Guideline Document

Ref: GD:012:01	**Guidance to support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'**				
Issue date:	May 2020	**Revised Date:**	August 2021	**Version No:**	2
Authors(s):	National Health & Safety Function (NHSF)				
Consultation With:					
Responsibility for Implementation:	All HSE Managers and employees whose laboratory work activities involve the risk of exposure to a COVID -19 during this pandemic phase.				
Note:	This guidance has been developed to support Managers when reviewing their Laboratory Biological Agents Risk Assessment during the COVID -19 pandemic. It is based on the interim guidance issued by the World Health Organization - *WHO (2020) Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19)* available at: https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2020-(covid-19) and on advice issued from the Health Protection Surveillance Centre (HPSC) https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/laboratoryguidance/ The guidance referenced in this document may be subject to change, hence all managers and employees must check HSE.ie daily to keep informed of up to date information and advice.					

Version	Date approved	Section amended	Author
2	August 2021	Reference to Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, updated throughout the document to reflect the 2020 Regulations and COP	NHSF
2	August 2021	**Manager Responsibilities** Included bullet point "Ensure a confirmed case of COVID-19 or death of an employee (e.g. informed by a medical practitioner, public health or other health professional) as a result of the employee carrying out work with the coronavirus (SARS-CoV-2) is notified to the Health and Safety Authority"	NHSF
2	August 2021	**CF:052:01 Biological Agents RA to support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'** Front Cover – inserted reference to legislation	NHSF
2	August 2021	**CF:052:01 Biological Agents RA to support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'** New question 60 "There are arrangements in place for a Manager to notify the Health and Safety Authority when they become aware of a confirmed case of COVID-19 or death of an employee (e.g. informed by a medical practitioner, public health or other health professional) as a result of the employee carrying out work with the coronavirus (SARS-CoV-2) https://www.hsa.ie/eng/topics/covid-19_coronavirus_information_and_resources/covid-19_guidance_and_advice/guidance_and_advice/covid_19_%E2%80%93_faqs_and_advice_for_employers_and_employees/reporting_of_covid-19_cases.html"	NHSF

Table of Contents

1.0	Introduction	3
2.0	Purpose	3
3.0	Scope	3
4.0	Roles and Responsibilities	3
5.0	Risk Assessment	4
6.0	Supporting Information	6
7.0	References	6
Appendix I- Health and Safety Risk Assessment Form to support the review And updating of Lab Biological Agents Risk Assessment Form		7

1.0 Introduction:

During this phase of COVID-19 pandemic many HSE Laboratories are testing clinical specimens of patients who meet the case definition of Coronavirus COVID-19. COVID-19 has been categorised as a Group 3 Biological Agent.

It is the policy of the HSE to reduce, as far as is reasonably practicable, the risks associated with exposure to COVID-19 and acknowledges that some employees may potentially be exposed through their work activities (e.g. Laboratory personnel) to COVID-19 and are committed to eliminating or reducing the risk of exposure.

2.0 Purpose:

This guideline has been developed to support Laboratory managers and employees in reviewing and updating their Laboratory Biological Agents Risk Assessment during the COVID -19 pandemic.

3.0 Scope:

This guideline applies to all Laboratory managers and employees whose work activities may involve the potential risk of exposure to a COVID-19 during this pandemic phase.

4.0 Roles and Responsibilities:

The Safety, Health and Welfare (Biological Agents) Regulations 2013 and 2020, places specific duties on managers and employees and are detailed in the ***HSE Policy on the Management of Biological Agents in the Healthcare Setting*** and are not reproduced here. In summary responsibilities are as follows:

Manager Responsibilities:

- Ensure that all hazards and the risks associated with exposure to COVID-19 are identified and assessed, and appropriate measures are put in place to eliminate, control or minimise the risk
- Ensure the risk assessment is in a written format (Refer to Appendix I)
- Where the results of the risk assessment identifies a risk to safety, health or welfare of employees, ensure relevant health surveillance is made available
- Ensure that employees are provided with appropriate information, instruction, supervision and training
- Ensure the implementation of appropriate responses for possible emergencies e.g. Spill management, management of contaminated employees
- Ensure that incidents involving potential exposure to COVID-19 are reported and managed in accordance with *Interim Guidance for Coronavirus- Healthcare Worker Management by Occupational Health* and *The HSE Incident Management Framework* and ensure that remedial measures identified through incident reviews are promptly implemented
- Ensure a confirmed case of COVID-19 or death of an employee (e.g. informed by a medical practitioner, public health or other health professional) as a result of the employee carrying out work with the coronavirus (SARS-CoV-2) is notified to the Health and Safety Authority.

Employee Responsibilities:

- Adhere to local procedures and safe systems of work and any associated risk assessments and risk controls
- Work in a safe and responsible manner and take reasonable care of their own safety, health and welfare and that of others
- Co-operate with the regular review of risk assessments and control measures
- Not engage in improper conduct or behaviour or place anyone at risk
- Attend training as appropriate
- Use safety equipment or PPE provided, or other items provided for their safety, health and welfare at work
- Report to the Line Manager any defects in equipment or the place of work and any unsafe systems of work
- Report any incident involving exposure or risk of exposure, to, or release of, a biological agent involving or likely to involve a risk to the health or safety of an employee.

5.0 Risk Assessment

The risk assessment process is broken down into four steps as outlined in Figure 1.

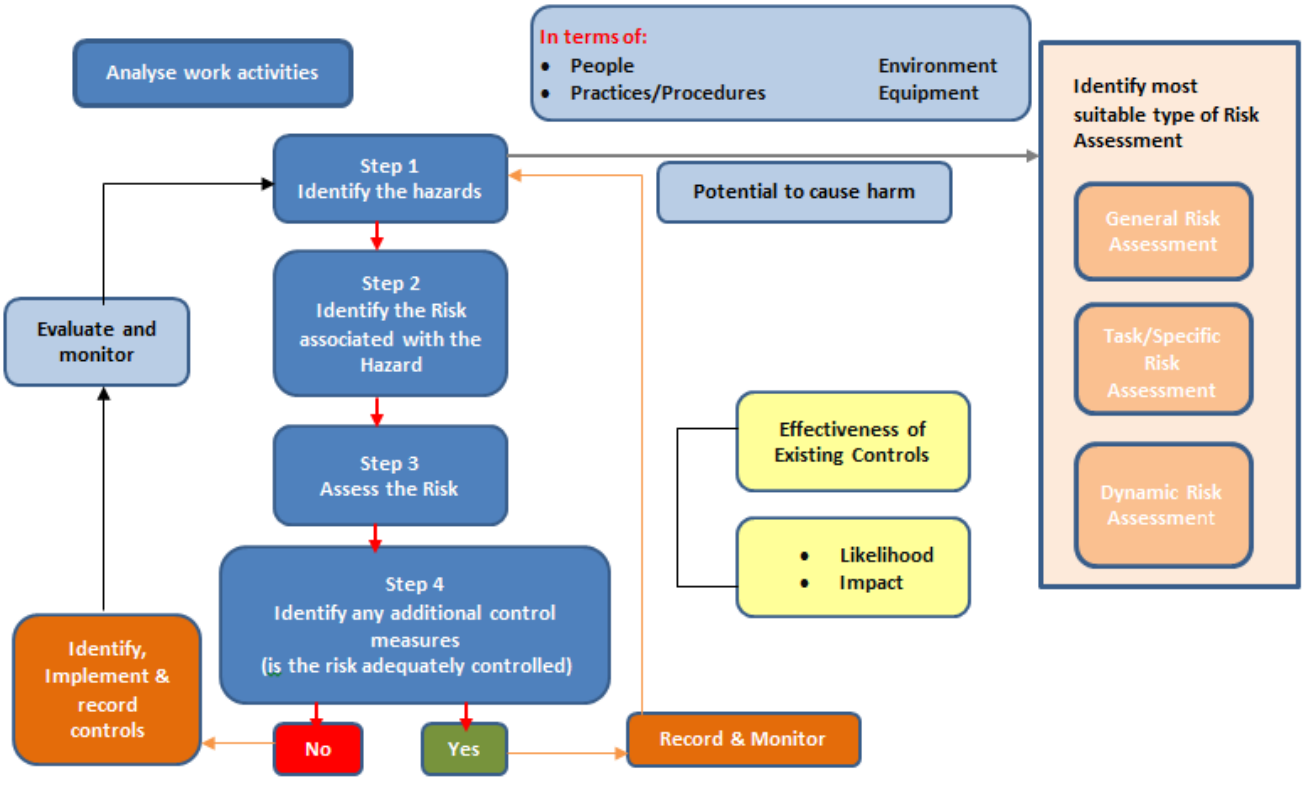

Figure 1

Note: The Risk Assessment Form in Appendix I must be used for the purpose of recording the assessment

5.1 Steps in the Risk Assessment Process

The risk assessment process **for a given task** comprises of the following four steps:

Step 1 - Identify the Hazard – Document the laboratory activities that are planned with COVID-19, the length of time of exposure to the infectious agent, the concentration of the virus during exposure, the method and route of exposure, the nature of the manipulations to be performed (formation of aerosols, use of needles, lancets or sharp instruments) etc.

Step 2- Identify the Risks associated with the hazard.

For the purpose of the assessment:

- Identify categories of employees who may be exposed
- Describe the risk associated with the hazard
- Consider whether existing control measures are adequate.

The *WHO (2020) Laboratory biosafety guidance related to coronavirus disease (COVID-19) Interim guidance* highlights the following laboratory biosafety measures:

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.
- Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2).
- Propagative work (for example, virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3).
- Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds).
- Patient specimens from suspected or confirmed cases should be transported as UN3373, “Biological Substance Category B”. Viral cultures or isolates should be transported as Category A, UN2814, “infectious substance, affecting humans”.

The Core requirements as per WHO (2020) Laboratory biosafety guidance related to coronavirus disease (COVID-19) have been integrated into the risk assessment process to assist in identifying both the existing control measures in place (tick YES) and any additional controls required (tick NO).

Note: 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 and 2020, and schedules 2, and 4 of the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2020.

Step 3 - Assess (i.e. Rate) the risks (Refer to HSE Risk Assessment Tool)
https://www.hse.ie/eng/about/qavd/riskmanagement/risk-assessment-tool.pdf

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

Where additional control measures are identified these should be documented on the Biological Agents Risk Assessment Form, assigned an 'action owner' and 'due date' for completion.

(See Appendix 1 Laboratory Biological Agents Risk Assessments during COVID 19)

6.0 Supporting Information

- HSE Policy on the Management of Biological Agents in the Healthcare Sector
- Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 and 2020
- CF:004:02 Guidance on Completion of Biological Agents Risk Assessment form

For further health and safety advice or support during the COVID-19 pandemic, please contact the HSE health and safety helpdesk by visiting https://healthservice.hse.ie/staff/benefits-services/health-and-safety/health-and-safety-helpdesk.html or alternatively phone 1850 420 420

7.0 References

- WHO (2020) Laboratory biosafety guidance related to coronavirus disease (COVID-19)
- HPSC/HSE (2021) Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible or confirmed infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Version 1.1 06.01.2021
- Herman, P., Verlinden, Y., Breyer, D., Van Cleemput E., Brochier, B., Sneyers, M., Snacker, R., Hermans, P., Kerkhofs, P., Liesnard, C., Rombaut, B., Van Ranst, M., Van der Groen, G., Goubau, P., and Moens, W., (2004) Biosafety Risk Assessment of the Severe Acute Respiratory Syndrome (SARS) Coronavirus and Containment Measures for the Diagnostic and Research Laboratories
- Interim Guidance for Coronavirus – Healthcare Worker Management by Occupational Health

Appendix I

Health & Safety Risk Assessment Form

Ref: CF:052:01	**To support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'**				
Issue date:	May 2020	**Revised date:**	August 2021	**Version No.**	2
Author(s):	National Health & Safety Function (NHSF)				
Legislation:	Under Section 19 of the ***Safety, Health and Welfare at Work Act, 2005*** and associated Regulations**,** it is the duty of the employer to identify the hazards and assess the associated risks in the workplace. All risk assessments must be in writing and the necessary control measures to eliminate or minimise the risks documented and implemented.				
Note:	The Core requirements as per *WHO (2020) Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19)* have been integrated into the risk assessment process to assist in identifying both the existing control measures in place (tick YES) and any additional controls required (tick NO). Where additional control measures are identified these should be documented on the Biological Agents Risk Assessment Form, assigned an 'action owner' and 'due date' for completion.				

To support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'			
Division:		**Source of Risk:**	
HG/CHO/NAS/ Function:		**Primary Impact Category:**	
Hospital Site/Service:		**Risk Type:**	
Dept/Service Site:		**Name of Risk Owner:**	
Date of Assessment:		**Signature of Risk Owner:**	
Unique ID No:		**Risk Co-Ordinator:**	
		***Risk Assessor(s):**	

Amendments to the Risk Assessment

Version	Date approved	Section amended	Author
2	August 2021	**CF:052:01 Biological Agents RA to support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'** Front Cover – inserted reference to legislation	NHSF
2	August 2021	**CF:052:01 Biological Agents RA to support the review and updating of Laboratory Biological Agents Risk Assessments during COVID 19'** New question 60 "There are arrangements in place for a Manager to notify the Health and Safety Authority when they become aware of a confirmed case of COVID-19 or death of an employee (e.g. informed by a medical practitioner, public health or other health professional) as a result of the employee carrying out work with	NHSF

		the coronavirus (SARS-CoV-2) https://www.hsa.ie/eng/topics/covid-19_coronavirus_information_and_resources/covid-19_guidance_and_advice/guidance_and_advice/covid_19_%E2%80%93_faqs_and advice_for_employers_and_employees/reporting_of_covid-19_cases.html"	

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
Good microbiological practice and procedure (GMPP)					
1	Never store food or drink, or personal items such as coats and bags in the laboratory. Activities such as eating, drinking, smoking and/or applying cosmetics are only to be performed outside the laboratory				
2	Never put materials such as pens, pencils or gum in the mouth while inside the laboratory, regardless of having gloved hands or not				
3	Thoroughly wash hands preferably with warm running water and soap after handling any biological material, before leaving the laboratory, and any time contamination is known or suspected to be present on the hands				
4	Ensure open flames or heat sources are never placed near flammable supplies and are never left unattended				
5	Ensure that coverings are placed over any cuts or broken skin prior to entering the laboratory				
6	Ensure, prior to entry into the laboratory, that supplies of laboratory equipment and consumables, including reagents, PPE and disinfectants, are sufficient and appropriate for the activities being performed				
7	Ensure supplies are stored appropriately (that is, according to storage instructions) and safely, to reduce the chance of accidents and incidents such as spills, trips or falls for laboratory personnel				
8	Ensure proper labelling of all biological agents and chemical and radioactive material				
9	Protect written documents from contamination using barriers (such as plastic coverings), particularly those that may need to be removed from the laboratory				
10	Ensure work is performed with care, in a timely manner and without rushing. Working when fatigued should be avoided				
11	Keep the work area tidy, clean and free of clutter and materials that are not necessary for the work being done				
12	Prohibit the use of earphones, which can distract personnel and prevent equipment or facility alarms from being heard				
13	Appropriately cover or remove any jewellery that could tear glove material, easily become contaminated or act as a fomite for infection. If worn regularly, cleaning and decontamination of the jewellery or spectacles should be considered				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
14	Refrain from using mobile electronic devices (for example, mobile telephones, tablets, laptops, flash drives, memory sticks, cameras and/or other portable devices, including those used for DNA/RNA sequencing) when not specifically required for the laboratory procedures being performed				
15	Keep mobile electronic devices in areas where they could not easily become contaminated or act as a fomite for infection. Where close proximity of such devices to biological agents is unavoidable, ensure they are either protected by a physical barrier or decontaminated before leaving the laboratory				
Technical procedures					
16	Avoid inhalation of biological agents. Use good techniques to minimize the formation of aerosols and droplets when manipulating specimens				
17	Avoid ingestion of biological agents and contact with the skin and eyes				
18	Wear disposable gloves at all times when handling specimens				
19	Avoid contact of gloved hands with the face				
20	Shield or otherwise protect the mouth, eyes and face during procedures where splashes may occur				
21	Wherever possible, replace any glassware with plastic ware				
22	For work needing scissors, use scissors with blunt or rounded ends in preference to those with pointed ends				
23	Handle all sharps, syringes and needles, if necessary, with care so as to prevent injury and injection of biological agents				
24	Use of ampoule openers for safe handling of ampoules				
25	Never re-cap, clip or remove needles from disposable syringes				
26	Dispose of any sharps materials (for example, needles, needles combined with syringes, blades, broken glass) in puncture- proof or puncture- resistant containers fitted with sealed covers				
27	Preventing dispersal of biological agents: - Discard specimens and cultures for disposal in leak-proof containers with the tops appropriately secured before disposal in dedicated waste containers - Consider opening tubes with disinfectant-soaked pad/gauze - Decontaminate work surfaces with a suitable disinfectant at the end of the work procedures and if any material is spilled or obviously contaminated - Ensure the disinfectant is efficacious against the pathogen being handled and is left in contact with infectious waste materials for sufficient time to effect complete inactivation				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
Personal competence and training					
	General familiarisation and awareness training				
28	General training should include an introduction to laboratory layout, codes of practice, local guidelines, safety manuals, risk assessments, legislative requirements and emergency response procedures				
	Job specific training				
29	Training requirements may vary depending on the job functions				
30	In general, all personnel involved in the handling of biological agents must be trained on GMPP				
31	Competency and proficiency assessment must be used and verified before working independently, followed by regular review and refresher training				
32	Relevant information such as new procedures must be updated and communicated to applicable personnel				
	Safety and Security Training				
33	All personnel must be aware of hazards present in the laboratory and their associated risks; safe working procedures; security measures; and emergency preparedness and response				
Facility Design					
34	Ample space and a designated hand-washing basin must be provided, with appropriate restriction to access				
35	Doors must be appropriately labelled, and laboratory walls, floors and furniture must be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory				
36	Laboratory ventilation, where provided (including heating/cooling systems and especially fans/local cooling split-system air-conditioning units- specifically when retrofitted) should ensure airflows do not compromise safe working. Consideration must be made of resultant airflow speeds and directions, and turbulent airflows should be avoided; this applies also to natural ventilation				
37	Laboratory space and facilities must be adequate and appropriate for safe handling and storage of infectious and other hazardous materials, such as chemicals and solvents				
38	Facilities for eating and drinking must be provided outside the laboratory, and first-aid-facilities must be accessible				
39	Appropriate methods for decontamination of waste, for example disinfectants and autoclaves, must be available in proximity to the laboratory				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
40	The management of waste must be considered in the laboratory design. Safety systems must cover fire, electrical emergencies and emergency/incident response facilities, based on risk assessment				
41	There must be a reliable and adequate electricity supply and lighting to permit safe exit				
42	Emergency situations must be considered in the design, as indicated in the local risk assessment, and should include the geographical/meteorological context				
Specimen receipt and storage					
43	A specimen received by the laboratory must be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed				
44	Consider unpacking the items in the Biological Safety Cabinet (BSC). Personnel unpacking and receiving specimens must be adequately trained in awareness of the hazards involved; how to adopt necessary precautions according to GMPP described earlier, how to handle broken or leaking containers, and how to handle spills and use disinfectants to manage any contamination				
45	Specimens must be stored in containers with adequate strength, integrity and volume to contain the specimen, leakproof when the cap or stopper is correctly applied; made of plastic whenever possible; free of any biological material on the outside of the packaging; correctly labelled, marked and recorded to facilitate identification; and made of an appropriate material for the type of storage required				
46	Inactivation methods must be appropriately validated whenever an inactivation step is used, before transferring the specimens to other areas for further manipulation, such as PCR analysis				
Decontamination and waste management					
47	Any surface or material known to be, or potentially be, contaminated by biological agents during laboratory operations must be correctly disinfected to control infectious risks				
48	Proper processes for the identification and segregation of contaminated materials must be adopted before decontamination and/or disposal				
49	Where decontamination cannot be performed in the laboratory area or onsite, the contaminated waste must be packaged in an approved (that is, leakproof) manner, for the transfer to another facility with decontamination capacity				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
Personal Protective Equipment (PPE)					
50	Laboratory coats must be used in laboratories to prevent personal clothing from getting splashed or contaminated by biological agents. Laboratory coats must have long sleeves, preferably with elasticated or fitted cuffs, and must be worn closed. Sleeves should never be rolled up. Coats must be long enough to cover the knees, but not trail on the floor. They should be fastened when worn in the laboratory. Where possible, the fabric of the laboratory coat should be splash-resistant and overlap to provide a solid front. Laboratory coats must only be worn in designated areas. When not in use, they should be stored appropriately; they should not be hung on top of other laboratory coats, or in lockers or hooks with personal items				
51	Appropriate disposable gloves must be worn for all procedures that may involve planned or inadvertent contact with blood, body fluids or other potentially infectious materials. They must not be disinfected or reused, as exposure to disinfectants and prolonged wear will reduce the integrity of the glove and decrease protection to the user. Gloves should always be inspected before use, to check they are intact				
52	Safety glasses, safety goggles, face shields (visors) or other protective devices must be worn whenever it is necessary to protect the eyes and face from splashes, impacting objects or artificial ultraviolet radiation. Eye protection can be reused, but must be regularly cleaned after every use. If splashed, it must be decontaminated with an appropriate disinfectant				
53	Footwear must be worn in the laboratory and must be of a design that minimizes slips and trips and can reduce the likelihood of injury from falling objects and exposure to biological agents				
54	Respiratory protection is generally not a part of the core requirements. In this particular context, however, a local risk assessment should be conducted to determine whether the use of respiratory protection is needed, especially when procedures that may create aerosols and droplets will be performed outside the BSC, for example, centrifugation, handling leaking samples and procedures that can cause splashes (for example, loading and unloading of sealed centrifuge cups, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressure may be different from the ambient pressure)				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
Laboratory equipment					
55	When used effectively together with GMPP, the safe use of laboratory equipment will help to minimize the likelihood of exposure of personnel when handling or manipulating biological agents				
56	For equipment to effectively reduce risks, laboratory management must make sure sufficient space is provided for its use. An appropriate budget must be available for the equipment's operation and maintenance, including equipment incorporated into the facility design, which should be accompanied by specifications that outline its safety features. All personnel operating or maintaining a piece of equipment must be properly trained and be able to demonstrate proficiency				
Emergency/Incident Response					
57	Even when carrying out low-risk work and following all core requirements for biosafety, incidents can still occur. To reduce the likelihood of exposure to/release of a biological agent, or to reduce the consequences of such incidents, a contingency plan must be developed that provides specific standard operating procedures (SOPs) to be followed in possible emergency scenarios that apply to the work and local environment. Personnel must be trained on these procedures and have periodic refresher training in order to maintain competency				
58	First-aid kits, including medical supplies such as bottled eye washes and bandages, must be available and easily accessible to personnel. These must be checked routinely to make sure products are within their use-by dates and are in sufficient supply				
59	There is a system in place for managing and reporting incidents of COVID-19 in line with *Interim Guidance for Coronavirus - Healthcare Worker Management by Occupational Health* and the HSE Incident Management Framework				
60	There are arrangements in place for a Manager to notify the Health and Safety Authority when they become aware of a confirmed case of COVID-19 or death of an employee (e.g. informed by a medical practitioner, public health or other health professional) as a result of the employee carrying out work with the coronavirus (SARS-CoV-2) https://www.hsa.ie/eng/topics/covid-19_coronavirus_information_and_resources/covid-19_guidance_and_advice/guidance_and_advice/covid_19_%E2%80%93_faqs_and_advice_for_employers_and_employees/reporting_of_covid-19_cases.html				

No.	Hazard controls to be considered when carrying out your risk assessment	Yes	No	N/A	Comment
Emergency/Incident Response					
61	Spill kits, including disinfectant, must be easily accessible to personnel. Depending on the size, location, concentration and/or volume of the spill, different protocols may be necessary. Written procedures for cleaning and decontaminating spills must be developed for the laboratory and followed by suitably trained personnel				
Occupational Health					
62	Access to Occupational Health Service regarding the provision of medical advice on COVID 19 related issues				

Use the columns below to document any local existing control measures not referenced above	
No.	

**HAZARD & RISK DESCRIPTION	EXISTING CONTROL MEASURES	ADDITIONAL CONTROLS REQUIRED	ACTION OWNER (i.e. the Person responsible for the action)	DUE DATE

INITIAL RISK			Risk Status		
Likelihood	Impact	Initial Risk Rating	Open	Monitor	Closed

Risk Assessor to be recorded for OSH risks only

Where the risk being assessed relates to an OSH risk please ensure that the HAZARD and associated risk are recorded on the form. All other risk assessments require a risk description only