	ure Plan	18
	3.1	Closure Tasks and Programmes	18
	3.2	Closure Plan Implementation	19
	3.3	Criteria for Successful Closure	19
	3.4	Closure Plan Validation & Environmental Monitoring During Decommissioning	20
	3.5	Closure Plan Costing and Financial Provision	21
	3.6	Closure Plan Update and Review	21
	3.7	Restoration and Aftercare Management Plan	21
4	Envi	ronmental Liabilities Risk Assessment	23
	4.1	Methodology	23
	4.2	Risk Identification, Analysis and Evaluation	25
	4.3	Financial Provision	26
5	Con	clusions	30
6	Revi	ew and Update	31
Арр	endix /	Α.	32

Page 3 of 61 Formal Issue



AbbVie Site Layout	32
Appendix B	34
AbbVie Closure Programme	34
Appendix C	47
Current AbbVie Environmental Liabilities Risk Register	47
Appendix D	54
Statement of Measures for AbbVie	54
Appendix E	58
Financial Model – Worst Case Scenario (Risk ID No. 13/14)	58
Appendix E Financial Model – Worst Case Scenario (Risk ID No. 13/14)	



### **Executive Summary**

AbbVie Ireland NL B.V. (AbbVie) operates a manufacturing installation at its Manorhamilton Road site on the outskirts of Sligo town. This Closure Plan and Environmental Liabilities Risk Assessment (ELRA) has been prepared to revise the site's existing Closure Plan and ELRA (PM Group Report No. IE0311080-22-RP-0001 Issue A) and accompanies an application for a review of the site's Industrial Emissions Licence which will be submitted to the EPA to take into account the installation of a new thermal oxidiser at the site and the removal of the site's existing thermal oxidiser.

This report fulfils Conditions 5.16, 10.1, 10.2, 10.3, 10.4 and 12.3 of the site's existing Industrial Emissions Licence (Register No. P0643-02) and has been prepared in accordance with the Environmental Protection Agency's (EPA) '*Guidance on Assessing and Costing Environmental Liabilities (2014)*'.

Baseline surveys undertaken on the site and its surrounding demonstrate that there is no historical environmental contamination which would present an environmental pollution risk. The most recent annual environmental report (AER) for the site (2014) shows that the AbbVie site is in compliance with the emission limit values (ELV) as stated in its Industrial Emissions Licence with the exception of one ELV exceedence for wastewater discharge to sewer. This exceedence was reported to the EPA in accordance with Condition 4 'Interpretation' and Condition 11 'Notifications, Records and Reports' of the site's Industrial Emissions Licence.

As part of the preparation of the Closure Plan a site evaluation has been carried out. All buildings, plant and equipment and materials decommissioning were accounted for and were costed. In accordance with the Agency guidance, an Aftercare Management Plan is not applicable to the AbbVie facility because of the fact that there is no expected significant soil or groundwater contamination or no landform changes. The conclusion of the Closure Plan is that anticipated decommissioning programme costs would be €7,466,250 (including a 25% contingency). A further annual cost of ca. €363,850 related to maintaining the site to its maximum asset value by providing an on-going, security, safety and environmental monitoring presence was also determined.

The site specific ELRA was carried out in accordance with the Agency Guidance above and an environmental risk register for AbbVie was prepared. Potential failures modes throughout the lifecycle of the installation were first identified followed by the application of semi-quantitative risk assessment techniques to identify the most significant risks. Mitigation measures were identified for significant risks to reduce either their likelihood or in some cases, their potential severity. A financial cost model has been prepared on the worst case scenario in accordance with the Agency Guidance. The calculated financial provision for unknown environmental liabilities for the AbbVie installation is €1,866,313.

A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated Closure Plan and ELRA.



## Summary – Closure Plan

The Closure Plan is summarised in the following table:

Activity Name and Address	AbbVie Ireland NL B.V., Manorhamilton Road,		
	Sligo,		
	County Sligo.		
Name of Operator	AbbVie Ireland NL B.V.		
Existing Licence Number	P0643-02		
Name and Address of Person/Organisation Who Prepared	PM Group,		
	Killakee House,		
the Plan	Belgard Square,		
	Tallaght,		
	Tallaght, Dublin 24		
Class(es) of Activity Licensed	5.16 The production of pharmaceutical products including intermediates.		
Details of any previous Closure Plans	PM Group Report Number IE0311080-22-RP-0001 Issue A		
and and a start of the start of	Residuals Management Plan Estimate: €5,973,000		
and the second se	Financial Provision: AbbVie Inc. (parent company) resources		
Scope constitu	Closure Only		
Financial Provision	It is estimated that a cost of ca. €7,466,250 (including 25% contingency) would be required to implement the Closure Plan to address known liabilities.		
	A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated Closure Plan.		
Review period for the closure and restoration/aftercare plans	The Closure Plan will be reviewed annually and any proposed amendments will be notified to the Agency for agreement as part of the Annual Environmental Report (AER), in accordance with the site's Industrial Emissions Licence.		



# Summary – Environmental Liabilities Risk Assessment

The ELRA is summarised in the following table:

Activity Name and Address	AbbVie Ireland NL B.V.,	
	Manorhamilton Road.	
	Sligo,	
	County Sligo.	
Name of Operator	AbbVie Ireland NL B.V.	
Existing Licence Number	P0643-02	
Name and Address of	PM Group,	
Person/Organisation Who Prepared the Plan	Killakee House,	
	Belgard Square,	
	Tallaght,	
	Tallaght, Dublin 24	
Class(es) of Activity Licensed	5.16 The production of pharmaceutical products including intermediates.	
Details of any previous ELRAs	PM Group Report Number IE0311080-22-RP-0001 Issue A	
the strange	ELRA Estimate: €73,812.50 (unknown liabilities)	
and the second	Financial Provision: AbbVie Inc. resources	
Financial Provision	The financial provision is based on the worst case scenario. This is the maximum liability that may be incurred and is calculated at €1,866,313 (including a 25% contingency).	
	A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated ELRA.	



### 1 Introduction

#### 1.1 General

PM Group has been commissioned by AbbVie Ireland NL B.V. to update its Closure Plan and Environmental Liabilities Risk Assessment for its site on Manorhamilton Road in Co. Sligo. This report has been prepared to accompany an application to review the site's Industrial Emissions Licence which will be submitted to the EPA to take into account the installation of a new thermal oxidiser at the site and the removal of the site's existing thermal oxidiser.

This report fulfils Conditions 5.16, 10.1, 10.2, 10.3, 10.4 and 12.3 of the site's existing Industrial Emissions Licence (Register No. P0643-02) and has been prepared in accordance with the Environmental Protection Agency's (EPA) '*Guidance on Assessing and Costing Environmental Liabilities (2014)*'. Section 2 provides the environmental context of the installation by first describing the AbbVie installation, production processes and baseline environmental conditions. Section 3 details the Closure Plan while Section 4 details the Environmental Liability Risk Assessment (ELRA).

### **1.2 Facility and Licence Details**

AbbVie Ireland NL B.V. (AbbVie) operates a pharmaceutical manufacturing installation at Manorhamilton Road in Sligo. The manufacture of pharmaceutical products and their intermediates is an activity that is listed as Class 5.6 in the First Schedule of the Environmental Protection Agency Act, 1992. Consequently AbbVie obtained an Integrated Pollution Control (IPPC) Licence, from the Environmental Protection Agency (the Agency) in November 2005 (Register No. P0643-02), which was amended to an Industrial Emissions Licence in 2013, to carry out the following activities:

### '5.16 The production of pharmaceutical products including intermediates'

This report has been prepared in compliance with the following conditions of the site's current Industrial Emissions Licence Register No. P0643-02 in accordance with the EPA's '*Guidance on Assessing and Costing Environmental Liabilities (2014)*':

10.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal recovery, any soil, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.

10.2 Residuals Management Plan:

10.2.1 The Residuals Management Plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the agreement of the Agency. The licensee shall refer to guidance published by the Agency including "Guidance Documents and Assessment Tools on Environmental Liabilities Risk Assessment and Residual Management Plans incorporating Financial Provision Assessment".

10.2.2 The audit shall be carried out in accordance with the guidance published by the Agency.

10.3 The Residuals Management Plan shall include as a minimum, the following:-

10.3.1 A scope statement for the plan.

10.3.2 The criteria which define the successful decommissioning of the activity or part thereof, which ensures minimum impact on the environment.

10.3.3 A programme to achieve the stated criteria.



10.3.4 Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.

10.3.5 Details of costings for the plan and the financial provisions to underwrite those costs.

10.4 A final validation report to include a certificate of completion for the residuals management plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

#### 12.3 Environmental Liabilities

12.3.1 The Licensee shall as part of the AER provide an annual statement as to the measure taken or adopted at the site in relation to the prevention of environmental damage. and the financial provision in place in relation to the underwriting of costs for remedial actions following anticipated events (including closure) or accident/incident, as may be associated with the carrying on the activity.

12.3.2 The Licensee shall review the Environmental liabilities Risk assessment (ELRA) as necessary to reflect any significant changes on site, and in any case at least every three years. The review results shall be notified to the agency as part of the AER. The Licensee shall refer to guidance published by the agency "Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision".

Schedule D: Annual Environmental Report also lists the reports arising from Condition 12.3 above, required namely;

- Review of residuals management plan,
- Review of Environmental Liabilities insurance cover.
- Environmental Liabilities Risk Assessment Review (every three years or more frequently as dictated by relevant on site change including financial provisions).

This report also fulfils the Condition 12.3.2 in relation to updating the Closure Plan and ELRA as necessary to reflect any changes on site. Changes on site, since the previous revision of the report, include the proposed removal of the site's existing thermal oxidiser as well as the proposed installation of a new thermal oxidiser.

#### 1.3 Scope of Closure Plan and Environmental Liabilities Risk Assessment

#### 1.3.1 **Closure Scenarios Covered in Closure Plan**

This report details the measures that have been undertaken at the site in order to prevent possible environmental damage as a result of the activities at the site under normal operating conditions. The term 'Known Liabilities' is used to describe foreseeable events with potential for environmental pollution. It also details the financial provisions that have been put in place for remedial and corrective actions that may have to be carried out should environmental pollution occur at the site.

The scope of this plan addresses the key issues, which would occur in an orderly shutdown of all or part of the site activities. It is envisaged that a complete shutdown would take place on a phased basis over an estimated time period of 9-12 months.

The scope of the plan includes the following major activities:

- Setting up a management structure to oversee the Closure Plan;
- Cessation of all production activities;
- Removal of all remaining raw materials, intermediates and final products from the site;
- Cleaning and decontamination of all equipment and buildings;
- Shutting down of all environmental and utility systems;



- Completion of a Closure Plan Validation Report on all aspects of the site within 60 days of completion of plan activities; and
- Maintaining on-going security and environmental monitoring on site.

#### 1.3.2 Scope of the Environmental Liabilities Risk Assessment

Potential pollution arising from unplanned, emergency or catastrophic conditions on the AbbVie site has been assessed by the Environmental Liabilities Risk Assessment report in Section 4 of this report. The Term 'Unknown Liabilities' is used to describe these scenarios.

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#### 2 Site Evaluation

#### 2.1 **Facility Description and History**

Planning permission for the development of the AbbVie facility was applied for in June 2001. As the development involved the manufacture of pharmaceuticals, the European Communities (Environmental Impact Assessment) Regulations, 1989 to 2000 were applicable and an Environmental Impact Statement (EIS) was completed for the project. The development is on a site which adjoins an AbbVie Ireland site at Ballytivnan, Sligo. The site spans the townlands of Ballytivnan and Rathbraghan and comprises a number of fields with a total area of 47 ha (116 acres). The facility is located on an area of about 12.5 ha at the eastern end of the site. The site's boundaries include the AbbVie Ballytivnan site, private housing, the Clarion Hotel immediately to the south, agricultural lands to the east and a public road and the Doonally River to the north.

A small stream runs through the southern part of the site and eventually joins the Doonally River as it enters Sligo Bay. The Institute of Technology, Sligo at Ballinode is approximately 1 km to the southeast and there is a school and Sligo General Hospital located approximately 1 km to the south. Saint John's Church is located approximately 1 km to the southwest. Sligo Town centre is located 2km to the south.

The site topography is defined by two valleys oriented east-west separated by a central spine. For many years parts of the property have been leased for livestock grazing. only any

#### **Operator Performance** 2.2

redfor AbbVie has established and maintains an Environmental Management System (EMS) which is accredited to the ISO 14001 International Standard.

The annual environmental report (AER) for the 2014 reporting period, the most recent AER for the site, shows that the AbbVie site is in compliance with the emission limit values (ELV) as stated in its Industrial Emissions Licence with the exception of one ELV exceedence for wastewater discharge to sewer. This exceedence was reported to the EPA in accordance with Condition 4 'Interpretation' and Condition 19 Notifications, Records and Reports' of the site's Industrial CÓ Emissions Licence.

There were no complaints received by the AbbVie site in 2014. In total there were 4 no. incidents recorded as follows:

- On two occasions, the monitoring equipment at the licensed emission point SE-1 went offline;
- On one occasion, the monitoring equipment at the licensed emission point A2-1(a) went offline;
- As discussed above there was one ELV breach for wastewater discharge to sewer.

#### 2.3 **Overview of Existing Pollution Sources and Sensitive Receptors**

An overview of existing potential sources of emissions to the environment and sensitive receptors in areas within 3km of the site is presented in this section. A number of baseline studies were undertaken for the EIS. These included flora and fauna, water and geology, air quality and noise. Full details of these surveys can be found in the EIS prepared for this development and in subsequent submissions to the Agency, which formed part of the IPPC Licence application. These studies identified if there are any existing sources or risks (e.g. existing groundwater contamination); sensitive receptors (e.g. Special Areas of Conservation); or pathways (e.g. rivers or streams) in the area. The findings are summarised as follows:

#### 2.3.1 Flora & Fauna

The principal habitat types within the property are improved pasture grassland, damp to wet grassland, hedgerows, stream, drains and a calcareous spring. In addition, the Doonally River skirts the northern property boundary. The field boundaries comprising mature hedgerows are of



some local value as wildlife habitats, though the hedges are typical of the surrounding countryside and are not unique in character.

The habitats of most note within the site are the small stream and the spring. The stream has clear water flowing over a limestone substrate and has well developed bank side vegetation. The spring, which appears to feed the stream, has deep clear water and an aquatic and wetland flora. Both of these habitats are likely to have an interesting flora in spring and summer. While probably not uncommon on a regional scale, these two habitats add diversity to the property and are considered to be of some local scientific interest.

The Doonally River, which occurs outside of the property but which skirts its northern boundary, is a watercourse of good quality and with considerable scientific importance. Of particular note is its rich invertebrate fauna and the presence of trout, otter and kingfisher.

No rare, threatened or protected species of flora were recorded during the survey or are known to have been recorded in the immediate area in the past. There is a possibility that Prunus padus, a Red Data Book species, may occur within the many hedgerows of the area.

No habitats of high scientific or conservation interest (that is, regional to national importance) occurs within the property. The property is, however, situated in the vicinity of areas with high scientific interests and which have conservation designations or proposed designations. Such designated sites (or receptors) within a radius of 3 km from the site are listed below under the various designations.

- Candidate Special Areas of Conservation (CSAC) under Council Directive 92/43/EEC on the conservation of natural habitats and of wild faune and flora (commonly known as the Habitats Directive and implemented in Ireland by Statutory Instrument number 94 of 1997).
  - Cummeen Strand/Drumcliff Bay (Sligo Bay) (site no. 0627)
  - Lough Gill (site no. 01976)
- Special Protection Area (SPA) under Council Directive 79/409/EEC on the conservation of wild birds (commonly known as the Birds Directive and implemented in Ireland by Statutory Instrument number 291 of 1985).
  - Cummeen Strand (designated on February 7, 1995; Statutory Instrument number 31 o1995).
- Proposed Natural Heritage Areas as nominated by National Parks and Wildlife Service
  - Cummeen Strand/Drumcliff Bay (site no. 0627)
  - Lough Gill (site no. 01976)
  - Colgagh Lough (site no. 01658)
  - Glencar Cliffs (site no. 0628)
- Ramsar Site under the RAMSAR Convention
  - Cummeen Strand

#### 2.3.2 Water and Geology

The bedrock geology underlying the site is of marine shelf facies; limestone and calcareous shale and is classified as a locally important bedrock aquifer – bedrock which is moderately productive only in local zones. The groundwater vulnerability varies across the site from low at the west of the site to high and extreme in the east of the site (Source: www.gsi.ie).

Six groundwater monitoring wells were installed as part of an initial groundwater/hydrogeological study and groundwater samples were taken.

Laboratory analytical results for a wide range of parameters confirmed that there is no evidence of groundwater contamination, i.e. no source of contamination prior to site development. Prior to the site being developed all surface and storm water from the area discharged into a small stream that



discharges to the estuary at Cartron. Water quality in the stream was established by Forbairt in 1997. The results indicated good water quality in the vicinity of the facility i.e. no source of contamination prior to site development. Groundwater monitoring is carried out biannually downstream of the AbbVie site in compliance with its existing Industrial Emissions Licence. Results of groundwater monitoring carried out in 2014 as reported in the site's Annual Environmental Report (AER) for 2014 were reviewed which show there were no exceedences in generic assessment criteria such as GTVs (Groundwater Threshold Values) or IGVs (Interim Guideline Values) and there has not been an upward trend in monitoring results in the last 5 years.

#### 2.3.3 Air Quality

Existing air quality at the site was established during the preparation of the EIS by measuring ambient concentrations of sulphur dioxide, nitrogen dioxide and smoke. All values were well within relevant air quality standards, indicating a satisfactory air quality in the area i.e. no source of contamination prior to site development.

#### 2.3.4 Noise

Baseline noise monitoring was carried out during the preparation of the EIS at 3 no. locations around the site for a maximum of 60 minutes. Noise levels were generally low, though there was some local traffic and activity noise; i.e. no noise issues prior to site development.

Noise monitoring is carried out annually at 4 no. boundar Nocations as well as 3 no. locations offsite. Results of the 2014 noise monitoring which was submitted in the site's AER for 2014 show that the noise limits as set in the site's current Industrial Emissions Licence were fully complied Owner require ection purpo with.

#### **Licensed Emission Points** 2.3.5

A list of the licensed emission points at the AbbVie site is given in Table 2.1 below.

### Table 2.1: AbbVie's Licensed Emission Points

Emission Type	Reference No.	Description	Quantity Emitted <sup>Note 1</sup>
Emission to Air	A1-1	Boiler	313,128 m <sup>3</sup> /day
Emission to Air	A1-2	Boiler	313,128 m <sup>3</sup> /day
Emission to Air	A1-3	Boiler	Unknown
Emission to Air	A1-4	Boiler	Unknown
Emission to Air	A1-5	Boiler	Unknown
Emission to Air	A1-6	Boiler	Unknown
Emission to Air	A2-1 (a)	Thermal Oxidiser <sup>Note 2</sup>	95,088 m <sup>3</sup> /day
Emission to Air	A2-1 (b)	Cryogenic Condenser	21,600 m <sup>3</sup> /day
Emission to Air	A2-1 (c)	Thermal Oxidiser <sup>Note 3</sup>	95,088 m <sup>3</sup> /day
Emission to Air	A2-2	Scrubber	19,200 m <sup>3</sup> /day
Emission to Air	A2-3	Dust Extraction Building 40	432,000 m <sup>3</sup> /day
Emission to Air	A2-4	Dust Extraction Building 20	96,480 m <sup>3</sup> /day



Emission Type	Reference No.	Description	Quantity Emitted <sup>Note 1</sup>
Emission to Air	A2-5	Dust Extraction Building 20	72,000 m <sup>3</sup> /day
Emission to Sewer	SE-1	Near southern boundary	300 m <sup>3</sup> /day
Emission to Stormwater	SW 1	Near western boundary	N/A

Note 1: Emission Limit Value as stated in the site's current Industrial Emissions Licence

Note 2: Current Thermal Oxidiser being decommissioned

Note 3: Proposed New Thermal Oxidisor

#### 2.3.6 Recent Developments in Site Locality

Since the initial site construction, the surrounding locality has not changed significantly with regards to residential or industrial areas. Therefore, conclusions drawn in the baseline reports in the EIS in relation to risks unrelated to the Abbvie plant remain unchanged.

#### 2.3.7 Summary of Historical Risks

The site was Greenfield in nature prior to being developed by AbbVie and was used for agricultural purposes. Groundwater analysis results show no evidence of historical pollution from activities associated with the site prior to development by Abbott Ireland, i.e. no sources of groundwater contamination. Air and noise baseline monitoring are indicative of a rural area with some industrial and residential presence.

In summary, the baseline surveys undertaken of the site and its surrounding demonstrate that there are no historical environmental hazards i.e. sources present to pose a risk.

# 2.4 Facility Infrastructure, and Processes and Activities

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#### 2.4.1 Plant Description

The plant manufactures a number of active pharmaceutical ingredients (API's) for medical applications. The API plant is multi-purpose for multiple products. The API's are manufactured using standard chemical synthesis routes and equipment of proven design. The facility also includes a drug production building, which uses standard formulation operations including blending, milling, and tablet compression equipment. The facility also includes a number of supporting utilities and services.

#### 2.4.2 Buildings Overview

The main buildings are as follows:

- Building 70 Utilities Building;
- Building 40 Bulk Pharmaceutical Building;
- Building 20 Drug Product Building;
- Building 10 Administration and Laboratory Building.

The ancillary facilities found at the site are as follows:

- Tank Farm;
- Tank Unloading/loading Bay;
- Process Water Storage Tank;
- Sprinkler Pump House and Fire Water Storage Tank;



- Emergency Generator;
- Air Emissions Abatement Systems ;
- Aqueous Waste Treatment System ;
- Drum Store:
- Security Building.

#### 2.4.3 Methods and Processes

#### **Bulk Pharmaceutical Building**

The production processes is operated in batch mode and the equipment used to manufacture the products and intermediates are glass-lined or stainless steel and of standard design for the industry. The following are brief descriptions of typical production processes involved in the manufacture of APIs, not all of which are required for each product.

The operations undertaken in the Bulk Pharmaceutical Building include the following:

#### Reactions

Appropriate solvents are weighed into a chemical reaction vessel, called a reactor. Specified quantities of raw materials are added and heated to the required temperature range before a reactant is added at the required flow rate. Reaction conditions such as pressure, time, addition rate and temperature are set for each product and in-process testing and sampling will be , 160 carried out.

#### Crystallisation

quite Crystallisation is carried out on some products.

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### Separation

Separations are required. These may be liquid-liquid separation of, for example, an aqueous and an organic solvent, using a phase splitter, or solid-liquid separation using a filter or centrifugation.

### Distillation

A variety of distillations are required, either at atmospheric pressure or under vacuum, in order to purify a material, separate materials, or recover solvents for disposal.

Drying

Drying is carried out in filter dryers or blender/dryers (with or without vacuum).

### De-Lumping / Sizing

De-lumping, that is grinding down of material to a uniform size, is carried out using mills under specified operating conditions.

### **Drug Product Building**

The operations undertaken in the Drug Product building include the following:

Blending

Blending is the addition and mixing of powder raw materials with different properties. The objective is to have, on completion of the blending step, a final product that is homogenous (uniform). To achieve this, a number of pre-blending steps are necessary.

### **Compression into Tablets**

Tablets are formed, under pressure in a tablet press, from the blended powder.

### Tablet Coating

Tablets are coated using the tablet coater.



#### Site Utilities

The following utilities are generated and distributed on site:

- Various Water Utilities;
- Propylene glycol heating/cooling system;
- Nitrogen;
- Compressed air to power certain controls and for an air supply to personnel protective equipment masks;
- Site drainage systems;
- Fire water retention pond;
- Electrical Supply;
- Steam/Condensate.

#### Public Supply Main Water

The water supply to the site is from the Sligo Borough Council public supply main (300 mm diameter), which runs near to the site. The demand for water is approx. 230-300 m<sup>3</sup>/year. other

#### Process, Softened and Purified Water

Process water is softened. The water then passes through water purification equipment. The water purification plant has a flow rate of up to 10.8m<sup>3</sup>/br, The normal usage will be approximately 1m<sup>3</sup>/hr. Purified water will be supplied to the Bulk Pharmaceutical building and the Drug Product building. tion P

#### **Cooling Water**

Three cooling towers are located to the west of the utilities building. They are outdoors and at ground level. These cooling towers will be used for cooling the process and HVAC chilled water systems. The cooling towers normally operates with two towers on duty and the third on standby.

#### Low Pressure Hot Water

Low pressure hot water is used to provide space heating in the administration and laboratory building, the Drug Product building and the Bulk Pharmaceutical building. It is generated in the plant room in each building.

#### Propylene Glycol Heating/Cooling System

Propylene glycol solution is heated in a packaged unit located in the Bulk Pharmaceutical building. The glycol is cooled, when required, using glycol from the chillier units. The propylene glycol solution is supplied to the jackets on vessels such as the reactors and the filter dryers, and is used to heat the filter dryer agitator.

#### Nitrogen

Nitrogen is stored on site in a bulk tank. It is supplied to all the main process equipment and tanks to provide an inert medium and to fill the space above the liquid in the tanks, to prevent a build-up of vapours.

#### Instrument Air / Breathing Air

The generation plants for the instrument air and breathing air systems are located in the utility building.

#### Site Drainage Systems

Separate sanitary drainage, storm water drainage and floor drain collection systems are provided on site.



#### Fire Water Retention Pond

A firewater retention pond is located at the south-western part of the site. In the unlikely occurrence of a fire, the water used to fight the fire may come in contact with potential pollutants. In order to minimise the environmental impact from the firewater, the facility has been designed so that the firewater drains to the retention pond. The outlet of this retention pond closes upon activation of the firewater deluge systems.

#### **Electrical Supply**

The 38 kV ESB sub-station at the existing Abbott Ireland site in Ballytivnan is used as the power source for the facility. The average energy use on-site is approximately 8000 MWH per year.

#### Steam

There are 4 no. LPG boilers located in the utilities building. 2 no. back-up kerosene fired steamgenerating boilers, rated at 8000kg steam/hour, are also located in the utilities building. The boilers provide steam for process use. Steam is supplied to the Bulk Pharmaceutical building, the Drug Product building and the laboratory. The boilers normally operate with one on a duty and the second on standby basis but can operate together if an exceptional demand arises. Kerosene for the boilers is stored in a single 70m<sup>3</sup> tank, located in a bund in the tank farm. Total kerosene demand is approximately 1000m<sup>3</sup>/year. Total natural gas demand is also estimated to be approximately 1000m<sup>3</sup>/year.

#### Abatement

2014 My There are a number of abatement systems in place on the site. These are outlined below. DULDC

COQ

Thermal Oxidiser

The new direct fire thermal oxidiser will replace the existing TO currently on-site. This is a more energy efficient piece of equipment and will be used to combust halogenated methylene chloride vapours that occur at the site.

#### Cryogenic Condenser

This system will be used as a back-up to the new TO. This piece of equipment is not suitable for the abatement of Volatile Organic Compounds which is why the TO will be the main abatement unit used on-site.

#### **Dust Extraction Systems - HEPA Filter**

There are 3 no. HEPA filters in place at the facility to extract dust containing active pharmaceutical ingredients from production areas.

#### **Recovery and Treatment**

#### Solvent Treatment

An aqueous waste solvent stripper is located on site. The purpose of this is to remove concentrated solvent material from aqueous streams. The concentrated solvent material is taken off-site for disposal via road tanker.

#### Waste Disposal

All waste is segregated by waste type and is clearly labelled. Aqueous waste and laboratory waste collected from around the site is stored in a dedicated hazardous waste storage area until ready for off-site shipment. This is a locked caged area. Hazardous waste generated from manufacturing buildings B20 and B40 and the laboratory areas are collected by the Total Waste Management (TWM) vendor or warehouse personnel. Waste is transported to a locked shipping container, located separate from the warehouse areas, where it is sorted and stored securely while awaiting offsite shipment. Hazardous waste comprising drug products or containers of APIs are never stored outside of a secure location. All waste shipped off-site is packaged to meet all applicable requirements and in a manner to prevent any release during transportation. No Hazardous waste leaves the AbbVie site unless both the driver and the transport vehicle are fully compliant with the above requirements.



### 3 Closure Plan

#### 3.1 Closure Tasks and Programmes

#### 3.1.1 Clean or Non-Clean Closure Considerations

Following any permanent cessation of activities on all or part of the site or for the planned cessation of activities for a period of six months or greater, AbbVie will safely decommission all or part of the site and equipment as necessary in accordance with a defined set of criteria agreed with the Agency. Prevention of polluting material entering the environment is the primary purpose of the plan and will be achieved by adherence to the planned decommissioning tasks.

In the event of the cessation of AbbVie activities, either partially or fully, the company will pursue the following options;

- Endeavour to find an alternative use for the facility within the AbbVie corporation,
- All reasonable efforts will be made to divest the site as a going concern to another pharmaceutical manufacturing operation to enable continuation of pharmaceutical operations on the site.

In the event that neither of the above options is practicable, the company will activate this Closure Plan to ensure that the site and facilities are rendered safe and pose no threat to the environment. Part of this process may require the transfer of equipment to another AbbVie facility or the sale of some equipment.

Upon cessation of operations and subsequent decommissioning at the facility, it is anticipated that there will be no remaining environmental liabilities, i.e. Clean Closure is expected.

### 3.1.2 Clean Closure Decommissioning Project Plan

The basis of the plan is to ensure that, upon implementing the plan, the facility would be in a suitable state for future industrial use and its condition would not pose a risk to public health and safety or the environment. In general, specialist equipment will be distributed to other AbbVie plants in the event of a shut down. It is not intended to remove all structures or systems from the site, as it would affect the potential for future industrial use.

The closure process will include the following activities for the AbbVie plant, equipment and materials to ensure clean closure:

- Equipment Cleaning;
- Manufacturing Plant and Equipment Decommissioning;
- Material Storage;
- Boiler Decommissioning;
- Process Water & Purifying System Decommissioning;
- Cooling Tower Decommissioning;
- Propylene Glycol Heating/Cooling System Decommissioning;
- Other Utilities System Decommissioning;
- Air Abatement Equipment Decommissioning;
- Aqueous Waste Treatment System Decommissioning;
- Hazardous Waste Disposal;
- Non-hazardous Waste Disposal;
- Laboratory Shutdown & Waste Disposal;
- Securing and Maintenance of Building;



- Securing and Maintenance of Site;
- Contractor and Supplier Supervision;
- Ongoing Costs (Maintenance & Facilities);
- Test Program (Validation).

The following measures will also be implemented as part of the Plan:

- All systems will be safely de-energised and made redundant
- Any hazardous materials or process equipment, remaining in the facility, will be properly removed.
- Any residual levels of hazardous materials, remaining after closure, on interior building surfaces or, where applicable, in the environment will be at a level which will not pose a treat to human health or the environment.
- All wastes generated will be properly recycled or disposed of at a licensed waste management facility.
- Interior building surfaces will be decontaminated as necessary to accommodate the future planned use of the facility.

The detailed AbbVie Decommissioning Plan is inlcuded in Appendix B. 2009 only

#### 3.2 **Closure Plan Implementation**

Afor AbbVie shall inform the Agency in writing at least 3-6 months in advance of commencing any partial or full closure activities. AbbVie will engage in discussions with the Agency at the earliest stage to ensure a timely and transparent execution of the Closure Plan.

In the event of activating the Closure Plan, it is expected that it will be a project managed by existing experienced AbbVie staff.

All AbbVie EHS management procedures, including Emergency Response arrangements, will remain operational until the closure plan has been fully implemented. Therefore, the existing high standards of safety and environmental performance will be applied to the decommissioning tasks to ensure that potential risks associated with the plan are avoided.

#### 3.3 **Criteria for Successful Closure**

#### 3.3.1 **Clean Closure**

This study has not identified any persistent or remaining known liabilities that could exist after the full decommissioning programme has been executed.

#### 3.3.2 Expected Outcome – Successful Closure

The expected successful clean closure will be demonstrated by the absence of any remaining environmental liabilities on-site.

Successful closure will depend on employing the most appropriate equipment & techniques as follows:

- All wastes generated will be handled, packaged, temporarily stored and disposed in accordance with existing site procedures by licensed waste disposal contractors approved by the agency.
- All records relating to wastes, materials movement and disposal will be retained by AbbVie in accordance with statutory requirements.
- All plant will be safely decommissioned by using standard methodology defined by existing plant procedures.



An essential component of safe decommissioning of plant will be cleaning of API equipment and areas, ancillary equipment to the appropriate standard. API contaminated equipment must be returned to a Class IV clean room standard as measured by site SLI-ML-022 Environmental Monitoring.

In the event that any activities are not adequately covered by existing SOPs, they shall be carried out in accordance with a task specific method statement & risk assessment prepared in accordance with site SOP-EHS-024 Contractor EHS Management. This SOP ensures that competent contractors will be engaged to carry out any decommissioning work projects and that a comprehensive risk assessment of all related tasks will be completed prior to commencement of on-site work. The risk assessment shall address potential Health & Safety incidents as well as the prevention of emissions to the external environment.

#### **Closure Plan Validation & Environmental Monitoring During Decommissioning** 3.4

AbbVie shall appoint an experienced independent Environmental Specialist to perform a site assessment following the announcement of closure and prior to actual decommissioning and closure operations taking place. The scope of the assessment will include the most up to date Closure Plan for AbbVie and will encompass all plant, equipment and wastes on the AbbVie site.

All necessary environmental monitoring requirements for the duration of decommissioning in relation to Noise, Atmosphere, Storm Water, Emissions to Sewer, Waste and Groundwater will be agreed with the Agency.

All AbbVie procedures for environmental management shall remain effective for the duration of the decommissioning programme to ensure decommissioning tasks do not contribute to a deterioration pection pur Compet requ of site environmental conditions.

#### 3.4.1 **Final Validation Report**

The decommissioning program shall include, on completion of all planned decommissioning activities, a detailed site inspection toverify all items identified in the site assessment have been successfully decommissioned and to verify the absence of environmental liabilities. Conset

#### **Test Programme** 3.4.2

During the execution of the Closure Plan, an audit will be conducted by a qualified independent Environmental Consultant to monitor and report the compliance status and any environmental risks of the plan.

The following points will be specifically covered:

- Regular contact with EPA;
- Verification / certification that underground sumps and all storage and waste water storage tanks and lines are not leaking;
- Physical examination of the facility to ensure removal of any or all contaminants;
- A summary report on the final outcome of the execution of the decommissioning programme and closure plan to include surveys, results, assessments, studies, proposals performed as part of the execution the plan; and
- Any ongoing environmental monitoring requirements will be identified (if required) and a contract set up with an appropriately qualified consultant to monitor and report as required.

#### 3.4.3 **Final Report**

In accordance with the terms of the site's Industrial Emissions Licence, a final validation report including a certificate of completion of the Closure Plan will be issued by AbbVie. This shall be completed within three months of the successful execution of the plan.



# 3.5 Closure Plan Costing and Financial Provision

The costs assessment is an order of magnitude estimate based on historical data and professional opinion. The estimation is determined by using costs for previous similar works and including a percentage for inflation, wage increases etc. The accuracy range is ±25%. The costings in the previous Closure Plan and Environmental Liabilities Risk Assessment submitted to the Agency in 2013 (PM Group Report Number IE0311080-22-RP-0001 Issue A) and has been updated to reflect changes to site and the installation of the new thermal oxidiser. The time to decommission the plant completely is likely to be approximately 9-12 months from the date of last production. This is an estimate and depends to a large degree on the phased shutdown of operations. The decommissioning programme in Appendix B indicates costings associated with each programme element or milestone.

The total cost of implementing this Closure Plan is expected to be ca. €7,466,250 (including a 25% contingency).

A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated Closure Plan.

## 3.6 Closure Plan Update and Review

The closure plan shall be kept up to date by taking account of changes to the facility's Industrial Emissions Licence and production activities at the site. The Closure Plan will be reviewed annually as part of the Annual Environmental Review submission to the EPA.

# 3.7 Restoration and Aftercare Management Plan

The Agency Guidance Note identifies two main circumstances for which a site Restoration and Aftercare Management Plans is necessary. These circumstances are the following:

- Soil and groundwater contamination and
- Landform changes, e.g. landfills, extractive waste facilities, mines, quarries and soil recovery facilities.

In accordance with the above guidance, a Restoration and Aftercare Management Plan is not applicable to the AbbVie facility for the following reasons:

- AbbVie was developed in 2001 from a Greenfield site. A Hydrogeological assessment of the site, including Groundwater monitoring, was carried out in advance of the original IPPC Licence application to establish the baseline condition of the soil and groundwater. Since the granting of the IPPC Licence (and thereafter Industrial Emissions Licence), monitoring of groundwater has been carried out biannually for a range of parameters specified by the agency. To-date, the results have shown an absence of polluting substances. Therefore, significant soil and groundwater contamination is not expected to result from the licensed activities at the AbbVie facility.
- The AbbVie facility's manufacturing process does not require excavation of the site or landfilling of waste on-site. Therefore, landform changes will not arise at the AbbVie site.

## 3.7.1 Estimated Annual Costs Following Closure

There will be a number of ongoing costs associated with maintaining the maximum asset value of the installation after a clean and successful decommissioning has been completed. Normal practice will be applied to minimize ongoing liabilities and to fulfil insurance requirements. The annual costs are estimated in Table 3.2.



Item	Estimated Cost
Buildings	€27,500
Site	€44,100
Fire System	€16,500
Landscaping	€22,100
Security	€137,900
Specialist environmental monitoring (if required)	€5,500
Electricity	€110,250
Total	€363,850

# Table 3.2: Estimated Annual Costs Associated With Maintenance of Site Post-Closure

€363,850 Econor convision on the required for any other the for inspection purposes only on any other the second for any



# 4 Environmental Liabilities Risk Assessment

## 4.1 Methodology

This ELRA has been prepared in accordance with the EPA's new "Guidance on assessing and costing environmental liabilities (2014)". This new guidance reflects changes in legislation since 2006, removal of the screening process used to define the risk category of activities and also amends the risk assessment approach, in particular the costing methodology.

The ELRA considers the risk of unplanned events occurring during the operation of a facility that could result in environmental liabilities materialising.

The two key objectives of the ELRA process are:

- To identify and quantify environmental liabilities focusing on unplanned, but possible and plausible events occurring during the operational phase; and
- To provide a mechanism to encourage continuous environmental improvement through the management of potential environmental risks.

In accordance with the new guidance document specified by the EPA, the procedures to achieve these objectives are as follows:

- Scoping to determine the type of environmental liabilities to be covered;
- Risk assessment including risk identification, risk analysis and risk evaluation;
- Risk treatment ensuring appropriate risk mitigation is incorporated into the facility design, construction and operation to manage potential environmental risks;
- Identification, quantification and costing of a plausible worst case scenario for financial provision.

The risk assessment methodology incorporates a site evaluation which looks at the site operation, operator performance and the environmental sensitivity of the site. This information directly feeds into the risk assessment process which is as follows:

- Identification of main processes on site;
- Identification of hazards associated with each process;
- Identification of potential environmental effects of each hazard;
- Determination of the probability of occurrence and severity of each hazard to rank/rate the risk level of the hazard;
- Documenting same in a risk assessment table (included in Appendix C).

## 4.1.1 Risk Identification

The risks identified are those included in the previous version of the site ELRA (PM Group Report Number IE0311080-22-RP-0001 Issue A). These risks have been updates to reflect the proposed removal of the current thermal oxidiser onsite and the proposed installation of a new thermal oxidiser.

Each risk was considered for relevance, potential hazards, environmental effects, potential severity and probability of occurrence. A number of additional risks were identified and considered. For each potential hazard to be considered appropriate for inclusion in the risk assessment table, it must have an effect on an environmental receptor, namely:

- Surface Water;
- Groundwater;
- Noise;



- Soil;
- Human Beings;
- Air Quality;
- Archaeology and Cultural Heritage;
- Waste Generation;
- Flora and Fauna; \_
- Landscape.

The hazards / risks identified are documented in the Risk Assessment Table in Appendix C. This risk rating takes into account controls / risk mitigation measures currently in place at the AbbVie facility.

#### 4.1.2 **Risk Ranking**

A risk assessment was carried out to identify potential environmental hazards and quantify the associated risks inherent in the operation of the facility. The risk classification Tables 4.1 and 4.2 below were used to evaluate and rank risks by assigning a probability of occurrence and severity to Winyofferuse each potential hazard identified.

Doting		A Static Likelihood
Rating	Category Description	
1	Very Low	Wery low chance of hazard occurring
2	Low Scott	Low chance of hazard occurring
3	Medium	Medium chance of hazard occurring
4	High	High chance of hazard occurring
5	Very High	Very high chance of hazard occurring

## Table 4.1: Risk Classification Table – Likelihood

Table 4.2: Risk Classification Table – Consequence

Dating		Consequence	
Rating	Category	Description	
1	Trivial	No impact or negligible change to the environment	
2	Minor	Minor impact / localised or nuisance	
3	Moderate	Moderate impact to the environment	
4	Major	Severe impact to the environment	
5	Massive	Massive impact to a large area, irreversible in medium term	



#### 4.2 **Risk Identification, Analysis and Evaluation**

#### 4.2.1 **Risk Identification and Ranking**

## Identification of Environmental Receptors

Environmental receptors describe those parts of the surroundings likely to be affected by the activities at the AbbVie installation under normal, abnormal or emergency conditions. The significant environmental receptors are detailed in the Site Evaluation in Section 2 of this report. This provides a detailed description of the existing baseline environmental quality and is the starting point for assessing significant environmental impacts of AbbVie operations. These were taken into account when assessing the potential impact of site activities.

## Identification of Processes

A detailed description of the current site activities is provided in Section 2 of this report. This forms the basis for understanding the potential failure modes at the installation that could give rise to a significant environmental impact.

## Identification of Environmental Risks

Consideration of significant environmental receptors and potential failure modes of AbbVie activities from past, present and future activities were taken into account to produce a risk register.

Refer to Appendix C, which illustrates the AbbVie Current Environmental Risk Register. Risks are ranked in relation to its severity and likeliehood in accordance with the methodology described in Section 4.1.2 above. A total of 25 risks were identified at the AbbVie site. A risk score was then calculated for each risk, prior to mitigation. The risk score is based on the product of the severity rating and the occurrence rating. This system aboved the risks to be ranked and compared. owne ectif

#### 4.2.2 **Risk Matrix**

A Risk Matrix has been developed (Table 4.3) and is based on the Current Risk Register presented in Appendix C, to allow the risks to be easily displayed and prioritised. The severity and occurrence ratings described in sections 4.1.2 above are used in the matrix; with the level of severity forming the x-axis and the likelihood of occurrence forming the y-axis. This matrix provides a visual tool for regular risk reviews since the success of mitigation can be easily identified.

The risks have been colour coded in the matrix to provide a broad indication of the critical nature of each risk. The colour code is as follows:

- Red: These are considered to be high-level risks requiring priority attention. These risks have the potential to be catastrophic and as such should be addressed quickly.
- Amber: These are medium-level risks requiring action, but are not as critical as a red-coded risk.
- Green: These are lowest-level risks and indicate a need for continuing awareness and monitoring on a regular basis. Whilst they are currently low or minor risks, some have the potential to increase to medium or even high-level risks and must therefore be regularly monitored and if cost-effective practicable mitigation can be carried out to reduce the risk even further, this should be considered.



	V. High	5					
	High	4					
Likelihood	Medium	3	3		16		
	Low	2	1, 4, 5, 6, 7, 11	25	15, 23, 24	9, 10 18	
	V. Low	1			20, 21, 22, 26	2, 8, 12, 13, 14, 17, 19	
			Trivial	Minor	Moderate	Major	Massive
			1	onit any other	3	4	5
			Consequence				

## Table 4.3: Risk ID Matrix

The current risk matrix table (Table 4.3) indicates that there are no risks in the red zone requiring priority attention. There are 3 risks in the amber zone requiring mitigation or management action but are not as critical as a red-code risk.

The risks located in the green zone indicate a need for continuing awareness and monitoring on a regular basis. Some possible mitigation measures have been identified and should be considered if cost-effective to further reduce the risks.

# 4.2.3 Statement of Measures

Examination of the potential failure modes resulted in a series of specific mitigation measures being proposed for each item. A list of mitigation measures have been proposed and are detailed in Appendix D of this report. A risk owner responsible for the ongoing management of the risk and a timeframe for implementation of the risk mitigation measure has been included in each case where a mitigation measure has been proposed.

# 4.3 Financial Provision

# 4.3.1 Identification of Plausible Worst Case Scenario

The EPA guidance states:

- The worst case scenario may be represented by the risk with the highest consequence rating.
   In that case, this risk should be the basis for financial provision;
- The likelihood is not taken into account in the analysis;
- Where two or more risks are identified as having the maximum consequence, then further analysis should be undertaken to identify the most significant of these for quantification and costing;
- There may be links / domino-effects between individual risks, in which case a number of risks may need to be grouped to represent a worst case scenario.



Risk ID	Process	Potential Hazard	Consequence Rating
2	Tank Farm; Tank Loading	Potential back fire and explosion due to oxygen present in the vent for inerting failure causing damage to the bund.	4
8	Tank Farm; Solvent distribution	Potential fire or explosion due to grounding or bonding not functioning properly and causing damage to the containment bund.	4
9	Tank Farm; Storage	Potential fire or explosion caused by the use of free flames, spark or energized equipment causing damage to the containment bund.	4
10	Tank Farm; Storage	Potential fire or explosion of an explosive atmosphere from a leakage ignited by traffic sources causing damage to the containment bund.	4
12	تنمی Tank Farm; Containment bund	Potential liquid leakage due to cracks in the bund.	4
13	Tanker Unloading/Loading Bay; Truck loading/ unloading.	Potential leakage & explosion of flammables from loose connection of flexible hoses. An explosion will damage the bund.	4
14	Tanker Unloading/Loading Bay; Truck loading/ unloading	Potential liquid leakage from pump seal. An explosion will damage the bund.	4
17	Drumstore; Storage	Potential liquid leakage due to cracks in the bund.	4
18	Thermal Oxidiser; Fuel Transfer	Potential fuel leakage from flanges or flexible hose connection causing. Explosion of propane would damage containment bund.	4
19	Thermal Oxidiser; Vapours Combustion	Possible backfire or explosion for Oxygen present in the streams would damage the bund. Event could result in distribution of dioxins to local area and result in human health concerns (e.g. by contamination of agricultural areas).	4

The facility operational risks with the highest consequence ratings are listed in Table 4.4 below.

# Table 4.4: Facility Operational Risks with Highest Consequence Rating

Following a review of the risks detailed in Table 4.4, it is considered that a leakage during tanker loading / unloading either from loose connection of flexible hoses (Risk ID 13) or from a faulty connection in the pump seals (Risk ID 14) represents the worst case scenario with potential for



environmental contamination and associated remediation costs. This could potentially lead to a fire/explosion which could damage the bund leading to possible soil and groundwater contamination as well as air pollution by mechanical release. Fire water used to fight the fire would likely be contaminated and could lead to further contamination of soil and groundwater due to the containment bund being destroyed in the fire/explosion.

## 4.3.2 Quantification and Costing

The worst case scenario (Risk ID's 13 and 14) have been quantified and costed in the Table in Appendix E. It is considered that both Risks 13 and 14 would have the same consequence and therefore the costing exercise for in Appendix E is applicable for both risks.

Both risks involve the leakage of flammable materials during loading/unloading. The worst case scenario that has been costed includes for any leak of flammable material potentially leading to a fire/explosion form an ignition source which could have knock-on effects such as damage to the bund which can lead to soil and groundwater contamination by the flammable material that has leaked and also by any fire water that has been used to fight the water that has become contaminated.

There are many preventive / controls measures in place to help reduce the consequence of such an event, such as:

- Drip trays are positioned underneath the filling hoses from the Road Tanker to ensure any flammable spills are prevented from pooling guiside the bund.
- Procedures SOP SLI-API #s 007,008, 009, 064, 062, 063 and ENG-005 are in place to manage unloading and include requirement for postable spill kits to be in position prior to tanker unloading.
- Emergency Response procedures in place to define actions for chemical spills.
- In the event of a spill from the tanker, liquid will drain to a sump beside Tanker Unloading area.
- SOP SLI-API-007'TK-901 Methanol Storage and Unloading from Road Tanker ' and SOP SLI-API-008 T"-901 Tanker or Bulk Storage. Work permit issued, Portable Oxygen monitors used during transfer. Pump seals are on PM schedule.
- Magnetic drive Pumps are located within the bund thus ensuring Atex zone is maintained within the bund.

With the extensive safety measures detailed above in place, it is considered unlikely that this worstcase scenario could occur. However, as stated in the EPA's guidance, the likelihood is not taken into account in this costing exercise.

If the above risks should occur, the consequences would be relatively high; therefore it has been taken as the worst case scenario for the costing exercise provided in Appendix E. The estimated amounts used for the purposes of costing were based on EPA guidance and also on previous ELRA experience for other EPA licensed sites.

## 4.3.3 Financial Provision

The cost to address and remediate the worst case scenario cost for an unknown environmental liability relating to the site is estimated in this ELRA as €1,866,313 (including 25% contingency).

A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated ELRA.

## 4.3.4 Review of Financial Provision

The ELRA will be reviewed as necessary to reflect any significant changes on site. The financial provision made to address environmental liabilities arising from incidents will be reviewed and



revised as necessary, at least annually, in accordance with the conditions of the site's Industrial Emissions Licence.

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# 5 Conclusions

The assessment of potential environmental liabilities can be separated into 'known' environmental liabilities and potential or 'unknown' environmental liabilities associated with the environmental risks identified at AbbVie.

The Closure Plan in Section 3 of this report has detailed the expected environmental liabilities associated throughout the lifecycle of AbbVie installation. The costs assessment is an order of magnitude estimate based on historical data and professional opinion. The estimation is determined by taking similar project elements and including a percentage for inflation, wage increases etc. The accuracy range is from -20% to +25%. It is derived from the previous Environmental Liability Risk Assessment submitted to the Agency in 2013 and has been updated to reflect the changes being made with the installation of a new thermal oxidiser on the site. The total cost of the closure plan for AbbVie, taking account of known environmental liabilities associated with decommissioning tasks, was calculated to be  $\in$ 7,466,250. In addition, the total cost of maintaining the site to its maximum asset value by maintaining an on-going, security, safety and environmental monitoring presence was calculated to be approximately  $\in$ 363,850 per annum.

The Environmental Liabilities Risk assessment described in Section 4 of this report has taken account of the 'unknown' environmental liabilities associated with the AbbVie installation. A financial cost model has been prepared on the worst case scenario in accordance with the Agency Guidance. The calculated financial provision for unknown environmental liabilities for the AbbVie installation is €1,866,313.

A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated Closure Plan and ELFA.



# 6 Review and Update

The Closure Plan and ELRA will be reviewed and kept up to date as necessary to reflect any significant changes on site. The financial provision made to address the closure of the site and any environmental liabilities arising from incidents will be reviewed and revised as necessary, at least annually, in accordance with the conditions of the site's Industrial Emissions Licence.

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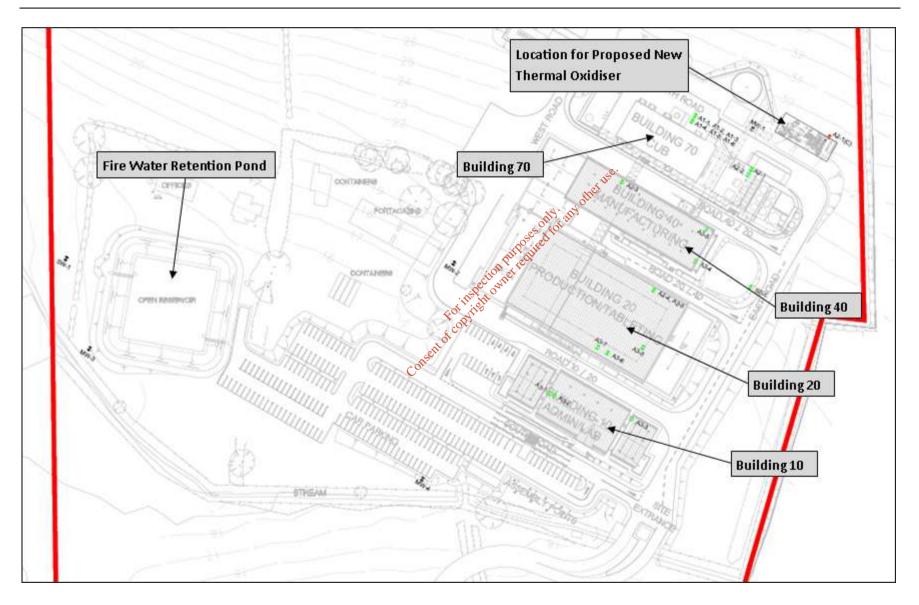


# Appendix A AbbVie Site Layout

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Page 32 of 61 Formal Issue





Page 33 of 61 Formal Issue



# Appendix B

AbbVie Closure Programme

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Page 34 of 61 Formal Issue



Activity & Method	Criteria	Estimated cost (€)	Duration
Planning			
1. Set up a management structure as soon as any closure decision is made	Roles (Staff Numbers)	3,000,000	12 months
2. Define roles, responsibilities & reporting lines	Management (5)		
3. Cessation of all construction project work onsite so that they are in a safe and orderly condition	Administration (10) Operations (20)		
4. Disbandment of contract personnel	Engineering (20)		
5. Termination of all non-essential maintenance and other contracts	IT support (5) and include		
6. Removal from site any temporary offices or storage areas	Administration (10) Operations (20) Engineering (20) Laboratory (5) IT support (5) Others (15) Under the formation of the second s		
7. Document a project schedule of all decommissioning tasks integrating appropriate timeframes for tendering work packages to external contractors as necessary, review of all method statements, Selection of competent contractors.			
8. Arrangements for communication and co-ordination of different work teams			
9. Arrange the secure archiving of all engineering documentation including drawings, P&IDs, validation documents, vendor manuals, project files maintenance records, Environmental Monitoring records and the Safety File			



Activity & Method	Criteria	Estimated cost (€)	Duration
Decontamination			
Manufacturing Equipment & Facilities			
Equipment Cleaning			
All manufacturing equipment shall be emptied of all materials and cleaned as per SOP SLI-API-039 cleaning of API Product Containers (CNRs) to ensure that no residual product or process reagents remain in the equipment that are likely to pose a threat to personnel or the environment.	SLI-ML-022 Environmental Monitoring CNC1 clean room standard (SLI-ML-022 Environmental Monitoring) SLI-API-037 Cleaning of Ancillary Equipment	750,000	10 weeks
Materials Removal	tion purice unit		
a) Main process intermediates will be consumed as part of the plant shutdown sequence. All final product material will be purchased by clients and out of specification material disposed of in accordance with the terms of the Industrial Emissions Licence. Main process solvents, inorganic salts and organic and inorganic acids will be consumed to minimum stock levels as part of the shutdown sequence. The small remaining amounts will be sent back to the supplier, which is the preferred method of disposal. In the event that that this is not practicable, the materials will be sent for offsite treatment/recovery or disposal by an appropriate method as per the requirements of the Industrial Emissions Licence.	SLI-EHS-033 – Procedure for the safe use and handling of Potent Drugs and Chemicals SLI-DP-024 Handling of spillage within the Drug Product Building SLI-DP-031 Handling of Drug Product Waste	Normal operating costs	6 months



Activity & Method	Criteria	Estimated cost (€)	Duration
Manufacturing Plant & Equipment Decommissioning			
Plant and equipment will be decommissioned in an orderly fashion and in accordance with the manufacturer's recommendations. In the event that the plant is to be "mothballed " in situ, the manufacturer's recommendations for long term storage of the equipment will be followed. In the event that the equipment is to be transferred to another location, or sold, it will be suitably packed and sent offsite as soon as is practical. Any remaining hazardous waste including solid waste, laboratory waste and waste oils shall be disposed of via approved waste management contractors as per the Industrial Emissions Licence.	SLI-API-039 cleaning of API Product Containers (CNRs)	375,000	4 months
Buildings - Cleaning	ion pure quie		
All buildings will be cleaned to remove all potential traces of APIs as well as any other contaminants by means of the standard operating procedures	SOP SLIAPI-026 Cleaning of Bulk Building SLIAPI-037, Cleaning of Ancillary Equipment SLI-DP-015 Cleaning of Drug Product Building SLI-API-039 cleaning of API Product Containers (CNRs) SLI-MFG-008 Visual Clean Determination SLI-ENG-059 Cleaning of Building 10 and 70 SLI-ENG-066 Pest Control Process	37,500	3 months



Activity & Method	Criteria	Estimated cost (€)	Duration
Material Storage / Tank Farm			
There is a tank farm on-site which stores a maximum of eight tanks. It currently holds six tanks, which include one 70 m <sup>3</sup> kerosene tank, three 30 m <sup>3</sup> tanks storing methanol, solvent waste and aqueous waste respectively and one 10 m <sup>3</sup> aqueous waste test tank. All of the tanks in the tank farm are bunded. There is also a 120 m <sup>3</sup> tank, which stores untreated process water. Drums and IBCs are stored in the external drum storage which has capacity for up to 300m <sup>3</sup> . The drum store is bunded to minimise impact from accidental spillage. All process waste drains are double contained and pipe racks are located over ground. In the event of cessation of activities at the facility all tanks and related piping and drains will be washed and decontaminated in accordance with recommended AbbVie cleaning procedures. Likewise all tank farm bunds will be washed and inspected to ensure they free from contamination. The waste generated from this cleaning process will be treated off site in accordance with the terms of the Industrial Emissions Licence. Tanks will be checked to ensure that they are clean and then they will be spaded off and stored for reuse or disposal.	EHS-023 Waste Management Procedure	750,000	10 weeks
Drum Storage			
Removal of all drums by; - Return to supplier, - Disposal as hazardous waste	EHS-023 Waste Management Procedure	Included in hazardous waste figure	1 month after last generated hazardous waste



Activity & Method	Criteria	Estimated cost (€)	Duration
Utilities			
As part of a cessation of activities it will be necessary to maintain the utilities systems in operation until all of the remaining systems have been decommissioned. The following is the list of utility systems on-site:	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure	7,500 Normal operating costs of Eng. Dept.	4 weeks (external contractor)
<ul> <li>Two kerosene fired boilers (Boiler A and B) produce steam/condensate for process use</li> </ul>	at the contract of the contrac		
<ul> <li>One gas fired boiler (Boiler C) to produce steam/condensate for process use</li> </ul>	For inspection purposes only, any other use.		
<ul> <li>Three gas fired boilers to produce steam/condensate for process use</li> </ul>			
<ul> <li>One diesel powered backup generator</li> </ul>			
<ul> <li>Process Water Softening &amp; Purifying System and Reverse Osmosis (RO) Unit</li> </ul>			
<ul> <li>Cooling towers (x3) which are used for cooling the process and the</li> </ul>	. at a cot		
- HVAC chilled water systems	815-		
<ul> <li>Propylene glycol heating/cooling system, which is used for supplying the jackets on vessels such as the reactors and the filter dryers and also used to heat the filter dryer agitator.</li> </ul>			
<ul> <li>Nitrogen System which is used for providing an inert medium in tanks to prevent the build-up of vapours</li> </ul>			
<ul> <li>Compressed air to power certain controls and for an air supply to personnel protective equipment masks</li> </ul>			
<ul> <li>Site drainage systems including sanitary drainage, storm water drainage and floor drain collection systems</li> </ul>			
<ul> <li>Firewater retention pond, which is used only in the event of a fire to contain any potentially, contaminated firewater.</li> </ul>			



Activity & Method	Criteria	Estimated cost (€)	Duration
<ul> <li>Electrical Supply, which is supplied by a 38, kV ESB sub- station located at the AbbVie Ballytivnan site.</li> </ul>			
<ul> <li>Ultimately, removal of any associated chemicals, oils, for redistribution, return to vendor or disposal as required</li> </ul>			
Boiler Decommissioning			
2 No. Boiler Decommissioning	15 <sup>6</sup> .	16,000	1 week
The two oil fired boilers currently on site shall be decommissioned in accordance with good engineering practice and the manufacturers recommendations. They will be prepared for "Dry Storage" or removal. This process will include decontamination of the boiler fireside and watersides. Wastewater from the boiler shall be released to the aqueous waste holding tank for off-site treatment.	. aspection purposes only any other use.		
4 No. Gas Boilers	Milion of	16,000	1 week
The gas boilers currently on site shall be decommissioned in accordance with good engineering practice and the manufacturers recommendations. They will be prepared for "Dry Storage" or removal. This process will include decontamination of the boiler fireside and watersides.	For instein owners		
Personnel: Boiler Specialists			
Process Water & Purifying System Decommissioning			
The supplier will decommission the water purification plant and any hazardous chemicals removed for reuse or disposed of via approved waste management contractors as per the site's Industrial Emissions Licence. Personnel: 2 operators	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure	9,000	1 week



Activity & Method	Criteria	Estimated cost (€)	Duration
Cooling Tower Decommissioning			
The three plant cooling towers will be decommissioned by the plant supplier, cleaned and disinfected to prevent growth of Legionella Pneumophila (LP) organisms. Personnel: 2 persons	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure	7,000	3 days
Propylene Glycol Heating / Cooling System Decommissioning	N. O' Other hee.		
The equipment supplier will decommission the propylene glycol heating/cooling system and the refrigerant removed will be returned to the supplier. Personnel: 2 persons	EHS-010 Control of Hazardous Energy SLI-MFG-001 Brocess Pipe Cleaning & Passivation Brocedure	10,000	1 week
Nitrogen System Decommissioning	Forthe		
Following the removal of all solvents from the site the nitrogen system will be decommissioned. This will require the liquid nitrogen supplier (BOC) to empty the liquid nitrogen bulk storage tank and remove the contents for reuse elsewhere.	Supplier's methodology will be managed by Supproved Method Statement by EHS-024 Contractor EHS Management	Supplier will bear cost	2 weeks
As this equipment is owned by the liquid nitrogen vendor, the entire skid will be removed for use elsewhere.			
LPG Tank			
Following the decommissioning of the gas boilers the LPG tank system will be decommissioned. This will require the supplier (Calor) to empty the LPG bulk storage tank and remove it. As this equipment is owned by the vendor, the entire skid will be	Supplier's methodology will be managed by approved Method Statement by EHS-024 Contractor EHS Management	Supplier will bear cost	1 week
As this equipment is owned by the vendor, the entire skid will be removed for use elsewhere.			



Activity & Method	Criteria	Estimated cost (€)	Duration
Air Emission Abatement Equipment Decommissioning			
The proposed new thermal oxidiser will used to treat the solvent off gases from the process vessels in the bulk pharmaceutical facility. A process scrubber is used to treat acid/caustic off gases from the bulk pharmaceutical facility and the drum charging room. The scrubber contains a packed column of polypropylene media and a sodium hydroxide solution. This material would be removed during decommissioning and disposed of via approved waste management contractors as per Industrial Emissions Licence conditions. Personnel: 2 persons	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure EHS-023 Waste Management Procedure Project specific method statements <sup>e.</sup>	10,000	1 week
Other Utilities System Decommissioning	outpositist		
All other utility systems will be shut-down and stored as per the equipment manufacturer's instructions. The only equipment that will be maintained in fully operating condition will be the firewater sprinkler system. This will be required to protect the vacant buildings in the event of fire. This system will be placed under maintenance contract with a specialist contractor to ensure it is fully serviceable in the event of it being required. All utility systems will be emptied to prevent frost damage. Where this is not possible due to the requirement to maintain some water systems live to feed the firewater system, appropriate trace heating will be installed and/or local building heating provided to ensure frost protection is effective. The electricity distribution system and the transformers will be maintained in operation and placed under maintenance contract. (redundant transformers would be drained of oils that will be disposed of as hazardous waste) All computer and control systems will be decommissioned, except where required for monitoring of systems still in operation.	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure EHS-023 Waste Management Procedure	250,000	9 months





Activity & Method	Criteria	Estimated cost (€)	Duration
Aqueous Waste Treatment			
An aqueous waste solvent stripper removes any organic solvents from the aqueous waste streams. Residual aqueous waste that remains after treatment in the solvent stripper (2 runs) is tankered off site for further treatment or disposal. The aqueous waste treatment system will be decommissioned and any hazardous chemicals removed for reuse or disposed of via approved waste management contractors as per the site's Industrial Emissions Licence. Personnel: 2 persons	EHS-010 Control of Hazardous Energy SLI-MFG-001 Process Pipe Cleaning & Passivation Procedure EHS-023 Waste Management Procedure Project specific method statements <sup>6</sup>	10,000	1 week
Waste Disposal/Recovery	Pupolited		
Hazardous Waste			
Hazardous waste including waste solvents, waste oils, passivation waste, fluorescent tubes, HVAC filter cartridges, contaminated plastic, and other hazardous waste requiring disposal/recovery shall be sent to an agreed waste disposal/recovery site as per the Industrial Emissions Licence conditions. All waste transported off site shall be transported in accordance with good environmental practice and appropriate National and European legislation. Personnel: 1 person	EHS 023 Waste Management Procedure	€400,000 (estimate for disposal costs)	Over the duration of plant decommissioning and cleaning
Non-Hazardous Waste			
Non-hazardous waste including canteen, office, process solid waste and other waste requiring disposal/ recovery shall be sent to an agreed waste disposal/recovery site as per the site's Industrial Emissions Licence. Personnel: 1 person	EHS-023 Waste Management Procedure	€50,000 (estimate for disposal costs)	Over the duration of plant decommissioning and cleaning



Activity & Method	Criteria	Estimated cost (€)	Duration
Laboratory Shutdown & Decommissioning - Instrumentation			
All laboratory instrumentation shall be decommissioned and cleaned on site. It shall then be either sold or sent to another AbbVie facility for further use.	Project specific method statement	Normal operating costs	10 weeks
Personnel: 8 persons			
Laboratory waste	tettee.		
Any unopened laboratory reagents and chemicals shall be returned to the suppliers. Any remaining laboratory reagents and chemicals shall be disposed of via an authorised hazardous waste disposal contractor in accordance with the site's Industrial Emissions Licence. Retained QC samples will be sent to AbbVie headquarters in the US for retention as per FDA requirements. Personnel: 1 person	SLI-CL-067 Disposal of Waste From Chemical Laboratory of the Promotion Purpose of the Promotion	5,000	Over the duration of laboratory decommissioning and cleaning
Buildings	La contr		
Following decommissioning of the facilities all buildings will be secured to prevent unauthorised entry. A maintenance program will be put in place to ensure that the buildings do not decay or present an unacceptable nuisance in the area. Personnel: 1 persons	Maintain buildings to maximum asset value	15,000	12 months



Activity & Method	Criteria	Estimated cost (€)	Duration
Fixtures & Fittings			
While the primary intention would be to maintain the maximum asset value of the facility, in the event that the facility is to be sold off in parts, it may become necessary to dispose of specific fixtures and fittings. This will be achieved without any negative external visual impact. All buildings will be left intact and secure. Any fixtures and fittings from plant areas, laboratories, offices and stores shall be removed off site if necessary and sold or sent to another AbbVie location for further use. Personnel: 10 persons	W. on other have.	Normal operating costs	2 weeks
Site Decommissioning Security	C SOL		
Following cessation of on-site activities, the site will be secured against unauthorised entry. A landscape maintenance program will be implemented to ensure that the site does not present an unacceptable nuisance in the area. A security program will be implemented to ensure that the site is regularly patrolled and checked for unauthorised access. Personnel: 4 persons (24/7 cover)	For inspection purper centred t	125,000	12 months
Decommissioning Supervision			
Contractors and Suppliers Supervision			
AbbVie Ireland Engineers/Supervisors will supervise this work. Personnel: 2 persons	AbbVie engineers or contract engineers	100,000	12 months



Activity & Method	Criteria	Estimated cost (€)	Duration
Final Validation Report			
<ul> <li>Test Programme</li> <li>During the execution of the Closure Plan, an assessment will be conducted by a qualified Environmental Consultant to monitor and report the compliance status and environmental risk factors of the plan. The following points will be specifically covered: <ul> <li>Regulatory contact with EPA;</li> <li>Verification/ certification that underground sumps and all storage and waste water storage tanks and lines are not leaking;</li> <li>Verification to ensure that there is no risk to surface water, groundwater or any soil contamination;</li> <li>Physical examination of the facility to ensure removal of any or all contaminants;</li> <li>A summary report on the final outcome of the execution of the residuals management programme to include surveys, results, assessments, studies, proposals performed as part of the execution the plan;</li> <li>Any ongoing monitoring programme will be identified, if required and a contract set up with an appropriately qualified consultant to monitor and report as required.</li> </ul> </li> </ul>	In accordance with the terms of the Industrial Emissions Licence, a final validation report will be issued by the company to include a Certificate Of Completion of the Closure plan. This shall be done within three months of end of the execution of the plan.	30,000	
SUBTOTAL		5,973,000	12 months
Contingency @ 25%		1,493,250	
TOTAL		7,466,250	



# Appendix C

Current AbbVie Environmental Liabilities Risk Register

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Page 47 of 61 Formal Issue



Risk ID	Process	Potential Risks	Potential Environmental Effect	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score (Consequence x Likelihood)
1	Tank Farm; Tank Loading	Overfill of Tank with liquid spill out from the top through the manhole.	Localised air pollution and hazardous atmosphere generation.	1	All tanks are in bunded areas, so any leakage will be contained in the bund. Procedures SOP SLI-API #s 007,008, 009, 054, 062, 063 and ENG-005 are in place to manage this aspect and include requirement for portable spill kits to be in position prior to tanker unloading. Emergency Response procedures in place to define actions for chemical spills.	2	A software High Level alarm system is in place and a hardwired interlock that stops the pump in case of overfilling. Area is classified as Atex Zone with local Ex warning signage posted.	2
2	Tank Farm; Tank Loading	Potential back fire and explosion due to oxygen present in the vent for inerting failure causing damage to the bund.	Possible soil and groundwater contamination.	4	Tank Farm heat detectors activate a deluge system and automatic shutoff of all outlet valves (Manual deluge activation at tank unloading area). Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	1	Oxygen monitoring system in line to detect Oxygen >6% and system is included in the site's Preventative Maintenance and Calibration Programmes. The High Oxygen alarm is interlocked to automatically close Vent Header and introduce Nitrogen to maintain Oxygen <6%. Liquid nitrogen purging is activated by interlock if the gaseous Nitrogen pressure drops. Flame arrestors are in place in the vent header line to the Thermal Oxidiser to dissipate ignition sources.	4
3	Tank Farm; Flange connection	Potential liquid leakage from the flanges due to gasket wear.	Localised air pollution and hazardous atmosphere generation.	1	All the pumps and valve are in bunded areas, eventual leakage will be collected in the bund or sent to tank farm to be either discharged to sewer or disposed of as Hazardous Waste.	3	Area has been classified as Atex Zone with local Ex warning signage posted. Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. SOP # EHS-012 requires a weekly visual inspection of all overhead pipe racks for early leak detection in accordance with existing Industrial Emissions Licence Condition 3.11.	3
4	Tank Farm; Bottom valve	Potential liquid leakage from the valve due to faulty seal.	Localised air pollution and hazardous atmosphere generation.	1	Potential leakage from the bottom valve will be collected in the containment bund to be either discharged to sewer or disposed of as Hazardous Waste.	2	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted.	2



Risk ID	Process	Potential Risks	Potential Environmental Effect	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score (Consequence x Likelihood)
5	Tank Farm; Tank bottom	Potential liquid leakage from cracks or holes in the base.	Localised air pollution and hazardous atmosphere generation.	1	Potential leakage from the bottom valve will be collected in the containment bund to be either discharged to sewer or disposed of as Hazardous Waste	2	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted.	2
6	Tank Farm; Solvent distribution	Potential liquid leakage from flange connections in the pipe or with the pumps.	Localised air pollution and hazardous atmosphere generation.	1	All the flanges are in bunded area, eventual leakage will be collected in the bund or drained in the sump.		Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted.	2
7	Tank Farm; Solvent distribution	Potential liquid leakage from pump seal.	Localised air pollution and hazardous atmosphere generation.	1	All the flanges are in bunded area, eventual leakage will be collected in the bund or drained in the sump.	2	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted.	2
8	Tank Farm; Solvent distribution	Potential fire or explosion due to grounding or bonding not functioning properly and causing damage to the containment bund.	Possible soil and groundwater contamination.	4	Tank Farm heat detectors activate a deluge system and automatic shutoff of all outlet valves (Manual deluge activation at tank unloading area). Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	1	Preventative Maintenance Schedules requires a check on continuity of grounding and bonding and resistance of <10 Ohms.	4
9	Tank Farm; Storage	Potential fire or explosion caused by the use of free flames, spark or energized equipment causing damage to the containment bund.	Possible soil and groundwater contamination.	4	Tank Farm heat detectors activate a deluge system and automatic shutoff of all outlet valves (Manual deluge activation at tank unloading area). Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	2	Hot Work is controlled by BOP EHS -007 Permit to Work programme and BOP EHS-009 Hot Work Programme. Area has been classified as Atex Zone with local Ex warning signage posted.	8
10	Tank Farm; Storage	Potential fire or explosion of an explosive atmosphere from a leakage ignited by traffic sources causing damage to the containment bund.	Possible soil and groundwater contamination and air pollution.	4	Tank Farm heat detectors activate a deluge system and automatic shutoff of all outlet valves (Manual deluge activation at tank unloading area). Releases to air are mitigated by deluge system. Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	2	Hot Work is controlled by SOP EHS -007 Permit to Work programme and SOP EHS-009 Hot Work Programme supported by induction training for all employees and contractors. Area has been classified as Atex Zone with local Ex warning signage posted	8



Risk ID	Process	Potential Risks	Potential Environmental Effect	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score (Consequence x Likelihood)
11	Tank Farm; Bund drainage	Potential liquid leakage from valve or pump flanges or pump seal.	Localised air pollution and hazardous atmosphere generation.	1	All the flanges are in bunded area, eventual leakage will be collected in the bund or drained in the sump	2	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted.	2
12	Tank Farm; Containment bund	Potential liquid leakage due to cracks in the bund.	Possible soil and groundwater contamination.	4 Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.		1	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years.	4
13	Tanker Unloading/Loading Bay; Truck loading/ unloading	Potential leakage & explosion of flammables from loose connection of flexible hoses. An explosion will damage the bund.	Possible soil and groundwater contamination and air pollution with hazardous atmosphere generation.	4	<ul> <li>Deluge system is interlocked with local heat. detectors.</li> <li>Drip trays are positioned underneath the filling hoses from the Road Tanker to ensure any flammable spills are prevented from pooling outside the bund.</li> <li>Procedures SOP SLLAPI #\$ 007,008, 009, 054, 062, 063 and ENG-005 are in place to manage this aspect and include requirement for portable spill kits to be in position prior to tanker unloading.</li> <li>Emergency Response procedures in place to define actions for chemical spills.</li> <li>In the event of a spill from the tanker, liquid will drain to a sump beside Tanker Unloading area.</li> <li>Aquifer underlying site classified as moderately to</li> </ul>		Hot Work is controlled by BOP EHS -007 Permit to Work programme and BOP EHS-009 Hot Work Programme. Area has been classified as Atex Zone with local Ex warning signage posted.	4
14	Tanker Unloading/Loading Bay; Truck loading/ unloading	Potential liquid leakage from pump seal. An explosion will damage the bund.	Possible soil and groundwater contamination and air pollution with hazardous atmosphere generation.	4	Deluge system is interlocked with local heat detectors and would prevent explosion propagation by diluting solvent below flammable concentration. Drip trays are positioned underneath the filling hoses from the Road Tanker to ensure any flammable spills are prevented from pooling outside the bund. Emergency Response procedure in place to define actions for chemical spills. Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	1	SOP SLI-API-007'TK-901 Methanol Storage and Unloading from Road Tanker ' and SOP SLI-API-008 T"-901 Tanker loading from Bulk Storage. Work permit issued, Portable Oxygen monitors used during transfer. Pump seals are on PM schedule. Magnetic drive Pumps are located within the bund thus ensuring Atex zone is maintained within the bund	3



Risk ID	Process	Potential Risks	Potential Environmental Effect	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score (Consequence x Likelihood)
15	Drumstore; IBC or drum handling	Potential liquid leakage due to damaged packaging during handling/moving and potential bund damage A) Fire/Explosion of flammables finding an ignition source B) mixing of incompatible flammable and corrosive compounds that currently share a common bund.	Possible soil and groundwater contamination and air pollution.	3	The area is fully bunded. Fire detection is in pace in main storage bay but not in room dedicated for Laboratory hazardous materials. Spill kit is available to personnel. Drumstore is not equipped with an automatic extinguish system (foam, sprinklers, deluge). Compressed Gas bottles at Drumstore entrance are stored within 15 meters of flammable material. Aquifer underlying site classified as moderately to highly vulnerable.	2	<ul> <li>Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years.</li> <li>Warehouse people are trained to DGSA standard.</li> <li>Area has been classified as Atex Zone and local Ex warning signage is posted.</li> <li>Forklift Truck is Atex rated '3G' for Zone 2 Liquids and Gas Vapours.</li> <li>Drumstore has defined storage and traffic layout and safe loading area.</li> <li>Area is not physically locked to prevent unauthorised access.</li> </ul>	6
16	Drumstore; Storage	Potential fire or explosion of an explosive atmosphere from a leakage ignited by the fork lift or truck sources.	Possible soil and groundwater contamination.	3	The area is fully bunded.	3	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. The area is an Atex rated zone with local 'Ex' signs posted. The fork lift is Atex rated '3G' for Zone 2 Liquids and Gas Vapours and has LEL detector to automatically shut off. Drumstore has defined storage and traffice layout and safe loading area. Area is not physically locked to prevent unauthorised access.	9
17	Drumstore; storage	Potential liquid leakage due to cracks in the bund.	Possible soil and groundwater contamination.	4	Aquifer underlying site classified as moderately to highly vulnerable.	1	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years.	4
18	Thermal Oxidisor; Fuel Transfer	Potential fuel leakage from flanges or flexible hose connection causing. Explosion of propane would damage containment bund.	Potential soil and groundwater contamination.	4	All the flanges are in bunded areas, eventual leakage will be collected in the bund to be either discharged to sewer or disposed of as Hazardous Waste. Aquifer underlying site classified as moderately to highly vulnerable.	2	Containment bunds are managed by SOP EHS-025 to comply with existing Industrial Emissions Licence Condition 3.6.5 which requires a weekly visual inspection and an integrity test every 3 years. Area has been classified as Atex Zone with local Ex warning signage posted. Gas tight fittings installed.	8



Risk ID	Process	Potential Risks	Potential Environmental Effect	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score (Consequence x Likelihood)
19	Thermal Oxidiser; Vapours Combustion	Possible backfire or explosion for Oxygen present in the streams would damage the bund. Event could result in distribution of dioxins to local area and result in human health concerns (e.g. by contamination of agricultural areas).	Possible soil and groundwater contamination and air pollution.	4	Aquifer underlying site classified as moderately to highly vulnerable.	1	Oxygen monitoring system in line to detect Oxygen >6% and system is included in the site's Preventative Maintenance and Calibration Programmes. The High Oxygen alarm is interlocked to automatically close Vent Header and introduce Nitrogen to maintain Oxygen <6%. Liquid nitrogen purging is activated by interlock if the gaseous Nitrogen pressure drops. Flame arrestors are in place in the vent header line to the Thermal Oxidiser to dissipate ignition sources.	4
20	Thermal Oxidiser; Combustion	Undetected dioxin formation and subsequent dispersion to soil could result in human health concerns (e.g. by contamination of agricultural areas).	Possible soil contamination and air pollution.	3	Stack monitoring for Dioxins and carried out as part of the licence.	1	Thermal Oxidiser performance is controlled by inclusion on the Preventative Maintenance Schedule.	3
21	Sewer; Liquid Drainage	Failure of pipe connection (i.e. crack or loose seal to the retention pond would result in leakage of material.	Possible soil and groundwater contamination.	3	Aquifer underlying site classified as moderately to highly vulnerable.	1	The foul sewer pipes are double contained and there are scheduled PM inspections & testing to check leakage including CCTV internal pipe inspections. The pipe from the sump to the retention pond is a single skin pipe encased in concrete to connection with retention pond. No existing detection method of such a leak outside of PM CCTV inspection. All bund liquid including rainwater is tested (pH, COD) before release to Retention Pond. Integrity testing of Retention Pond lining and tie connection has been completed successfully and will be repeated on a 3 year cycle.	3
22	Transformer (2 No.)	Possible explosion with potential for soil pollution	Possible soil and groundwater contamination.	3	Aquifer underlying site classified as moderately to highly vulnerable in location of tank farm.	1	Oil in transformers has been analysed annually to confirm it is free from A) PCBs and B) Chloride traces	3
23	Retention Pond; Storage of Firewater	Damaged containment resulting in discharge of Firewater from pond.	Possible soil and groundwater contamination.	3	Aquifer underlying site classified as moderately to highly vulnerable.	2	Engineered Firewater Retention Pond was constructed c. 2001. Integrity testing of Retention Pond lining and pipe connection has been completed successfully and will be repeated on a 3 year cycle.	6



24 LPG								Likelihood)
	PG Tank; Bulk tank	Potential gas leakage from tank and potential explosion.	Localised air pollution and hazardous atmosphere generation.	3	Fire in area of the storage tank will activate fire alarm and stop supply of LPG to boilers.	2	LPG storage tank designed to IS 3216 2010 standard - Code of Practice for the Bulk Storage of Liquefied Petroleum Gas Area has been classified as Atex Zone with local Ex warning signage posted. No naked flame signs also in place. Ex rated equipment.	6
·/h	PG Tank; Gas istribution	Potential gas leakage from distribution and potential explosion.	Localised air pollution and hazardous atmosphere generation.	2	A safety interlock is installed on the pipe going to the boilerhouse, which will stop the LPG in case a major leak is detected. This safety interlock (which includes the whole safety loop of detector, actuator, logic control and shut-off valve) is certified as SIL 1. Fire in area of the storage tank will activate fire alarm and stop supply of LPG to boilers.	2	There are leak detectors on at each of the gas boilers in case of a leak. Area has been classified as Atex Zone with local Ex warning signage posted. No naked flame signs also in place. Ex rated equipment.	4
	vaste Management nd Disposal	Incorrect disposal of Waste	Possible soil and groundwater contamination and odour.	3	Aquifer underlying site classified as moderately to highly vulnerable.	1	All waste contractors on site are licensed operators for the collection and disposal of waste. Waste management procedures in place on site. Audit of waste contractors is carried out and maintenance of disposal records are kept.	3



# Appendix D

Statement of Measures for AbbVie

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Page 54 of 61 Formal Issue



Risk ID	Process	Potential Risks	Risk Score	Proposed Mitigation Measures	Outcome	Owner Contact Person
1	Tank Farm; Tank Loading	Overfill of Tank with liquid spill out from the top through the manhole.	2	None required.	N/A	N/A
2	Tank Farm; Tank Loading	Potential back fire and explosion due to oxygen present in the vent for inerting failure causing damage to the bund.	4	None required.	N/A	N/A
3	Tank Farm; Flange connection	Potential liquid leakage from the flanges due to gasket wear.	3	None required.	N/A	N/A
4	Tank Farm; Bottom valve	Potential liquid leakage from the valve due to faulty seal.	2	None required.	N/A	N/A
5	Tank Farm; Tank bottom	Potential liquid leakage from cracks or holes in the base.	2	None required.	N/A	N/A
6	Tank Farm; Solvent distribution	Potential liquid leakage from flange connections in the pipe or with the pumps.	2	None required.	N/A	N/A
7	Tank Farm; Solvent distribution	Potential liquid leakage from pump seal.	2	None required.	N/A	N/A
8	Tank Farm; Solvent distribution	Potential fire or explosion due to grounding or bonding not functioning properly and causing damage to the containment bund.	4	None required for an	N/A	N/A
9	Tank Farm; Storage	Potential fire or explosion caused by the use of free flames, spark or energized equipment causing damage to the containment bund.	8	Lestan LEL to alarm via DCS Post required warning signage on prohibition of naked flames.	The likelihood of a fire or explosion without pre-warning will be reduced.	Facilities Manager
10	Tank Farm; Storage	Potential fire or explosion of an explosive atmosphere from a leakage ignited by traffic sources causing damage to the containment bund.	Cansent of C	Install permanent LEL monitoring of area.	The likelihood of a fire or explosion without pre-warning will be reduced.	Facilities Manager
11	Tank Farm; Bund drainage	Potential liquid leakage from valve or pump flanges or pump seal.	2	Install LEL to alarm via DCS.	The likelihood of a fire or explosion without pre-warning will be reduced.	Facilities Manager
12	Tank Farm; Containment bund	Potential liquid leakage due to cracks in the bund.	4	None required.	N/A	N/A
13	Tanker Unloading/Loading Bay; Truck loading/ unloading	Potential leakage & explosion of flammables from loose connection of flexible hoses. An explosion will damage the bund.	4	Carry out pre-use checks of flexible hoses. Develop a procedure, training and checklist on same.	The potential for leakage during unloading will be reduced.	Personnel involved in unloading activities
14	Tanker Unloading/Loading Bay; Truck loading/ unloading	Potential liquid leakage from pump seal. An explosion will damage the bund.	3	Carry out pre-use checks of flexible hoses. Develop a procedure, training and checklist on same.	The potential for leakage during unloading will be reduced.	Personnel involved in unloading activities



Risk ID	Process	Potential Risks	Risk Score	Proposed Mitigation Measures	Outcome	Owner Contact Person
15	Drumstore; IBC or drum handling	Potential liquid leakage due to damaged packaging during handling/moving and potential bund damage A) Fire/Explosion of flammables finding an ignition source B) mixing of incompatible flammable and corrosive compounds that currently share a common bund.	6	Prevent potential for mixing of spills from incompatible corrosive and flammables by moving corrosives to another bund or positioning this material on portable bunds within the Drumstore bund. Prevent unauthorised access by installing a locked gate.	The likelihood of a fire/explosion occurring due to the presence of an unauthorised person will be reduced. Preventing the mixing of spills may help to reduce the consequence in the event of a fire in the area.	Facilities Manager
16	Drumstore; Storage	Potential fire or explosion of an explosive atmosphere from a leakage ignited by the fork lift or truck sources.	9	Improve fire detection by extending it to the Drumstore room used to house Laboratory Hazardous Waste. Improve fire fighting measures by installing an automatic extinguish system (foam, sprinklers, deluge in Drumstore. Ensure Compressed Gas bottles are stored more than 15 meters of flammable material. Prevent potential for mixing of spills from incompatible corrosive and flammables by moving corrosives to another bund or positioning this material on portable bunds within the Drumstore bund. Prevent unauthorised access by installing a locked gate.	The likelihood of a fire or explosion in the Drumstore will be reduced. In the event of a fire, the automatic extinguishing system will extinguish the fire in a quicker manner to reduce the overall consequence.	Facilities Manager
17	Drumstore; storage	Potential liquid leakage due to cracks in the bund.	4	None required.	N/A	N/A
18	Thermal Oxidisor; Fuel Transfer	Potential fuel leakage from flanges or flexible hose connection causing. Explosion of propane would damage containment bund.	8 Consent of C	Ensure Propane cylinder is a Pressure Vessel and is documented on AbbVie schedule for Pressure Vessels for pressure testing.	Regular pressure testing will ensure the integrity of the fuel transfer system is not compromised, reducing the likelihood of a leakage.	Environmental Manager
19	Thermal Oxidiser; Vapours Combustion	Possible backfire or explosion for Oxygen present in the streams would damage the bund. Event could result in distribution of dioxins to local area and result in human health concerns (e.g. by contamination of agricultural areas).	4	None required.	N/A	N/A
20	Thermal Oxidiser; Combustion	Undetected dioxin formation and subsequent dispersion to soil could result in human health concerns (e.g. by contamination of agricultural areas).	3	None required.	N/A	N/A
21	Sewer; Liquid Drainage	Failure of pipe connection (i.e. crack or loose seal to the retention pond would result in leakage of material.	3	None required.	N/A	N/A
22	Transformer (2 No.)	Possible explosion with potential for soil pollution with PCBs	3	None required.	N/A	N/A
23	Retention Pond; Storage of Firewater	Damaged containment resulting in discharge of Firewater from pond.	6	None required.	N/A	N/A
24	LPG Tank; Bulk tank	Potential gas leakage from tank and potential explosion.	6	None required.	N/A	N/A



Risk ID	D	Process	Potential Risks	Risk Score	Proposed Mitigation Measures	Outcome	Owner Contact Person
25		LPG Tank; Gas distribution	Potential gas leakage from distribution and potential explosion.	4	None required.	N/A	N/A
26		Waste Management and Disposal	Incorrect disposal of Waste	3	None required.	N/A	N/A

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# Appendix E

Financial Model – Worst Case Scenario (Risk ID No. 13/14)

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Page 58 of 61 Formal Issue



Item	Quantity	Unit Rate	Cost (€)	Source of Unit Rate
Fire Brigade Charges (assumed 4 no. Fire Brigade stations for 5 hours each)	20 hours	€500 / hour	10,000	Sligo County Council
Site Supervisor – 4 weeks	20 days	€600 / day	12,000	PM Group Estimate based on Previous Work
General Operatives – 4 persons for 4 weeks	80 days	€350 / day	28,000	PM Group Estimate based on Previous Work
Health and Safety Equipment Rental – Signage, Bollards, Beacons, etc. – 4 weeks rental	4 weeks	€1,000 / week	4,000	PM Group Estimate based on Previous Work
Crane Hire for 1 week	5 days	Pur E800 / day	4,000	PM Group Estimate based on Previous Work
Dismantling of selected plant and equipment (specialist contractor)	5 days the	own €2,800 / day	14,000	PM Group Estimate based on Previous Work
Water Pumps	1 item	€3,000 / item	3,000	PM Group Estimate based on Previous Work
Testing of fire water (prior to disposal)	10 samples	€150 / sample	1,500	PM Group Estimate based on Previous Work
Disposal of fire water including transportation (assumed to be hazardous) <sup>1,2</sup>	3,116m <sup>3</sup>	€300 / m <sup>3</sup>	934,800	PM Group Estimate based on Previous Work
Disposal of Raw Materials including Transportation (quantity estimated)	55 tonnes	€450 / tonne	24,750	PM Group Estimate based on Previous Work

<sup>&</sup>lt;sup>1</sup> Volume of fire water based on the fire water retention pond being full and all water assumed to be contaminated.

<sup>&</sup>lt;sup>2</sup> As a conservative approach this amount is included in the overall total coast estimate for the disposal of contaminated firewater, i.e. all firewater assumed to be hazardous



Item	Quantity	Unit Rate	Cost (€)	Source of Unit Rate
Miscellaneous Waste Disposal - Estimate of €10,000	-	-	10,000	PM Group Estimate based on Previous Work
Excavation of Potentially Contaminated Soil <sup>3</sup>	400m <sup>3</sup>	€10 / m <sup>3</sup>	4,000	Waste Disposal Contractor
Removal of Contaminated Soils off-site (non-hazardous, within Ireland) <sup>4</sup>	600 tonnes	€20 / tonne	12,000	PM Group Recent Contract Rates
Removal of Contaminated Soils off-site (hazardous, within $\ensuremath{Ireland}\xspace)^5$	200 tonnes	€20 / tonne met	4,000	PM Group Recent Contract Rates
Disposal of Contaminated Soil at Gate (non-hazardous, within Ireland)	600 tonnes	€50% tonne	30,000	PM Group Recent Contract Rates
Disposal of Contaminated Soil at Gate (hazardous, within Ireland)	. ASK		22,000	PM Group Recent Contract Rates
Removal of Construction and Demolition Waste, incl. fire damaged materials (non-hazardous) <sup>6</sup>	200 tonnes Prise	€20 / tonne	4,000	PM Group Recent Contract Rates
Disposal of Construction and Demolition Waste, incl. fire damaged materials (non-hazardous)	200 tonnes	€50 / tonne	10,000	PM Group Recent Contract Rates
Imported Soils	800 tonnes	€40 / tonne	32,000	PM Group Estimate based on Previous Work

<sup>&</sup>lt;sup>3</sup> The fire will occur around an area of hardstanding, therefore contaminated firewater will be picked up by the drainage system instead of going to ground. However it is assumed that some area of undeveloped land may be affected, i.e. 400m<sup>3</sup>, which is based on an assumed 400m<sup>2</sup> affected area on-site at 1m deep.

 $<sup>^{\</sup>rm 4}$  Tonnage based 300m  $^{\rm 3}$  with an estimated average bulk density of soil of 2kg/m  $^{\rm 3}$ 

 $<sup>^{5}</sup>$  Tonnage based 100m  $^{3}$  with an estimated average bulk density of soil of 2kg/m  $^{3}$ 

 $<sup>^{\</sup>rm 6}$  Assumed tonnage for C&D / fire damaged materials waste



Item	Quantity	Unit Rate	Cost (€)	Source of Unit Rate
Landscaping of Affected Area	400m <sup>2</sup>	€15 / m²	6,000	PM Group Estimate based on Previous Work
Hydrogeological Investigation and Report including Trial Pits	-	€20,000	20,000	PM Group Recent Tender Rates
<ul> <li>Installation of pump and treat for Groundwater remediation (if required)</li> <li>Site set up / Mobilisation of drilling equipment / installation of wells and required plant</li> <li>Pump and Treat (assuming 6 month requirement)</li> <li>Site Operator for 6 months</li> </ul>	-	€115,000 00000000000000000000000000000000	2 <sup>.</sup> 193,000	PM Group Recent Tender Rates
Environmental Monitoring – various samples throughout the year	200 samples geo	S <sup>MT</sup> €150 / sample	30,000	PM Group Estimate based on Previous Work
Environmental Consultancy	40 days of the	€1,000 / day	40,000	PM Group – Environmental Consultancy Rate
Project Management	40 days	€1,000 / day	40,000	PM Group – Project Management Rate
SUBTOTAL	1,493,050			
Contingency @ 25%	373,623			
TOTAL	1,866,313			