HSE Policy on the Management of Biological Agents[1] in the Healthcare Sector 2022

Policy ☒ Procedure ☐ Protocol ☐ Guideline ☐

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4	Feburary 2022	Step 3 Assess and Rate the Risk – Updated link to HSE Risk Assessment Tool	NHSF
4	February 2022	Appenidx 1 Risk Assessment Tool – Removed	NHSF

[1] Biological Agents include bacteria, viruses (e.g. HIV, COVID-19), fungi (including yeasts and moulds) and internal human parasites (endoparasites)

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PART A:

1.0 Introduction

Biological agents are widely found in the natural environment and as a result are found in many work sectors. They include bacteria, viruses (e.g. HIV, COVID-19, influenza), fungi (including yeasts and moulds) and internal human parasites (endoparasites). **"Biological agent" means micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity[2].**

In the healthcare environment, exposure to biological agents can be:

- Deliberate or intentional, where the employee works directly (recognised and planned) with the biological agent, in a laboratory or research facility, or
- Incidental or unintentional, where the employee is potentially exposed to the biological agent as a consequence of their work e.g. a healthcare worker may be exposed through direct contact with patients or with contaminated materials, including waste, laundry, contaminated surfaces etc.

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 set down obligations on employers regarding the determination and assessment of risk with respect to biological agents; the prevention and control of exposure to hazardous biological agents; specific protection and preventive measures; arrangements to deal with accidents, incidents and emergencies; information, training and consultation; health surveillance; record-keeping; notification requirements to the Health and Safety Authority (HSA); and duties for employees.

Prevention of exposure to a biological agent is an underlying principle of the Regulations. To ensure this preventative principle is followed a documented biological agents risk assessment must be undertaken 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 I) and
- Schedule 2, and 4 of the 2020 Biological Agents Code of Practice [3] (pages 46-47 and pages 51-56)

The Biological Agents Risk Assessment form is available to download here.

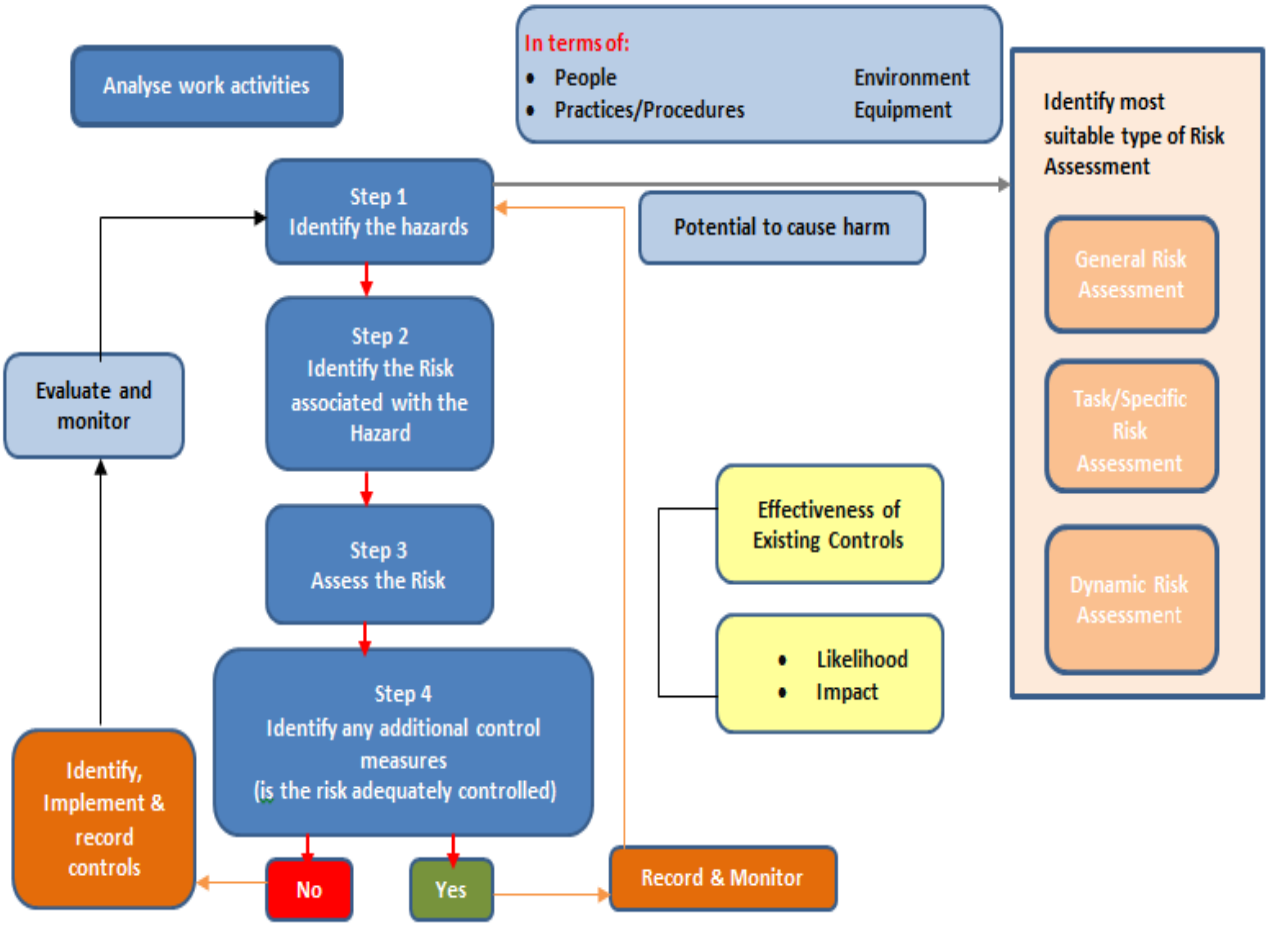
The management of biological agents is an integral part of managing the control of infection and control measures required by legislation should be largely in place as part of infection control procedures.

Key Message: Undertake a biological agent's risk assessment to ensure that, where a risk of injury and/or infection from a biological agent (bacteria, virus (e.g. COVID-19, HIV), fungi or human parasites) is identified, control measures are implemented to eliminate or reduce the risk.

[2] Safety, Health and welfare at Work (Biological Agents) Regulations 2013 and 2020

[3] Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020), hereafter referred to as the 2020 Biological Agents Code of Practice,

Figure 1. Risk Assessment Process



1.1 Risk Assessment Process

Step 1 - Identify the hazard associated with the work activity	
Consider the work activities where exposure to biological agents may occur	Examples (non-exhaustive): • Clinical activities e.g. caring for any patient or service user and particularly those who have or are likely to have a bacterial infection e.g. tuberculosis, or a viral infection e.g. Norovirus, influenza, COVID-19, HIV etc. • Laboratory activities e.g. testing of pus, sputum, faeces, blood and other biological samples • Preparation of biological specimens for transport[4] • Handling and disposal of waste and particularly clinical risk waste

[4] For further advice, see (HSE, 2019) Guidelines for the Preparation for Transport pf Patient Specimens and other Biological Materials

Identify and classify the biological agent(s) in accordance with the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 and Schedule 1 of the 2020 Biological Agents Code of Practice	Examples (non-exhaustive): • Group 2 Biological Agent e.g. Legionella, norovirus, influenza • Group 3 Biological Agent e.g. Mycobacterium tuberculosis , SARS-CoV-2 virus • Group 4 Biological Agent e.g. Ebola Virus
Identify route of transmission	• Direct contact • Droplet • Airborne (inhalation) • Ingestion • Inoculation

If there is the potential for a risk of infection continue with the Risk Assessment as outlined below

Step 2 - Identify the risks associated with the hazard - Identify who is at risk of exposure and examine the work environment and work practices.	
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-exhaustive): • Doctors, nurses, healthcare assistants, dentists, allied health professionals, phlebotomists, medical scientists, other laboratory personnel, household, portering staff, contractors, who may be at risk of exposure to a biological agent and should be accounted for • Sensitive risk and at risk employees e.g. pregnant employees and immuno suppressed individuals
Consider the work environment where there is the potential for exposure to biological agents	Overcrowded conditions, poor infrastructure, fatigue, stress and emergency situations could increase the risk of exposure to biological agents
Consider the training, competence and experience and supervision of employees	Training received based on training needs assessment (refer to section 4.0) Supervision of • Work practices, systems of work • New and inexperienced staff (who may be at greater risk of potential exposure to biological agents)

Step 3 – Assess and Rate the Risk

The next step is to:

(1) Identify and document the existing control measures and

(2) Assess and rate the risk associated with the hazard taking into account any existing control measures (Refer to Risk Assessment Tool)

- The likelihood and impact 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, level of supervision provided, the system of work and the available resources
- Other contributory factors that may increase the likelihood of an incident should also be considered including:
    - The type of work involved and whether such activities increase the likelihood of infection, e.g. employees involved in invasive, emergency, or aerosol generating procedures associated with an increased risk of infection
    - 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 and HIV) or respiratory infections e.g. COVID-19 and TB
    - The skill and competence of the employee(s), i.e. new or inexperienced employees may be at greater risk
    - The service users mental or behavioural capacity, e.g. patients who have challenging behaviours
    - The work environment, e.g. working in areas that are understaffed and overcrowded

- 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 and impact rating should be selected from the Risk Assessment Tool

Step 4 – Identify any additional control measures required

If the risk is not adequately controlled, further measures must be considered.

Where additional controls are identified account must be taken of:

- Schedules 2, 3, 4 and 5 of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (Schedule 2 contained in Appendix I, Part A)

- For Laboratories and Isolation Facilities account must be taken of Schedule 2 and Schedule 4 of the 2020 Biological Agents Code of Practice (pages 46 – 47 and pages 51-56)

Note: Schedule 4 of the 2020 Biological Agents Code of Practice lists the dispensation from minimum containment measures for Laboratories for certain Group 3 biological agents (pages 51-56)

2.0 Monitoring and Periodic Review

Once control measures have been introduced, they must be evaluated on a regular basis to assess their effectiveness and ensure they are achieving the desired result. This should be proactive to include audits/workplace inspections, analysing local performance indicators, and reactive following an incident.

In line with legislation risk assessments must be reviewed where:
(a) There has been significant change in the matters to which they relate
(b) There is another reason to believe they are no longer valid.

Examples include: when new procedures, new equipment, technology, personnel or biological agents are introduced.

It is best practice and HSE policy, to review risk assessments at least annually.

3.0 Communication and Notification of Risk

Where additional resources are required for the control of a hazard and such resources are not immediately available, the risks associated with the hazard should be incorporated onto the relevant risk register and prioritised for action or notified to the next level. In the interim the risk will continue to be managed and monitored so far as is reasonably practicable at local level and the relevant manager informed of any changing circumstances[5].

4.0 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 and circumstances of exposure
- 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), cleaning and disinfection, social/physical distancing measures etc.
- 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
- Local standard operating procedures (SOPs) that may include some or all of the above

Training must be provided prior to commencement of work involving incidental exposure to 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). For further details refer to Part A, Appendix II "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),

[5] HSE, (2017), Integrated Risk Management Policy (Part 3, Managing and Monitoring Risk Registers) – Guidance for Managers 2017

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 contact, droplet, airborne, ingestion or inoculation.

In addition a number of HPSC / HSE training supports are available. These include HPSC video resources and HSELand modules – 'Supporting Resources in the Fight Against COVID-19'.

For specific guidance for laboratories please refer to Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible or confirmed infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

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

5.0 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.

The risk assessment should also consider non-responders to vaccinations or employees who do not wish to avail of vaccinations, as additional control measures may be required.

Whilst immunisation is an effective healthcare intervention, it is just one part of a wider strategy to prevent the transmission of 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.

6.0 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. Health surveillance, where appropriate, must be made available prior to exposure to the biological agent(s) and at regular intervals as necessary 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.

7.0 Incident Management

1. All incidents must be reported and managed in accordance with *the HSE Incident Management Framework*
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 Emergency 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. Incidents involving potential exposure to COVID-19 must also be reported and managed in accordance with HPSC/HSE *Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health*
4. Cases of COVID-19 disease, or death, in employees resulting from confirmed occupational exposure in connection with the carrying out of work with coronavirus (SARs-CoV-2) are reportable to the HSA
5. In addition, where an accident or incident 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
6. When a biological hazard is a notifiable disease in Ireland, under the Infectious Diseases (Amendment) Regulations 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:
https://www.hpsc.ie/notifiablediseases/listofnotifiablediseases/

Key message:
Ensure:

- Incidents are reported and managed in line with HSE policy
- Incidents involving potential exposure to COVID-19 are reported and managed in accordance with HPSC/HSE *Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health*
- Cases of COVID-19 disease, or death, in employees resulting from confirmed occupational exposure in connection with the carrying out of work with coronavirus (SARs-CoV-2) are reportable to the HSA
- Where the release of a biological agent could cause severe human infection or illness or both, the details are reported immediately to the HSA.
- Ensure notifiable diseases are reported to the MOH to investigate and control outbreaks, and for onward notification to the HPSC.

8.0 Roles and Responsibilities

8.1 Chief Executive Officer (CEO)

The CEO has overarching responsibility to ensure, so far as is reasonably practicable the safety, health and welfare at work of all employees and others affected by the HSE activities by:

8.1.1 Ensuring that arrangements are in place for identifying, evaluating and managing the risks associated with exposure to biological agents

8.1.2 Ensuring compliance with this Policy

8.1.3 Delegating operational responsibility for the day-to-day discharge of statutory duties under the Safety, Health and Welfare at Work, 2005 to the Executive Management Team, Senior Management Team, Extended Senior Management Team, Senior Managers and Line Managers for all matters within their control

8.2 Local Senior Management e.g. Hospital GM/CEO, Heads of Service, Directors of Nursing

8.2.1 Ensure that all employees are aware of this Policy

8.2.2 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 2020 and the 2020 Biological Agents Code of Practice

8.2.3 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

8.2.4 Ensure that risk assessments are undertaken in a written format and form part of the site or service safety statement

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

8.2.6 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

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

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

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

8.2.10 Ensure a biological agent's emergency plan is in place to prevent or mitigate the potential for emergency situations

8.2.11 Ensure that incidents involving exposure to biological agents are reported and managed in accordance with *HSE Incident Management Framework* and HPSC/HSE *Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health* and ensure that remedial measures identified through incident reviews are promptly implemented

8.2.12 Ensure any case of COVID-19 disease, or death, in an employee resulting from a confirmed occupational exposure in connection with the carrying out of their work with coronavirus (SARs-CoV-2) is reported to the HSA

8.2.13 Ensure that where an accident or incident 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

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

8.2.15 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

8.2.16 Ensure an occupational exposure [6] 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 2020 Biological Agents Code of Practice for a minimum period of 10 years after the exposure

8.2.17 Ensure employees and/or their safety representative(s) have access (when requested) to the anonymised collective information in 8.2.14

8.2.18 Monitor and review the effectiveness of preventative procedures and measures

8.3 Line Managers - Clinical Directors, Ward Managers, Department Managers, Service Managers, Person in Charge (Responsible Persons)

General responsibilities of Line Managers are documented in the local Site or Service Safety Statement and hence are not reproduced here (refer to said document for further information). However, the integral role of the Line Manager in assessing and reducing the risk from exposure to a biological agent in day-to-day healthcare work activities include:

8.3.1 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 2020 and the associated 2020 Biological Agents Code of Practice

[6] In the case of certain biological agents with chronic health effects (denoted by "D" in Schedule 1 of the 2020 COP), this list must be kept for a longer period not exceeding 40 years

8.3.2 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

8.3.3 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 I, Part A

8.3.4 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 hand hygiene facilities, washing and toilet facilities, which may include eye washes and supplies of suitable solution for skin decontamination
- 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

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

8.3.6 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

8.4 Employees

8.4.1 Understand what constitutes a biological agent

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

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

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

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

8.4.6 Attend training as appropriate

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

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

8.4.9 In line with the *HSE Incident Management Framework*, report to the Line Manager as soon as is practicable any accidents/incidents, near misses involving the exposure or release of a biological agent and any case of COVID-19 disease resulting from a confirmed occupational exposure in connection with the carrying out of work with coronavirus (SARs-CoV-2)

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.

8.5 Health Protection Surveillance Centre (HPSC)

8.5.1 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.

Appendix I 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 II Core Infection Prevention and Control knowledge and skills - click here for framework document[7]

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

PART B:

1.0 Initiation

1.1 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 2020 and the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020), hereafter referred to as the 2020 Biological Agents Code of Practice
- To provide a framework for the effective management of biological agents to include the development and review of biological agents risk assessments

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 prevention control procedures.

Note: This Policy supersedes the HSE Policy on the Management of Biological Agents in the Healthcare Sector, 2020 (*HSP:009:04*) and must be implemented with immediate effect.

1.2 Policy Statement

It is the policy of the HSE to reduce, so 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 2020 and the associated 2020 Biological Agents Code of Practice are committed to eliminating or reducing the risk of exposure. Healthcare workers may be exposed to a wide range of viruses and bacteria e.g. influenza, COVID-19, tuberculosis, hepatitis and HIV infection[8].

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.

To prevent and or minimise the potential exposure, biological agents risk assessments will be conducted and the necessary preventive and protective measures implemented to ensure the safety and health of employees and those affected by our work activities.

1.3 Scope

1.3.1 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 which may involve the risk of exposure to a biological agent.

In line with the HSE Code of Governance (2015) Section 38 and Section 39 organisations are to adopt this policy or develop a policy of their own which is consistent with this policy and provide an assurance to the HSE regarding same.

[8] EU OSHA (2019) Exposure to Biological Agents and Related Health Problems for Healthcare Workers

1.3.2 Out of Scope

This Policy does not address Sharps injuries in healthcare settings which may result in the transmission of blood borne viruses (BBV) such as Hepatitis B (HBV), Hepatitis C (HCV) or Human Immune Deficiency Virus (HIV). This is covered in the HSE Policy on the Prevention and Management of Sharps Injuries, 2020.

1.4 Objective

To review and update the HSE Policy on the Management of Biological Agents in the Healthcare Sector, 2020 in line with Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 Regulations and 2020 Biological Agents Code of Practice

1.5 Outcomes

- A safer working environment for employees and others who fall under the scope of this policy by providing a framework for managing exposure to biological agents
- Clear roles and responsibilities of responsible persons are clearly outlined as part of this policy
- The management of biological agents is incorporated into the risk assessment process
- There is clear guidance on preventative and protective measures, containment measures and containment levels to minimise the risks associated with exposure to biological agents in the context of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 and the associated 2020 Biological Agents Code of Practice
- Clear guidance on the requirements for incident management and reporting to the Health and Safety Authority

1.6. Policy Development Group

Members of the Policy Development Group can be found in Part B, Appendix II of this Policy. Conflict of Interest Declaration Forms were signed by members of the Policy Development Group and are retained on file by the National Health and Safety Function (NHSF), Policy Team.

1.7 Policy Governance Group

Members of the Policy Governance Group can be found in Part B, Appendix III of this Policy.

1.8 Supporting Evidence

1.8.1 The following legislation is pertinent and was referred to during the development of this Policy:

- 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
- Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations 2020
- Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020)
- European Agreement concerning the International Carriage of Dangerous Goods by road 2019 (ADR 2019)
- 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 2020 (SI No. 53/2020)
- European Agency for Safety and Health at Work (EU-OSHA), (undated), Exposure to Biological Agents and Related Health Problems for Healthcare Workers available at: https://osha.europa.eu/en/publications/exposure-biological-agents-and-related-health-problems-healthcare-workers/view

1.8.2 Related PPPGs

- HSE Policy on the Management of Sharps and Prevention of Sharp injuries (available here)
- HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials (available here)
- See https://www.hpsc.ie/ for latest Infection, Prevention and Control guidance documents
- HPSC/HSE Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health
- HSE Incident Management Framework (available here)

1.9 Glossary of Terms/Definitions/Abbreviations

Refer to Appendix IV, Part B.

2.0 Development of Policy

2.1 Literature Review Question

The objective of the literature review was to identify any legislative updates, establish current evidence and best practice in relation to the management of biological agents in the health and social care setting.

2.2 Literature Search Strategy

A literature review was undertaken by the Policy Development Working Group. The search terms used were 'biological agents', 'infectious diseases', 'healthcare associated infections' (HCAI), 'infection prevention control' (IPC), 'preventative and protective measures', 'containment levels'. Search dates were confined from 2017-2020.

Websites accessed included the following: hse.ie, hsa.ie, hse.gov.uk, hpsc.ie, gov.ie, eu-osha.eu,
The literature accessed was predominately legislation, articles, commentaries or health organisation policies or guidance.

2.3 Method of appraising evidence

The process outlined in this document is based on a review of the relevant legislation, codes of practice and relevant publications as documented in section 1.8 and Section 8.0.

The following questions were considered:

- The legislative requirements under the Biological Agents Regulations and associated Code of Practice
- Definition of a biological agent
- The risk of infection to healthcare workers from biological agents
- The preventative and protective measures, containment measures and containment levels to minimise the risks associated with exposure to biological agents

Information which was deemed relevant for the purpose of reviewing this policy was extracted from these sources.

2.4 Recommendations

The Policy Development Working Group reviewed the results from the literature review in relation to the prevention of exposure to a Biological Agent. The evidence supported the objectives as outlined in Section 1.4.

Key recommendations from the literature review are to:

- Review and revise the HSEs national policy to support implementation of The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 and the 2020 Code of Practice in order to meet the objectives set out in section 1.4
- The management of biological agents is an integral part of managing the control of infection
- Highlight the importance of information, training and instruction
- Raise awareness of vaccination programmes available for healthcare workers
- Promote the reporting and management of incidents and ensure corrective actions are implemented

These recommendations informed the revision of this Policy as set out in Part A of this document.

2.5 Resources necessary to implement the PPPG Recommendations

This policy revision requires local senior managers and line managers to review existing practices and procedures to ensure they are aligned with the requirements as set out in this Policy.

3.0 Governance and Approval

Formal governance for this policy is provided by the National Director of Human Resources (see Appendix III, Part B). The PPPG Checklist for developing Non-Clinical PPPGs was signed prior to approval and is retained on file by the NHSF, Policy Team.

4.0 Communication and Dissemination

The Policy will be disseminated by the National HR Directorate for immediate implementation by relevant Services, in line with the agreed HSE protocol and is available on https://healthservice.hse.ie/staff/benefits-services/health-and-safety/

5.0 Implementation

5.1 Managers (Responsible Persons) are responsible for implementation of this policy to include the identification of responsible person(s), specifying the necessary actions and timeframes for implementation within their areas of responsibility.

5.2 Education & Training

To support implementation of this Policy, any queries and or requests for training can be made through the National Health and Safety Function, Helpdesk
https://healthservice.hse.ie/staff/benefits-services/health-and-safety/

6.0 Monitoring, Audit and Evaluation

6.1 Managers are required to monitor and audit the implementation of this Policy within their area of responsibility using the checklist in appendix V, Part B and maintain evidence of same.

6.2 Implementation of this Policy shall be audited periodically at national level and by the National Health and Safety Function.

7.0 Revision/Update

7.1 This Policy shall be reviewed at national level every three years or earlier if circumstances require it.

8.0 References

General

HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020)
https://www.hsa.ie/eng/Publications_and_Forms/Publications/Codes_of_Practice/biological_agents_code_of_practice_2020.93153.shortcut.html

HSE Corporate Safety Statement
https://healthservice.hse.ie/filelibrary/staff/corporate-safety-statement-2020.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 (2017) Integrated Risk Management Policy, 2017.
https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/hse%20integrated%20risk%20management%20policy%202017.pdf

HSE, (2020) Incident Management Framework
https://www.hse.ie/eng/about/qavd/incident-management/

Health Protection Surveillance centre (HPSC), (Sept 2012, updated 2016, updated 2018), Guidelines for the Emergency 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
http://www.hpsc.ie/A-Z/EMIToolkit/EMIToolkit.pdf

HSE/RCPI, (2015). 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
https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhai/guidelines/File,15111,en.pdf

HSE/ RCPI, (2015). Guidelines for Hand Hygiene in Irish Healthcare Settings https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhai/guidelines/File,15060,en.pdf

Useful websites and links

HSE Safety & Wellbeing website: https://healthservice.hse.ie/staff/benefits-services/health-and-safety/

States Claims Agency: http://stateclaims.ie/contact-us/reporting-events-or-incidents/

HSE Safety Statements: https://healthservice.hse.ie/staff/benefits-services/health-and-safety/safety-statement.html

HSE Risk Assessments: https://healthservice.hse.ie/staff/benefits-services/health-and-safety/carrying-out-a-risk-assessment.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 (https://www.hsa.ie/eng/Publications_and_Forms/Publications/Information_Sheets/Safety_and_Health_Signs_Information_Sheet.html)

Training Resources

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

In addition a number of HPSC / HSE training supports are available. These include HPSC video resources and HSELand modules – 'Supporting Resources in the Fight Against COVID-19'.

9.0 Appendices

Appendix I	**Signature Sheet**
Appendix II	**Membership of the Policy Development Group**
Appendix III	**Membership of Policy Governance Group**
Appendix IV	**Glossary of Terms/Definitions/Abbreviations**
Appendix V	**Checklist for the implementation of the HSE Policy on the Management of Biological Agents in the Healthcare Sector**

Appendix I

Signature Sheet

I have read, understand and agree to adhere to this Policy and Procedure:

Print Name	Signature	Area of Work	Date

Appendix II Membership of the Policy Development Group

Brid Cooney, National Health and Safety Advisor
Elaine Sheridan, Health and Safety Admin Support
Chairperson: Ms. Margo Leddy, National Health and Safety Manager

Acknowledgements:

The Policy Development Subgroup would like to acknowledge the contribution of:

Dr. Lynda Sisson, HSE HR Lead - Staff Health and Wellbeing and Occupational Health, Diversity and Inclusion Lead.

Dr. Lena Murphy, Specialist Registrar in Occupational Medicine, Workplace Health and Wellbeing.

Ms. Mary McKenna, Infection, Prevention and Control, Assistant Director of Nursing, HPSC.

Professor Martin Cormican, Consultant Microbiologist, Galway University Hospitals, Professor of Bacteriology NUI Galway School of Medicine, National Clinical Lead Antimicrobial Resistance & Infection Control Team.

Appendix III Membership of the Policy Governance Group

Anne Marie Hoey, National Director HR	Signature:  Date: 12.01.2021
Nicholas Parkinson, Head of National Health and Safety Function	Signature: Date:

Appendix IV Glossary of Terms/Definitions/Abbreviations

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)*
Containment Level	Refers to the four biosafety levels ranging from basic containment level 1 [CL1] to the maximum containment level 4 [CL4]. Containment levels may also be referred to as biosafety levels [BSL-1 to BSL-4]. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*
Containment Measures	Refer to the design features, construction, containment facilities, equipment, practices and operational procedures required for working with biological agents from the various risk groups. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*
Deliberate/Intentional exposure	Refers to where an employee works directly with a biological agent such as in a laboratory or research facility. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*

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)*
Incidental/ unintentional exposure	Refers to where an employee is exposed to the biological agent due to their work, for example a healthcare worker who is exposed to a blood borne virus. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*
Isolation Facility	Refers to a room, unit or suite where human patients who are or are suspected of being infected with a group 3 or group 4 biological agent are isolated in order to minimise the risk of infection.
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)*
Schedule 1 of the 2020 Biological Agents Code of Practice	Lists the applicable biological agents (bacteria, fungi, helminths, protozoa, prions and viruses) and their classifications, including any relevant notes (e.g. T=toxin, A=allergen, V=vaccine available). *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*
Schedule 2 of the 2020 Biological Agents Code of Practice	Lists the containment measures and containment levels for Laboratories and Isolation Facilities. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*

Schedule 4 of the 2020 Biological Agents Code of Practice	Lists the dispensation from minimum containment measures for Laboratories for certain Group 3 biological agents. *(Ref: HSA (2020) Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020))*

Abbreviations

HSA	Health and Safety Authority
HSE	Health Service Executive
IPC	Infection Prevention & Control
BBF	Blood or Bodily Fluids
PPE	Personal Protective Equipment
HPSC	Health Protection Surveillance Centre
CEO	Chief Executive Officer
MOH	Medical Officer -of Health

Appendix V Checklist for the implementation of the HSE Policy on the Management of Biological Agents in the Healthcare Sector

	Checklist for the implementation of the HSE Policy on the Management of Biological Agents in the Healthcare Sector, 2022	Yes	No	NA	Comment
1	Is there a system in place for the appropriate circulation/communication of this Policy to all employees?				
2	Does each relevant department / unit have access to this Policy?				
3	Have biological agents risk assessments been completed in line with the risk assessment process as outlined in Part A - Figure 1?				
4	Where the risk is not adequately controlled have additional measures been identified utilising the hierarchy of control outlined in Part A - Step 4?				
5	Have the control measures identified been implemented?				
6	Have control measures been evaluated (proactively and reactively) to determine their effectiveness?				
7	Where identified risks cannot be managed are they communicated and notified onto the relevant risk register for action?				
8	Has appropriate information, awareness and training been provided based on an assessment of training needs?				
9	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 Immunisation Guidelines for Ireland?				
10	Is there a procedure in place for reporting incidents in line with the HSE Incident Management Framework?				
11	Are reported incidents and complaints analysed regularly to identify learning and support quality improvements?				
12	Is there a system in place for reporting and managing potential exposure to COVID-19 in accordance with HPSC/HSE, Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health?				
13	Is there a system in place for reporting cases of COVID-19 disease, or death, in an employee resulting from a confirmed occupational exposure in connection with the carrying out of their work with coronavirus (SARs-CoV-2) to the HSA?				
14	Is there a system in place to report incidents to the HSA where, the release of a biological agent could cause severe human infection or illness or both (reference Part A- Section 7)?				

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