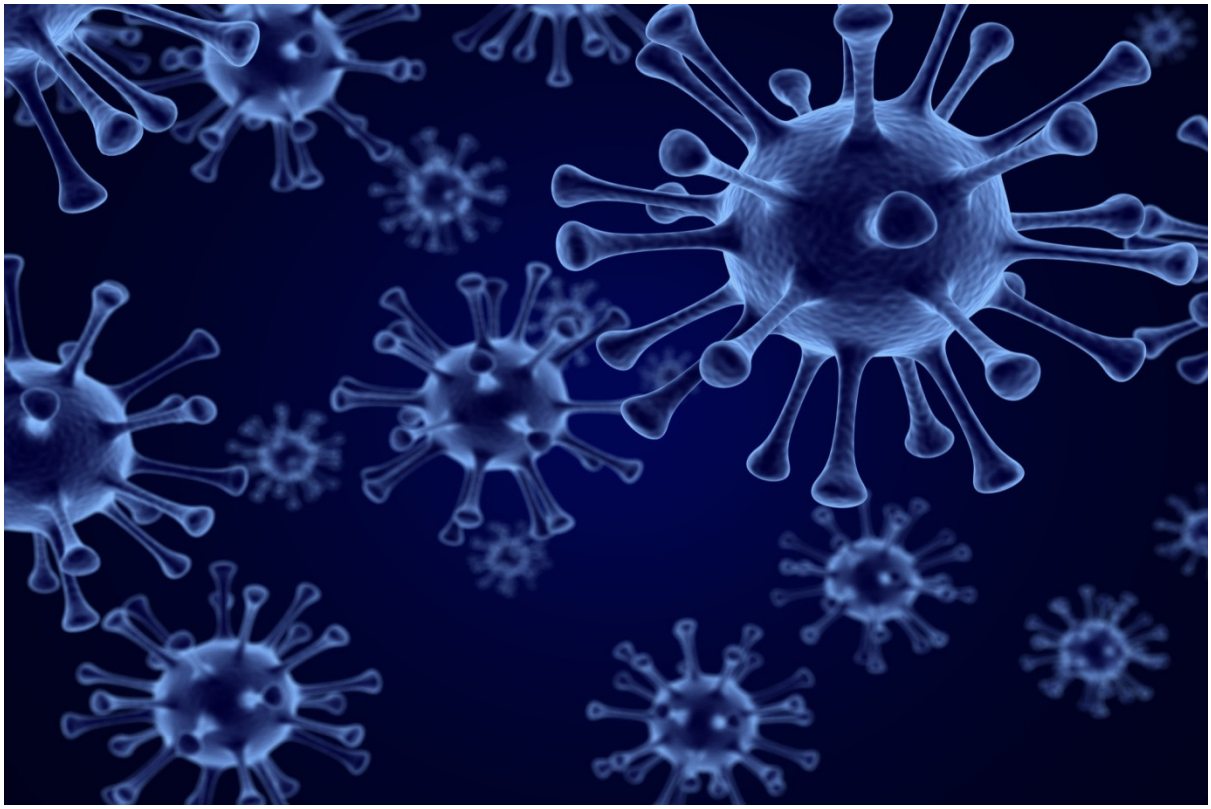
Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE Policy on the Management of Biological Agents in the Healthcare Sector



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Health Service Executive

Policy on the Management of Biological Agents in the Healthcare Sector 2017

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Signature Sheet

I have read, understood and agree to adhere to the attached Policy on the Management of Biological Agents in the Healhtcare Serctor .

Print Name	Signature	Area of Work	Date

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1.0 Policy Statement

It is the policy of the HSE to reduce, as far as is reasonably practicable, the risks associated with exposure to biological agents at work.

The HSE acknowledges that employees may be exposed through work activities to a biological agent(s) and in compliance with the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, and the associated Code of Practice (2013)(CoP), are committed to eliminating or reducing the risk of exposure. All hazards associated with exposure to a biological agent(s) will be identified, the risks assessed, control measures identified and implemented to ensure the safety and health of employees and those affected by our work activities.

2.0 Purpose

The purpose of this Policy is to raise awareness and provide support to managers (responsible persons) and employees:

- In meeting their legal obligations under the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and associated CoP and
- In the development of the necessary risk assessments and associated policies and procedures

This Policy demonstrates how the management of biological agents is an integral part of managing the control of infection and that the control measures required by health and safety legislation should already largely be in place as part of infection control procedures.
This policy supersedes the *HSE Guidance for developing the Biological Agents Risk Assessment for the Healthcare Sector 2011.*
Individual services may develop local Guidelines and/or Standard Operation Procedures to support implementation and ongoing monitoring of this Policy.

3.0 Scope

This Policy applies to all HSE employees, fixed term employees, temporary employees and students. It also applies to agency workers, contractors or any other persons work activities may involve the risk of exposure to a biological agent.

4.0 Legislation

- Safety, Health and Welfare at Work Act, 2005
- The Safety Health and Welfare at Work (General Application) Regulations, 2007
- The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (CoP)
- European Agreement concerning the International Carriage of Dangerous Goods by road 2015 (ADR 2015)
- The European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011, S.I. No. 349 of 2011 and the subsequent amendments

- The European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014 (S.I. No. 135 of 2014).
- Infectious Diseases (Amendment) Regulations 2004 (SI No. 865 of 2004)

5.0 Glossary of Terms / Definitions

Term	Definition
Biological Agent	A biological agent is a micro-organism, including those that have been genetically modified, a cell culture or a human endoparasite, which may be able to provoke any infection, allergy or toxicity, classified into 4 risk groups according to their level of risk of infection, as follows (if the biological agent to be assessed cannot be classified clearly in one of the following groups, it shall be classified in the highest risk group among the alternatives) • a "group 1 biological agent", means one that is unlikely to cause human disease to employees • a "group 2 biological agent", means one that can cause human disease and might be a hazard to employees, but is unlikely to spread to the community and in respect of which, there is usually effective prophylaxis or treatment available • a "group 3 biological agent" means one that can cause severe human disease and presents a serious hazard to employees and that may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available • a "group 4 biological agent" means one that causes severe human disease and is a serious hazard to employees and that may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available "**cell culture**" means the in-vitro growth of cells derived from multicellular organisms; "**micro-organism**" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material *(Ref: Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013)*
Employee	Means any person who has entered into or works under (or, where the employment has ceased, entered into or worked under) a contract of employment and includes a fixed-term employee and a temporary employee and references, in relation to an employer, to an employee shall be construed as references to an employee employed by that employer. *(Ref Safety, Health & Welfare at Work Act, 2005)*
Employer	In relation to an employee: (*a*) Means the person or persons with whom the employee has entered into or for whom the employee works under (or, where the employment has ceased, entered into or worked under) a contract of employment, (b) Includes a person (other than an employee of that person) under whose control and direction an employee works, and (c) Includes where appropriate the successor of the employer or an associated employer of the employer. *(Ref Safety, Health & Welfare at Work Act, 2005)*
Exposure	Means exposure of an employee at a place of work to a biological agent *(Ref: Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013)*

PPE	Personal Protective Equipment means "all equipment designed to be worn or held by an employee for protection against one or more hazards likely to endanger the employee's safety and health at work, and includes any additions and accessories to the equipment, if so designed" …. *(Ref Safety, Health & Welfare at Work (General Application) Regulations, 2007*

Abbreviations

Term	**Definition**
CoP	Code of Practice
DG	Director General
HSA	Health and Safety Authority
HSE	Health Service Executive
IPC	Infection Prevention & Control
BBF	Blood or Bodily Fluids
ND/AND	National Director/Assistant National Director
PPE	Personal Protective Equipment
SHWW Act	Safety, Health and Welfare at Work Act, 2005
HPSC	Health Protection Surveillance Centre
CO	Chief Officer
CEO	Chief Executive Officer
CHO	Community Healthcare Organisation
MOH	Medical Officer for Health

6.0 Roles and Responsibilities

6.1 Responsibilities of Director General (DG)

6.1.1 The DG has overall responsibility to ensure as far as is reasonably practicable, the safety, health and welfare at work of all employees and others affected by the activities of the HSE

6.1.2 The DG delegates accountability for co-ordinating and monitoring implementation of this Policy and any associated procedures to National Directors, Assistant National Directors, Hospital Group Chief Executive Officers, Chief Officers Community Health Organisations

6.2 Responsibilities of National Directors

6.2.1 Ensure arrangements are in place for identifying, evaluating, managing, monitoring and auditing the risks associated with work related exposure to a biological agent

6.2.2 Ensure the necessary resources are provided for implementing this Policy

6.3 Responsibilities of the Assistant National Directors, Hospital Group Chief Executive Officer's , Chief Officers Community Health Organisations

6.3.1 Ensure there are adequate and appropriate arrangements in place for the successful implementation, monitoring, evaluation, audit and review of this Policy throughout their respective areas of responsibility

6.3.2 Ensure necessary resources are allocated and are available for the implementation of this Policy

6.3.3 Ensure systems are in place to offer employees relevant vaccines free of charge and ensure employees have access to an appropriate Health Surveillance programme

6.3.4 Integrate performance indicators in relation to work related exposure to biological agents

6.4 Local Senior Managers e.g. Hospital GM/CEO, Area Manager, Operations/Business Manager or Support Services GM/Directors of Nursing are responsible to:

6.4.1 Ensure that all employees are aware of the Policy

6.4.2 Have an understanding of what constitutes a biological agent and has available to them the Safety, Health and Welfare at Work (Biological Agents) Regulations (2013) and associated CoP

6.4.3 Ensure that all hazards and the risks associated with exposure to biological agents are identified and assessed, and appropriate measures are put in place to eliminate, control or minimise the risk

6.4.4 Ensure that risk assessments are undertaken in a written format and form part of the service/site specific safety statement

6.4.5 Have access to and seek the advice of competent personnel (Health and Safety , Infection Prevention and Control , Occupational Health) as required

6.4.6 Where the risk assessment indicates that there is a risk of exposure to a biological agent for which an effective vaccine exists, ensure vaccines are offered to the employees at risk free of charge

6.4.7 Where the results of the risk assessment identifies a risk to safety, health or welfare of employees, ensure relevant health surveillance is made available

6.4.8 Ensure that employees are provided with appropriate information, instruction, supervision and training

6.4.9 Establish a waste management strategy for Healthcare Risk Waste to include the segregation, packaging and presentation of waste for collection

6.4.10 Ensure a biological agents emergency plan is in place to prevent or mitigate the potential for emergency situations

6.4.11 Ensure that incidents involving exposure to biological agents are reported and managed in accordance with *HSE Safety Incident Management Policy 2014* and ensure that remedial measures identified through incident reviews are promptly implemented

6.4.12 Ensure that where an incident or accident has or may have resulted in the release of a biological agent which could cause severe human infection or illness, (or both), report the details immediately to the HSA

6.4.13 Provide the HSA when requested with information used to complete the biological agents risk assessment

6.4.14 Where the results of the risk assessment reveal a risk to the employees health or safety provide the HSA, when requested, with the following information:

- the results of the risk assessment
- the activities in which the employee has or may have been exposed
- the number of employees exposed
- the name and competencies of the persons responsible for health and safety
- the protective and preventative measures taken, including work procedures and methods; and
- relevant emergency plans for the protection of the employees

6.4.15 Ensure an occupational exposure list is maintained of employees who may be exposed to any Group 3 or Group 4 biological agent and limited numbers of Group 2 agents as specified in the CoP for a minimum period of 10 years after the exposure

6.4.16 Ensure employees and/or their safety representative(s) have access (when requested) to the anonymised collective information in 6.4.14

6.4.17 Monitor and review the effectiveness of preventative procedures and measures

6.4.18 Audit the implementation of this Policy

6.5 Responsibilities of Line Managers

6.5.1 Responsibilities of Ward/Department/Line Managers are detailed in the local Service/Site Specific Safety Statement and hence are not reproduced here (refer to said document for further information).

In the context of this Policy responsibilities include:

6.5.2 Having an understanding of what constitutes a biological agent and have available to them the Safety, Health and Welfare at Work (Biological Agents) Regulations (2013) and associated CoP

6.5.3 Carrying out written risk assessments which identify the hazards and the risks associated with exposure to biological agents, and ensuring appropriate measures are put in place to eliminate, control or minimise the risk

6.5.4 Where the results of the risk assessment reveal that it is not technically possible to prevent exposure, apply the prevention and risk reduction measures detailed in Appendix III.

6.5.5 Where there is a risk to the health or safety of employees caused by working with a biological agent ensure:

- employees do not eat or drink in the workplace where there is a risk of contamination by a biological agent
- employees are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and skin antiseptics
- procedures are specified for taking, handling and processing samples of human origin (where appropriate)
- employees are provided with:

✓suitable work clothing,
✓special protective clothing (where necessary) and
✓ personal protective equipment (PPE)

- suitable work clothing, special protective clothing and PPE are removed on leaving the working area, kept separately from other clothing in a designated area, and checked before and after each use, and cleaned and decontaminated or, if necessary, destroyed
- Implementation of appropriate responses for possible emergencies e.g. Spill Management, management of contaminated employees

6.5.6 Carry out a Training Needs Assessment (informed by the risk assessment) to identify appropriate employee training

6.5.7 Implementing, monitoring and reviewing practices, procedures, control measures, risk assessments and the findings of incident investigation as are necessary to prevent or reduce to the lowest level reasonably practicable the risk of exposure to a biological agent.

6.6 Employee Responsibilities

6.6.1 Understand what constitutes a biological agent

6.6.2 Adhere to and apply this Policy, local procedures and safe systems of work and any associated risk assessments and risk controls

6.6.3 Work in a safe and responsible manner and take reasonable care of their own safety, health and welfare and that of others

6.6.4 Co-operate with the regular review of risk assessments and control measures

6.6.5 Not engage in improper conduct or behaviour or place anyone at risk

6.6.6 Attend training as appropriate

6.6.7 Use safety equipment or PPE provided, or other items provided for their safety, health and welfare at work

6.6.8 Report to the Line Manager any defects in equipment or the place of work and any unsafe systems of work

6.6.9 In line with the *HSE Safety Incident Management Policy 2014,* report to the Line Manager as soon as is practicable any incidents / accidents, near misses involving the exposure or release of a biological agent

Employees must not:

(i) Interfere with, misuse or damage anything provided for securing the safety, health and welfare of those at work

Failure to comply with this Policy may result in disciplinary action.

6.7 Role of Health Protection Surveillance Centre (HPSC)

6.7.1 HPSC is the specialist agency for the surveillance of communicable diseases as per International Health Regulations, 2005 and may require detailed reports and records to be kept in relation to infectious diseases.

7.0 Procedure

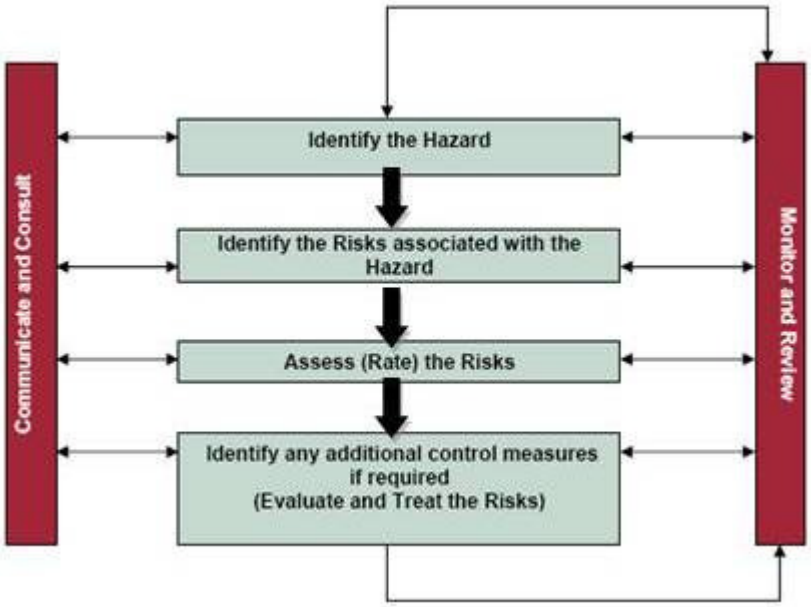
7.1 Risk Assessment

Prevention of exposure to a biological agent is an underlying principle of the Regulations. To ensure this preventative principle is followed a biological agents risk assessment must be undertaken using the CF:004:01 Biological Agents Risk Assessment Form (Appendix II) to determine if existing workplace controls are adequate. Where additional controls are identified they must take account of:

- Schedules 2, 3, 4 and 5 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (Schedule 2 contained in Appendix III) and
- Schedule 2,3 and 4 of the 2013 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (CoP) (pages 30-37).

7.1.1 The risk assessment process can be broken down into a number of steps as outlined in Figure 1.

Figure 1. Risk Assessment Process



For detailed guidance on the risk assessment process refer to Appendix I

Key Message: Undertake a biological agents risk assessment to ensure that, where a risk of injury and/or infection from a biological agent is identified, control measures are implemented to eliminate or reduce the risk (Refer to Appendix I, Appendix II and Appendix III)

7.2 Information, Training and Instruction

Where there is a risk to the safety or health of employees due to work with a biological agent, the employer must ensure that employees receive sufficient and appropriate training and information as identified through the training needs assessment to include:

- the hazardous properties of the biological agents handled
- the level, type and duration of exposure and the circumstances of work involving such biological agents
- potential risks to health
- appropriate precautions to safeguard themselves and others in the workplace to prevent exposure e.g. hygiene requirements, use of Personal Protective Equipment (PPE)
- vaccines available
- steps to be taken to prevent incidents and in the case of an incident occurring to whom potential health problems/symptoms should be reported
- the process if a suspected exposure has occurred
- standard operating procedures (SOPs) that may include some or all of the above

Training must be provided prior to commencement of work involving contact with a biological agent.

Training provided in line with the National Framework document *'Core Infection Prevention and Control Knowledge and Skills: A Framework Document', May 2015,* will provide the core Infection, Prevention & Control (IPC) knowledge and skills required by employees and others who have direct patient contact or who have a risk of exposure to blood or body fluids (BBF)

The core IPC knowledge and skills required for employees reflects the level of direct contact that they have with patients according to the following 3 Groups:

- **Group 1 - Direct patient contact with care and perform invasive procedures**
- **Group 2- Direct patient contact with care but no invasive procedures performed**
- **Group 3 - Direct patient contact in a support role or no patient contact with a BBF exposure risk**

For further details refer to Appendix IV "Core Infection Prevention and Control knowledge skills"

Infection Prevention and Control training ensures that HSE employees understand the potential risk of transmissible, infectious agents being present in blood, body fluids, secretions, excretions (except sweat), non- intact skin and mucous membranes. IPC training includes knowledge and skills on how to prevent and/ or manage any case of an infectious agent caused by a biological agent, dependent on its mode of transmission, such as by inhalation, ingestion, by direct contact etc.

Key message: Line Managers should undertake a training needs assessment based the activities undertaken by their staff and address the training requirements accordingly.

7.3 Vaccination

Where the risk assessment indicates that there is a risk of exposure to a biological agent for which an effective vaccine exists, the employer must offer the vaccine (free of charge) to the employee at risk.

The Immunisation Guidelines for Ireland, Royal College of Physicians of Ireland, list the vaccines recommended for certain categories of workers based on the type of work they carry out. See www.hpsc.ie for further information.

Employees must be informed of the benefits and drawbacks of both vaccination and non-vaccination. Records of vaccination and follow-up (where required) should be retained and should be kept confidential.

Whilst immunisation is an effective healthcare intervention, it is just one part of a wider strategy to prevent the transmission of blood borne infections. It should never be regarded as a substitute for good infection control practices such as hand-hygiene and standard precautions.

Key message: Offer employees vaccines free of charge where the risk assessment indicates that there is a risk of exposure to a biological agent for which an effective vaccine exists

7.4 Health Surveillance

Where the results of the risk assessment identifies a risk to safety, health or welfare of employees, it is the employer's duty to make available relevant health surveillance. Such health surveillance, where appropriate, must be made available prior to exposure to the biological agent(s) and at regular intervals thereafter.
Health surveillance is appropriate if:

- the exposure is such that an identifiable disease or adverse health effect may be related to it
- there is reasonable likelihood that the disease or effect may occur under particular conditions of work
- there are valid techniques for detecting indications of the disease or effect.

Key message: Make available health surveillance to employees where the results of the risk assessment identifies a risk to their safety, health or welfare

7.5 Incident Management

1. All accidents, incidents, near misses must be reported and managed in accordance with *the HSE Safety Incident Management Policy, 2014* .
2. Where there is a risk of transmission of a blood borne virus (BBV) infection the management of the injury should be in accordance with *the HSE/HPSC (2016) Guidelines for the Emeregency Management of Injuries (including needlestick and sharps injuries, sexual exposure and human bites) where there is a risk of transmission of bloodborne viruses and other infectious diseases*
   Further information can be found on: http://www.hpsc.ie/A-Z/EMIToolkit
3. In addition, where an incident or accident has or may have resulted in the release of a biological agent which could cause severe human infection or illness or both, the employer must immediately report the details to the HSA .
4. When a biological hazard is a notifiable disease in Ireland, under the Infectious Diseases (Amendment) Regulations 2016 (S.I. No. 276 of 2016), all medical practitioners and laboratories are required to notify the event to the Medical Officer of Health (MOH).

HPSC is then notified by the MOH of:

- notifiable infectious diseases
- unusual clusters and changing patterns of illness

Information on the process of notifying infectious diseases including the case definitions of the different infectious hazards and MOH contacts is available on the HPSC website.

Some infectious diseases require immediate preliminary notification to a medical officer of health (MOH).

The full list of all notifiable diseases is available at the following link:
http://www.hpsc.ie/NotifiableDiseases/ListofNotifiableDiseases/File,678,en.pdf

Key message: Ensure incidents are reported and managed, & where the release of a biological agent which could cause severe human infection or illness or both, report the details immediately to the HSA
Report notifiable diseases to the MOH to investigate and control outbreaks, and for onward notification to the HPSC.

8.0 Implementation Plan

Implementation of this Policy forms an integral part of the Safety Management Programme and is underpinned by effective consultation, communication, supervision, monitoring, audit and review.

8.1 Communication

The HSE must make this Policy available to all employees. Electronic and other communication means can be used to maximise distribution. Copies should also be made available to external providers of services to the HSE.
Managers must ensure that personnel under their supervision have read and understand the Policy. A signature sheet is provided for this purpose.

8.2 Responsibilities for Implementation

Managers (Responsible Persons) at all levels are responsible for implementing this Policy within their area (See Section 6.0) and hence develop an implementation plan, including identification of responsible persons, specifying the actions to implement the Policy and timeframes for implementation.

9.0 Monitoring, Audit and Review

9.1 Managers are required to monitor the implementation plan supporting this Policy
9.2 Managers are required to audit implementation of this Policy using the Audit Checklist in Appendix V and maintain evidence of same
9.3 Implementation of this Policy shall be audited periodically at national level
9.4 This Policy shall be reviewed at national level every three years or earlier if circumstances require it.

10.0 References

HSA (2013). Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations . http://www.hsa.ie/eng/Publications_and_Forms/Publications/Codes_of_Practice/Code_of_Practice_Biological_Agents_SI_572.pdf

HSE (2014) Corporate Safety Statment. http://www.hse.ie/eng/services/publications/corporate/css.pdf

HSA (2014) Guidelines to the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013. http://www.hsa.ie/eng/Legislation/New_Legislation/Biological%20Agents%20Regulations%202013.pdf

HSE, (2011). Risk Assessment Tool and Guidance (including Guidance on application) OQR012. https://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/riskoctober.pdf

HSE Safety Incident Managment Policy. http://www.hse.ie/eng/who/qualityandpatientsafety/incidentrisk/Riskmanagement/SafetyIncidentMgtPolicy2014.pdf

HSE/ HPSC, (2012). Guidelines for the Emergency Management of Injuries. http://www.hpsc.ie/A-Z/EMIToolkit/EMIToolkit.pdf

HSE/RCPI, (2013). Immunisations Guidelines for Ireland. http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

HSE/ RCPI, (2015). Core Infection Prevention and Control Knowledge and Skills: A Framework Document. http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/HCAI_Programme/HCAI_Documents/CoreInfectionPreventionandControl.pdf

HSE/ RCPI, (2015). Guidelines for Hand Hygiene in Irish Healthcare Settings. https://www.hpsc.ie/A-Z/Gastroenteric/Handwashing/Publications/File,15060,en.pdf

Useful websites and links

HSE Safety & Wellbeing website: http://www.hse.ie/Safetyandwellbeing States Claims Agency: http://stateclaims.ie/contact-us/reporting-events-or-incidents/

HSE Safety Statements & Risk Assessments:

https://www.hse.ie/eng/staff/safetywellbeing/HealthSafetyand%20Wellbeing/SafetyStatementsandRiskAssessments.html

Health Protection Surveillance centre: www.hpsc.ie

HSE National Immunisations Office: www.immunisation.ie

- Biological Agents: Managing the Risks in Laboratories and Healthcare Premises. HSE-UK
  http://www.hse.gov.uk/biosafety/biologagents.pdf
- Reference - HSA Signs Information Sheet 2009 (www.hsa.ie/eng/Topics/Signage/Safety_Signs/Signs_Information_Sheet.pdf)

Training Resources

HSE elearning and development service: www.hseland.ie. From this website the national 'Hand Hygeine' and 'Breaking the Chain of Infection' e- elarning programmes can be accessed.

11.0 Acknowledgements:

Members of the HSE Policy on the Management of Biological Agents in the Healthcare Sector sub group

Ms. Margo Leddy, National Health and Safety Manager (Policy Team)
Ms. Margaret Moran, Community Infection, Prevention and Control Nurse Manager
Dr. Lynda Sisson, Consultant and Accredited Specialist in Occupational Medicine
Ms. Elaine Sheridan, Admin Support, National Health and Safety Policy Team

Acknowldege contributions from:
Ms.Karen McKiernan, National Health and Safety Advisor (Information and Advice Team)
Ms. Eileen O'Connor, Occupational Health Nurse, HSE DNE

Appendix I

Steps in the Risk Assessment Process

The Risk Assessment Process comprises of the following four steps:

Step 1 - Identify the **Hazard**

Step 2- Identify the **Risks** associated with the hazard

Step 3 - **Assess** (i.e. Rate) the risks

Step 4 - Identify any additional control measures (if any) required (i.e. **evaluate and treat the risks**)

Step 1 - Identify the hazard associated with the work activity

- Consider the work activities (to include the transport of dangerous goods) /tasks/clinical procedures being undertaken where exposure to biological agents may occur
- Identify and classify the biological agent(s) in accordance with the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and Schedule 1 of the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013
- Identify route of transmission (i.e. inhalation, direct, ingestion, inoculation)

Step 2 - Identify the Risks

It is necessary to decide who is at risk from the exposure to a biological agent and the associated impact. For the purpose of the assessment:

- Identify categories of employees where exposure may be incidental (through work in the Healthcare environment) or deliberate (when working with an agent in a laboratory). These employees include (non-exhaustively):
  - Doctors, nurses, healthcare assistants, dentists, phlebotomists, laboratory personnel, household and portering staff, contractors, who may be at risk of exposure to a biological agent and should be accounted for
  - Susceptible employees e.g pregnant employees, immune-compromised patients
- Describe the risk associated with the hazard
- Consider whether existing control measures are adequate. Control programmes must accord with the prevention and risk reduction measures contained in Schedule 2, 3, 4 and 5 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, available here and schdules 2,3 and 4 of the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, available here.

Step 3 - Assess and Rate the Risk

The next step is to assess and rate the likelihood of the anticipated risk and the harm (impact) it may cause whilst taking into account any existing control measures in place. To assist with this the HSE has adopted a standardised approach to the assignment of likelihood and impact scores and the rating of risk i.e. the HSE Risk Assessment Tool. This tool should be applied uniformly to all processes where risk assessment is required. For further information, please refer to the ***HSE Integrated Risk Management Policy, Part 2, Risk Assessment and Treatment- Guidance for Managers"***

1. The Likelihood will depend on the control measures already in place, how effective they are, the experience, knowledge and skill of the employee(s) undertaking the task, the system of work and the available resources. However other contributory factors that may increase the likelihood of an incident should be considered. For example (non-exhaustive list):

   - The type of work involved and whether such activities increase the likelihood of injury, e.g. employees involved in invasive or emergency procedures.
   - The likely prevalence of disease in the patient population, e.g. Employees may be working with patients known to be (or likely to be) infected with a blood-borne virus (Hepatitis B, Hepatitis C or HIV).
   - The skill and competence of the employee(s), i.e. new or inexperienced employees may be at greater risk.
   - The patient's mental or behavioural capacity, e.g. patients who are confused or small children.
   - The work environment, e.g. working in areas that are understaffed and overcrowded.

2. Additional information from the review of incidents that have occurred and audits that have been undertaken will assist in determining the likelihood and impact of the risk.

   Based on a consideration of the above factors, a numerical likelihood rating should be selected from the "Likelihood Table".

3. Having selected a rating for the Likelihood, the process should be repeated for the Impact(s) discussed in Step 2 above. Ratings are given in the "Impact Table[1]"

4. Finally, the scores are plotted on the "HSE Risk Matrix"to determine the overall rating of the risk being assessed

Step 4 - Identify any additional control measures required

Lastly identify and document any additional control measures required.

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 builds on the Safety Health and Welfare At Work Act 2005 and place a duty on the employer to ensure that, where a risk of injury and/or infection from a biological agent is identified, control measures are implemented to eliminate or reduce the risk.

Health and Safety General Risk Assessment Form					
Division:			**Source of Risk:**		
HG/CHO/NAS/Function:			**Primary Impact Category:**		
Hospital Site/Service:			**Risk Type:**		
Dept/Service Site:			**Name of Risk Owner (BLOCKS):**		
Date of Assessment:			**Signature of Risk Owner:**		
			Risk Co-Ordinator		
Unique ID No:			**Risk Assessor (s):**		
HAZARD & RISK DESCRIPTION	**EXISTING CONTROL MEASURES**		**ADDITIONAL CONTROLS REQUIRED**	**ACTION OWNER**	**DUE DATE**
INITIAL RISK			**Risk Status**		
Likelihood	**Impact**	**Initial Risk Rating**	**Open**	**Monitor**	**Closed**

Explanatory Notes on completion of a Biological Agents Risk Assessment.

Employers are required to identify the biological agent to which employees are, or maybe, exposed. They must assess the risk, making use of the list of biological agents, their classification, containment levels and measures provided for in the *2013 Code of Practice for Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013* and proceed in accordance with the remaining Regulations where appropriate.

HAZARD & RISK DESCRIPTION	EXISTING CONTROL MEASURES	ADDITIONAL CONTROLS REQUIRED	ACTION OWNER	DUE DATE
Describe the **activity** being undertaken and the frequency of exposure. Identify the **hazard** i.e. Biological Agent(s), their Classification and the route of exposure. Refer to the 2013 Code of Practice for the Safety, Health & Welfare at Work (Biological Agents) Regulations 2013 Identify **number & category of employees** who might be affected. Describe the **associated risk.** E.g. Risk of infection from potential exposure to Hep B, Hep C or HIV to nursing staff through inoculation when giving injections on a daily basis.	Detail the existing control measures taking account of Schedule 2, 3, 4 & 5 of the Safety, Health and Welfare (Biological Agents) Regulations 2013, and Schedule 2, 3 & 4 of the Code of Practice 2013. When examining the existing control measures, consider their adequacy, method of implementation and level of effectiveness in eliminating or minimising risk to the lowest reasonably practicable level.	Detail the measures necessary to eliminate or further reduce the level of risk. Consider the hierarchy of controls: elimination/substitution /engineering/ administrative/PPE. Consider the interim and long term measures.	Enter the name of the person responsible for implementation of each additional control measure.	Enter the date by which implementation of the additional controls to mitigate the risk are due.

INITIAL RISK			RESIDUAL RISK			Status
Likelihood	Impact	Initial Risk Rating	Likelihood	Impact	Residual Risk Rating	

Appendix III

Prevention and risk reduction measures

Schedule 2 of The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

Measures to be taken where it is not technically possible to prevent exposure to a biological agent:

1. The keeping as low as possible of the number of employees exposed or likely to be exposed to a biological agent.

2. The design of work processes and engineering control measures so as to avoid or minimise the release of a biological agent into the place of work.

3. The use of both collective protection measures and individual protection measures where exposure cannot be avoided by other means.

4. The use of hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the place of work.

5. The use of the biohazard sign depicted in Schedule 3, and other relevant warning signs which are in compliance with Regulations 158 to 162 of and Schedule 9 to the Safety, Health and Welfare at Work (General Application) Regulations 2007 (S.I. No. 299 of 2007).

6. The drawing up of plans to deal with accidents involving a biological agent.

7. The testing, where necessary and technically possible, for the presence,outside the primary physical confinement, of a biological agent used at work.

8. The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.

9. The making of arrangements for the safe handling and transport of a biological agent within the place of work.

Appendix IV: Core Infection Prevention and Control knowledge and skills - click here for framework document[1]

Table 1: Core Infection Prevention and Control knowledge and skills

IPC Core Knowledge and Skills	Content	Staff Categories[1]		
		Direct patient care and invasive procedures	Direct patient care but no invasive procedures	Direct patient contact in a support role *or* No patient contact with a BBF exposure risk
Basic Microbiology	Chain of infection	√	√	√
	Healthcare-associated infections	√	√	√
	Antimicrobial resistance	√	√	√
	Infectious disease regulations	√	x	x
	Reservation/obtaining laboratory specimens	√	√	x
	Handling and transporting laboratory specimens	√	√	x
	Principles of clean to dirty workflow	√	√	√
Standard and transmission-based precautions	Introduction to standard and transmission-based precautions	√	√	√
	Hand hygiene including use of different agents, technique	√	√	√
	Respiratory hygiene and cough etiquette	√	√	√
	Management of blood or body fluid exposure	√	√	√
	Vaccination to prevent infections	√	√	√
Standard and transmission-based precautions	Infectious conditions that may require absence from work or work restrictions	√	√	√
	Personal protective equipment	√	√	√
	Safe use and disposal of sharps including use of safety devices to minimise their use	√	x	x
	Management of waste including safe disposal of sharps	√	√	√
	Environmental hygiene and management of spillages	√	√	√
	Patient care equipment/instruments and devices	√	√	√[2]
	Management of linen	√	√	x
	Safe injection practices and procedures for lumbar punctures	√	x	x
	Aseptic technique	√	x	x
	Patient placement	√	x	x
	Patient transfer	√	√	x
	Transmission-based precautions including PPE and instituting precautions based on signs and symptoms	√	√	√[2]
Clinical Assessment Skills	Awareness of how to access authoritative sources of IPC	√	x	x
	Identifying incidents and risks relating to IPC	√	√	√
	Communication relating to IPC	√	√	x

Table adapted with permission from Carrico *et al*. IPC competencies for hospital-based health care personnel. Am J Infect Control 2008 Dec; 36(10):691-701
√: This element is generally required for staff in this category. **x:** This element is not generally required for staff in this category

[1] Due to the diversity of roles within individual healthcare facilities/services, service managers may need to adjust the core knowledge and skills listed
[2] This element is not required for staff who have no direct patient contact

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[1] HSE/RCPI, (2015) Core Infectoion Prevention and Control Knowledge and Skills: A Framework Document

Appendix V Management of Biological Agents in the Healthcare Sector Audit Tool

	Audit on the Implementation of the Policy on the Management of Biological Agents in the Healthcare Sector	Yes	No	NA	Comment
1	Does the department have the Policy on the Management of Biological Agents in the Healthcare Sector 2016?				
2	Is there a system in place for the appropriate circulation/communication of this policy to all employees?				
3	Have risk assessments been completed using the National Biological Agents Risk Assessment Form (CF:004:01) for all activities where there is a potential exposure to Biological Agents?				
4	Has appropriate information, instruction, supervision and training been provided based on risk assessment?				
5	Where risk assessment indicates a risk of exposure to a Biological Agent for which there is a safe and effective vaccine, have employees been offered the vaccination in line the National Immunisation Guidelines for Ireland?				
6	Where the results of the risk assessment identifies a risk to safety, health or welfare of employees, has relevant health surveillance been made available?				
7	Is there a procedure in place for reporting accidents/incidents/near misses?				
8	Where an incident/accident or dangerous occurrence has or may have resulted in the release of a Biological Agent which could cause severe human infection or illness or both, is there a mechanism in place for reporting to the HSA?				
9	Are notifiable diseases reported to the MOH to investigate and control outbreaks, and for onward notification to the HPSC?				
10	Is there a system in place to monitor co mpliance with this Policy?				

Action Plan: Each criterion that scored 'no' must have a comment placed in the comment column – this comment will form the basis of your Quality Improvement Plan (QIP)/Action Plan

Appendix VI

Step-by -Step Procedure for Policy Implementation

Director of HR in relation to Occupational Safety and Health	Reference
• Ensure this policy is reviewed and updated as appropriate	HSE Corporate Safety Statement Section 2.5

National Health and Safety Function	
• Review and revise this Policy three yearly or following any significant change in the matters to which it relates, whichever is the soonest • Provide Occupational Safety and Health support	HSE Corporate Safety Statement Section 2.9

National Directors	
• Ensure arrangements are in place for identifying, evaluating, managing, monitoring and auditing the risk associated with work related exposure to a biological agent	6.2.1
• Ensure the necessary resources are provided for implementing this Policy	6.2.2
Assistant National Directors, Hospital Group Chief Executive Officers, Chief Officers Community Health Organisations	
• Ensure there are adequate and appropriate arrangements in place for the successful implementation, monitoring, evaluation, audit and review of this Policy throughout their respective areas of responsbilitiy	6.3.1
• Ensure necessary resources are allocated and are available for the implementation of this Policy	6.3.2
• Ensure systems are in place to offer employees relevant vaccines free of charge and ensure employees have access to an appropriate Health Surveillance programme	6.3.3
• Integrate performance indicators in relation to work related exposure to biological agents	6.3.4

Local Senior Manager	
• Ensure that all employees are aware of the Policy	6.4.1
• Have an understanding of what constitutes a biological agent and has available to them the Safety, Health & Welfare at Work (Biological Agents) Regulations (2013) and associated CoP	6.4.2
• Ensure that all hazards and the risks associated with exposure to biological agents are identified and assessed, and appropriate measures are put in place to eliminate, control or minimise the risk	6.4.3
• Ensure that risk assessments are undertaken in a written format and form part of the service/site specific safety statement	6.4.4
• Have access to and seek the advice of competent personnel (Health and Safety, Infection, Prevention & Control , Occupational Health) as required	6.4.5
• Where the risk assessment indicates that there is a risk of exposure to a biological agent for which an effective vaccine exists, ensure vaccines are	6.4.6

offered to the employees at risk free of charge	
• Where the results of the risk assessment identifies a risk to safety, health or welfare of employees, ensure relevant health surveillance is made available	6.4.7
• Ensure that employees are provided with appropriate information, instruction, supervision and training	6.4.8
• Establish a waste management strategy for Healthcare Risk Waste to include the segregation, packaging and presentation of waste for collection	6.4.9
• Ensure a biological agents emergency plan is in place to prevent or mitigate the potential for emergency situation	6.4.10
• Ensure that incidents involving exposure to biological agents are reported and managed in accordance with *HSE Safety Incident Management Policy 2014* and ensure that remdedial measures identified through incident reviews are promptly implemented	6.4.11
• Ensure that where an incident or accident has or may have resulted in the release of a biological agent which could cause severe human infection or illness, (or both), report the details immediately to the HSA	6.4.12
• Provide the HSA when requested with information used to complete the biological agents risk assessment	6.4.13
• Where the results of the risk assessment reveal a risk to the employees health or safety provide the HSA, when requested, with the following information: ◦ the results of the risk assessment ◦ the activities in which the employee has or may have been exposed ◦ the number of employees exposed ◦ the name and competencies of the persons responsible for health and safety ◦ the protective and preventative measures taken, including work procedures and methods; and ◦ relevant emergency plans for the protection of the employees	6.4.14
• Ensure an occupational exposure list is maintained of employees who may be exposed to any Group 3 or Group 4 biological agent and limited numbers of Group 2 agents as specified in the CoP for a minimum period of 10 years after the exposure	6.4.15
• Ensure employees and/or their safety representative(s) have access (when requested) to the anonymised collective information in 6.4.14	6.4.16
• Monitor and review the effectiveness of preventative procedures and measures	6.4.17
• Audit the implementation of this Policy	6.4.18

Line Managers e.g. Clinical Directors, Ward Managers, Department Managers, Service Managers, (Responsible Persons) are responsible:	
• Have an understanding of what constitutes a biological agent and have available to them the Safety, Health & Welfare at Work (Biological Agents) Regulations (2013) and associated CoP	6.5.2
• Carrying out written risk assessments which identify the hazards and the risks associated with exposure to biological agents, and ensuring appropriate measures are put in place to eliminate, control or minimise the risk	6.5.3
• Where the results of the risk assessment reveal that it is not technically possible to prevent exposure, apply the prevention and risk reduction measures detailed in Appendix III	6.5.4

• Where there is a risk to the health or safety of employees caused by working with a biological agent ensure:
  • employees do not eat or drink in the workplace where there is a risk of contamination by a biological agent
  • employees are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and skin antiseptics
  • procedures are specified for taking, handling and processing samples of human origin (where appropriate)
  • employees are provided with:
  ✓ suitable work clothing,
  ✓ special protective clothing (where necessary) and
  ✓ personal protective equipment (PPE)
  • suitable work clothing, special protective clothing and PPE are removed on leaving the working area, kept separately from other clothing in a designated area, and checked before and after each use, and cleaned and decontaminated or, if necessary, destroyed
	6.5.5

• Carrying out a training needs assessment (informed by the risk assessment) to identify appropriate employee training	6.5.6
• Implementing, monitoring and reviewing practices, procedures, control measures, risk assessments and the findings of incident investigation as are necessary to prevent or reduce to the lowest level reasonably practicable the risk of exposure to a biological agent	6.5.7

Employee	
• Have an understanding of what constitutes a biological agent	6.6.1
• Adhere to and apply this Policy, local procedures and safe system of work and any associated risk assessments and risk controls	6.6.2
• Work in a safe and responsible manner and take reasonable care of their own safety, health and welfare and that of others	6.6.3
• Co-operate with the regular review of risk assessments and control measures	6.6.4
• Not engage in improper conduct or behaviour or place anyone at risk	6.6.5
• Attend training as appropriate	6.6.6
• Use safety equipment or PPE provided, or other items provided for their safety, health and welfare at work	6.6.7
• Report to the Line Manager any defects in equipment or the place of work and any unsafe systems of work	6.6.8
• In line with the *HSE Safety Incident Management Policy 2014* report to the Line Manager as soon as is practicable any incidents/accidents, near misses involving the exposure or release of a biological agent	6.6.9

Health Protection Surveillance Centre (HPSC)	
• HPSC is the specialist agency for surveillance of communicable diseases as per International Health Regulations, 2005 and may require detailed reports and records to be kept in relation to infectious diseases	6.7.1

Appendix VII
Implementation Plan

Implementation of this Policy forms an integral part of the Safety Management System and is underpinned by effective consultation, communication, supervision, monitoring, audit and review. The following flowchart illustrates the day to day implementation steps.