Decommissioning Management Plan

Vistakon Ireland Ltd
Environmental Support

IE0311273-22-RP-0002, Issue: A

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Document Sign Off

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IE0311273-22-RP-0002, Issue A

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1 Executive Summary

Vistakon Ireland develops, manufactures and distributes a range of soft, disposable contact lenses. The facility is located in the National Technology Park, Castletroy, Co. Limerick.

In 1994, Vistakon obtained planning permission for the construction of the first phase of the existing buildings, the manufacturing process and ancillary facilities. The second production block and ancillary services were installed in 1997-1998, along with ancillary support areas. The facility has continued to expand in recent years with the most recent works being the Phase V extension and installation of the 3GT waste water treatment plant. The site infrastructure includes bulk storage and transfer facilities, thermal oxidiser/carbon absorber, combined cooling and power (CCP) system and firewater retention facilities.

Until 2007, the production of the disposable contact lenses included a water-based washing step. Vistakon has since converted some of the existing production to the manufacture of products, using either Isopropyl Alcohol (IPA) or Propylene Glycol (PG) mix with water. This is in addition to the existing de-ionised water process.

The site was granted an Integrated Pollution Prevention Control (IPPC) Licence (ref. P0818-01) by the EPA in August 2007. A Technical Amendment to the Licence was granted in December 2008 to cater for increased production and the resultant increase in wastewater volumes. In 2010 the site was granted a review of its IPPC Licence (ref. P0818-02) to allow for a number of new installations on-site and associated emissions:

Two additional Technical Amendments were a granted in 2013 to allow for increases in the volumes of wastewater discharged due to the expansion of the facility to include additional water based production lines. The second of these Technical Amendments granted in August 2013 also coincided with the installation of a small wastewater treatment facility on site as the increase in wastewaters also increased the organic load of the discharge.

In December 2013, Vistakon were informed of a Section 82A (11) amendment to their licence which had the purpose of bringing the licence into compliance with the requirements of Directive 2010/75/EU (Industrial Emissions Directive). Under this amendment, the licence (ref. P0818-02) is now deemed to be an Industrial Emissions Licence.

Condition 10.2.1 of the current Industrial Emissions Licence requires that:

"The licensee shall maintain a fully detailed and costed plan for the decommissioning or closure of the site or part thereof."

PM Group has been retained by Vistakon to carry out a review of the existing DMP (PM Report No. 011644-22-RP-0003 Issue B) in accordance with the requirement of Condition 10.2.1. This Decommissioning Management Plan is based on the EPA's new "Guidance on Assessing and Costing Environmental Liabilities" (2014).

The scope of this plan addresses the key issues, which will occur in the event of both a planned and unplanned closure. A planned closure is estimated to happen over a time period of six months. The basis of the plan is to ensure that, upon completion of 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 to the environment. It is not intended to remove all structures or systems from the site. In general, specialist equipment will be distributed for re-use to other plants or sold off in the event of closure.

In the event of a planned closure, Vistakon intends to utilise existing staff resources to form a team to manage and execute the plan, supplemented where appropriate by external resources. This team would be responsible for managing and executing the complete plan. External contractors required for cleaning, waste disposal, incineration or recycling activities will be fully approved and licensed. A qualified third party will be giving access to the plan in the event Vistakon are not in a position to carry out the plan due to a sudden unforeseen closure.

In the event of a spillage, leak or fire during decommissioning, Vistakon's Emergency Response Plan would be fully implemented in order to minimise the risk to health and the environment.

The costs associated with decommissioning are generally related to the disposal and recycling of equipment and the use of external resources to implement the Decommissioning Management Plan (DMP). In certain instances, costs will be recouped through the sale of equipment or materials or fixed assets.

It is estimated that a cost of approximately €766,502 (including 20% contingency and VAT) would be incurred to decommission the site, including external resource costs.

Vistakon confirms that the company has more than adequate resources from operations to fund the DMP. In addition, the value of the facility itself as a fixed asset worth in excess of €366m will far outweigh any remediation cost.

2 Introduction

2.1 Facility and Licence Details

Vistakon Ireland develops, manufactures and distributes a range of soft, disposable contact lenses, including the 1-DAY ACUVUE® Visitint, 1-DAY ACUVUE® TruEye, 1-DAY ACUVUE® Define, 1-DAY ACUVUE® Moist, ACUVUE® 2, ACUVUE® Advance and ACUVUE® Oasys.

The site is licensed by the EPA under an Industrial Emissions Licence (Ref. P0818-02).

This Decommissioning Management Plan (DMP) has been prepared in order to furnish the information required by Condition 10.2.1 of the Industrial Emissions Licence.

"The licensee shall maintain a fully detailed and costed plan for the decommissioning or closure of the site or part thereof."

PM Group (PM) was appointed by Vistakon to perform the review of the DMP.

2.2 Facility Closure Scenarios covered in this Plan

To develop a fully detailed and costed DMP, it is necessary to present a number of assumptions regarding the mode and management of a hypothetical site shut down.

Site closure is considered to include:

- Cessation of the Industrial Emission Directive activity under Article 90 of EPA Act, 1992 as amended by the POE (Protection of the Environment) Act 2003;
- Voluntary or involuntary liquidation of the company or organisation holding the Industrial Emissions Licence which results in the cessation of the activity;
- Transfer of ownership under Article 91 of EPA Act, 1992 as amended by the POE (Protection of the Environment) Act 2003;
- Site closure as a result of corporate rationalisation or relocation;
- Mothballing

Vistakon Ireland is a subsidiary of Johnson & Johnson, a world-leading healthcare corporation. Vistakon is continuously expanding its state-of-the-art manufacturing operation in Limerick, Ireland where it produces ACUVUE® and other market-leading disposable contact lenses for the European and Asian market.

The company operates a strict environmental policy. Therefore, it is firstly assumed that any shutdown of the site will be a well-planned and well-resourced event. This implies that the shutdown date will be known well in advance and that both production schedules and raw materials purchasing will be planned with the shutdown already factored in.

It is not intended to remove all structures or systems from the site. In general, specialist equipment will be distributed to sister plants or sold off in the event of closure.

Vistakon will have the resources in terms of both financial inputs and manpower to implement the DMP through to completion, with no requirement for external financing or manpower other than for expert advice. Vistakon intends to utilise existing staff resources to form a team to manage and execute the plan, supplemented where appropriate by outside resources. This Decommissioning Management Team would be responsible for managing and executing the complete plan. Outside contractors required for cleaning, waste disposal, incineration or recycling activities would be fully approved and licensed.

A qualified third party will be given access to the plan in the event Vistakon are not in a position to carry out the plan due to a sudden unforeseen closure.

It is estimated that the duration of decommissioning and decontamination would be 3 to 6 months. Environmental monitoring would continue while the plan is in operation and for a period following

the completion of the plan to be determined by the EPA and/or local authority. The EPA and the local authority would be informed of the results of the monitoring programme and the status of the plan. The objective of the plan is to ensure that, upon completion of 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.

3 Site Evaluation

This section gives an overview of the site operations, operator performance and environmental sensitivity at the Vistakon facility for the risk identification exercise.

3.1 Site Operation

3.1.1 Facility Activities

Vistakon Ireland Ltd develops, manufactures and distributes a range of soft disposable contact lenses.

The processes carried out at Vistakon consist of the following:

- Injection Moulding
- Lens Fabrication
- Hydration
- Post Hydration
- Sterilization
- Cartoning

The production process for all products is essentially the same apart from the hydration step. At this stage, the lenses are hydrated as they move through the production line using de-ionised water which flows through the lenses. A small number of the production lines require the use of an Iso-propyl Alcohol (IPA)/water mixture or a Propylene Glycol (PG) based solvent for this stage. These process steps are supported by typical plant utilities including; water systems, boilers, compressed air, nitrogen gas and HVAC. In addition, the IPA rich off-gases are vented to a thermal oxidiser (TO).

New Developments on Site

Additional water based production lines were added since the previous ELRA as part of the Phase V works. The new lines are identical to existing lines however due to the increase in waste water discharge volumes and the associated increase in organic load, a small waste water treatment facility on site was installed. The new 3GT waste water treatment facility is designed to treat the relatively high strength waste stream from the 3GT production lines (50% of site BOD load). This is the waste stream from the production lines that that utilise the IPA and PG solvents in the Hydration step. The amount of effluent to be treated represents a relatively low (<5% total) volume of the site effluent.

3.1.2 Infrastructure

The following infrastructure is present on site:

Main Production Building:

- Production area
- Administration and Laboratory
- Canteen
- Offices

Outside of the main building:

- Warehouse
- External services compound
- Utilities area

- Chemical stores
- Water room
- Tank farm
- Nitrogen compound
- Water storage tanks
- 3 No. Natural gas fired steam generating boilers
- Sprinkler tanks and pump house
- Firewater retention pond
- Compressors
- 3GT waste water treatment plant
- Thermal oxidiser
- Combined cooling & power (CCP) plant

Parking for the site is located to the south of the site, in front of the administration area.

3.1.3 Raw Materials

The raw materials, packaging and finished product used in production are stored in the Warehouse. The maximum quantity of material in these stores is 65T.

Non-hazardous waste materials are stored in designated waste receptacles in the yard prior to disposal. The following summarises the main process materials used on-site:

Material	Estimated Maximum Quantity (Tonnes unless specified)		Storage Area
Monomer 1	5	108	Staging
Monomer 2	1		
Monomer 3	1		
Monomer 4	1		
Tween	1		
Polymer 1	59		
Polymer 3	20		
Polymer 4	20		
Isopropyl Alcohol	300	300	IPA Tank Farm
Propylene Glycol	17	17[1]	PG Storage Compound
Methanol	0.01	3.5	Chemical Store/Lock-up
Hydrocarbon Mineral Transformer Oil	0.05		
Hydraulic 32 - Lubricating Oil	2.5		
Hydraulic 46 oil	0.6		

[1] Mass of propylene glycol (PG) estimated conservatively, assuming 100% concentration and density of PG equal to 1036kg/m^3. It is noted that approx. 50% of PG stored on-site is 90% concentration with 10% water.

Material	Estimated Maximum Quantity (Tonnes unless specified)		Storage Area
Gear Oil	0.1		
Tri-solvent	0.25		
Nitrogen	200	200	N_2 Tank Farm
Acetone	0.005	0.65	Chemistry Lab
Acetonitrile	0.025		
Lab standard	0.6		
AZO Wipes	-		
Diesel Fuel	1.36	1.36	Fire Pump House
Hydrochloric Acid (Battery)/Water room	0.1	33.9	Water Room
Polyethylene glycol	0.001		
Sodium Hydroxide	0.2		
Amertrol BCL A 60SM	0.5		
Sulfuric Acid	0.02		
Sodium Chloride	22.6		
Sodium Borate	0.15		
Roclean 2	0.1		
Diovasin Activ Hydrogen Peroxide Acetic acid Peracetic acid	0.06		
Drewbrom TA	1		
Drewgard (Performax) 2021A	1		
R-134a	7		
Performax 330	0.3		
Sodium Hypochlorite	0.3		
Amersite	0.5		
Colorant	0.05	0.05	Colours Lab
Polymer 2	0.5	0.5	Production
Biosperse 3001	0.3	0.9	CCP Chemical Store
Drewbrom TA	0.3		
Performax 3400	0.3		
Hydrogen Peroxide	$30m^3$	59	WWTP
Sodium Hydroxide	$2m^3$		
Suphuric Acid	$2m^3$		
Iron Chloride	$2m^3$		

3.1.4 Overview of Wastes Generated

Hazardous Waste Management

Pallets, paper, cardboard and plastic are segregated and collected for recycling by licensed waste contractors. General non-hazardous waste is compacted on-site and collected for disposal by a licensed waste contractor. All documentation is retained on-site in accordance with legislative requirements and the ISO 14001 certified Environmental Management System.

Hazardous Waste Management

All hazardous wastes are labelled and covered and then stored in contained areas onsite before being collected and disposed of by licensed hazardous waste contractors.

This includes laboratory wastes, empty hazardous containers, waste oils and IPA. Where possible, these are sent for recycling or recovery. All documentation is retained on-site in accordance with legislative requirements and the ISO 14001 certified Environmental Management System.

3.1.5 Emissions from Site

The Vistakon site has a network of storm water drains, which collect surface/rainwater from the paved areas and roof areas of the site. These storm waters drain by gravity to the north-eastern corner of the site and discharge at SW1 and SW2 to the storm water sewer, which in turn discharges into the River Mulkear.

Process wastewaters are discharged to Castletroy Sewage Treatment Plant operated by Limerick County Council. A relatively low (< 5% of total) volume of the wastewater stream will be treated at the new on-site wastewater treatment plant before joining the main process wastewater line.

There are some minor emissions to atmospheres from the site boilers. The main emission to atmosphere comes from the thermal oxidiser and backup carbon abatement plant used to abate the volatile organic carbon (VOC) emissions from the lens production lines that utilise the IPA and PG.

There are various items of equipment which generate noise associated with the normal operation of the Vistakon plant. Various noise control measures have been incorporated into the design of the plant including the siting of equipment within the plant, housing of equipment within buildings, acoustic insulation of equipment and pipe-work. The plant is designed so that the noise contributions do not exceed the criteria in accordance with the EPA Guidance note on Noise in relation to Scheduled Activities. Thus the plant does not have any significant impacts on ambient noise levels.

3.2 Operator Performance

Vistakon has been in operation in Ireland since 1994 and has operated under Licence since 2007. Vistakon has established and maintains an ISO 14001 accredited Environmental Management System (EMS). This has been in place since June 1999 and is audited each year.

The site is generally compliant with its Industrial Emissions Licence conditions. Between 2007 and 2010, a small number of administrative/minor non-compliances were reported. These related to BOD and COD levels discharged to public sewer above the limits permitted under licence P0818-01. However increased discharge limits were previously agreed with Limerick County Council, pending approval by the EPA. These increased discharge limits were subsequently granted under licence P0818-02. On-going notification to the EPA regarding compliance with previous discharge limits was required until the new licence took effect in July 2010.

Other notifications to the EPA from 2007 to 2010 related to malfunctioning monitoring equipment. There was one minor breach of the hourly TOC limit in relation to air emissions due to machinery/equipment issues in 2011 and there were no environmental incidents or licence non-compliances in relation to the activity for the reporting period of 2012. In 2013, the site recorded no exceedances in relation to its environmental emissions.

3.3 Environmental Sensitivity

The bedrock geology underlying the site is Waulsortian Limestone and is classified as a regionally important karstified bedrock aquifer dominated by diffuse flow (RKD). The groundwater vulnerability has been classed as high.

The nearest natural surface water body to the site is the River Mulkear which is a tributary of the Shannon. The available chemical and biological monitoring data indicate that the Mulkear River is of a good water quality standard in the vicinity of the Vistakon site at Annacotty Bridge.

The Mulkear flows at a distance of from 200m to 500m to the north and east of the site. The Vistakon site has a network of storm water drains, which collect surface/rainwater from the paved areas and roof areas of the site. These storm waters drain by gravity to the north-eastern corner of the site and discharge at SW1 and SW2 to the storm water sewer, which in turn discharges into the River Mulkear.

The site is located within 1 km of the Special Area of Conservation (SAC) Lower River Shannon (Site Code 002165).

The nearest residential receptors are located approximately 150m from the south-eastern boundary of the site. There is no farming activity within 150m of the Vistakon site.

4 Closure Considerations

4.1 General

Vistakon as a corporation does have a prescribed Decommissioning Guide to be adhered to in the event of planned or unplanned closure or divestiture of the site. A copy of this is provided in Attachment 1.

4.2 Clean or Non-Clean Closure Declaration

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.

4.3 Plant or Equipment Decontamination Requirements

All plant and equipment will be decontaminated to ensure the removal of any hazardous materials. Equipment will be verified either analytically or through a visual inspection, as appropriate.

4.4 Plant Disposal or Recovery

Plant may be removed for use at other locations, left in place as part of the asset to be disposed of, or scrapped, based on risk assessment and cost benefit analysis.

Utility plant will be left with the asset, as mothballed equipment or ready-to–operate, depending on the best economic option.

4.5 Waste Disposal or Recovery

All wastes, both non-hazardous and hazardous, will be sent for appropriate recycling, recovery, treatment or disposal, as per the conditions of the Industrial Emissions Licence.

4.6 Soil Removal

The facility is not obliged under its licence to conduct regular soil monitoring, as the processes conducted on site have little potential for the contamination of soil. Under Vistakon's current Industrial Emissions Licence, annual monitoring of groundwater takes place and this will indicate if any contamination of soil has occurred or if testing is required.

5 Closure Tasks and Programme

Particular actions are listed below for specific areas of the facility as part of the DMP. In general, care and attention will be given during the implementation of the plan to ensure that the potential risks associated with the plan are avoided. In the event of a spillage, leak or fire during decommissioning, Vistakon's Emergency Response Plan will be fully implemented in order to minimise the risk to health and the environment.

5.1 Production Areas

The DMP for all production areas will consist of the following actions:

- Cessation of all production other than completion of work in progress in the event of a planned closure.
- All products will be sent for suitable re-use, recovery, treatment or disposal. Any hazardous waste arising from the plant and utilities areas will be removed from site by an authorised haulier and disposed of to a suitably licensed facility.
- Cleaning and decontamination of all equipment which has had contact with hazardous materials. Existing site cleaning procedures would be sufficient for these operations. Additional specific procedures would be developed, if required. The state of cleanliness would be verified either analytically or through a visual inspection, as appropriate.
- Cleaning and decontamination of any ducting or enclosure that would have hazardous material contact.
- Shutting off unnecessary services to the building. Heating and ventilation capability would be maintained.
- Maintenance of key instrumentation and computer systems required for on-going monitoring of the status of the equipment, the remaining instrumentation to be disconnected and rendered safe.
- Cleaning and decontamination of all floor drains and sumps.
- All remaining specialised equipment will be sent for suitable re-use or sold to an interested party. Obsolete equipment will be recycled where possible or otherwise disposed of by a licensed contractor.

5.2 Utilities/Chemical Stores

The DMP for the utilities areas would consist of shutting down the following systems on a phased basis, depending on plant status and requirements:

- Removal of any associated chemicals, oils or any other materials used in the utilities/staging area for redistribution, return to vendor or disposal, if required, according to best practice.
- The firewater pump house/water room including the water supply system would be maintained due to the needs for fire protection and sanitary services.
- Waste oils, lubricants and diesel will be sent for suitable re-use, recovery, treatment or disposal as appropriate. Any hazardous waste arising from the plant and utilities areas will be removed from site by an authorised haulier and disposed of to a suitably licensed facility.

5.3 Tank Farms

- Running down any chemicals or material in the tanks
- Cleaning and decontamination of the tanks.
- All remaining chemicals will be sent for suitable re-use, recovery, treatment or disposal, as appropriate. Any hazardous waste arising from the plant and utilities areas will be removed from site by an authorised haulier and disposed of to a suitably licensed facility.

- The Thermal Oxidiser and Carbon Beds will be decommissioned in accordance with good engineering practice and the manufacturer's recommendations.

5.4 Cooling Towers

The DMP for the cooling towers would consist of the following actions:

- Cleaning and decontamination of the tanks;
- Any hazardous waste arising from the cooling towers area will be removed from site and disposed of to a suitably licensed facility
- Methods adopted will ensure any risk of contracting legionnaires disease is minimal;
- Dismantling of equipment and general cleaning and maintenance.

The site currently has the following cooling towers installed:

- 2 No. twin cell open circuit cooling tower: F1-EX-CT-1 & 2, F1-EX-CT-7 & 8;
- 2 No. open circuit cooling tower: F1-EX-CT-3, F1-EX-CT-4;
- 2 No. closed circuit cooling towers: F1-EX-CT5, F1-EX-CT6;
- 8 No. CCP dry air cooler: Cells 1-4 & Cells 5-8.

5.5 Fuel Tanks

The DMP for the fuel tank would consist of shutting down the following systems on a phased basis, depending on plant status and requirements:

- Removal of any associated materials used in the fuel tank area for redistribution, return to vendor or disposal, if required, according to best practice;
- Waste oils, lubricants and diesel will be sent for suitable re-use, recovery, treatment or disposal. Any hazardous waste arising from the plant and utilities areas will be removed from site and disposed of by an authorised haulier to a suitably licensed facility;
- Dismantling of equipment and general cleaning and maintenance.

The site has 2 x 1000l tanks at the pumphouse that supply the generator that runs the water sprinkler system and 1 x 50l tank for the boilerhouse emergency generator.

5.6 3GT Waste Water Treatment Facility

All trade wastewater that need to be treated prior to discharge under the current licence will be treated as normal. Any additional wastewater produced from the cleaning of 3GT lines that requires treatment prior to discharge will be treated in the waste water treatment facility before it is decommissioned and decontaminated. The DMP includes:

- Cleaning and decontamination of the tanks;
- Removal of any associated chemicals, oils or any other materials used in the utilities/staging area for redistribution, return to vendor or disposal, if required, according to best practice.
- Dismantling of equipment and general cleaning and maintenance.

5.7 Maintenance and Engineering

- All engineering documentation including drawings, process and instrumentation diagrams, validation documentation, vendor manuals and data, project files, maintenance records, inspection records and all other appropriate documentation will be securely archived.

- All remaining equipment will be disconnected to leave in a secure state. Equipment will be sent for suitable re-use or sold to an interested party. Obsolete equipment will be recycled where possible, otherwise disposed of by a licensed contractor.

5.8 Offices, Administration, Reception

The DMP for the offices, administration areas, and reception would involve the removal of administration equipment for reuse or sale to interested party, where possible, otherwise for disposal by a licensed contractor.

5.9 Laboratory Areas

The DMP for laboratory areas would consist of the following actions:

- Completion of all necessary analytical work on production in progress and all final products before removal from site.
- Return to vendor or sell on all unopened and in-date laboratory chemicals
- Removal of all opened chemical containers and out-of-date chemicals for recycling or for disposal by a licensed contractor.
- Cleaning and decontamination of laboratory instruments
- Cleaning and decontamination of all glassware, storage areas, waste systems and any other equipment or systems.
- Shutting down of all computer systems other than those deemed necessary for ongoing monitoring of the area.
- All remaining specialised equipment will be sent for suitable re-use or sold to an interested party. Obsolete equipment will be recycled where possible, otherwise disposed of by a licensed contractor.

5.10 Canteen and Kitchen

- Canteen equipment would be removed for reuse or sale to an interested party, where possible, otherwise it would be disposed of by a licensed contractor.

5.11 Warehouse

The DMP for the stores warehouse would consist of the following actions:

- Cancellation of all orders for incoming materials to the site;
- Negotiation with other plants with a view to distribution of unused materials;
- Negotiation with relevant suppliers to return unused materials to supplier;
- Dispatch of opened containers and non-returnable or out-of-date goods for appropriate treatment or disposal;
- Cleaning and decontamination of the storage areas.

5.12 Industrial Emissions Licence Documentation

All Industrial Emissions Licence related documentation will be maintained on file at a designated location for a minimum of 7 years post closure of the facility. Where a transfer of the licence takes place, the associated documentation will reside with the new licensee.

5.13 Other Areas

The following other actions would be required to ensure the implementation of the DMP on a site-wide basis:

- Cessation of any construction project work on site so that the site is left in a safe and orderly condition. Contractors will be required to decommission any construction compounds and remove all construction equipment, construction materials and waste, storage units and temporary offices from the site at the completion of construction projects.
- Disbandment of contract personnel, facilities and equipment.
- Termination of all non-essential maintenance and other contracts.
- Removal from site any temporary offices or storage areas.
- Continuation of on-going monitoring programmes to insure the integrity of the groundwater and surface waters on site.
- Rationalisation of the site electricity supply. This would involve removing transformers from service, allowing remaining site operations to run from one transformer. Oils would be removed from redundant transformers.
- Testing of soils and groundwater at the time of decommissioning would be performed and remediation carried out, if necessary. Groundwater wells on-site shall be capped and locked off.
- Retention of all necessary fire alarms and fire protection systems.
- Retention of standard security patrols, CCTV monitoring and defined site access procedures.
- Removal of all items that may contain mercury (for example fluorescent lights) or any other controlled compounds for recycling or disposal if necessary.
- Decommissioning of underground sumps in the tanker loading and unloading bay / foul / process and drainage area with be emptied and cleaned following the completion of cleaning and decommission of the areas they serve. The drains and sumps will be surveyed. The sumps will then be filled with inert material (if not longer needed) and sealed to prevent unauthorized access. The silt traps will be cleaned out and the contents disposed of as per the licence.
- The contents of the petrol interceptors shall be emptied and disposed of by an authorised contractor to a suitable licensed facility.
- The boilers onsite will be decommissioned in accordance with good engineering practice and the manufacturer's recommendations. It will be prepared for 'dry storage' or removal.

6 Criteria for Successful Closure

Successful clean closure will be expected to be achieved when it can be demonstrated through an Environmental Due Diligence Audit that there are no remaining environmental liabilities at the site. In practice this will require demonstration that the following criteria have been met:

- Continued compliance with Industrial Emissions Licence requirements;
- All plant was safely decontaminated using standard procedures and authorised contractors;
- All wastes were handled, packaged, temporarily stored and disposed of or recovered in a manner which complies with regulatory requirements;
- All relevant records relating to waste and materials movement and transfer or disposal were managed and retained throughout the closure process;
- There was no soil or groundwater contamination at the site. This was verified using monitoring data and a soil/groundwater assessment at the time of closure (if required);
- The Environmental Management System remained in place and was actively implemented during the closure period;
- The asset is suitable for use as a commercial development site, as demonstrated by an environmental due diligence assessment.

7 Closure Plan Validation

7.1 Closure Validation Audit

Condition 10.4 of the licence requires that *"A final validation report to include a certificate of completion for the Decommissioning 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."*

The scope of due diligence will be based on the size and complexity of the subject transaction, facility, and the property. The following measures will be taken into account when executing the due diligence audit:

- An environmental consulting firm will be retained to conduct the due diligence audit under the direction of Vistakon.
- The due diligence audit will follow a phased approach, designed to provide more in-depth information with each successive phase.
- Ample time will be allowed to complete all phases, including any required fieldwork and associated analytical testing.
- Where required, the scope of environmental assessments will comply with applicable standards, such as the ASTM Standard Practice for Environmental Assessments: Phase 1 Environmental Site Assessment Process.

A Due Diligence report will be prepared which shall include a summary and a detailed explanation of issues, grouped as follows:

- Environmental liabilities, past and present;
- Regulatory non-compliance issues along with a ranking of their severity and implications;
- Major environmental risks;
- Approximate cost estimate to bring closure to these issues.

7.1.1 Divestitures and Exiting Leases

When divesting of facilities or real estate properties, an environmental assessment will be conducted to identify all environmental liabilities and establish a baseline report on the environmental conditions of the property at the time of transfer. These conditions should be documented and communicated to the purchaser representatives. A copy of the environmental assessment report will be submitted to Johnson & Johnson.

If environmental contamination is discovered, the decision to remediate conditions shall be agreed upon with the purchaser, in consultation with Johnson & Johnson and shall be reflected in the agreement of sale.

If long-term (greater than two years) environmental warranty is given to purchaser, the scope of environmental assessment will be accordingly expanded to allow for the establishment of a much more comprehensive baseline. In these cases, at a minimum, sewer integrity testing should be added to the scope of the environmental assessment, unless testing had been recently completed.

7.1.2 Closure Validation Audit Report

For an Industrial Emissions Licence to be transferred or surrendered there must be a consultation process with the EPA. Normally, the EPA conducts a post-closure audit of the site and thereafter the EPA must be satisfied that the facility is fully compliant with its licence conditions at the time of closure in order to facilitate the formal surrender or transfer of a licence. Vistakon will implement

any closure plan in consultation with the Agency, towards satisfying the authority that no residual risk(s) will remain.

8 Closure Plan Costing

8.1 Decommissioning Costs

The costs associated with decommissioning are generally related to the disposal and recycling of equipment and the use of external resources to implement the DMP. In certain instances, costs will be recouped through the sale of equipment or materials.

It is expected that external resources will be required in order to implement the DMP in full. A list of these resources and associated costs is shown in Table A of Appendix A.

It is estimated that a cost of approximately €766,502 would be incurred to decommission the site, including external resources costs.

The following assumptions were made in estimating the likely costs involved:

- The processes and operations at the facility do not give rise to any reasonable probability that site remediation in the form of groundwater or soil clean-up would be a likely requirement.
- The site would be left in a clean condition, i.e. decontaminated and certified as being free of any chemical hazard. All buildings would be retained. All raw materials, products, and hazardous materials would be removed.
- No liabilities would be incurred due to activities of contractors storing and disposing of materials removed from the Vistakon site, as Vistakon will continue to apply its current waste management principles.
- No civil liability would be incurred as a result of third parties alleging environmental damage arising from the operational phase or closure.
- Normal practice would be applied to minimise ongoing liabilities and to fulfil insurance requirements.
- It is assumed that the planning authority would not take any action to prevent site dereliction, as the existing facilities would be maintained in a condition suitable for future beneficial use. The planning authority will be notified of the plans to decommission and will be consulted in relation to the isolation of facilities and services on site.
- In addition, no factors have been identified that would indicate an unusual liability for the site in comparison with other process industry sites.

8.2 Funding of DMP

Vistakon confirms that the company has more than adequate resources from operations to fund the DMP as set out above. In addition, the value of the facility itself as a fixed asset worth in excess of €366m will far outweigh any remediation cost.

9 Closure Plan Update and Review

9.1 Proposed Frequency of Review

The DMP will be reviewed annually and submitted to the EPA as part of the site's Annual Environmental Report.

Proposed Scope of Review

The scope of the annual review of the DMP will cover the following at a minimum:

- Review compliance with the Industrial Emissions Licence conditions;
- Review any incidents that may result in soil contamination;
- Review changes on site including processes and associated ancillary developments.

Appendix A
Decommissioning Costs

Table A1: Decommissioning Costs

Item	Breakdown of Costs[2]	Cost	Source
Production Areas			
Cleaning and Maintenance of all equipment	6 persons/ 4 weeks @ €50/hr	48,000	PM Group Recent Tender Rates
Disposal of contaminated wash water	€120/tonne (~75 tonnes)	9,000	PM Group Recent Tender Rates
Dismantling and transport costs in bringing to buyer	6 persons/4 weeks @ €50/hr	48,000	PM Group Recent Tender Rates
Disposal of unsold equipment	12t @ €190/tonne	2,280	PM Group Recent Tender Rates
Utilities Area			
Cleaning and Maintenance	2 persons/2 weeks @ €50/hr	8,000	PM Group Recent Tender Rates
Disposal of chemicals in store (50 Tonnes)	€120/tonne	600*	PM Group Recent Tender Rates
Return of Diesel to supplier	1 Drum @ €30/drum	30	PM Group Recent Tender Rates
Tank Farm			
Disposal/ Treatment of all remaining chemical	€120/tonne (~10 tonnes)	1,200*	PM Group Recent Tender Rates
Cleaning and Decontamination of the tanks	2 person/2 weeks @ 50/hr	8,000	PM Group Recent Tender Rates
Disposal of contaminated wash-water	€120/tonne (~500 tonnes)	60,000	PM Group Recent Tender Rates

[2] Based on 40 hour working week

*Based on 10 % of total inventory

Item	Breakdown of Costs[2]	Cost	Source
Cooling Towers			
Cleaning and Decontamination of the cooling towers	2 persons/2 weeks @ €50/hr	8,000	PM Group Recent Tender Rates
Dismantling of equipment and general cleaning and maintenance	2 persons/2 weeks @ €50/hr	8,000	PM Group Recent Tender Rates
Fuel Tank			
Disposal of all remaining chemicals	€120/tonne (1 tonne)	120*	PM Group Recent Tender Rates
Dismantling of equipment and general cleaning and maintenance	2 persons/1 week @ €50/hr	4,000	PM Group Recent Tender Rates
Waste Water Treatment Plant			
Disposal of all remaining chemicals	€120/tonne (43 tonne)	5160	PM Group Recent Tender Rates
Cleaning and Decontamination of the tanks	4 persons/2 weeks @ €50/hr	16,000	PM Group Recent Tender Rates
Environmental Monitoring of Site			
Industrial Emissions Licence monitoring	6 months	5,000	PM Group Recent Tender Rates
Security	€38/hr (24/7 for 6 months)	166,400	PM Group Recent Tender Rates
Laboratory			
Dismantling of other equipment and general cleaning and maintenance	2 persons/2 weeks @ €50/hr	8,000	PM Group Recent Tender Rates
Cleaning and decontamination of the laboratory/instruments	2 persons/2 weeks @ €50/hr	8,000	PM Group Recent Tender Rates
Removal of all opened chemical containers and out-of-date chemicals for recycling or for disposal by a licensed contractor.	€120/tonne ~ 1 tonne	120	PM Group Recent Tender Rates

Item	Breakdown of Costs[2]	Cost	Source
Offices			
Cleaning and Mainteance	2 persons/ 3 weeks @€50/hr	12,000	
Warehouse			
Cleaning and decontamination of storage area	2 persons/2 weeks @€50/hr	8,000	PM Group Recent Tender Rates
General Waste			
Disposal of general waste	€200/tonne ~ 10 tonne	2,000	PM Group Recent Tender Rates
Recycling of cardboard/packaging waste	€200/tonne ~ 25 tonne	5,000	PM Group Recent Tender Rates
Other			
Civil an structural, mechanical, electrical and instrumentation contractors	5 persons/5 weeks @ €50/hr	50,000	PM Group Recent Tender Rates
Decommissioning of underground sumps	2 persons/3 weeks @€50/hr	12,000	PM Group Recent Tender Rates
Groundwater testing	4 Boreholes @ €350 each	1,400	PM Group Recent Tender Rates
Environmental Due Diligence Audit by professional consultant		15,000	PM Group
Subtotal		**519,310**	
Contingency @ 20% - (to take into account a sudden closure)		**103,862**	
Total		**623,172**	
+ VAT @ 23%		**€766,502**	

Attachment 1
J&J Facility Decommissioning Guide

FACILITY DECOMMISSIONING GUIDE

Facility:	
Address:	

Site Contact:		Phone:	
Title:		Fax:	

Completed by:		Date:	
Reason for completion:			

INTRODUCTION

The Facility Decommissioning Guide is intended to assist the Decommissioning Project Manager in systematically assessing the numerous requirements to effectively and safely manage a facility closure. The guide is divided into several chapters and includes checklists with important criteria to consider when executing a closure project. Careful review should be taken to ensure that these facility closure considerations are evaluated and addressed appropriately. In addition, an understanding of national/local legislation and/or regulation will need to be defined.

The Facility Decommissioning Guide includes six chapters. Each chapter addresses specific aspects of a decommissioning project that should be considered. It is important that the Decommissioning Project Manager create a file to include all records of evidence where documentation is required.

Chapter 1: Facility Decommissioning - General
This section contains general items that should be reviewed prior to completing the specific chapters.

Chapter 2: Facility Decommissioning - Environmental
This section addresses the environmental aspects of a decommissioning project.

Chapter 3: Facility Decommissioning – Quality & Compliance Services
This section addresses the quality & compliance aspects of a decommissioning project.

Chapter 4: Facility Decommissioning - Health & Safety
This section addresses the health & safety aspects of a decommissioning project.

Chapter 5: Facility Decommissioning – Laboratories
This section addresses the unique laboratory aspects of a decommissioning project.

Chapter 6: Facility Decommissioning - Loss Prevention/Risk Management
This section addresses the risk management of a decommissioning project and is divided into two sections:

1. During Facility Deactivation
2. Facility Closure Guidelines

PURPOSE & SCOPE

The purpose of this Facility Decommissioning Guideline is to describe the common requirements and activities that comprise the facility decommissioning process. The guideline checklists highlight the various discipline recommended actions necessary to carry out a successful decommissioning project. The final decommissioning report should include all documentation necessary to provide details of the steps taken to ensure proper closure of the facility. Each chapter will provide a list of recommended documents that should be included in the final report.

The guideline is intended to assist in the closure of a facility but may be used for the transfer of facility activities. Initial commissioning of a new, or re-commissioning of a previously decommissioned facility, or entire facility demolition (limited demolition is included) is outside the scope of this guideline. If the facility is intended to be demolished, contact WW EHS, and/or your franchise EHS leader, for guidance.

HOW TO USE THIS GUIDE

The Facility Decommissioning Guide contains information for the project team responsible for the shut-down of a facility. Complete each chapter by answering each question, ensuring that any supporting documentation is transferred to the Decommissioning Project Manager. It should be noted that "Yes" answers to the questions in the checklists should drive a need for documentation in many cases, i.e. proof of completion. "No" responses to the questions in the checklists may include comments as to why it's not needed and a Decommissioning Action Item (DAI) may be developed to track closure.

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In certain circumstances, decommissioning may include process safety management covered processes that require special attention, for example thermal oxidizers. In such cases, process safety management subject matter experts should be consulted prior to decommissioning such operations.

If the decommissioning project includes selective demolition, particular attention should be given to items such as asbestos, local exhaust ventilation systems including dust collectors, chemical tank farms and process piping. In such cases, subject matter experts should be consulted prior to all demolition activities.

Criticality/Scale of the Decommissioning Project

Proper facility decommissioning is a critical step in the lifecycle of a facility. Just as we build facilities to be compliant with all J&J policies, governmental rules and regulations, the decommissioning process needs to do the same. It is important to follow these steps and answer the questions identified in this document to assure that the key aspects of all affected departments are met when decommissioning the facility.

The effort required to decommission a facility should not be underestimated. There are many department personnel involved including Environmental, Health & Safety, Engineering, Risk Management, Quality, and others that must ensure the success of the overall decommissioning project. The effort needed will depend on the size and type of facility to be decommissioned. A small office building will require less effort than a laboratory or a pharmaceutical manufacturing facility. The level of effort should be commensurate with the level of risk that the decommissioning project creates for Johnson & Johnson.

RESPONSIBILITIES

1. Decommissioning Project Manager (DPM)

The Decommissioning Project Manager (DPM) has overall responsibility for the project and maintaining all documentation related to the closure project, including the following:

- Ensure all project team members for the site are trained in this guideline.
- Responsible for coordinating all decommissioning activities and ensure required inputs/ outputs and relevant communications are distributed to and/ or received from all parties included in this guideline.
- Ensure all documentation supporting the decommissioning effort conforms to the requirements of local legislation, good documentation practices in general, and to all other governing procedures, work instructions and quality practices specified in other chapters of this guideline.
- Ensure all work performed in the decommissioning effort by Facilities' contractors conforms with: J&J WWEHS standards, local EHS regulations, proof of Insurance with acceptable liability & coverage, etc.
- Ensure the shutdown plan is aligned with the milestones and timetable of the larger deactivation plan.
- Report progress to management on key milestones until the facility is shut down.
- Identify key personnel (i.e. Quality, EHS, Facilities, etc.) required to ensure the complete, efficacious and compliant decommissioning of the facilities.

2. Decommissioning Project Team

The Decommissioning Project Team led by the Decommissioning Project Manager, should at a minimum have representation from Facilities, Risk Management, Engineering, Maintenance Environmental, Health & Safety, Legal, and site/area manager. Representation from Quality, Loss Prevention and Sterilization Process Technology should be selected if applicable based on project scope. The Decommissioning Project Team is responsible for collaborating on the planning, execution, verification and closure activities associated with the project. Depending on the project parameters, other individuals may also become members as the need arises.

3. Subject Matter Experts

There are times during a decommissioning project where consultation is needed with subject matter experts prior to commencing the project, especially when limited demolition work is planned. The list below includes departments within Johnson & Johnson World Headquarters that include subject matter experts or can direct you to those experts who should be consulted when unique aspects of a decommissioning project arise.

• Engineering & Design • Quality Compliance Services • Risk Management • Sterile Process Technology • Worldwide Environmental, Health & Safety

DEFINITIONS & ACRONYMS

- BOM - Bill of Material
- CAD Drawings (Computer Aided Drafting) associated with a specific facilities system or set of facilities systems that are maintained current and under revision control throughout the associated system's life cycle.
- CAR - Capital Appropriation Request
- CE - Conformity Standard (European)
- Commissioning (COM) - A well planned, documented, and managed engineering approach to the startup and turn-over of a facility system to the Owner/ User that results in a safe and functional environment that meets established design requirements and documented expectations.
- DAI - Decommissioning Action Items
- Decommissioning - A well planned, documented, and managed engineering approach to remove a facility system from use or qualified status.
- DPM – Decommissioning Project Manager
- Facility - Building and all the contents including utilities & process equipment
- Facility System - An organization of engineering outputs that have a defined operational function (e.g., buildings, utilities, mfg equipment, instrumentation, controls, etc.).
- EHS – Environment, Health & Safety
- HVAC - Heating, Venting and Air Conditioning
- IQ - Installation Qualification
- JSA - Job Safety Analysis
- MSDS - Material Safety Data Sheets
- NRC - Nuclear Regulatory Commission (United States)
- OQ - Operational Qualification
- Owner - An individual or department that has the responsibility for the operation and maintenance of a system and bears the ultimate responsibility for compliance with regulatory requirements for that system (typically Facilities Maintenance).
- PPE - Personal Protection Equipment
- PQ - Performance Qualification
- SOP - Standard Operating Procedure
- User - An individual or department that is the beneficiary of the services provided by a system or interacts directly with a system; can be different from the owner. In the latter case, the system user bears the ultimate responsibility for conformance to product/ process requirements for that system.

CHAPTER 1

GENERAL

FACILITY DECOMMISSIONING – GENERAL CONSIDERATIONS

1. GENERAL:
   - Management appoints a Decommissioning Project Manager (DPM) to ensure that the decommissioning is done in compliance with all applicable rules, regulations, norms and standards.
   - The Decommissioning Project Manager is responsible for the implementation of the shutdown plan.
   - The DPM has developed a process for the transition, consulting with Johnson & Johnson Corporate resources as needed.
   - The DPM needs to be aware of the site's history, its operations, its high risk activities, and the high risk activities introduced by the decommissioning itself. This will complement and give context to the decommissioning action items.DAI
   - Plans have been made for the archiving of appropriate records (Quality, Environmental, Health and Safety and Employee Health). If operations will be transferred to another Johnson & Johnson facility, pertinent records need to be transferred to the receiving facility (such as standard operating procedures, emergency plans, Material Safety Data Sheets (MSDS), chemical inventory, waste characterization data, process flow diagrams, decommissioning documents, etc.).
   - The Project Team shall specify a person or organization that is responsible for the long-term, post-decommissioning management and retention of these records.
   - There is a communication plan in place to address inquiries from stakeholders and the community.
   - The impact on emergency response teams has been evaluated and action plans established to assure their ongoing effectiveness.
   - All pre-post transfer costs from above have been included in the move's capital appropriation request (CAR).
   - Each specific section in this document should be completed.

2. EQUIPMENT:
   - Determine whether equipment will be retained within Johnson & Johnson or sold. If equipment is to be sold or redeployed within Johnson & Johnson, the EquipNet Asset Redeployment Management System (ARMS) must be used. [refer to # 3 below]
   - In case of equipment transfer to other locations, a plan identifying functional responsibilities and key personnel for handling the various aspects of the transfer activities must be deployed.

- Ensure vital computer software (Building & Process Controls/Systems) critical to plant functions and regulatory compliance has been maintained.

3. ASSET REDEPLOYMENT MANAGEMENT SYSTEM (ARMS) – A process for redeploying assets, including internal redeployment and external sales.

When any piece of equipment is to be redeployed within J&J or sold externally via the EquipNet Asset Redeployment Management System (ARMS), a process must be followed in order to have the equipment eligible for redeployment or sale in the system. The first course of action will be to complete all of the questions which MUST be answered. Once the answers are submitted, an e-mail will be generated to the appropriate EHS professional to ensure review and sign off. After the EHS professional approves the form, the equipment can continue through the process for redeployment or sale.

The ARMS system will track all approval flows via an electronic system that can be easily referenced and tracked to ensure the correct approval processes have taken place before equipment is redeployed or sold. It is important to note that equipment cannot be redeployed or sold externally until the appropriate EHS approval. After this initial step is completed, the equipment will continue through the redeployment process to be evaluated for legal, insurance and financial purposes before it is released for redeployment or sale.
Click for link to EquipNet ARMS website

FACILITY EQUIPMENT/PROCESS:	YES	NO	Comments
Does the plan address requirements for transferring/shipping of a specific process, including transfer of related documentation (e.g., equipment manuals, maintenance/calibration documents)?			
Before transferring, has the specific equipment/process been evaluated for compliance with current engineering codes, standards and practices (i.e., ASME, NEC, J&J Zero Access, etc.)?			
For transferred processes, is the following information available: process and product hazard analysis risk, JSAs, SOPs and specifications, materials waste profiles and or analytical data (if any)?			
Has an inventory of equipment for sale, transfer or scrap been developed?			
Has an inventory of the assets on site of the decommission facility been created to ensure they are accounted for during the entire process. (Computers, AV equipment, LCD projects, etc.)			
Has a consensus been reached with the receiving (for Johnson & Johnson locations) on upgrades (i.e., rewiring for new voltages, shipment to machine rebuilders, CE upgrading to comply with European regulations and local language requirements)?			
For equipment planned for transfer - Has an equipment inspection visit been conducted to determine final equipment planned (including spare parts, guarding, manuals, etc) for Johnson & Johnson companies or outside purchasers?			

Has management agreement been obtained regarding decisions (price/acceptance) on all equipment dispositions (scrapping, relocation, or sale to competitive companies)?			
Has the ARMS process been completed regarding the availability of equipment for locations inside and outside the company?			
Has the ARMS process been followed regarding plans to disassemble, disconnect, scrap, and group equipment by recognized industry types? (Textile, material handling, shop tools, packaging, facilities equipment, liquids, tanks, and other appropriate groupings)?			
Has an action plan been established to define roles and responsibilities, timetables, and scope relating to the transfer of equipment and work within the facility?			
Are appropriate safe work rules and practices for contractors / internal personnel during disassembly operations established, enforced and confirmed?			
Has an individual been assigned to gather, control and maintain confidential information on all computer equipment?			
Has equipment been identified to match and mark critical parts, (e.g. Zero Access™ guards) for reassemble at final location?			
Has equipment spare parts been collected to group them with equipment to be sold?			
Has all equipment been appropriately packaged to ensure the safe storage, transportation, and arrival at the final destination?			
If the equipment itself is subject to government registration, licensing, or permitting (e.g. lasers, RF), is there a plan to terminate the registration or license?			
FACILITY - GENERAL:	**YES**	**NO**	**Comments**
Have steps been taken for the shutdown and lockout of all non-vital functions including the following:			
a) Maintain & periodically inspect all fire protection systems, equipment and operations e.g. fire extinguishers, fire watch, permits, hoses, and emergency gear during closedown?			
b) Modify contracts for waste disposal, fuel delivery, water treatment chemicals and other production related services?			
c) Adjust to meet the needs of changing activities within the facilities, (vending machines, cafeteria contracts termination, outside services as appropriate)?			
d) Maintain vital subcontractor services (snow removal, grass cutting, landscape maintenance, reduced housekeeping etc), and reduce or terminate non-essential building related services?			
e) Clean production residue in/on building systems/ structures to limit potential liability and safety related issues (toxic materials, silicone contamination, flammable materials, asbestos, tritium exit signs, mercury filled devices, heavy metal wastes etc.)?			
f) Optimize energy management systems for none operational situation?			
g) Winterize (or weatherproof) building-related non-operational functions?			

If there are any EHS issues that could expose Johnson & Johnson to third party liability, have all items been communicated to the Decommissioning Project Manager?			
Does the plan include transfer of product, raw materials, chemicals, and work-in-process materials? Specifically, have any required hazard communications obligations, including MSDSs and labelling, been generated? Have the materials been properly classified, packaged, marked and labelled for transportation as per regulations by a regulatory qualified person?			
Have waste chemicals, residual oils and other hazardous materials been properly disposed while maintaining required documentation?			
Have company-related signs on exterior or interior facades been removed?			
Does management plan to repair Building Code related deficiencies to pass inspection by local building code officials for future approval (electrical issues, plumbing issues, roof repairs, broken curbs, stack and vent removal, local re-roofing, signage, and health & safety issues relating to building occupancy- emergency exits)? If yes, are all action items added to the project DAI?			
Are there plans to repair the facility for sale, remove extraneous foundations, fill concrete holes / trenches, remove excess conduit / wire-way ducts and add or relocate light fixtures appropriate with equipment removal? If yes, are all action items added to the project DAI?			
Is there a plan to prepare the building for sale condition (painting plan, roofing repairs, re-lamping of fixtures, carpeting or tile replacement in worn areas, and parking lot repairs, etc.)? If yes, are all action items added to the project DAI?			
If there are plans to lease back space from a facility buyer, are any risks present that need to be addressed.			
If we are leasing space from the new buyer, has the purchasing company's EHS professional(s) performed a risk assessment of both areas providing a report with all EHS issues of concern?			
Heating Ventilation and Air Conditioning (HVAC) Systems			
Was the HVAC unit used for general office space or pharmaceutical / laboratory processing / research areas? (To determine risk and how in depth the decontamination project would have to be.			
Has an overall inspection of the system been conducted?			
Did the visual inspections of the system determine if humidifiers are part of the system? If yes, are these systems functioning as intended? (Note* Improper functioning humidifiers can lead to microbial growth and other indoor air quality issues.)			
Is the ductwork a potential source of historical contamination from chemicals, biological, or radiological materials or fiberglass due to the materials of construction? If yes, consider testing to confirm contamination to determine whether the system needs to be cleaned, isolated, or removed.			
Have visual inspections been conducted to ensure the HVAC units condensate drip pans function as intended and are free of any microbial growth due to standing water/moisture?			

If the HVAC units are to be removed, have the refrigerants been captured prior to the planned demolition work?			
If the HVAC units are to be removed, have all of the connections to plant utilities been disconnected and all of the interconnecting piping and coils drained? If not, are proper lock out tag out procedures in place?			
If the ductwork is to remain during any demolition work, have air intakes or returns been isolated to prevent contamination of the HVAC system and/or cross-contamination of other areas.			
If the HVAC system is to remain during the decommissioning project but will eventually be removed, the system can be used as a means to provide negative pressure in the areas being demolished as long as the ductwork does not become contaminated from the demolition process.			
Have all of the components in the ductwork system been disconnected from utilities (hot water, electrical, chilled water, steam, etc) ie reheat coils, humidifiers, VAV boxes, etc?			
Has the ductwork insulation been tested for asbestos or other hazardous materials?			
If the HVAC system is to be removed or partially removed:			
a. Is there a process or method developed to safely cut into and remove system components (piping, filters, collectors, etc.) along with protection for the contractors performing the work?			
b. Does the historical use of the system allow for decontamination?			
c. Does the historical use of the system allow for recycling?			
d. Does the historical use of the system justify isolating the system components (e.g. capping the ends of the ductwork) and removing it as a classified waste?			
e. For HVAC – Are there current drawings of the systems available with defined demolition boundaries, if not how will demolition be controlled?			
Local Exhaust Ventilation (LEV) Systems & Pollution Control Devices			
If the facility LEV system including fans, ductwork, and pollution abatement equipment (dust collector, thermal oxidizer, activated carbon bed, and scrubber) is to remain with the building, have these systems been cleaned to a predefined criterion?			
a. Has this item been reviewed by the functional area responsible for the transfer of the property?			
If the LEV system is to be removed or partially removed:			
a. Is there a process or method developed to safely cut into and remove system components (piping, filters, collectors, etc.) along with protection for the contractors performing the work?			
b. Does the historical use of the system allow for decontamination?			
c. Does the historical use of the system allow for recycling?			
d. Does the historical use of the system justify isolating the system components (e.g. capping the ends of the ductwork) and removing it as a classified waste?			
e. For LEV – Are there current drawings of the systems available with defined demolition boundaries, if not how will demolition be controlled?			
MANAGEMENT:	**YES**	**NO**	**Comments**
Will key safety services be maintained during phase-down and facility close-down for fire, first aid, security, winterizing equipment plans, and critical contracting services?			

Will key facilities maintenance equipment / people maintain the building to provide vital services during sale/transfer?			
Are there firm dates to terminate appropriate operating and regulatory permits / contracts, (i.e., radiation licenses, waste disposal, sewer, environmental, gas, electric, water, supply contracts etc.)? If no, have all action items added to the project DAI?			
Has the lead time to obtain government closure of permits, licensing, etc. been estimated or determined to understand the potential impact on the project timeline?			
Has all vital information been archived on personnel issues/MSDS/health records, hazardous substance exposure monitoring data, chemical inventories, equipment operating instructions, equipment bill of materials, appropriate drawings, and building-related vital information, permits and operating instructions etc.? If no, have all action items added to the project DAI?			
PRODUCTION PROCESS – GENERAL:	**YES**	**NO**	**Comments**
Has the decommissioning plan included action items for the safe termination of production, return or scrap remaining raw materials), cleaning of storage tanks (confined space issues), cleaning of equipment, and shutdown and lockout of appropriate energy sources while maintaining essential building services?			
Has the safe shipment of final production inventory, disposal of questionable products, return/transfer of remaining raw materials, and closedown relating to production assets been completed?			
Is there critical Material Handling Equipment available to maintain a safe working environment and a final release date for the sale/transfer (i.e., maintenance of building high lift and heavy duty lift trucks?			

CHAPTER 2

ENVIRONMENTAL

FACILITY DEACTIVATION – ENVIRONMENTAL CONSIDERATIONS

There are two aspects that need to be considered in the deactivation of facilities:

A. Issues relating to the manufacturing facility that is closing and/or transferring manufacturing out.

B. Issues relating to the facility that will be receiving additional manufacturing.

This section addresses both aspects. It is intended as a tool to effect a smooth transition.

A. THE TRANSFERRING (CLOSING) FACILITY OR THE FACILITY THAT IS TRANSFERRING MANUFACTURING OUT

All environmental systems and procedures are to remain in effect throughout the closedown period until manufacturing ceases. The following issues need to be taken into account in these particular circumstances, in addition to the routine management of environmental affairs.

GENERAL:	YES	NO	Comments
Is there a plan to ensure that, if tenured personnel are lost, all items pertaining to the environmental compliance of the facility (during and post-operations) will be transferred to an equally competent individual?			
Has an assessment been conducted and documented to identify all EHS liabilities and establish a baseline report on the EHS conditions prior to transfer of the property? The facility must identify any regulatory requirements relative to the closure of a facility and ensure that the assessment performed satisfies those obligations. The assessment is mandatory and should be performed in accordance with ASTM E1527 - 05 Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process (or equivalent), with the additional elements required by the applicable authorities.			
Has management ratified a corrective action or remedial action work plan to address any/all issues identified during the Phase I assessment, particularly any issues that are required to be resolved to achieve formal regulatory agency approval for closure? (The DPM is encouraged to seek WW EHS input for this process.)			

In the event corrective or remedial actions are projected to continue beyond the date that the facility is vacated, and/or beyond the date of property transfer outside of J&J, has a J&J EHS professional been identified to manage and drive the actions to closure?			
In the event corrective or remedial actions will continue beyond the date that the facility is vacated, and/or beyond the date of property transfer outside of J&J, does the Finance department have a mechanism in place to provide appropriate financial reserve on an ongoing basis to fund the corrective/remedial actions required, up to and including obtaining any formal regulatory agency approval?			
In the event corrective or remedial actions will continue beyond the date that the facility is vacated, and/or beyond the date of property transfer outside of J&J, has a member of the J&J Law Dept. been formally engaged to represent the interest of the Company in any real estate negotiations related to maintaining access to allow for remedial actions, sharing in costs if appropriate, and establishing any relevant indemnifications?			
Has the minimum capability of the emergency response organization (staffing, equipment, materials) required to support both the safe and controlled decline in operations and the concurrent decommissioning activities been formally determined and vetted with management?			
Have alternative (i.e., potentially external) arrangements for emergency response capability to support declining operations and ongoing decommissioning activities been identified? If this risk will be addressed via a third party(ies), has an agreement been ratified such that, as soon as the minimum capability of the internal emergency response organization (staffing, equipment, materials) is not able to be reliably satisfied internally), the third party service will commence?			
Has management considered establishing special/additional training sessions for temporary personnel (with no facility experience) that may need to be utilized to support the facility's normal operations during decommissioning (non-employees/standing contractors)?			
Have all contractors providing decontamination, waste removal, and/or deconstruction/demolition support during the facility decommissioning received site and project task specific EHS training commensurate with their work during the facility decommissioning? For those who have not, has a training needs assessment been performed and delivery system been developed?			
For any equipment being transported to a) either a receiving facility or b) third party, which contain any regulated liquid or gaseous materials that might be released in transport, for example, mercury containing devices (switches, bulbs, thermostats), oil reservoirs, and/or gases (refrigerant, flammable, and/or toxic), are there plans to ensure those materials are properly removed and containerized at the facility **prior** to any transportation of the equipment?. (Any removed materials must also be disposed of properly, as is the case with all regulated wastes.)			

Has an inventory of all wastes (including non-regulated) to be generated pursuant to the decommissioning, including non-routine wastes (cement, roofing, textiles) and projected quantities, indicating disposal method and facility, been generated? Have all disposal facilities been confirmed as being capable and legally permitted to receive the intended wastes, and been confirmed to satisfy any applicable J&J TSDF approval process?			
Are plans in place to maintain and archive all documentation related to disposal (agreements, audits, manifests/bills of lading, disposal instructions/restrictions, waste profiles/analytical data, weight tickets, confirmation of end fate (i.e., certificate of recycling, certificate of disposal)?			
In the event of demolition, has a screening been performed for any/all potential environmental issues (for example, asbestos, silica, polychlorinated biphenyls (PCB) in caulk, deposited active materials, etc.) been identified or determined not to be present, and, if present, have proper containment, abatement, and disposal activities been arranged?			
Are plans are in place for the final submission of environmental data to the regulatory agencies and WWEHS, such as waste volumes, energy use, water use, etc?			
REGULATORY:	**YES**	**NO**	**Comments**
Are plans in place to notify regulatory agencies to rescind permits and regulatory approvals when operations cease?			
Has a list of all required formal documents/reports routinely (minimum 1/five years) submitted to regulatory agencies been generated? Has someone been identified and a plan created to notify the party(ies) receiving these documents? Have plans been formalized to inform these third parties that the facility is no longer subject to the requirement to report? Does the plan include the timeline for mailing each report, based on the decommissioning timeline?			
If there are environmentally related units that require obtaining a formal closure certificate from regulatory agencies (i.e., underground tanks, incinerators, and waste management units) are plans in place to submit the closure application well in advance of operation cessation to allow ample time for regulatory review?			

B. THE RECEIVING FACILITY

GENERAL:	**YES**	**NO**	**Comments**
Has management considered providing training to the facility's environmental professionals (by the transferring operations management) on aspects of environmental issues of the operations being transferred?			

Are there plans in place to obtain pertinent records from the transferring facility, (i.e., standard operating procedures, emergency plans, MSDS, chemical inventory, waste characterization data, process flow diagrams, etc.)?			
(*Each item requires its own response*.) Is there a plan to carefully review environmental aspects of operations being transferred, such as water use, wastewater discharge, waste generation, chemicals use, air emissions, to ensure that:			
a) Adequate storage facilities are in place for the safe storage of materials and chemicals?			
b) Adequate waste disposal infrastructure is in place regionally to manage the waste generated from operations being transferred?			
c) The facility's emergency response and preparedness/prevention are adequate for the additional operations and if not, that pertinent modifications are made to ensure their adequacy?			
d) Adequate resources are in place to manage the environmental affairs of the operations being transferred?			
e) Facility's emission control and discharge treatment system are in place or are adequate to handle the additional load?			
f) Considerations are made to minimize environmental impacts of operations?			
REGULATORY:	**YES**	**NO**	**COMMENTS**
Are plans in place to review the aspects of operations being transferred to determine what new permits or modifications to existing ones are required to absorb the operations?			
Are plans in place to review the aspects of operations being transferred to determine what additional regulatory requirements, approval, and reporting will result from the new operations?			
Are plans in place to review the additional pollution load from the new operations to evaluate if there are limiting factors in obtaining the permits and/or authorizations from the regulatory agencies for handling the additional load (i.e., the local sewerage authority may have reached its capacity and cannot receive additional wastewater load)?			

CHAPTER 3

QUALITY & COMPLIANCE SERVICES

FACILITY DEACTIVATION – QUALITY CONSIDERATIONS

There are two categories of issues that should be considered in facility deactivation:

A. Issues relating to the manufacturing facility that is closing and/or transferring manufacturing out.

B. Issues relating to the facility that will be transferring in/receiving additional manufacturing or will be supplying new countries.

This section addresses issues in both categories. It is intended as a tool to effect a smooth transition.

A. THE TRANSFERRING (CLOSING) FACILITY OR FACILITY THAT IS TRANSFERRING MANUFACTURING OUT

All existing quality systems, policies and procedures are to remain in operation throughout the closedown period until all manufacturing ceases, or until the particular processes in question are transferred out. The following issues need to be taken into account in these particular circumstances, in addition to the routine running of the quality system.

COMPLAINT HANDLING:	**YES**	**NO**	**Comments**
Does a complaint handling system remains in place through the expiration date of the last product manufactured?			
Has an adequately trained person been assigned the responsibility of complaint handling?			
COMPONENTS/INVENTORY:	**YES**	**NO**	**Comments**
Has the Decommissioning Project Manager assigned someone responsibility to transfer existing components/inventory? **If Yes:**			
a) Are there documented provisions to protect components/materials from contamination or damage during transit?			
b) Do the provisions include requirements for transferring related documentation (e.g. material/component specifications, LHRs)?			
c) Do the provisions for special handling/environmental controls as required, during the transfer of components/inventory?			

EQUIPMENT:	YES	NO	Comments
Has the Decommissioning Project Manager assigned someone responsibility for equipment transfer to another facility? **If Yes:**			
a) Will the transfer of equipment address requirements for transferring/shipping including transfer of related documentation (e.g. equipment manuals, maintenance/calibration documents)?			
FACILITY:	**YES**	**NO**	**Comments**
Has the Decommissioning Project Manager assigned someone responsibility to oversee any space renovations, construction, electrical, utility or heating, ventilation & air conditioning (HVAC) modifications? **If Yes:**			
a) Is there documented re-qualification activities for any product which will not be transferred?			
b) Does the documentation include provisions for protecting components/products from adulteration or contamination?			
c Does the documentation include provisions for performing validations of the facility changes or changes affecting other elements of the master validation plan?			
d) Is there a facility cleaning validation plan?			
HANDLING, STORAGE, AND DISTRIBUTION:	**YES**	**NO**	**Comments**
Have relevant procedures been documented related to handling, storage and distribution been reviewed and adapted in preparation for the transition to a marketing company?			
MANAGEMENT RESPONSIBILITY:	**YES**	**NO**	**Comments**
Has an in-depth quality risk assessment been performed and documented to identify potential issues of concern and their possible impact?			
Is there a documented contingency quality plan in place to monitor and identify any possible, deliberate tampering or interference with product and processes, or deliberate attempts to compromise quality or compliance by dissatisfied employees?			
Is there a documented contingency plan, or have adequate provisions been made should loss of key operations or of quality personnel, occur prior to close down or transfer?			
Are there adequate resources to fulfil ongoing quality responsibilities as manufacturing continues, to monitor the closedown or to assist in the transfer?			
Has the Decommissioning Project Manager assigned an adequately trained, sufficiently senior person to assume responsibility for the quality function once manufacturing ceases (e.g., manufacturing ceases but marketing continues)?			
PERSONNEL:	**YES**	**NO**	**Comments**
Has the Decommissioning Project Manager identified functional responsibilities and key personnel for handling the various aspects of the closedown or to transfer activities?			
Has adequate training been provided to those staff responsible for closing down and/or transferring processes?			

Are there sufficient personnel to achieve the tasks required?			
Has a written policy been established that addresses the use of temporary employees during the closedown period or transfer?			
Does this written policy address where temporary employees may or may not be employed?			
Has the regulatory impact of the use of temporary employees been taken into account?			
Have limits been documented regarding the authority and/or decision making powers that may be delegated to temporary employees?			
Are there provisions for the adequate training and documentation of such training for temporary employees?			
PURCHASING:	**YES**	**NO**	**Comments**
Have alternate suppliers (including JOHNSON & JOHNSON companies) been identified to replace product manufactured in-house?			
Have detailed requirements been clearly communicated to the supplying company?			
Are such companies able to supply product that will comply with requirements?			
Will the supplying company be able to comply with regulatory requirements?			
Is the formulation or the makeup of the product being acquired equivalent to that which had been manufactured locally?			
Do proposed labelling and packaging comply with requirements?			
Has the supplying company been informed of any requirements to notify companies receiving product of any product or packaging changes?			
Are there any external manufacturers who will no longer be manufacturing for the company?			
Is there a documented quality plan in place to handle the closing down of manufacturing at the external manufacturer?			
Will any external manufacturers continue manufacturing for the company after internal manufacturing has closed down? **If Yes:**			
a) Have adequate internal resources and personnel been allocated to monitor and maintain ongoing quality at the external manufacturer, as the quality function in the JOHNSON & JOHNSON company is scaled down?			
Have any requirements or regulations been identified calling for the local testing of incoming product?			
Have requirements for quality-related documents to accompany products been communicated to the supplying company?			
Have proposed packaging and shipping containers from the supplying company been reviewed and evaluated for acceptability and performance?			
QUALITY SYSTEM:	**YES**	**NO**	**Comments**
Is the quality system being reviewed and redeveloped to take into account the transition?			
Have existing CAPA's been reviewed and adapted to take into account the specific requirements of closing down/transferring out manufacturing?			

Has a documented action plan been prepared that incorporates quality considerations for the closedown and/or transfer of manufacturing?			
Does a documented action plan include provisions made to maintain or increase the level of quality assessments during transition?			
Is there a documented action plan to review and/or redevelop the quality system if the facility is not transferring all product lines & plans to continue manufacturing other product?			
Is there a documented action plan to review the CAPA to ensure that system deficiencies will be corrected so that the same deficiencies will not be inherited by the receiving facility if processes are being transferred?			
Is there a system for appropriate executive management review of complaints and stability results through the lifetime of the last product manufactured?			
RECORDS:	**YES**	**NO**	**Comments**
Has a documented review been carried out of all records to ascertain those which must be retained and those which need to be transferred to the supplying company, or company to whom any equipment/processes are being transferred?			
Has a documented action plan been developed to include a provision for records that are to be retained and archived for at least two years, or for the life of the product, or according to regulatory requirements?			
Have the documented action plan provisions been made for retrieval of records for possible inspection (especially electronic records)?			
Has a documented action plan been established for the official removal and disposition of all documents from circulation (e.g.: specifications, test methods, batch records etc.)?			
REGULATORY:	**YES**	**NO**	**Comments**
Is there a documented action plan to notify regulatory bodies of the facility changes and transfer of product?			
Have appropriate regulatory bodies been notified?			
Is there a timeline in place to ensure supply to market while submission for change of site is under review by the regulatory bodies?			
Is there a system in place to update regulatory filings with stability results when required?			
Is there a plan to notify environmental agencies?			
RETAIN SAMPLES AND STABILITY STUDIES:	**YES**	**NO**	**Comments**
Has a documented action plan been developed to include provisions made for the maintenance of an existing retains sample program?			
Have documented action plans been made for continuing or transferring any stability studies that are ongoing In support of marketed product?			
If product on stability study is to be transferred, have arrangements been made to transport this product under the correct environmental conditions?			
Are all retains labelled in compliance with regulatory requirements (chemical name and hazard)? Have arrangements been made to ensure that relocation and/or storage activities are conducted safely and in compliance with regulatory requirements?			

B. THE RECEIVING FACILITY THAT WILL BE TRANSFERRING IN/RECEIVING ADDITIONAL MANUFACTURING OR WILL BE SUPPLYING NEW COUNTRIES.

All existing quality systems, policies and procedures are to remain in operation throughout the closedown period until all manufacturing ceases, or until the particular processes in question are transferred out. The following issues need to be taken into account in these particular circumstances, in addition to the routine running of the quality system.

B.THE RECEIVING FACILITY

COMPONENTS/INVENTORY:	**YES**	**NO**	**Comments**
Is there a documented action plan for receiving, inspecting, testing, identifying and segregating components/inventory being transferred from another facility?			
Does the documented action plan include requirements for reviewing related documentation for completeness and adequacy (e.g. material/component specifications, LHRs)?			
Are there documented provisions for special handling/environmental controls as required by components/inventory and/or by standards and testing procedures?			
EQUIPMENT:	**YES**	**NO**	**Comments**
Is there a documented Master Validation Plan for qualifying and validating equipment being transferred from another facility?			
Is there a documented action plan to address equipment cleaning validation?			
Is there a documented action plan to address equipment calibration and maintenance?			
Is there a documented action plan to verify receipt of related documentation from the transferring facility (e.g. equipment manuals, maintenance/calibration documents)?			
FACILITY:	**YES**	**NO**	**Comments**
Is there adequate space to transfer new equipment, product, inventory and personnel?			
Is there a documented action plan to perform any space renovations, construction, electrical, utility or heating, ventilation & air conditioning (HVAC) modifications? **If Yes:**			
a) Does the documented action plan include provisions for protecting components/products from adulteration or contamination?			
b) Does the documented action plan include provisions for performing qualifications and validations of the facility changes or changes affecting other elements of the master validation plan for any products being manufactured before the transfer?			
Is there a facility cleaning validation documented action plan?			
Is there a documented action plan to address material flow changes?			

QUALITY SYSTEM:	YES	NO	Comments
Is there a documented action plan to review and/or redevelop the quality system to ensure all required systems are in place to manufacture the transferred product?			
Is there a documented action plan to review the CAPA to ensure that system deficiencies identified in the transferring facility are corrected so that the same deficiencies will not be inherited by the receiving facility?			
Are there documented action plans to develop inspection, testing and audit programs to ensure the integrity and quality of the product being transferred into the facility?			
Are there documented action plans to conduct product, process and test method validations?			
Are there documented action plans for retain samples, stability testing and test method transfer?			
PERSONNEL:	**YES**	**NO**	**Comments**
Is there a documented action plan to identify functional responsibilities and key personnel for handling the various aspects of the transfer activities?			
Has the Decommissioning Project Manager assigned an adequately trained, senior person been identified to assume management responsibility for the quality function?			
Are there adequate resources and training for personnel in each functional discipline?			
Has a written policy been established that addresses the use of temporary employees during the scale up period?			
Has the written policy regarding temporary employees addressed the need for adequate documented training?			
PURCHASING:	**YES**	**NO**	**Comments**
Is there a documented action plan to notify existing suppliers of the transfer?			
Is there a documented action plan to use new suppliers or external manufacturers? **If Yes:**			
a) Is there a documented action plan to evaluate, assess, qualify and then monitor the quality of product to be supplied by new suppliers?			
Is there a documented action plan to communicate detailed requirements to suppliers?			
Has the inventory control system been updated to reflect changes in manufacturing (e.g. lead times, production schedules)?			
RECORDS:	**YES**	**NO**	**Comments**
Is there a documented action plan for storing and/or archiving quality and production records?			
Is there a documented action plan to review all specifications and related quality and production documentation for adequacy and completeness prior to manufacturing?			
Is there a documented action plan to address compatibility of systems and hardware used to store data electronically?			

REGULATORY:	YES	NO	Comments
Is there a documented action plan to notify regulatory bodies of the facility changes and transfer of product?			
Is there a documented action plan to notify environmental agencies?			
Are there plans to change components, materials or formulations? **If Yes:**			
a) Are there documented action plans to conduct equivalency testing, compatibility testing, etc.?			
Is there a documented action plan to assign responsibilities for complaint handling?			
Is there a timeline for regulatory approval in each country where product will be marketed?			

CHAPTER 4

HEALTH & SAFETY

The H&S section checklist is intended to help identify hazards & programs that need to be evaluated and managed as appropriate during any decontamination/deactivation process. The H&S topics covered by this section includes: Hazard communication, emergency response, flammable liquids, general safety (confined space, LO/TO, welding, elevated heights), industrial hygiene, personal protective equipment, biosafety and decontamination procedures. For radiation, lead, asbestos and silica hazard, subject matter experts should be consulted.

A general principal that should be followed prior to beginning any decontamination activities is to conduct very thorough baseline hazard and risk assessment to understand the scope of the work that needs to be completed. Based on the risk assessment conclusions, develop a project specific plan to manage all the activities until work is complete. If the team does have the appropriate subject matter expert, then ensure help, perhaps from corporate resources, should be requested. It's important to recognize that the attached checklist is not designed to address all scenarios but rather serve as a prompt for issues that need to be considered while develop and managing the task at hand.

Hazard Communications	**YES**	**NO**	**Comments**
Is there a hazard communications plan in place for both employees and contractors?			
Is this plan incorporated into the contractor safety training program?			
Has a review of historical processes, utilities and equipment to identify the hazards and risks from past or current operations in building(s) been identified and documented?			
Do any identified hazards require any specialty training, authorization (including licensing or professional qualification), or equipment to be able to decontaminate and or remove? i.e. (HAZMAT, Radioactive, Asbestos, Bio-hazards, lead etc.)			
Is there a plan in place to assure appropriate warning signage is in place while specific tasks are being performed?			
Are proper interim storage containers or areas in place before work starts, along with proper signage?			
Have all required documentation of known hazards been made available to associates or contractors? (MSDSs, etc.)			
Emergency Response	**YES**	**NO**	**Comments**
Are procedures or system in place to identify either internal or external local emergency responses to typical situations?			
Are these procedures or systems part of employee and/or contractor safety training programs?			
Are appropriate emergency response phone or contact numbers clearly posted for contractors to access?			

If emergency response is by internal associates, is proper equipment in place and easily accessed?			
Have travel routes and emergency access to specific areas been considered for emergency responders?			
Before dealing with specific hazardous tasks will/are emergency responders pre-warned of activities? (i.e. local fire departments)			
Flammable Liquids	**YES**	**NO**	**Comments**
Have all flammable liquids to be removed been identified and located?			
Are proper procedures in place to remove and appropriate disposal routes identified?			
Have proper grounding and bonding procedures been developed?			
Is remaining flammable liquids properly tagged, appropriate warning signage in place, and stored in a properly ventilated area?			
Are there any liquids that require specialty training for handling or disposal?			
Are proper interim storage containers or areas in place before decommissioning work starts, along with proper signage? (approved flammable liquid containers required?)			
Confined Space	**YES**	**NO**	**Comments**
Have all known confined space areas been identified before decommissioning work begins?			
Are proper procedures in place for working in confined space?			
Is proper equipment and signage available for working in confined space? (i.e. retrieval equipment, air testing, communication devices, etc.)			
Are these procedures or systems, and equipment part of employee and/or contractor safety training programs?			
Lock Out Tag Out	**YES**	**NO**	**Comments**
Is there a LO/TO procedure in place for both employees and contractors?			
Are these procedures or systems part of employee and/or contractor safety training programs?			
Is there appropriate equipment and signage available for use to LO/TO? (are suitable locks and tags on site or on location, includes locks for electrical and pressure systems)			
For systems to be de-energized and locked out permanently is there a transfer process in place for the turnover or documenting of keys?			
Have updated drawings and inventory of systems that will require LO/TO before work starts, been made available to the right personnel?			
Have boundary of work drawings been made available to right personnel? i.e which systems will remain intact and which to be decommissioned?			
Welding/Cutting	**YES**	**NO**	**Comments**
Is a process or procedure in place to control welding & cutting operations by using a hot works permit or other control system?			
Is this part of the contractor training process?			
Are appropriate system checks in place to tanks or piping that will be cut to assure cleaned or decontaminated?			
Is there a list of required safety equipment to be on site and or in place before work starts? (extinguishers, signage, spark cloths, etc)			
Is proper attaching of welding lead ground in place? (is clamp to building ground sufficient or specific local grounds required?)			
Are there any local emergency responders that need to be notified of specific welding or cutting tasks?			

Elevated Heights	YES	NO	Comments
Does site have a current policy and or requirements for working at elevated heights (or fall protection)?			
Is working at elevated heights part of the contractor safety training program?			
Are all ladders, platforms, scaffolds, man-lifts, fall restraint, etc. used compliant with local legislation?			
Is this equipment supplied by the contractor or site?			
Is an inspection frequency in place to check any equipment being used on site?			
Industrial Hygiene	**YES**	**NO**	**Comments**
Have we identified all the hazardous chemicals that may be present?			
Do we have MSDSs for all these chemicals?			
Do we have established OELs for all these chemicals?			
Have we conducted a qualitative risk assessment for the activities that will be performed?			
Is it necessary to conduct a quantitative risk assessment for inhalation and dermal hazards? If so:			
Is there validated air and wipe sampling methods available?			
Is there air and wipe sampling plan developed and reviewed by the project coordinator before the assessment is conducted?			
Is the exposure controls (engineering, work practices and PPE) required based on the risk assessment results?			
Has training on the proper use of the engineering controls been provided to all impacted employees and contractors?			
Has a written strategy to conduct a post–decontamination 'clearance' assessment been developed? Does the plan need to include air and/or wipe sampling?			
Personal Protective Equipment (PPE)	**YES**	**NO**	**Comments**
Has appropriate (exposure level, compatibility, durability) personal protective equipment (gloves, coveralls, respirators, work boots, head protection, eye and face protection) requirements been identified to safely handle hazardous materials and are these requirements based on risk assessment results?			
Are gloves selected for hand hazards present (chemical, puncture, laceration) hazards?			
Have procedures been implemented to properly remove, collect and dispose of used PPE to minimize chemical contamination?			
Are disposable coveralls required? If so, are they are compatible with the chemicals, equipment and activities being decommissioned?			
If respirators are required, have they been selected based on results of chemical risk assessment, e.g. appropriate protection factors and chemical cartridges?			
Has medical clearance provided for all workers utilizing respirators?			
Have employees been provided appropriate facilities and training for gowning and de-gowning based on the PPE requirements including cleaning and disposal?			

Biosafety	YES	NO	Comments
Were biological agents, toxins, and materials used at the site?			
Have risk assessments been completed for decommissioning activities involving biological agents, toxins, research animals, and animal tissue materials?			
Are biohazard labels applied to contaminated equipment, materials, and containers?			
Are biosafety procedures and training requirements established for workers performing decontamination and decommissioning tasks inside BSL/ABSL spaces?			
Are workers performing activities involving bio-hazardous and/or biological materials included in medical surveillance programs?			
Are cleaning/disinfecting agents such as 10% bleach solution or Cidex specified for removing contaminants and contaminant residues from contaminated equipment, materials, and surfaces?			
Are equipment cleaning and removal activities sequenced in a manner that will allow appropriate engineering controls (ventilation, waste containment systems) to remain in use until contaminated equipment, materials, and surfaces are containerized and/or decontaminated?			
Are biohazard labels removed from equipment and material surfaces prior to its removal from the facility?			
Decontamination and Work Zone	**YES**	**NO**	**Comments**
For hazardous materials has a work zone or containment area been established to minimize exposures outside of containment area?			
Are contaminated equipment, materials, and spaces designated for decontamination activities identified?			
Will portable airlock, showers and change room be required to properly decontaminate people and equipment before exiting the containment zone?			
Are agents and processes expected for use during decontamination activities determined to be effective in removing contaminants from contaminated equipment and material prior to its removal from the site? Can they be safely handled?			
Are “clean” endpoint criteria identified for decontaminated equipment and material?			
• Where applicable, are the criteria defined by sample collection and laboratory analysis?			
Are valid sampling and analytical methods developed for contaminants of concern?			
• Do assessments specify hazard mitigation and/or minimization methods to be used during decontamination activities, i.e., administrative controls, engineering controls; and personal protective equipment (PPE)?			
• Do decontamination procedures maximize the use of engineering controls for worker safety?			
Are procedures implemented that identify equipment, material, and personnel traffic flow into and from contaminated or “hot” areas?			

Ergonomics	YES	NO	Comments
Has an Ergonomics Risk Assessment been completed for any proposed materials handling activities? (J&J preferred tool is the MHEJA : Manual Handling Ergonomics Job Analyser)			
Have measures been implemented to reduce the risk of injury from manual materials handling activities to as low a level as reasonably practicable.			
If transferring equipment to another J&J site has an appropriate Ergonomics Risk Assessment been passed to the EHS contact (consideration should be given to changes in anthropometric details of the new working population).			
Special Consideration – Radiation, Asbestos, Lead, Silica, Steroids, Beta-Lactams	**YES**	**NO**	**Comments**
Have an assessment for the presence of radiation, lead, silica and/or asbestos been conducted? If so, have appropriate procedures and controls to safely manage these hazards been developed? Consult a subject matter expert to obtain technical input.			
Will sensitive or regulated materials/equipment be transferred/stored to an intermediate location (neither the facility subject to decommissioning nor the destination facility)? If yes:,			
a. Have adequate provisions for the security, safety, control, and inspection of these materials been established?			
b. Have any/all regulatory registration and/or notification been identified and processed?			
c. Has the interim facility's property insurer been contacted to ensure appropriate asset coverage is secured?			
Were steroids or beta-lactams used in the facility planned for decommissioning? If yes:			
a) What methods will be used to determine the level of contamination?			
b) What is the desired target level below which is considered clean?			
c) What method(s) will be used to ensure the area has been cleaned to a desired target level?			
d) Is there a sampling plan to measure areas before/after cleaning? (e.g. aggressive air sampling)			

CHAPTER 5

LABORATORIES

The laboratory decommissioning section applies to all laboratory and auxiliary spaces serving as laboratories. The decommissioning process should be the same for these spaces as if decommissioning any other building or facility. Facilities with laboratories should also answer questions in the other chapters referenced in this guideline. The laboratory checklist can be used as a guide to eliminate and/or manage risks in laboratories when they are:

- Vacated[1],
- Remodeled
- Moved to another building,
- Relocated to another laboratory area within the same building,
- Decommissioned due to a change in laboratory function

This checklist should be used in conjunction with Johnson & Johnson's Laboratory Decommissioning Guidelines and American National Standard Institute's (ANSI) Laboratory Decommissioning Standard (ANSI Z9.11-2008) or local legislation.

The decommissioning process should, at a minimum, have a written plan that includes, but is not limited to a scope of work, risk assessment and characterization (historical, initial, etc.), decontamination and remediation, verification of decontamination and documentation.

LABORATORY QUESTIONS	YES	NO	Comments
Is there a written decommissioning plan defining the scope or work, risk assessment process, decontamination procedures, and final documentation deliverables?			
Has risk assessment been conducted to characterize the existing facility conditions and hazards? This includes historical and current uses of the decommissioned areas and includes a historical document review, interviews of occupant and other knowledgeable individuals and inspection of the facility.			
Has sampling been performed to determine if potential contaminants are present and to delineate the extent of contamination?			
Has a review been conducted to document and manage chemicals (including active pharmaceutical ingredients) and biological materials used and stored in the laboratory? This includes chemical raw materials, working solutions, unknown materials including container integrity and labelling (chemical name & hazards), chemical reactivity, etc.?			
If a perchloric acid fume hood was used, special precautions must be made prior to removing or dismantling the hood.			

[1] This includes laboratory operations at Johnson & Johnson owned properties, leased properties or spaces, or external contract laboratory sites

Was mercury or mercury containing devices (i.e. thermometers) used in the laboratory? If yes:			
a. Were there any mercury spills or releases? Is a mercury vapor survey needed to delineate the extent of any contamination?			
Are all compressed gas cylinders removed from the area?			
Were radioactive materials used in the laboratory? If so, answer questions a to l.			
a) Has the Radiation Safety Officer, Health Physicist, qualified radiation professional, consultant, etc. been notified?			
b) Has a historical site assessment of the radioactive materials used in the laboratory been conducted? This includes types of radioactive materials, activities performed, areas of use, control measures, etc.			
c) Has radiation survey or sampling plan been developed to assess levels and extent of contamination?			
d) Has a release criteria been established to determined what equipment or structures (floors, bench tops, hoods, etc.) need to be decontaminated or disposed?			
e) Is a Final Status Survey Report (FSSR) or similar document required to be prepared and submitted to the governing authority to document the radiological release criterions have been satisfied?			
f) Has the shipping and disposal of the radioactive waste been coordinated with an appropriate licensed disposal company?			
g) Is an amendment required to terminate or modify your radioactive materials license? If so, has the appropriate paperwork been submitted to the governing authority?			
h) Is the radioactive material(s) being transferred to another laboratory or facility? If so, laboratory listed on the material license or does the receiving facility have the appropriate license or permit?			
i) Were any sealed sources (i.e. scanning gauges) or generally licensed devices (i.e. liquid scintillation counters, tritium exit signs) used?			
j) Were all the personnel monitoring badges collected?			
k) Have all the radioactive materials labels, placards, etc. been removed?			

l) Has a final walk-through been conducted by the Radiation Safety Officer, Health Physicist, qualified radiation safety professional, consultants, etc. to review documentation and release the space for unrestricted use?			
Are any of the biological agents or stocks or hazardous chemicals being transferred or shipped to another location? If yes:,			
a. Does the receiving facility have the appropriate license or permits?			
b. Does the person shipping the material have the appropriate dangerous goods/IATA training			
c. Is the material packaged in accordance with applicable transportation specifications (i.e. IATA, DOT, etc.)			
d. Are any special permits required to transport this material?			
Are all the unwanted biological agents or stocks destroyed or deactivated? Note: Select agents or regulated agents may require the appropriate documentation?			
Has the biological and chemical waste and contaminated consumables that cannot be decontaminated been segregated, labeled and packaged in accordance governing regulations?			
Has the biological and chemical waste been removed from the laboratory and shipped with an approved and licensed disposal company?			
Is an amendment required to terminate or modify the facility's permit or license to handle biological and/or regulated agents? If so, has the appropriate paperwork been submitted to the governing authority?			
Have all the biological and chemical materials labels, placards, etc. been removed?			
Has a final walk-through been conducted by the Biological Safety Officer, EH&S, consultants, etc. to ensure decontamination and removal of biological agents and hazardous waste, review documentation and release the space for unrestricted use?			
Has a historical site assessment of the active pharmaceutical ingredients or pharmaceutical intermediate materials used in the laboratory been conducted? This includes the areas where these compounds were used and stored, activities performed, equipment used in conjunction with the compounds, control measures, and any known spills.			
Is there a decommissioning scope of work that defines the acceptable decontamination process and release criteria (i.e. total removal, partial removal, encapsulate in place, etc.)?			
Has EH&S performed a final review of the decontamination reports and conducted a final walk-thru of the space prior to releasing for unrestricted use?			
Has the decontamination of work surfaces, storage areas, equipment and control measures with the appropriate disinfectant been performed and documented?			
Has a release criteria been established to determined what equipment or structures (floors, bench tops, hoods, etc.) need to be decontaminated or disposed?			

Has the appropriate cleaning or disinfection solution been identified for the specific contaminant(s)?			
Has the personal protective equipment required to decontaminate the structures, equipment, control devices (hoods, HEPA filters, etc.) been defined?			
Has the decontamination waste generated been classified and disposed in the proper waste stream?			
Has a final walk-through been conducted EH&S, consultants, etc. to ensure decontamination, removal waste, review documentation and release the space for unrestricted use?			

CHAPTER 6

LOSS PREVENTION/RISK MANAGEMENT

This section contains two parts:

A. Loss Prevention during facility decommissioning provides guidance on the issues to be addressed before and during the deactivation of a facility.

B. Facility Closure Guidelines covers issues to be addressed when a facility is closed.

A. LOSS PREVENTION DURING FACILITY DECOMMISSIONING

Facilities being decommissioned present a significant threat of property loss. A recent analysis of losses by FM Global over a 26 year period in these facilities indicated a total of 1,112 losses amounting to $393 million in total loss. Loss costs broken down by peril were:
Fire – 48%
Arson / vandalism / theft – 20%
Weather related – 31%
Other – 1%

Contractor activities are a major source of destructive fires in industrial and commercial buildings. Decommissioning activities in particular are the cause of such fires. This is sometimes due to the lack of adequate guidance given to contractors.

The term “decommissioning” applies to those activities necessary to prepare facilities in anticipation of selling the building, preparing the building or a portion thereof for a different type of manufacturing operation or demolishing the building. It is assumed that production stock has been removed but that utilities and piping systems are still activated when the contractors arrive at the plant.

This document provides a checklist covering the planning and preparations to be taken before the contractor begins operations, precautions to be instituted during contractor activities, and the requirements to be followed to place the fire protection into a custodial status.

This checklist covers the more common loss prevention issues that must be considered when decommissioning a facility. There are many types of equipment and systems that may be found in J&J plants that are not specifically covered in this checklist. There are resources available at J&J Risk Management and FM Global to provide specific advice. When informed of the decommissioning of a facility, FM Global will normally arrange for an engineer to visit the facilities to provide advice specific to the facility.

The term “contractor” shall include Company employees engaged in similar activities on Company premises.

The term “Decommissioning Coordinator” shall mean a qualified representative of the Company designated by JOHNSON & JOHNSON (J&J) to coordinate fire, safety and environmental matters and to oversee the enforcement of J&J standards and national regulations, whether explicitly written in the contract, or not.

Preparation for Decommissioning	**YES**	**NO**	**Comments**
Has a qualified employee been designated as the “Decommissioning Coordinator”?			
Have additional employees been qualified to assist the Decommissioning Coordinator as Needed?			
Has responsibility for building and equipment preparation and critical housekeeping functions been established before the arrival of contractors and the start of the decommissioning process (i.e. purging of pipelines, cleaning and waste removal, etc)?			
Have Johnson & Johnson Risk Management and FM Global, the fire insurance company, been advised of the plans to decommission the facility and given the opportunity to provide advice regarding loss prevention?			
Have all areas of the facility been designated as No Smoking areas?			
If smoking areas are needed, are they located outside the facility and provided with proper receptacles for cigarette butts?			
Have fire extinguishers, fire hose, shut-off valves, fire pumps, sprinkler systems and other emergency equipment been inspected and any needed testing, repairs, and replacements been completed prior to the start of decommissioning activities?			
Have hot work and impairment procedures been reviewed and implemented and has a supply of hot work permits and impairment tags been obtained from FM Global?			
Are safe cleaning methods being used for any equipment that may require cleaning prior to being removed from the site?			
Has equipment for storage or transfer to other locations been moved to an isolated staging area (i.e. an onsite warehouse or decommissioned area of the property) and has proper security been provided to control access to this area?			
Contractor Specifications	**YES**	**NO**	**Comments**
Have all contractors been instructed to work closely with the Decommissioning Coordinator throughout the project?			
Have all contractors been instructed on all J&J rules regarding their work?			
Does all equipment being used by contractors conform to J&J requirements?			
Do J & J employees present at the facility have the ability to immediately shut down a portion of the work or the entire project, if any unsafe practices are being performed?			
Are periodic meetings (at least once weekly) held to coordinate removal work, to assure fire-safe operations and continuity of fire protection at all times?			
Are all contractors aware of J&J fire prevention rules?			

Are all contractors aware of their responsibility to prevent damage to the building and equipment (i.e. fire equipment, sprinkler piping, heating equipment, electrical equipment, etc.) during the course of their decommissioning activities?			
Are contractors aware of the proper methods to disconnect utilities and equipment and is this work performed by qualified contractor employees?			
Fire Protection Systems and Equipment	**YES**	**NO**	**Comments**
Is it planned that building sprinkler systems are to remain in operation at all times including prior to any deactivation work?			
Before any portion of the building's fire protection is permanently impaired or terminated, has prior written approval of the Decommissioning Coordinator and J&J Risk Management been obtained?			
Is the closing of any sprinkler system valves under the control of the Decommissioning Coordinator?			
Is FM Global notified of all fire protection control valve closures?			
Are impairment tags being used to assure that no system valve is inadvertently left closed and is FM Global notified when valves are reopened?			
Before any transfer or removal of fire protection equipment, has prior written approval of the Decommissioning Coordinator and J&J Risk Management been obtained?			
If plant air systems are planned to be shutdown, are alternate sources of air provided for fire protection systems such as dry pipe sprinkler systems?			
During freezing weather, is sufficient heat maintained to prevent fire protection equipment from freezing?			
During freezing weather, are large wall or roof openings properly closed to retain building heat?			
Is the fire alarm system maintained in service at all times?			
Is FM Global notified if work is being done on fire alarm systems?			
Are only qualified contractors being used for work on fire protection systems and equipment and fire alarm systems?			
Hot Work	**YES**	**NO**	**Comments**
Are alternatives to hot work utilized whenever possible?			
Are all contractors familiar with the hot work procedures and use of the hot work permit system?			
Are hot work permits used at all times except in areas specifically designated for hot work operations?			
Is the area where hot work is done checked by the hot work permit issuer both before and after the work is completed?			
Are trained fire-watchers provided during hot work operations?			
Is sprinkler protection in service when hot work is being done?			
Is a fire watch provided to periodically monitor the area when hot work is done?			
Housekeeping	**YES**	**NO**	**Comments**
Is trash removed from each area before a contractor is permitted to begin work?			
Is combustible trash and liquid waste removed promptly by the contractor as it is generated?			

Is combustible trash and liquid waste properly disposed of?			
Is particular attention paid to areas where trash tends to accumulate?			
Are residues, oil, lint and other combustibles removed as needed?			
Are spilled oils and other flammable liquids properly and promptly cleaned up?			
Flammable Liquids	**YES**	**NO**	**Comments**
Are alternatives to the use of flammable liquids used whenever possible?			
If flammable liquids must be used, are less hazardous Class II and III materials used instead of Class I materials?			
Are flammable liquids stored properly in a designated area?			
Are approved safety containers used for transporting flammable liquids?			
Are all safety containers returned to the designated flammable liquid storage area during off hours?			
Are flammable liquid wastes collected in approved waste containers and properly disposed of?			
Are oily rags or wiping waste placed in approved containers and properly disposed of?			
Are proper cleaners used for floors, walls, windows, light fixtures etc. And not flammable liquids?			
Are pipelines containing flammable or combustible liquids properly purged and flushed before any decommissioning activities are performed on the equipment?			
Fuel / Compressed Gas Systems	**YES**	**NO**	**Comments**
When gas fired equipment is disconnected, is the gas supply shut off at the supply piping, disconnected and the opening plugged?			
Are cylinder manifolds for compressed gases shut and the cylinders disconnected?			
Are all compressed gas cylinders in the facility on an approved cart of vehicle and properly secured?			
Is an approved area provided for the storage and replacement of empty and full cylinders?			
Are all empty and full cylinders in this area properly secured?			
Are qualified contractors used for decommissioning gaseous fuel and compressed gas systems?			

B. FACILITY CLOSURE GUIDELINES

Whenever a plant is idle or vacated, proper safeguards against fire and other perils take on added importance. There may be less plant supervision, and operations such as de-activation, can increase the chances of a fire. The following represents general guidelines to reduce the chance of a loss occurring at an idle or vacant facility.

Most of the loss prevention guidelines and requirements under Section A above for facilities being deactivated also apply to idle or vacated facilities. Some additional important guidelines and requirements are covered below.

1. Definitions

A. Vacated Plant

The term “vacated plant” refers to a location where normal operations have been halted and will not be resumed. Most or all of the production equipment is removed from a vacated plant. Sprinkler systems, gravity tanks, fire pumps, and other protective equipment remain in service.

B. Idle Plant

An idle plant is a location where normal operations have been temporarily interrupted. Both protective equipment and production facilities are maintained serviceable.

Electric Power	**YES**	**NO**	**Comments**
Are lights maintained in service and emergency systems tested regularly?			
Is power maintained in service for fire pumps, sump pumps, etc., and tested regularly?			
For circuits that are not be in use, are the switches open (at main switchboard if possible)?			
Are transformers shut down, except those providing needed power for essential equipment?			
Flammable Liquids and Substances	**YES**	**NO**	**Comments**
Are flammable liquids and substances stored in portable containers removed from the site?			
Except when needed for building heat, are discharge valves on butane or propane storage tanks closed?			
Except when needed for building heat, are the pumps that supply fuel oil under pressure to plant distribution piping shutoff and the valves shut to isolate this equipment?			
Are all in-service tanks monitored and checked for leakage?			
Are all valves on gauge glasses closed?			
Are all lines, tanks and other systems carrying flammable liquids or substances drained and purged or are at least valves closed to isolate this equipment to prevent release of contents?			
Fire Protection Equipment	**YES**	**NO**	**Comments**
Unless all combustibles are removed and the building is totally of non-combustible construction, is sprinkler protection in service and sufficient heat provided to prevent sprinkler systems from freezing?			
Have J&J Risk Management and FM Global been notified if any sprinkler systems are removed from service?			
Is fire protection equipment inspected periodically to ensure that it is in proper working order?			
Are all fire doors kept closed to reduce fire spread were a fire to occur?			
Natural Gas, Flammable and Other Compressed Gases	**YES**	**NO**	**Comments**
Are main gas valves closed outside buildings or at the meters?			
Are all burner valves closed?			

Are all compressed gas cylinders shutoff or disconnected at manifolds?			
Is the number of portable cylinders inside buildings reduced to the minimum required for building needs?			
Heating	**YES**	**NO**	**Comments**
Is sufficient heat maintained as needed for the buildings and to prevent water lines, plumbing fixtures, etc. from freezing or has this equipment been drained?			
Housekeeping and Waste Disposal	**YES**	**NO**	**Comments**
Has all waste material from buildings and from the yard been removed and properly disposed of?			
Has all lint or combustible deposits from machines, electric motors, switchgear, fixtures and the building structure been removed and properly disposed of?			
Have all residues from equipment, hoods and ducts been removed and properly disposed of?			
Has vegetation been trimmed as needed to maintain proper access to the facility and to fire protection equipment?			
Maintenance of Protective Equipment	**YES**	**NO**	**Comments**
Is all fire protection equipment periodically inspected to make sure it is in proper working order and are any deficiencies found promptly repaired?			
For an idle plant, is fire protection equipment maintained and tested?			
For a vacated plant, is fire protection equipment maintained and tested if it is practicable to do so?			
Notification of Shutdowns	**YES**	**NO**	**Comments**
Have J & J Risk Management and FM Global, the insurance carrier, been notified of plans to idle or vacate the facility?			
Has the public fire department been notified of plans to idle or vacate the facility?			
Plant Supervision	**YES**	**NO**	**Comments**
Is the plant alarm system and/or guard service being maintained at all times or has watchman service been provided/			
Are hot work operations properly supervised with a written permit system used?			
Are guards and any remaining plant employees kept aware of proper procedures to follow in case of an emergency?			
Have public authorities (such as the fire department) been notified that the plant is shut down so they can respond properly in case of an emergency?			
Security	**YES**	**NO**	**Comments**
Has an assessment been carried out to establish the level of security needed at an idle or vacated plant and the types of security systems that may need to be provided?			
Are guards on each shift properly trained to operate security and fire alarm systems?			
Is a remote monitoring system (such as a central station system) provided for fire alarm and security systems with the information being relayed to a central monitoring station?			

Environmental Liability Risk Assessment

Vistakon Ireland Ltd
Environmental Support

IE0311273-22-RP-0001, Issue: A

Issue date: 20th May 2014

Document Sign Off

Environmental Liability Risk Assessment

Vistakon Ireland Ltd
Environmental Support

IE0311273-22-RP-0001, Issue A

File No: IE0311273.22.040

CURRENT ISSUE					
Issue No: A	Date: 20/05/2014	Reason for issue: IRPC Licence Compliance			
Sign Off	Originator	Checker	Reviewer	Approver	Customer Approval (if required)
Print Name	Ciarán Reay	Mags Dalton		Ciarán Reay	
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Date	22/01/2014	22/01/2014		20/05/2014	

PREVIOUS ISSUES							
Issue No	Date	Originator	Checker	Reviewer	Approver	Customer	Reason for issue

Contents

1 Executive Summary

Vistakon Ireland develops, manufactures and distributes a range of soft, disposable contact lenses. The facility is located in the National Technology Park, Castletroy, Co. Limerick.

In 1994, Vistakon obtained planning permission for the construction of the first phase of the existing buildings, the manufacturing process and ancillary facilities. The second production block and ancillary services were installed in 1997-1998, along with ancillary support areas. The facility has continued to expand in recent years with the most recent works being the Phase V extension and installation of the 3GT waste water treatment plant. The site infrastructure includes bulk storage and transfer facilities, thermal oxidiser/carbon absorber, combined cooling and power (CCP) system and firewater retention facilities.

Until 2007, the production of the disposable contact lenses included a water-based washing step. Vistakon has since converted some of the existing production to the manufacture of products, using either Isopropyl Alcohol (IPA) or a Propylene Glycol (PG) mix with water. This is in addition to the existing de-ionised water process.

The site was granted an Integrated Pollution Prevention Control (IPPC) (ref. P0818-01) by the EPA in August 2007. A Technical Amendment to the licence was granted in December 2008 to cater for increased production and the resulting increase in wastewater volumes. In 2010 the site was granted a review of its IPPC Licence (ref. P0818-02) to allow for the following developments on-site:

1. Installation of three number wells to abstract water from the aquifer below the site to be used as non-contact cooling water.
2. Use of propylene glycol (PG) in the hydration and washing stages of two production lines, replacing IPA in some processes
3. Installation of the Combined Cooling and Power (CCP) plant to minimise energy use
4. Increase in flow rate from emission point associated with Thermal Oxidiser (TO).

Two additional Technical Amendments were granted in 2013 to allow for increases in the volumes of wastewater discharged due to the expansion of the facility to include additional water based production lines. The second of these Technical Amendments, granted in August 2013, coincided with the installation of a small wastewater treatment facility on site as the increase in wastewaters also increased the organic load of the discharge.

In December 2013, Vistakon were informed of a Section 82A (11) amendment to their licence which had the purpose of bringing the licence into compliance with the requirements of Directive 2010/75/EU (Industrial Emissions Directive). Under this amendment, the licence (ref. P0818-02) is now deemed to be an Industrial Emissions Licence.

Condition 12.3.2 of the current Industrial Emissions Licence requires that:

"The licensee shall arrange for the completion, by an independent and appropriate qualified consultant, of a comprehensive and fully costed review of the Environmental Liabilities Risk Assessment (ELRA) to address the proposed changes on-site."

PM Group has been retained by Vistakon to carry out a review of the existing ELRA (PM Report No. 011644-22-RP-0004 Issue B) in accordance with the requirement of Condition 12.3.2. The findings of this review are detailed in this report and this document comprises a complete update of the ELRA previously undertaken in March 2011. This ELRA is based on the EPA's new *"Guidance on Assessing and Costing Environmental Liabilities"* (2014) and covers all existing operations on site in addition to the new Phase V works and also the new 3GT waste water treatment plant. The ELRA addresses all activities on site, operator performance and the existing environmental sensitivity of the Vistakon site, before identifying and assessing environmental risks present on site and finally the costing of the worst case scenario in terms of environmental damage.

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 €402,287 (including 25% contingency and

VAT). It is noted that the EPA guidance states that the EPA expects the minimum costs determined by ELRA for EPA-authorised activities should be €1,000,000, with higher amounts for higher risk activities.

Vistakon confirms that the company has more than adequate resources from operations to fund the ELRA. In addition, the value of the facility itself as a fixed asset worth in excess of €366m will far outweigh any remediation cost.

The Environmental Liabilities Risk Assessment will be reviewed as necessary to reflect any significant change on site, and the financial provisions made to address unknown environmental liabilities will be reviewed and revised as necessary in accordance with Condition 12.3 of the licence.

An updated Decommissioning Management Plan (PM Report No. IE011273-22-RP-0002 Issue A) has also been prepared which addresses the remediation and decommissioning of the facility (known liabilities). The cost of implementation of the Decommissioning Plan is estimated to be €766,502.

2 Summary – Environmental Liabilities Risk Assessment

The ELRA is summarised in Table 2.1:

Table 2.1 – ELRA Summary

Activity Name and Address	Johnson & Johnson Vision Care (Trading as Vistakon Ireland) National Technology Park Plassey Co. Limerick
Name of Operator	Johnson & Johnson Vision Care (Trading as Vistakon Ireland)
Licence Number	Reg No. P0818-02
Name & Address of Person/Organisation who prepared the plan	PM Group Kilakee House Belgard Square Tallaght, Dublin 24
Classes of Activity licensed	12.2.1 The surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more 150 kg per hour or more than 200 tonnes per year.
Risk Category	Risk Based Methodology for Enforcement (RBME)
Details of any previous ELRAs	PM Group Report No. 011644-22-RP-0004 Issue B (29/03/2011) PM Group Report No. 011644-22-RP-0004 Issue A (31/07/2008)
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 €402,287. Vistakon confirms that the company has more than adequate resources from operations to fund the ELRA. In addition, the value of the facility itself as a fixed asset worth in excess of €366m will far outweigh any remediation cost.

3 Introduction

Vistakon Ireland develops, manufactures and distributes a range of soft, disposable contact lenses, including the 1-DAY ACUVUE® Visitint, 1-DAY ACUVUE® TruEye, 1-DAY ACUVUE® Define, 1-DAY ACUVUE® Moist, ACUVUE® 2, ACUVUE® Advance and ACUVUE® Oasys.

The site is licensed by the EPA under an Industrial Emissions Licence (Ref. P0818-02). Condition 12.3.2 of this licence requires that:

"The licensee shall arrange for the completion, by an independent and appropriate qualified consultant, of a comprehensive and fully costed review of the Environmental Liabilities Risk Assessment (ELRA), to address the proposed changes on-site. The assessment shall include those liabilities and costs identified in Condition 10 for execution of the DMP. A report on this review shall be submitted to the Agency for agreement within twelve months of date of grant of this licence. The ELRA shall be further reviewed as necessary to reflect any significant change on site, and in any case every three years following initial agreement. The results of the reviews shall be notified as part of the AER."

PM Group (PM) was appointed by Vistakon Ireland Ltd to perform the review of the ELRA.

3.1 Operational Changes since previous issue of ELRA

The previous issue of the ELRA for Vistakon was completed in March 2011 (PM Report No. 011644-22-RP-0004 Issue B). Since this time, new developments and operational changes on-site affecting the ELRA may be summarised as follows:

A new extension was built on the northwest side of the facility to house two new water based production lines under (Planning Reference No. 12/80). A second extension was added soon afterwards (Planning Reference No. 12/499) to accommodate two additional water based production lines as well as staff facilities and utilities area and a link to the administration area. A small waste water treatment plant was also built on site due to the increase in wastewater and the associated increase in organic (BOD/COD) load of the site effluent.

Two Technical Amendments to the Licence were applied for to address both operational changes associated with the extensions. Technical Amendment A was granted in March 2013 to cater for the increase in wastewater volumes relating to the first extension. The site was subsequently granted Technical Amendment B in August 2013 for the further increases in site wastewater due to the second extension.

4 Environmental Liability Risk Assessment

This ELRA is based on 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 approach of 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 the worst case scenario for financial provision

4.1 Risk Assessment Methodology

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 A)

4.1.1 Risk Identification

Recent Planning Documentation, previous IPPC Licence Documentation and the Annual Environmental Reports (AER) for the facility were used as starting points to identify potential environmental hazards/risks associated with the facility. Each risk was considered for relevance, potential hazards, environmental effects, potential severity and probability of occurrence. For each potential hazard to be considered appropriate for inclusion in the risk assessment table, it must pose an environmental risk leading to a potential or anticipated liability including risks to:

- Surface water
- Groundwater
- Land / Ground
- Atmosphere
- Human health
- Ecology

The hazards/risks identified are documented in the Risk Assessment Table in Appendix A. The risk rating / ranking was carried out with the intended controls / risk mitigation measures in place.

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 each potential hazard identified.

Table 4.1 Probability of Occurrence of Hazard

Rating	Probability of Occurrence of Hazard	
	Category	Description
1	Very Low	Very low chance (0-5%) of hazard occurring in 30 yr period
2	Low	Low chance (5-10%) of hazard occurring in 30 yr period
3	Medium	Medium chance (10-20%) of hazard occurring in 30 yr period
4	High	High chance (20-50%) of hazard occurring in 30 yr period
5	Very High	Greater than 50% of hazard occurring in 30 yr period

Table 4.2 Severity of Potential Hazard

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

5 Scoping

This ELRA is submitted to achieve compliance with Condition 12.3.2 of the Industrial Emissions Licence (ref. P0818-02).

"The licensee shall arrange for the completion, by an independent and appropriate qualified consultant, of a comprehensive and fully costed review of the Environmental Liabilities Risk Assessment (ELRA), to address the proposed changes on-site. The assessment shall include those liabilities and costs identified in Condition 10 for execution of the DMP. A report on this review shall be submitted to the Agency for agreement within twelve months of date of grant of this licence. The ELRA shall be further reviewed as necessary to reflect any significant change on site, and in any case every three years following initial agreement. The results of the reviews shall be notified as part of the AER."

The ELRA considers all plausible risks that could occur during the operational phase at the Vistakon site.

Planned liabilities associated with closure are not considered in this ELRA and have been addressed in the Decommissioning Management Pan (DMP) which has been prepared separately (PM Report No. IE0311273-22-RP-0002 Issue A).

6 Site Evaluation

This section gives an overview of site operations, operator performance and environmental sensitivity of the Vistakon facility for the risk identification exercise.

6.1 Site Operation

6.1.1 Facility Activities

Vistakon Ireland Ltd develops, manufactures and distributes a range of soft disposable contact lenses. The processes carried out consist of the following:

- Injection Moulding
- Lens Fabrication
- Hydration
- Post Hydration
- Sterilization
- Cartoning

The production process for all products is essentially the same apart from the hydration step. At this stage, the lenses are hydrated as they move through the production line using de-ionised water which flows through the lenses. A small number of the production lines require the use of an Iso-propyl Alcohol (IPA)/water mixture or a Propylene Glycol (PG) based solvent for this stage. These process steps are supported by typical plant utilities including; water systems, boilers, compressed air, nitrogen gas and HVAC. In addition, the IPA rich off-gases are vented to a thermal oxidiser (TO).

New Developments on Site

Additional water based production lines were added since the previous ELRA as part of the Phase V works. The new lines are identical to existing lines however due to the increase in waste water discharge volumes and the associated increase in organic load, a small waste water treatment facility on site was installed. The new 3GT waste water treatment facility is designed to treat the relatively high strength waste stream from the 3GT production lines (50% of site BOD load). This is the waste stream from the production lines that utilise the IPA and PG solvents in the Hydration step. The amount of effluent to be treated represents a relatively low (<5% total) volume of the site effluent.

6.1.2 Infrastructure

The following infrastructure is present on site:

Main Production Building:

- Production area
- Administration and Laboratory
- Canteen
- Offices

Outside of the main building:

- Warehouse
- External services compound
- Utilities area
- Chemical stores

- Water room
- Tank farm
- Nitrogen compound
- Water storage tanks
- 3 No. Natural gas fired steam generating boilers
- Sprinkler tanks and pump house
- Firewater retention pond
- Compressors
- 3GT waste water treatment plant
- Thermal oxidiser
- Combined cooling & power (CCP) plant
- Waste plastics store

Parking for the site is located to the south of the site, in front of the administration area.

6.1.3 Raw Materials

The raw materials, packaging and finished product used in production are stored in the Warehouse. The maximum quantity of material in these stores is 65T.

Non-hazardous waste materials are stored in designated waste receptacles in the yard prior to disposal. The following summarises the main process materials used on-site:

Material	Estimated Maximum Quantity (Tonnes unless specified)		Storage Area
Monomer 1	5	108	Staging
Monomer 2	1		
Monomer 3	1		
Monomer 4	1		
Tween	1		
Polymer 1	59		
Polymer 3	20		
Polymer 4	20		
Isopropyl Alcohol	300	300	IPA Tank Farm
Propylene Glycol	17	17[1]	PG Storage Compound
Methanol	0.01	3.5	Chemical Store/Lock-up
Hydrocarbon Mineral Transformer Oil	0.05		

[1] Mass of propylene glycol (PG) estimated conservatively, assuming 100% concentration and density of PG equal to 1036kg/m^3. It is noted that approx. 50% of PG stored on-site is 90% concentration with 10% water.

Material	Estimated Maximum Quantity (Tonnes unless specified)		Storage Area
Hydraulic 32 - Lubricating Oil	2.5		
Hydraulic 46 oil	0.6		
Gear Oil	0.1		
Tri-solvent	0.25		
Nitrogen	200	200	N_2 Tank Farm
Acetone	0.005	0.65	Chemistry Lab
Acetonitrile	0.025		
Lab standard	0.6		
AZO Wipes	-		
Diesel Fuel	1.36	1.36	Fire Pump House
Hydrochloric Acid (Battery)/Water room	0.1	33.9	Water Room
Polyethylene glycol	0.001		
Sodium Hydroxide	0.2		
Amertrol BCL A 60SM	0.5		
Sulphuric Acid	0.02		
Sodium Chloride	22.6		
Sodium Borate	0.15		
Roclean 2	0.1		
Diovasin Activ Hydrogen Peroxide Acetic acid Peracetic acid	0.06		
Drewbrom TA	1		
Drewgard (Performax) 2021A	1		
R-134a	7		
Performax 330	0.3		
Sodium Hypochlorite	0.3		
Amersite	0.5		
Colorant	0.05	0.05	Colours Lab
Polymer 2	0.5	0.5	Production
Biosperse 3001	0.3	0.9	CCP Chemical Store
Drewbrom TA	0.3		
Performax 3400	0.3		

Material	Estimated Maximum Quantity (Tonnes unless specified)		Storage Area
Hydrogen Peroxide	$30m^3$	59	WWTP
Sodium Hydroxide	$2m^3$		
Sulphuric Acid	$2m^3$		
Iron Chloride	$2m^3$		

6.1.4 Overview of Wastes Generated

Hazardous Waste Management

Pallets, paper, cardboard and plastic are segregated and collected for recycling by licensed waste contractors. General non-hazardous waste is compacted on-site and collected for disposal by a licensed waste contractor. All documentation is retained on-site in accordance with legislative requirements and the ISO 14001 certified Environmental Management System.

Hazardous Waste Management

All hazardous wastes are labelled and covered and then stored in contained areas onsite before being collected and disposed of by licensed hazardous waste contractors.

This includes laboratory wastes, empty hazardous containers, waste oils and IPA. Where possible, these are sent for recycling or recovery. All documentation is retained on-site in accordance with legislative requirements and the ISO 14001 certified Environmental Management System.

6.1.5 Emissions from Site

The Vistakon site has a network of storm water drains, which collect surface/rainwater from the paved areas and roof areas of the site. These storm waters drain by gravity via an interceptor to the north-eastern corner of the site and discharge at SW1 and SW2 to the storm water sewer, which in turn discharges into the River Mulkear.

Process wastewaters are discharged to Castletroy Sewage Treatment Plant operated by Limerick County Council. A relatively low (< 5% of total) volume of the wastewater stream will be treated at the new on-site wastewater treatment plant before joining the main process wastewater line.

There are some minor emissions to atmospheres from the site boilers. The main emission to atmosphere comes from the thermal oxidiser and backup carbon abatement plant used to abate the volatile organic carbon (VOC) emissions from the lens production lines that utilise the IPA and PG.

There are various types of equipment which generate noise associated with the normal operation of the Vistakon site. Various noise control measures have been incorporated into the design of the plant including the siting of equipment within the plant, housing of equipment within buildings, acoustic insulation of equipment and pipe-work. The plant is designed so that the noise contributions do not exceed the criteria in accordance with the EPA Guidance note on Noise in relation to Scheduled Activities. Thus the plant does not have any significant impacts on ambient noise levels.

6.2 Operator Performance

Vistakon has been in operation in Ireland since 1994 and has operated under an EPA Licence since 2007. Vistakon has established and maintains an ISO 14001 accredited Environmental Management System (EMS). This has been in place since June 1999 and is audited each year.

The site is generally compliant with its licence conditions. Between 2007 and 2010, a small number of administrative/minor non-compliances were reported. These related to BOD and COD levels discharged to public sewer above the limits permitted under licence P0818-01. However increased discharge limits were previously agreed with Limerick County Council, pending approval by the EPA. These increased discharge limits were subsequently granted under licence P0818-02. On-going notification to the EPA regarding compliance with previous licence discharge limits was required until the new licence took effect in July 2010.

Other notifications to the EPA from 2007 to 2010 related to malfunctioning monitoring equipment. There was one minor breach of the hourly TOC limit in relation to air emissions due to machinery/equipment issues in 2011 and there were no environmental incidents or licence non-compliances in relation to the activity for the reporting period of 2012. In 2013, the site recorded no exceedances in relation to its environmental emissions.

6.3 Environmental Sensitivity

The bedrock geology underlying the site is Waulsortian Limestone and is classified as a regionally important karstified bedrock aquifer dominated by diffuse flow (RKD). The groundwater vulnerability has been classed as high.

The nearest natural surface water body to the site is the River Mulkear which is a tributary of the Shannon. The available chemical and biological monitoring data indicate that the Mulkear River is of a good water quality standard in the vicinity of the Vistakon site at Annacotty Bridge.

The Mulkear flows at a distance of from 200m to 500m to the north and east of the site. The Vistakon site has a network of storm water drains, which collect surface/rainwater from the paved areas and roof areas of the site. These storm waters drain by gravity to the north-eastern corner of the site and discharge at SW1 and SW2 to the storm water sewer, which in turn discharges into the River Mulkear.

The site is located within 1 km of the Special Area of Conservation (SAC) Lower River Shannon (Site Code 002165).

The nearest residential receptors are located approximately 150m from the south-eastern boundary of the site. There is no farming activity within 150m of the Vistakon site.

7 Risk Identification, Analysis, Evaluation

A large number of risks were identified at the Vistakon site and are listed in Table 7.1. These risks were assessed against the risk classification tables as provided in Tables 4.1 and 4.2 and a rating level was applied to the severity and the probability of each risk.

A risk score was calculated for each risk using the ratings as shown in Table 7.2. From this information the Risk Matrix was populated in Table 7.3.

Discussion of the risk levels and on-going monitoring or mitigation actions required are listed in Table 7.4.

Table 7.1: Unplanned events that may result in Environmental Liability

Unplanned Event	Comment
1. Fire at facility	Flammable solvents (IPA, propylene glycol) are used within the process at Vistakon Ireland Ltd. The facility is provided with automatic fire detection and fire- fighting systems. The CCP plant is provided with automatic fire suppression, controlled by heat detection. Fixed fire-fighting facilities, i.e. sprinklers and fire hoses are present on site at the Vistakon facility. An automatic diverter valve is fitted to the surface water system. In the event of a fire alarm or a TOC exceedance, this valve will automatically divert all flow to the fire water retention system, which has a capacity of 300m^3. The firewater retention pond is designed to protect the surface water system. Essentially this system is designed to take the volume of contaminated firewater that would overflow into the surface water system in the event of a fire, which would involve 60 minutes of fire water usage and tank failure of the largest tank in the bund. This system, described in more detail in the Firewater Risk Assessment report (011644-22-RP-0001) submitted to and agreed with the EPA, ensures that contaminated firewater or chemical spillages are prevented from entering the River Mulkear and from contaminating surrounding land and hence groundwater. The majority of process wastewater is drained to the tank farm area and then to the process sump. The process wastewaters are directed to the process sewer normally or to the firewater system on activation of the fire alarms. In the event any bunds are contaminated, the tank farm area sump pump out will have a manual option to direct the contaminated waste to the waste tanker loading arm. Should there be a fire at the facility and the run-off is deemed hazardous subsequent to analysis, it will be disposed of as part of normal operating costs.
2. Leaks from above ground storage tanks	There are a number of above ground storage tanks at the Vistakon facility. All vessels and tanks containing hazardous materials are bunded according to the EPA volume requirements, i.e. 110% of the stored volume of the largest vessel in the bund. In addition to the retention pond, chemical spill response materials, such as absorbent mats, are maintained on-site. High level alarms are installed on solvent storage tanks to mitigate overfilling.
3. Leaks from underground storage tanks	There are no underground storage tanks at the Vistakon facility.

Unplanned Event	Comment
4. Spillages from bunds	All bunds are designed, tested and operated in accordance with the requirements of the EPA Guidance Note on the Storage and Transfer of Materials for Scheduled Activities. All new tanks associated with the on-site WWTP will be bunded.
5. Leaks from process and effluent drains	All pipe work used to carry foul and process effluent is designed appropriately according to use. Inspections as part of routine maintenance checks are conducted regularly which identify any leaks. Any leaks identified are repaired as soon as practicable.
6. Leaks/Rupture from underground/above ground pipes	Underground pipelines that carry process waste liquids are inspected by CCTV cameras at a minimum every three years. The main above-ground pipes carrying liquids are those in the Process areas. All pipe work used to carry foul and process effluent is designed appropriately according to use. Inspections as part of routine maintenance checks are conducted regularly which identify any leaks. All inspections include all flanges and joints. Any leaks identified are repaired as soon as practicable. Good design and installation of pipes was applied at the Vistakon site.
7. Overspill from fire water storage at facility	Firewater for hydrants and the sprinkler system is currently stored in two 400m^3 firewater storages tank at the Vistakon facility. These tanks are enclosed and there is no risk of overspill.
8. Any tank overflows	High level indicators in place on tanks make this scenario unlikely. Nonetheless, any material overflowing from a tank will enter either local bunding/containment or the main process effluent system, which drains to the Castletroy Sewage Treatment Plant. Any spills in the 3GT area of production building will be sent to the 3GT waste water treatment facility before discharge to public sewer.
9. Mobile tanker spills on site	The materials brought on or offsite in tankers are Isopropyl Alcohol (IPA) (70%), propylene glycol (PG) (90-100%) and diesel. The delivery of this material by mobile tanker is covered in the site Standard Operating Procedure for Unloading of Bulk Chemicals. Surface water drains are protected against spillage when unloading is taking place by control valves. It is established site practice that Vistakon personnel must be present when loading/unloading occurs.

Unplanned Event	Comment
10. Leak/rupture of a container during loading/unloading.	Chemicals are brought on site in bulk quantities. Unloading of Bulk Chemicals procedure covers these operations. Surface water drains are protected against spillage when unloading by control valves. The storage, containment and handling facilities for all materials at the facility are designed in accordance with statutory requirements and best practice to minimise the likelihood of accidental leaks/spillages occurring and to contain any such leaks / spillages should they occur. There are dedicated tanker unloading areas surrounded by a drainage channel which drain to a sump designed to contain 110% volume of the tanker. All hazardous materials used on-site are stored in bunded areas or on spill pallets appropriate to the quantity of material stored. Propylene glycol is pumped directly from IBC storage to the production line. Preventative maintenance and routine monitoring of tanks and equipment will minimise the likelihood of leaks/spills occurring and ensure that any leaks are quickly detected and controlled.
11. Failure/Leaks from underground sumps	A sump is located under the tanker unloading area. According to the Condition 6.10 of Vistakon's Industrial Emissions Licence 'The integrity and water tightness of all underground pipes, tanks, bunding structures and containers and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee at least once every three years and reported to the Agency on each occasion. This testing shall be carried out in accordance with any guidance published by the Agency. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.' A bund integrity assessment report was completed in January-February 2009, with results reported in the 2008 AER. All remedial works and reassessment have been completed based on the 2009 report. There is a planned bund integrity assessment scheduled for Q1 2014.
12. Leak from fire water retention pond	Water testing will occur every three years in all bunds including the Firewater Retention Pond. Fire water retention facilities are to be reassessed in near future.
13. Uncontrolled releases to Atmosphere from the Thermal Oxidiser (TO)	In the event of a TO failure/shutdown, the process vents will be diverted to the carbon beds. It is anticipated that this will not occur more than 2% of the plant operating time. Modelling has indicated that during this time, Irish and UK ground level Environmental Action Levels will not be exceeded.
14. Uncontrolled releases to Atmosphere from the Carbon beds	The Carbon bed is a secondary (backup) abatement method and procedures are in place for regular maintenance and inspection of system.

Unplanned Event	Comment
15. Contaminated water released to the River Mulkear	All vessels and tanks containing hazardous materials are bunded according to the EPA volume requirements, i.e. 110% of the stored volume of the largest vessel in the bund. In addition to the retention pond, chemical spill response materials, such as absorbent mats, are maintained on-site. Surface water from the IPA storage and tanker areas is monitored by TOC analyser and diverted if contaminated to the fire water retention system, which has a capacity of 300m^3. This system, described in more detail in the firewater report submitted to and agreed with the EPA, ensures that contaminated firewater or chemical spillages are prevented from entering the River Mulkear and from contaminating surrounding land and hence groundwater.
16. Incorrect disposal of waste	All waste contractors on site are licenced operators for the collection and disposal of waste. Waste management procedures in place on site.
17. Noise limit exceedance	Annual monitoring at 4 No. Boundary location and 2 No. Noise sensitive locations as per licence conditions. Complaints procedure in place. There were no complaints in 2012 or 2013.

7.1 Risk Evaluation

Risk evaluation assists in making decisions on the treatment of risks on site. Risk ratings were applied to each unplanned event for severity and occurrence as taken from the risk classification tables. A risk score was then calculated for event using the ratings. The risk score is based on the product of the severity rating and the occurrence rating. This system allowed the risks to be ranked and compared. The table of unplanned events listing all the major risks identified at the site is provided in Table 7.1.

Table 7.2 provides a summary of the risks and the associated risk scores for the site but a more extensive version is explained in Appendix A.

Table 7.2 Risk Ratings & Risk Score

Risk ID	Description	Severity Rating	Occurrence Rating	Risk Score
1	Fire at facility	4	2	8
2	Leaks from above ground storage tanks	3	2	6
3	Leaks from underground storage tanks	1	1	1
4	Spillages from bunds	4	2	8
5	Leaks from process and effluent drains	3	3	9
6	Leaks from above ground pipes	3	3	9
7	Overspill from fire water storage at facility	4	2	8
8	Any tank overflows	3	2	6
9	Mobile tanker spills on site	3	3	9
10	Leak/rupture of a container during loading/unloading	3	3	9
11	Leaks from underground sumps	2	1	2
12	Failure/Leak of Fire Water Retention Pond	3	2	6
13	Uncontrolled releases to Atmosphere from the TO	3	2	6
14	Uncontrolled releases to Atmosphere from the Carbon beds	3	2	6
15	Contaminated water released to the River Mulkear	3	2	6
16	Incorrect disposal of waste	3	1	3
17	Noise limit exceedance	2	2	4

7.2 Risk Matrix

Each risk has been given an ID number which is displayed on the Risk Matrix (Table 6.3) below. The matrix shows the ranking/rating for each hazard/risk. A colour coding system is used to give an indication of the risk level for each identified hazard/risk 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.

Yellow: These are medium-level risks require action, but are not as critical as a red-coded risk.

Green (light and dark): 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. In particular, if cost-effective practicable mitigation can be carried out to reduce the risk even further, this should be considered.

Table 7.3 Risk ID Matrix

Severity	**Massive**	**5**					
	Major	**4**		**1, 4, 7**			
	Moderate	**3**	**16**	**2, 8, 12, 13, 14, 15**	**5, 6, 9, 10**		
	Minor	**2**	**11**	**17**			
	Trivial	**1**	**3**				
			V. Low	**Low**	**Medium**	**High**	**V. High**
			1	**2**	**3**	**4**	**5**
			Occurrence				

It can be seen from the matrix that there are no risks in the red area, requiring priority attention. All risks lie in the low level risk range. As outlined above these are lowest-level risks and indicate a need for continuing awareness and monitoring on a regular basis.

7.3 Discussion of Risk Levels

All risks lie in the green zone. These risks require continuing awareness and monitoring on a regular basis. If not carried out these risks may have the potential to increase to yellow or red zone risks.

The following actions which need to be maintained are:

- Complaints procedure
- Annual noise monitoring
- All vessels and tanks containing hazardous materials are bunded according to the EPA volume requirements, i.e. 110% of the stored volume of the largest vessel in the bund
- Use of approved waste contractors
- Use of chemical spill response materials, such as absorbent mats
- Testing and demonstration of the integrity and water tightness of all underground pipes, tanks, bunding structures and containers (to occur every three years)
- Preventative maintenance and routine monitoring of tanks and equipment
- Unloading of Bulk Chemicals procedure
- Surface water drains are protected against spillage when unloading by control valves
- Vistakon personnel must be present when loading/unloading occurs
- Any leaks identified are repaired as soon as practicable
- All bunds are designed, tested and operated in accordance with the requirements of the EPA Guidance Note on the Storage and Transfer of Materials for Scheduled Activities.

The continued mitigation measures above and regular monitoring and maintenance should keep the risks in the low or minor risk category and prevent them from increasing to medium or even high-level risks.

7.4 Identification of Mitigation Actions & Risk Management Programme

Table 7.4 provides the risks in descending order of risk score with the proposed mitigation measure. The current controls are also provided.

Every risk requires a certain amount of management in order to reduce the risk or manage the risk at an acceptable level. Risk owners have therefore been allocated to each risk to undertake this role. For the all of the risks identified, the management of the risk will involve the maintenance of current controls.

The risks identified were judged to have satisfactory current risk controls and additional mitigation measures were not identified. In this instance the Risk owner is required to ensure that the current levels of controls are maintained and that the level of risk does not increase.

The risk owner must be someone competent enough to understand the risk and the suggested mitigation proposals for that risk, and have the authority to implement the mitigation measure. The risk owner must also be able to be held ultimately responsible for the risk also. The persons considered suitable to act as risk owners at the site is:

- Facilities Director
- EHS Manager

Table 7.4 Risk Mitigation Table

Risk	Potential Failure Mode/Risk	Current Controls	Recommended Mitigation Measures	Current Risk Score	Revised Risk Score
9	Mobile tanker spills on site	Site personnel monitoring when unloading. Spill clean-up equipment and procedures for tankers loading/unloading in place. Unloading is carried out in bunded area	None – actions in place already results in low risk (any risks score above 15 would be considered medium to high level risks requiring action)	9	9
10	Leak/rupture of a container during loading/unloading	Site personnel monitoring when unloading. Spill clean-up equipment and procedures for tankers loading/unloading in place Unloading is carried out in bunded area	None – actions in place already results in low risk	9	9
5	Leaks from process and effluent drains	Routine maintenance / monitoring and procedures in place	None – actions in place already results in low risk	9	9
6	Leaks from above ground pipes	Routine maintenance / monitoring and procedures in place / valve positioning allows for shutting-off supply	None – actions in place already results in low risk	9	9
7	Failure/overspill from fire water storage tanks at facility	Routine maintenance / monitoring and procedures in place	None – actions in place already results in low risk	8	8
1	Fire at facility	Control of ignition sources; smoking banned; correct electric installations; proper welding tools and inspection of waste. Fire training of all personnel. Maintenance of site security procedures	None – actions in place already results in low risk	8	8
4	Spillages from bunds	Routine maintenance / monitoring and procedures in place	None – actions in place already results in low risk	8	8

Risk	Potential Failure Mode/Risk	Current Controls	Recommended Mitigation Measures	Current Risk Score	Revised Risk Score
12	Leak of Fire Water Retention Pond	Routine maintenance and monitoring.	None – actions in place already results in low risk	6	6
2	Leaks from above ground storage tanks	Routine maintenance / monitoring and procedures in place / good design and procedural controls / any spills or fire water run-off will be contained in bund / spill response procedure / equipment & trained operators to respond to spill	None – actions in place already results in low risk	6	6
8	Any tank overflows	110% bund capacity and water tightness test occurs every 3 years.	None – actions in place already results in low risk	6	6
13	Uncontrolled releases to Atmosphere from the TO	Routine maintenance and monitoring. Continuous gas monitoring on site. Procedure for regular maintenance and inspection of system	None – actions in place already results in low risk	6	6
14	Uncontrolled releases to Atmosphere from the Carbon beds	Routine maintenance and monitoring. Continuous monitoring on site	None – actions in place already results in low risk	6	6
15	Contaminated water released to the River Mulkear	Maintenance and continuous monitoring of TOC.	None – actions in place already results in low risk	6	6
17	Noise limit exceedance	Annual monitoring at 4 no. boundary locations and 2 no. noise sensitive locations as per Industrial Emissions Licence conditions. Complaints procedure in place.	None – actions in place already results in low risk	4	4
16	Incorrect disposal of waste	All waste contractors on site are licenced operators for the collection and disposal of	None – actions in place already results in low risk	3	3

Risk	Potential Failure Mode/Risk	Current Controls	Recommended Mitigation Measures	Current Risk Score	Revised Risk Score
		waste. Waste management procedures in place on site. Audit of waste contractors (three year audit cycle) and maintenance of disposal records			
11	Leaks from underground sumps	Routine maintenance and monitoring.	None – actions in place already results in low risk	2	2
3	Leaks from underground storage tanks	Routine maintenance / monitoring and procedures in place and water tightness test occur every three years as per Licence conditions.	None – actions in place already results in low risk	1	1

8 Financial Provision

8.1 Identification of Worst Case Scenario

The EPA guidance issued in March 2014 'Guidance on Assessing and Costing Environmental Liabilities ' 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

After a review of the risk assessment it was concluded that the worst case scenario in terms of environmental consequence identified in the ELRA would be a fire at the facility in the production area that utilises the IPA wash equipment and a subsequent spread to the external chemical storage compound. This could potentially be a combination of Risk ID 1 (Fire at the Facility), Risk ID 2 (Leaks from above ground storage tanks) and also Risk ID 4 (Spillages from bunds). All these risks have high consequence rating of either 3 or 4. These combined risks are considered the worst case scenario for the facility and are quantified and costed for the purposes of financial provision in Table B of Appendix B. The cost of this worst case environmental liability is given in this Risk Assessment as €402,287 (including 25% contingency).

It is noted that the EPA guidance states that the EPA expects the minimum costs determined by ELRA for EPA-authorised activities should be €1,000,000, with higher amounts for higher risk activities.

Vistakon confirms that the company has more than adequate resources from operations to fund the ELRA. In addition, the value of the facility itself as a fixed asset worth in excess of €366m will far outweigh any remediation costs.

8.2 Review of Financial Provision

The ELRA will be reviewed as necessary to reflect any significant change on site. The financial provisions 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 Industrial Emissions Licence.

Appendix A
Risk Assessment Table

Table A: Risk Assessment Table

Risk ID	Process	Potential Hazards	Environmental Effect	Severity Rating	Basis of Severity	Occurrence Rating	Basis of Occurrence	Risk Score (severity x occurrence)
1	Fire or explosion	Fire at facility	Contamination of air and firewater	4	Potential for smoke, fume, odorous, irritating and harmful gases and vapours to be released off-site. Could cause contamination of the local environment and local residences	2	Assumes low probability	8
2	Storage tanks	Leaks from above ground storage tanks	Surface and Groundwater contamination	3	Cost of remediation	2	Assumes low probability	6
3	Storage tanks	Leaks from underground storage tanks	Surface and Groundwater contamination	1	Cost of remediation	1	Low level due to high level of control	1
4	Spillages during transfer of materials	Spillages from bunds	Surface and Groundwater contamination	4	Cost of remediation	2	Assumes low probability	8
5	Effluent from all of the processes and sanitary waste	Leaks from process and effluent drains	Surface and Groundwater contamination	3	Cost of remediation	3	Medium probability	9
6	Leaks from above ground process pipes carrying liquids	Leaks from above ground pipes	Surface and Groundwater contamination	3	Cost of remediation	3	Medium probability	9
7	Flammable Solvent Storage in Tank Farm	Overspill from fire water storage at facility	Surface and Groundwater contamination	4	Cost of remediation	2	Assumes low probability	8
8	Storage tanks	Any tank overflows	Surface and Groundwater contamination	3	Cost of remediation	2	Assumes low probability	6

Risk ID	Process	Potential Hazards	Environmental Effect	Severity Rating	Basis of Severity	Occurrence Rating	Basis of Occurrence	Risk Score (severity x occurrence)
9	Spillages during transfer of materials	Mobile tanker spills on site	Surface and Groundwater contamination	3	Cost of remediation	3	Medium probability	9
10	Leaks during transfer of materials	Leak/rupture of a container during loading/unloading	Surface and Groundwater contamination	3	Cost of remediation	3	Medium probability	9
11	Storage tanks	Leaks from underground sumps	Surface and Groundwater contamination	2	Cost of remediation	1	Low level due to high level of control	2
12	Construction	Failure/Leak of Fire Water Retention Pond	Surface and Groundwater contamination	3	Cost of remediation	2	Assumes low probability	6
13	Process use and recovery of solvents	Uncontrolled releases to Atmosphere from the TO	Impact to local air quality	3	Could cause contamination of the local environment and local residences	2	Assumes low probability	6
14	Process use and recovery of solvents	Uncontrolled releases to Atmosphere from the Carbon beds	Impact to local air quality	3	Could cause contamination of the local environment and local residences	2	Assumes low probability	6
15	Failure of TOC equipment	Contaminated water released to the River Mulkear	Surface water contamination	3	Cost of remediation	2	Assumes low probability	6
16	Waste Contractors	Incorrect disposal of waste	Soil/ Groundwater contamination	3	Cost of soil and groundwater remediation	1	Low level due to high level of control	3

Risk ID	Process	Potential Hazards	Environmental Effect	Severity Rating	Basis of Severity	Occurrence Rating	Basis of Occurrence	Risk Score (severity x occurrence)
17	Noise is generated by process and utilities equipment and site activities such as transport and construction	Noise limit exceedance	Noise impact, causing nuisance to local residences	2	Minor once off events, but nuisance level rises with rising incidences	2	Assumes low probability	4

Appendix B
Financial Model – Worst Case Scenario

Table B: Financial Model – Worst Case Scenario

Scenario Description: Fire breaks out in the 3GT production area on the North-Eastern part of the Facility which uses the highly flammable IPA washing equipment leading to external fire spread to the chemical storage area adjacent to the production area resulting in loss of containment of hazardous materials. Potential overspill of some bunded areas due to loss of containment and fire-fighting operations. The potential hazards include emissions to air, contaminated firewater and chemicals discharge to surface water or groundwater.

Extensive fire safety measures in place so in the unlikely event of a fire incident, there is a low risk it would spread beyond a small portion of the facility. Widespread loss of containment of hazardous material and contaminated firewater unlikely due to bunding of tanks and fire water retention pond.

Item	Breakdown of Costs	Cost	Source
Fire Brigade (Chemical Incident Unit)	1st hr @ €1,650 Additional hrs – 1 @ €1,100	2,750	Local Authority
Site Supervisor – Primary Clean-up Operation	4 weeks* @ €60/hr	9,600	PM Group Recent Tender Rates
General Operatives	4 persons/4 weeks @ €45/hr	28,800	PM Group Recent Tender Rates
H&S Equipment Rental – Signage, Hoarding, Lighting etc	4 weeks rental @ €1000/week	4,000	PM Group Recent Tender Rates
Crane Hire	5 days rental @ €800/day	4,000	PM Group Recent Tender Rates
Dismantling of Selected plant & Equipment	4 persons/1 week @ €50/hr	8,000	PM Group Recent Tender Rates
Disposal of firewater	300m^3 @ €150/m^3	45,000	PM Group Recent Tender Rates
Disposal of non-hazardous waste	100 Tonne @ €120/tonne	12,000	Waste Disposal Contractor
Excavation of potentially contaminated soil	200 m^3 @ €20/m^3	4,000	PM Group Recent Tender Rates

Item	Breakdown of Costs	Cost	Source
Removal & Disposal of contaminated soil	400 Tonne @ €200/tonne	80,000	PM Group Recent Tender Rates
Transport of material/plant off-site	5 Containers @ €700/Container within Ireland	3,500	Haulier Company
Landscaping of affected area	1000m^2 @ €15/m^2	15,000	PM Group Recent Tender Rates
Import Soil	200m^2 @ €40/m^2	8,000	PM Group Recent Tender Rates
Environmental Consultancy	40hrs@ €100/hr	4,000	PM Group Estimate
Hydrogeological Investigation & Report including Trial Pits	Investigation & Report	20,000	PM Group Recent Lab costs
Environmental Sampling & Analysis	Lab Work	5,000	PM Group Recent Estimate cost
Project Management	80hrs @ €100/hr	8,000	PM Group Estimate
Sub Total		**€261,650**	
Contingency @ 25 %		**€65,413**	
Total		**€327,063**	
+VAT@23%		**€402,287**	

*Based on a 40 hour working week