1. Objective

1.1. The objective of this procedure is to establish the Alexion Ireland requirements for responding to chemical and biological spill events.

2. Scope

2.1. The scope of this procedure covers all Alexion Ireland facilities that have the potential to have chemical and/or biological spills events that require a clean- up response.

3. Responsibilities

3.1. Alexion Ireland Senior Management

3.1.1. Responsible for providing the resources necessary to implement an effective chemical and biological spill response process.

3.2. EHS Department

3.2.1. Establishing the guidelines for chemical and biological spill response process.

3.2.2. Determining if chemical and biological spills require an EHS Incident Investigation

3.2.3. Following up with EHS Regulatory Agencies in the event that a spill is required to be reported.

3.3. Facilities

3.3.1. Ensuring there is sufficient spill response material at each Alexion Ireland facility for dealing with potential spill events. Ensure the spill kits are stocked and routinely inspected.

3.3.2. Facilities must coordinate with the spill owner to ensure swift clean-up of the spill area.

3.3.3. Ensuring there is a process for disposal of the waste generated as part of the spill clean-up according to **ALXN-SOP-0004205, Alexion Ireland Waste Management Procedure.**

3.4. Alexion Ireland Personnel

3.4.1. Be knowledgeable of the EHS requirements for an effective chemical and biological spill response process.

3.4.2. Implement this procedure as described.

3.5. Spill Owner

3.5.1. The system and or chemical/biological owner of which the spill originated is responsible for coordinating the response to the spill with the ERT i.e. identification of type of substance, isolating the system etc.

3.5.2. Once the spill has been contained and deemed safe by the ERT, the spill owner is responsible for coordinating the clean up of the spill with facilities.

3.5.3. Similarly, if the spill is deemed a non-hazardous substance it is the spill owner who is responsible for the clean up of the spill in conjunction with facilities.

3.6. Emergency Response Team

3.6.1. Responsible for completing chemical and biological spill clean up where there is a significant EHS risk to workers and therefore workers are unable to complete the spill clean-up process outlined in this procedure.

4. Definitions and Abbreviations

4.1. ABP – Animal By Products are intermediate products of animal origin used in the manufacture of medicinal products

4.2. Bio-hazardous Material - Includes any material, which is infectious or, because of its physical and/or biological characteristics, may pose a potential hazard to human health, animals, plants, or the environment. Bio-hazardous material includes but is not limited to bacteria, fungi, viruses, mycoplasma, GMM, human and other mammalian cell lines, blood, blood products and DNA. Bio-hazardous blood products do not include those that have been filtered, irradiated, and tested to indicate non-detection of blood borne pathogens.

4.3. BSC – Biological Safety Cabinet

4.4. Chemical - A substance or mixture that has physical (e.g. flammable), health (e.g. toxic) or environmental (e.g. aquatic toxicity) hazards associated with it. Spills of pharmaceutical product will be treated in the same way as a chemical spill.

4.5. ERT - Emergency Response Team - trained to respond to emergency events including large spills of hazardous or bio-hazardous materials.

4.6. GMM - Genetically Modified Microorganism means a micro-organism in which generic material has been altered in a way that does not occur naturally by mating or natural recombination or by a combination of both

Class 1 – Activities of no or negligible risk, that is to say activities for which the level 1 containment is appropriate to protect human health as well as the environment

4.7. IPA – Isopropyl Alcohol

4.8. PPE – Personal Protective Equipment

4.9. SDS – Safety Data Sheets

4.10. Spill - is an accidental/unplanned release of a hazardous or bio-hazardous material causing a realistic possibility of an escape to air, soil, outside drain or surface water, or posing a risk of contamination of personnel or product. Releases that are planned as part of routine operations e.g. making and breaking connections are not regarded as spills and should be risk assessed and protective measures included in the relevant procedure for that activity.

4.11. Significant Spill - A spill of chemical or biological material that due to the nature and/or size of the spill is likely to cause harm to workers cleaning up the spill or to other workers in the area. Such spill required additional controls for the spill clean-up.

4.12. RA - Risk Assessment.

4.13. Risk Group 1 – Bio- hazardous Material - any organism, which is unlikely to cause human disease. Class 1 GMMs are included in this definition.
4.14. Risk Group 2 - Bio-hazardous Material/Class 2 GMM - any organism, which can cause human disease and might be a hazard to workers, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available. This includes blood or blood products that could potentially harbour blood borne pathogens.
4.15. QC – Quality Control

5. Safety Information

5.1. This procedure must be followed carefully due to potentially hazardous situations that could involve injury to workers, plant, and/or the environment.
5.2. Minimum PPE when cleaning chemical/biological spills include safety glasses, protective gloves, safety shoes and coveralls (e.g. la b coat, chemical gown). When handling spills of corrosive or toxic materials a face shield must be worn. Where there is the risk of splashing during the spill clean up a face shield must be worn.
5.3. If a splash occurs to laboratory coat, remove, and replace with a new one.

6. Procedure

6.1. Chemical and Biological Spills (Including ABP and GMM)

6.1.1. Personnel should not endanger themselves and should notify anybody who could be affected by the spill.
6.1.2. If the spill enters the drainage system, the fire water retention tank pumps in AAMF and the PenStock Valve in ADMF must be switched off / closed.
6.1.3. Determine the nature, extent, and type of spill. Spill clean-up can only proceed if the following is determined
6.1.4. Personnel must be familiar with the chemical/biological material spilled and its associated hazards/biohazards. If possible, reference should be made to the SDS for the chemical and RA for the particular Bio- hazardous material in question.
6.1.5. The spill must remain a manageable size and can be cleaned up safely and easily without presenting any significant hazards to the colleague cleaning up the spill or to any other workers in the area e.g. exposure by inhalation of harmful vapours, risk of a fire/explosion.
6.1.6. Even if the spill is a non-hazardous material e.g. water, consideration must be given to any hazards associated with the clean-up e.g. water near electrical panels or electrical equipment etc.

6.1.7. If it is deemed unsafe to complete a spill clean-up, then contact your manager/supervisor to determine the pathway forward to complete the clean-up, this may include contacting ERT.

6.1.8. The procedure is a simple 4 step approach.

6.1.8.1. Contain

6.1.8.1.1. Contain the source of the spill by isolating the source if possible, e.g. turning off a valve/pump. Prevent the material from moving further by containing the spill using spill mats.

6.1.8.2. Absorb

6.1.8.2.1. Absorb the spilled material using spill mats, soaking up the liquid. If the spill is a large spill a wet vacuum can be used to remove the spill if it will not damage the vacuum. If the material is a powder, dampen the powder with water before cleaning up to avoid the creation of dust.

6.1.8.3. Clean–up

6.1.8.3.1. Chemical: Clean up the area where splashing has occurred using wipes, absorb any remaining liquid and if necessary, request a clean of the area to remove any remaining residue.

6.1.8.3.2. Biological: Clean up the area where splashing has occurred by over spraying the spillage, with an appropriate disinfectant being careful to minimize aerosols. Allow at least 10 minutes wet contact time with disinfectant. Absorb any remaining liquid using wipes or spill mats and if necessary, request a clean of the area to remove any remaining residue.

6.1.8.3.3. GMM: In the event of a GMM Spill the area should be cleaned with suitable absorbents and placed in the Biohazard bins. The area shall then be cleaned with a solution of bleach or 0.05 Mol NaOH Solution

6.1.8.3.4. Broken glass must be picked up using forceps or puncture proof gloves. If Bio-hazardous spray the sharp items with appropriate disinfectant before being picked up.

6.1.9. Once the spill has been contained, the contents of the fire water retention tank in AAMF or the fire water retention pond in ADMF will be assessed and a suitable disposal method determined depending on the results.
If the results show that there has been no contamination, then the fire water retention pumps in AAMF or the penstock valve in ADMF will be reactivated / opened.

6.1.9.1. Manage the Waste

6.1.9.1.1. If material is non-hazardous e.g. water, glycol place spill mats in a general waste bag. There is no labelling requirement for general waste.

6.1.9.1.2. If the material is hazardous e.g. flammable, corrosive, toxic ensure all spill mats, wipes etc. are placed in red hazardous waste bags, label indicating content of waste and seal with cable tie in accordance with **ALXN-SOP-0004205, Alexion Ireland Waste Management Procedure.**

6.1.9.1.3. If the material is bio-hazardous or GMM e.g. spill mats, wipes etc. are placed in yellow bio-hazardous autoclave bags, label indicating content of waste and seal with cable in accordance with **ALXN-SOP-0004205, Alexion Ireland Waste Management Procedure.**

6.1.9.1.4. If there is a leakage of liquid out of the bags, use double bags

6.1.9.1.5. Bags should not be over filled so as to create a manual handling hazard.

6.1.9.1.6. Broken glass or other sharp items must be disposed of in a sharps bin and labelled as hazardous/bio- hazardous waste.

6.1.10. Ensure all clean-up personnel are wearing:

6.1.10.1. Nitrile or neoprene gloves

6.1.10.2. Safety shoes
6.1.10.3. Safety Glasses
6.1.10.4. Face shield for corrosive or toxic spill and/or risk of splashing
6.1.10.5. Lab coat/chemical gown/chemical suit

6.1.11. Spills including glass breakages

6.1.11.1. All broken glassware should be collected using a dustpan and brush or thongs/tweezers/Litter picker. It should not be handled where possible and disposed to a sharps bin.

6.1.11.2. Cut resistance gloves should be worn when handling glass.
6.1.11.3. Broken Glass should be collected in an appropriately classified bucket or drum.

Note: In the event you leave the spill unattended ask a colleague to stay in the area or place barrier/sign in the area or equipment where a spill has occurred.

6.2. Biological Spill within a BSC (Including GMM)

6.2.1. All microbial manipulations must be carried out within BSC.
6.2.2. Do not turn off BSC until clean-up is completed.
6.2.3. Place low lint wipes over the spill, covering area twice the size of the spill.
6.2.4. Soak low lint wipes with IPA and allow stand for 20 minutes.
6.2.5. Wipe down back and side panel of the BSC with disinfectant.
6.2.6. Use forceps to clean up any broken glass, place all broken glass into bio- hazardous sharps bin.
6.2.7. Wipe down work surface with appropriate disinfectant.
6.2.8. Place all disposable PPE and all contaminated wipes into bio-hazardous bag.

6.3. Chemical and Biological (Including ABP & GMM) Exposure

6.3.1. If exposed to a bio-hazardous material or hazardous chemical call or request a colleague to call for First Aid assistance.
6.3.2. To decontaminate areas of the body exposed to bio-hazardous materials/chemicals, follow the appropriate guidelines as outlined below:
6.3.2.1. Eyes – rinse eyes with copious amounts of water for at least 15 minutes at the nearest eyewash station.
6.3.2.2. Splashes into mouth - Wash mouth with copious amounts of water - do not swallow/ingest water.
6.3.2.3. Skin – remove all contaminated clothing and wash with copious amounts of water for at least 15 minutes.
6.3.3. Inform your supervisor of any chemical exposure including any needle stick events. Provide a copy of the SDS for the chemical you have been exposed to, if bio-hazardous materials provide copy of risk assessment, to the first aider to determine if further medical attention is required.
6.3.4. Any lab coats/gowns/overalls, which become contaminated during a chemical/bio-hazardous spill or clean up, must be disposed as hazardous/bio-hazardous waste.

7. Temporary Safety Shower

7.1. Temporary showers will be supplied and used by the ERT under the direction and supervision of ERT
7.2. Safety showers should have a minimum volume (approximately 120L) to provide to provide sufficient rinse water for at least 90 seconds to remove the initial chemical exposure.

7.3. Where a temporary shower is in place and the activities involving hazardous/bio-hazardous materials cannot cease, a plan must be prepared to allow transfer of a exposed colleague to the nearest permanent safety shower in the event of an exposure to ensure decontamination for at least 15 minutes

8. References

8.1. ALXN-SOP-0004205 - Alexion Ireland Waste Management Procedure

9. Revision History

Version	Change Type *(New, Revise or Admin)*	Description of Change(s)	Justification
4.0	Revise	• Updated references and formatting. • Updated to include detailed spill management for GMM spill *"In the event of a GMM Spill the area should be cleaned with suitable absorbents and placed in the Biohazard bins . The area shall then be cleaned with a solution of bleach or 0.05 Mol NaOH Solution"* • Re-formatting • Added Information relating to ABP • Re-defined the definition of GMM Included Biological Spills for GMM • Update PRC to SOP numbers • Section added to reference the closure / shutoff of the fire water retention tank pumps in AAMF or the penstock valve in ADMF and their reactivation.	IEL
3.0	Revise	• Re-formatting • Added information relating to ABP • Re-defined the definition of GMM • Included Biological Spill for GMM	IEL

Document Approvals

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