**CWA 15793:2011 Planning and Implementation**

Evaluation Report

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# CWA Requirement 4.1.1: Biorisk management system

The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this laboratory biorisk management standard.

## Guiding Questions:

1. Have all elements of the biorisk management system been demonstrably established and implemented?

Institutional Response: {pgZero\_gqOne}

1. Is the biorisk management system currently operational?

Institutional Response: {pgZero\_gqTwo}

1. Is the biorisk management system documentation in accordance with the requirements of CWA 15793:2011?

Institutional Response: {pgZero\_gqThree}

1. Does the biorisk management system include references and links to the management systems related to other risks present in the work place, such as operational controls and general safety?

Institutional Response: {pgZero\_gqFour}

1. Has top management determined if current biorisk management documentation is sufficiently comprehensive to ensure that the biorisk management programme can be adequately understood and effectively and efficiently implemented?

Institutional Response: {pgZero\_gqFive}

### What is the importance of this requirement?

Institutional Response: {pgZero\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgZero\_range}

# CWA Requirement 4.1.2: Continual improvement

The organization shall continually improve the effectiveness of the biorisk management system through the use of the policy, objectives, self-audit programme, audit results, analysis of data, risk assessment, corrective and preventative actions and the management review.

## Guiding Questions:

1. Does the organization perform self-audits of their biorisk management system on regular intervals?

Institutional Response: {pgOne\_gqOne}

1. Does the organization document review of risk assessments, policies and procedures, and update control measures as necessary through a defined change management process?

Institutional Response: {pgOne\_gqTwo}

1. Does the organization retain documentation of corrective and preventative actions taken since the last regular review of the biorisk management system?

Institutional Response: {pgOne\_gqThree}

1. Does the organization document improvements made to the biorisk management system following regular reviews?

Institutional Response: {pgOne\_gqFour}

1. Does the biorisk management policy clearly state the biorisk management objectives and the commitment to improve biorisk management performance?

Institutional Response: {pgOne\_gqFive}

1. Are biorisk management improvement goals established and documented, based on a regular review?

Institutional Response: {pgOne\_gqSix}

1. Are specific objectives to meet biorisk management system improvement goals established and documented?

Institutional Response: {pgOne\_gqSeven}

1. Is a regular review of the biorisk management system based on performance-related information performed, and areas for improvement identified?

Institutional Response: {pgOne\_gqEight}

1. Does the review include an evaluation of the status of the organization's progress towards the achievement of goals and objectives?

Institutional Response: {pgOne\_gqNine}

### What is the importance of this requirement?

Institutional Response: {pgOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgOne\_range}

# CWA Requirement 4.2.1: Biorisk management policy

The organization’s top management shall develop, authorize, and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity). It shall clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance. The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities and commit to: a) protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility; b) reducing the risk of unintentional release of, or exposure to biological agents and toxins; c) reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures; d) complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard; e) ensuring that the need for effective biorisk management shall take precedence over all non “health and safety” operational requirements; f) effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups; g) continually improving biorisk management performance.

## Guiding Questions:

1. Has a biorisk management policy been written, authorized, and signed by top management?

Institutional Response: {pgTwo\_gqOne}

1. Does the biorisk management policy clearly state the biorisk management objectives and commitment to improve biorisk management performance?

Institutional Response: {pgTwo\_gqTwo}

1. Is the policy appropriate to the nature and scale of the risk associated with the facility and associated activities?

Institutional Response: {pgTwo\_gqThree}

1. Does the biorisk management policy establish organizational commitments in line with the requirements of section 4.2.1 of CWA 15793:2011?

Institutional Response: {pgTwo\_gqFour}

1. Is the biorisk management policy regularly reviewed to ensure its continued suitability, and updated as appropriate?

Institutional Response: {pgTwo\_gqFive}

1. Does the biorisk management policy require all relevant projects and/or work areas to be assessed for biological risks and a full assessment prepared, before work is approved to commence?

Institutional Response: {pgTwo\_gqSix}

1. Does the biorisk management policy demonstrate that the organization and top management are committed to implementing and monitoring an effective biorisk management system?

Institutional Response: {pgTwo\_gqSeven}

1. Does the policy commit to protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility?

Institutional Response: {pgTwo\_gqEight}

1. Does the policy commit to reducing the risk of unintentional release of, or exposure to biological agents and toxins?

Institutional Response: {pgTwo\_gqNine}

1. Does the policy commit to reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures?

Institutional Response: {pgTwo\_gqTen}

1. Does the policy commit to complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard?

Institutional Response: {pgTwo\_gqEleven}

1. Does the policy commit to ensuring that the need for effective biorisk management shall take precedence over all non “health and safety” operational requirements?

Institutional Response: {pgTwo\_gqTwelve}

1. Does the policy commit to effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups?

Institutional Response: {pgTwo\_gqThirteen}

1. Does the policy commit to continually improving biorisk management performance?

Institutional Response: {pgTwo\_gqFourteen}

1. Is the biorisk management policy well integrated and compatible with the organization's other health, safety and environmental policies (HSE)?

Institutional Response: {pgTwo\_gqFifteen}

### What is the importance of this requirement?

Institutional Response: {pgTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwo\_range}

# CWA Requirement 4.3.1.1: Planning and resources

The organization shall ensure that a risk assessment system is established, implemented and maintained in accordance with this standard and that the performance of the risk management system is reported to senior management for review and as a basis for improvement. The organization shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review. The organization should continuously assess and mitigate risk. The organization should seek to understand the hazards and threats in and around the facility, the risk that they pose to employees and the surrounding community, and the impact they could have on operations. Planning for hazard identification, risk assessment, and risk control should include understanding the external influences which may define the level of risk tolerance and risk control measures.

## Guiding Questions:

1. Does planning for hazard identification, risk assessment, and risk control include analysis of legal and other requirements?

Institutional Response: {pgThree\_gqOne}

1. Does planning for hazard identification, risk assessment, and risk control include a review of internal policy?

Institutional Response: {pgThree\_gqTwo}

1. Does planning for hazard identification, risk assessment, and risk control include management approval of and provision of appropriate resources?

Institutional Response: {pgThree\_gqThree}

1. Does planning for hazard identification, risk assessment, and risk control include qualification and training of personnel?

Institutional Response: {pgThree\_gqFour}

1. Are the roles and responsibilities of personnel who perform and verify work affecting biorisk management defined and documented?

Institutional Response: {pgThree\_gqFive}

1. Does planning for hazard identification, risk assessment, and risk control include defining a process for identifying biological hazards within the organization?

Institutional Response: {pgThree\_gqSix}

1. Does planning for hazard identification, risk assessment, and risk control include defining a process for identifying hazards and threats in the environment around the organization?

Institutional Response: {pgThree\_gqSeven}

1. Does planning for hazard identification, risk assessment, and risk control include identifying and understanding the external influences on risk tolerance (risk acceptance) and risk control measures?

Institutional Response: {pgThree\_gqEight}

1. Does planning for hazard identification, risk assessment, and risk control include mechanisms to communicate and consult internally and externally as appropriate?

Institutional Response: {pgThree\_gqNine}

### What is the importance of this requirement?

Institutional Response: {pgThree\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThree\_range}

# CWA Requirement 4.3.1.2: Risk assessment timing and scope

The organization shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive. Risk assessments should be carried out before new activities begin. Risk assessment also should be conducted whenever there is a change that affects the work environment, or in response to a laboratory incident. Risk assessments should be applied to all procedures and activities in the facility, including normal operations, periodic or rare laboratory procedures, and cleaning and maintenance. The scope of the risk assessment should be focused on specific procedures and agents; multiple risk assessments may be required to adequately identify the risks and use the assessment to support risk control efforts. Conducting risk assessments requires a comprehensive understanding of the organization’s activities.

## Guiding Questions:

1. Do the following events trigger either a new risk assessment or review of an existing one?

Institutional Response: {pgFour\_gqOne}

1. Is a risk assessment performed or an existing risk assessment reviewed upon commencement of new work or changes to the programme of work, including the introduction of new biological agents or alterations to work flow or volume?

Institutional Response: {pgFour\_gqTwo}

1. Is a risk assessment performed or an existing risk assessment reviewed upon new construction/modifications to laboratories, plant and equipment, or its operation?

Institutional Response: {pgFour\_gqThree}

1. Is a risk assessment performed or an existing risk assessment reviewed upon introduction of altered or unplanned staffing arrangements (including contractors, visitors, and other noncore personnel)?

Institutional Response: {pgFour\_gqFour}

1. Is a risk assessment performed or an existing risk assessment reviewed upon significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection/waste management methodologies, Personal Protective Equipment (PPE), provision/usage entry/exit protocols, etc.)?

Institutional Response: {pgFour\_gqFive}

1. Is a risk assessment performed or an existing risk assessment reviewed following the occurrence of unexpected events that may have relevance for the management of biorisks are observed, such as accidents, incidents (near misses) or changes in the security threat environment?

Institutional Response: {pgFour\_gqSix}

1. Is a risk assessment performed or an existing risk assessment reviewed upon discovery of an actual or potential non-conformity with internal or external rules and regulations?

Institutional Response: {pgFour\_gqSeven}

1. Does the scope of risk assessments include consideration of emergency response and contingency planning requirements?

Institutional Response: {pgFour\_gqEight}

1. Is a risk assessment performed or an existing risk assessment reviewed upon occurrence of an existing management system review process (e.g. annually or at another appropriate and predetermined frequency)?

Institutional Response: {pgFour\_gqNine}

1. Does the organization verify that actual risk assessments are conducted and completed in a manner consistent with the planned scope and timing for the risk assessments?

Institutional Response: {pgFour\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgFour\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFour\_range}

# CWA Requirement 4.3.1.3: Hazard identification

The hazards associated with proposed work shall be identified and documented. The first stage in the biorisk management process is to identify all hazards and threats that are relevant for biorisk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and biorisk management. A hazard may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting), an external condition (e.g. weather, individuals who could steal and / or misuse materials or information) or a material (in this case the principal hazard is most likely to be a biological agent or toxin, but others will include chemicals, radiological materials and asphyxiating gases such as nitrogen). The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be. Biological hazards and threats should be identified and assessed in relation to their potential damage to humans, animals, or the environment and requires knowledge of the facility, operational practices and experience of personnel. Generally, this identification process requires a multidisciplinary biorisk management team that relies on information and guidance from internal or external experts on safety, security, and biorisk management. Conducting a hazard identification exercise should also involve a review of legal and regulatory requirements, and a review of applicable guidelines and organization's codes of practice. This legal review will assist in identifying materials that are required by law, regulation, or guidance to be controlled within the facility. Where hazardous materials are classified into hazard or risk groups based on international and / or foreign country classification schemes local diverging needs and constraints should be considered.

## Guiding Questions:

1. Do hazard identification exercises use all appropriate and available information (such as organizational experience and knowledge, external expertise, results of previous risk assessments, incident and accident reports, hazardous materials data, general guidelines and codes of practice, facility drawings, manuals and SOPs, process maps and flow charts, results of task analysis)?

Institutional Response: {pgFive\_gqOne}

1. Is hazard identification conducted in a systematic way?

Institutional Response: {pgFive\_gqTwo}

1. Is a multi-disciplinary team involved in the hazard identification process?

Institutional Response: {pgFive\_gqThree}

1. Have applicable legal and regulatory requirements pertaining to hazard identification been identified and followed?

Institutional Response: {pgFive\_gqFour}

### What is the importance of this requirement?

Institutional Response: {pgFive\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFive\_range}

# CWA Requirement 4.3.1.4: Risk assessment

The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.

## Guiding Questions:

1. Does risk assessment also include a threat assessment component that identifies and characterizes the potential internal and external threats specific to a facility or laboratory and to determine if and how a threat could cause harm?

Institutional Response: {pgSix\_gqOne}

1. After definition and implementation of control measures, are the risks reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented?

Institutional Response: {pgSix\_gqTwo}

1. Are organizational risk assessment results documented and communicated to appropriate personnel?

Institutional Response: {pgSix\_gqThree}

1. Has the organization identified, implemented, and documented suitable methodologies for conducting and recording risk assessments?

Institutional Response: {pgSix\_gqFour}

1. Does the organizational risk assessment include consideration of personnel health status, qualifications, training, and human factors (e.g., behavior, reliability, errors)?

Institutional Response: {pgSix\_gqFive}

1. Does the organizational risk assessment include consideration of environmental conditions, including endemic pathogens, and external threats?

Institutional Response: {pgSix\_gqSix}

1. Does the organizational risk assessment include consideration of legislation, rules, and requirements where appropriate?

Institutional Response: {pgSix\_gqSeven}

1. Does the organizational risk assessment include mechanisms to categorize and prioritize risks to identify those which need to be eliminated or controlled?

Institutional Response: {pgSix\_gqEight}

1. Do risk assessments consider the relevant properties of the biological agents and toxins (including transmission routes, availability of treatment, vaccines, or prophylaxis, host range, mortality and morbidity, treatment options, and info from material safety data sheets etc.), as well as how that risk changes based on the way that the biological agents are used in the laboratory?

Institutional Response: {pgSix\_gqNine}

1. Does risk assessment specifically analyze the unique experiment and protocols, equipment and controls, personnel, and laboratory environment where those agents will be used?

Institutional Response: {pgSix\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgSix\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSix\_range}

# CWA Requirement 4.3.1.5: Risk management

The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained?

## Guiding Questions:

1. Has organizational management demonstrated commitment to risk management, including through the allocation of resources for risk management?

Institutional Response: {pgSeven\_gqOne}

1. Are the organization's risk management approaches based on results of the risk assessments, including identification of institutional level of risk tolerance?

Institutional Response: {pgSeven\_gqTwo}

1. Are the organization's risk management approaches based on results of internal and external monitoring and evaluations?

Institutional Response: {pgSeven\_gqThree}

1. Has the organization identified risk mitigation and risk control measures (a risk management plan), including considering the "hierarchy of controls?"

Institutional Response: {pgSeven\_gqFour}

1. Has the organization identified who is responsible and accountable for implementation of the risk management plan?

Institutional Response: {pgSeven\_gqFive}

1. Has the organization determined what resources are to be utilized (e.g. people, budget) to implement the risk management plan?

Institutional Response: {pgSeven\_gqSix}

1. Has the organization established a feasible timetable for implementation of the risk management plan?

Institutional Response: {pgSeven\_gqSeven}

1. Has the organization determined the mechanism(s) and frequency of review of the status of institutional compliance with the risk management plan?

Institutional Response: {pgSeven\_gqEight}

### What is the importance of this requirement?

Institutional Response: {pgSeven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSeven\_range}

# CWA Requirement 4.3.2: Conformity and compliance

The organization shall ensure that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national / federal, regional / state, provincial, city and local regulatory requirements with which the organization has to comply.

## Guiding Questions:

1. Has the organization identified all relevant legal requirements, including national, federal, regional, state, provincial, city and local legal requirements?

Institutional Response: {pgEight\_gqOne}

1. Has the organization fulfilled all relevant requirements included in legislation, including laws, decrees, directives, statutes, regulations?

Institutional Response: {pgEight\_gqTwo}

1. Has the organization fulfilled all relevant requirements included in orders and regulatory guidelines issued by regulators?

Institutional Response: {pgEight\_gqThree}

1. Has the organization fulfilled all relevant requirements included in permits, licenses or other forms of authorization?

Institutional Response: {pgEight\_gqFour}

1. Has the organization fulfilled all relevant requirements included in judgments of courts or administrative tribunals?

Institutional Response: {pgEight\_gqFive}

1. Has the organization fulfilled all relevant requirements included in applicable international treaties, conventions, protocols?

Institutional Response: {pgEight\_gqSix}

1. Has the organization fulfilled all relevant requirements included in contractual conditions?

Institutional Response: {pgEight\_gqSeven}

1. Has the organization fulfilled all relevant requirements included in agreements with interested parties, including employees, health authorities, and other stakeholders?

Institutional Response: {pgEight\_gqEight}

1. Has the organization identified all relevant non-regulatory requirements and guidelines, such as public commitments of the organization or its parent organization, and corporate/company requirements?

Institutional Response: {pgEight\_gqNine}

1. Has the organization identified all relevant requirements that are included in voluntary principles, best practices or codes of practice, charters (e.g. National Sanitation Foundation Code No. 49, biological safety cabinets)?

Institutional Response: {pgEight\_gqTen}

1. Does the organization appoint a responsible person to monitor new and upcoming requirements, to ensure that relevant information is disseminated and incorporated into the biorisk management system?

Institutional Response: {pgEight\_gqEleven}

1. Does the organization seek out relevant applicable biorisk legislative or other requirements using external sources (internet, libraries, professional associations, regulators, legal services, experts, manufacturers, contractors or customers, etc.)?

Institutional Response: {pgEight\_gqTwelve}

### What is the importance of this requirement?

Institutional Response: {pgEight\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgEight\_range}

# CWA Requirement 4.3.3.1: Objectives, targets, and programme

Biorisk control objectives and targets: The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.

## Guiding Questions:

1. Have organizational goals and objectives related to biorisk management been defined and documented?

Institutional Response: {pgNine\_gqOne}

1. Have biorisk management goals been prioritized based on a risk assessment?

Institutional Response: {pgNine\_gqTwo}

1. Have measurable objectives, milestones and timelines been established for each goal?

Institutional Response: {pgNine\_gqThree}

1. Are goals clear, well-defined, and easily understandable?

Institutional Response: {pgNine\_gqFour}

1. Are goals and objectives achievable and realistic, and relevant to the activities and biorisks of the organization?

Institutional Response: {pgNine\_gqFive}

1. Has a program of action (action plan) been established and communicated to achieve biorisk management goals, including the establishment of objectives, roles and responsibilities, and anticipated outputs and deliverables?

Institutional Response: {pgNine\_gqSix}

1. Have organizational goals and objectives related to biorisk management been communicated to appropriate personnel?

Institutional Response: {pgNine\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgNine\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgNine\_range}

# CWA Requirement 4.3.3.2: Monitoring controls

Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

## Guiding Questions:

1. Does management regularly monitor the effectiveness of biorisk management controls (mitigation)?

Institutional Response: {pgTen\_gqOne}

1. Are controls monitored by regular inspections and audits which include assessment of the biorisk management system?

Institutional Response: {pgTen\_gqTwo}

1. Is there a process to report corrective actions when problems have been identified in biorisk control?

Institutional Response: {pgTen\_gqThree}

1. Are accidents/incidents and nonconformities related to biorisk correctly managed (i.e. reported, recorded, investigated) leading to controls improvement?

Institutional Response: {pgTen\_gqFour}

1. Does management ensure that adequate resources are provided to maintain the effectiveness of the biorisk controls?

Institutional Response: {pgTen\_gqFive}

### What is the importance of this requirement?

Institutional Response: {pgTen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTen\_range}

# CWA Requirement 4.4.1.1: Roles, responsibilities and authorities

Top Management: Top management shall take ultimate responsibility for the organization’s biorisk management system. Top management shall ensure that roles, responsibilities and authorities related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins. Top management shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.

## Guiding Questions:

1. Does overall responsibility for biorisk management reside with the facility's top management?

Institutional Response: {pgEleven\_gqOne}

1. Has top management ensured that roles, responsibilities, and authorities related to biorisk management are defined and documented for all organizational personnel?

Institutional Response: {pgEleven\_gqTwo}

1. Has top management communicated roles, responsibilities, and authorities to all relevant personnel within the facility?

Institutional Response: {pgEleven\_gqThree}

1. Has top management made available, in a timely and efficient manner, the resources (financial, human resources and specialized skills, organizational infrastructure, technology) needed to establish, implement, maintain, and improve the biorisk management system?

Institutional Response: {pgEleven\_gqFour}

1. Has top management made sure that personnel have the authority necessary to execute biorisk management-related responsibilities?

Institutional Response: {pgEleven\_gqFive}

1. Does top management periodically review the resources allocated for the biorisk management system, to ensure that resources are adequate (including for new/planned activities)?

Institutional Response: {pgEleven\_gqSix}

1. Is top management involved in periodic reviews of the biorisk management system, and aware of the outcomes of these reviews?

Institutional Response: {pgEleven\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgEleven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgEleven\_range}

# CWA Requirement 4.4.1.2: Senior management

Senior Management: A senior manager shall be designated with operational responsibility for overseeing the system for management of biorisk. Functions of the system for the management of biorisk shall include: a) providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility; b) reporting to top management on the performance of the biorisk management system and any need for improvement; c) ensuring promotion of the biorisk management system throughout the organization; d) instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.

## Guiding Questions:

1. Is a senior manager designated to oversee the biorisk management system?

Institutional Response: {pgTwelve\_gqOne}

1. Does senior management have decision-making authority with respect to the biorisk management needs of the facility, including the allocation of resources?

Institutional Response: {pgTwelve\_gqTwo}

1. Does senior management report to top management on the performance of the biorisk management system, including areas in need of improvement?

Institutional Response: {pgTwelve\_gqThree}

1. Does senior management ensure that appropriate resources are provided to ensure implementation of the biorisk management system?

Institutional Response: {pgTwelve\_gqFour}

1. Does senior management promote the biorisk management system within the organization?

Institutional Response: {pgTwelve\_gqFive}

### What is the importance of this requirement?

Institutional Response: {pgTwelve\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwelve\_range}

# CWA Requirement 4.4.1.3: Biorisk management committee

Biorisk management committee: A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management, the committee shall: a) have documented terms of reference; b) include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken; c) ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively; d) be chaired by a senior individual; e) meet at a defined and appropriate frequency, and when otherwise required.

## Guiding Questions:

1. Has a biorisk management committee been established to act as an independent review group for biorisk issues?

Institutional Response: {pgThirteen\_gqOne}

1. Does the biorisk management committee have documented terms of reference?

Institutional Response: {pgThirteen\_gqTwo}

1. Does the committee include a representative cross-section of expertise, chaired by a senior individual, appropriate to the nature and scale of activities undertaken at the facility?

Institutional Response: {pgThirteen\_gqThree}

1. Does the committee meet at a defined and appropriate frequency, or when otherwise required?

Institutional Response: {pgThirteen\_gqFour}

1. Does the committee review and approve proposals for new or modified work, including protocols and risk assessments for work with biological agents and toxins?

Institutional Response: {pgThirteen\_gqFive}

1. Does the committee review information relating to significant accidents or incidents, trends, organizational actions and associated communication needs?

Institutional Response: {pgThirteen\_gqSix}

1. Does the committee report to senior and/or top management on the status of the biorisk management system?

Institutional Response: {pgThirteen\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgThirteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirteen\_range}

# CWA Requirement 4.4.1.4: Biorisk management advisor

Biorisk Management Advisor: A competent individual(s) shall be designated to provide advice and guidance on biorisk management issues. This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.

## Guiding Questions:

1. Has an individual (or individuals) been assigned responsibility to provide advice and guidance on biorisk management issues, i.e., to serve as a biorisk management advisor?

Institutional Response: {pgFourteen\_gqOne}

1. Does the individual possess adequate competency and independence from the implementation of the work to perform this function?

Institutional Response: {pgFourteen\_gqTwo}

1. Has top management delegated authority in writing to the biorisk management advisor(s) to execute their biorisk management responsibilities, including the authority to stop work if judged necessary?

Institutional Response: {pgFourteen\_gqThree}

1. Has top management taken necessary steps to ensure that the biorisk management advisor(s) have adequate resources to execute their responsibilities?

Institutional Response: {pgFourteen\_gqFour}

1. Does the biorisk management advisor(s) actively contribute to the development of biorisk management-related policies, plans, and procedures?

Institutional Response: {pgFourteen\_gqFive}

1. Does the biorisk management advisor(s) ensure that biorisk policies, plans and procedures are applied to all relevant work in the facility, and are consistent with all facility requirements?

Institutional Response: {pgFourteen\_gqSix}

1. Does the biorisk management advisor(s) help to ensure that relevant biorisk management information and guidance is made available to the facility, through advice, consultation, training, documentation, signage, etc.?

Institutional Response: {pgFourteen\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgFourteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFourteen\_range}

# CWA Requirement 4.4.1.5: Scientific management

Scientific Management: An individual(s) with responsibility for the scientific programme within the facility shall be designated with responsibilities relevant to biorisk management. Functions shall include: a) ensuring that all work is conducted in accordance with established policies and guidelines described in this standard; b) supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility; c) planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available; d) ensuring required authorizations for work are in place; e) ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place; f) ensuring that all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).

## Guiding Questions:

1. Has scientific management taken adequate steps to ensure that all work is conducted in accordance with biorisk management policies, plans, procedures and guidelines, including ensuring that laboratory staff under direct supervision understand their roles and responsibilities with respect to biosafety and biosecurity?

Institutional Response: {pgFifteen\_gqOne}

1. Has scientific management taken adequate steps to ensure that risk assessments are performed, reviewed, approved, and necessary biorisk control measures are put in place BEFORE work begins, or if the scope of work changes significantly?

Institutional Response: {pgFifteen\_gqTwo}

1. Has scientific management taken steps to ensure that the program of work under his/her supervision has undergone all necessary reviews and work authorizations have been received and recorded?

Institutional Response: {pgFifteen\_gqThree}

1. Has scientific management taken adequate steps to ensure that staffing levels, time, space, equipment, and other resources are adequate to perform work activities safely and securely?

Institutional Response: {pgFifteen\_gqFour}

1. Has scientific management taken adequate steps to ensure that only competent, authorized personnel have access to work areas?

Institutional Response: {pgFifteen\_gqFive}

1. Has scientific management taken steps to ensure that all at-risk personnel have been informed of potential risks associated with their responsibilities?

Institutional Response: {pgFifteen\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgFifteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFifteen\_range}

# CWA Requirement 4.4.1.6: Occupational health

Occupational Health: The organization shall have access to appropriate occupational health expertise and establish an occupational health programme commensurate with the activities and risks of the facility.

## Guiding Questions:

1. Has the facility established an occupational health programme that is appropriate for the activities and risks at the facility?

Institutional Response: {pgSixteen\_gqOne}

1. Do personnel have access to occupational health services?

Institutional Response: {pgSixteen\_gqTwo}

1. Is the occupational health professional aware of, and familiar with, all of the biological agents and/or toxins that are handled within the facility?

Institutional Response: {pgSixteen\_gqThree}

1. Does the occupational health professional provide inputs into relevant aspects of the biorisk management program, including risk assessments, work practices, biorisk control measures, and pre- and post-exposure protocols?

Institutional Response: {pgSixteen\_gqFour}

### What is the importance of this requirement?

Institutional Response: {pgSixteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSixteen\_range}

# CWA Requirement 4.4.1.7: Facility management

Facility Management: Facilities manager(s) shall be appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this standard.

## Guiding Questions:

1. Has a facility manager been designated to manage facilities, containment equipment and buildings?

Institutional Response: {pgSeventeen\_gqOne}

1. Does the facility manager possess detailed knowledge and understanding of the laboratory facilities and containment equipment?

Institutional Response: {pgSeventeen\_gqTwo}

1. Has top or senior management assigned and communicated relevant biorisk management-related responsibilities to the facility management based on the facility manager's role?

Institutional Response: {pgSeventeen\_gqThree}

1. Does the facility manager provide inputs to risk assessments from a facility management perspective?

Institutional Response: {pgSeventeen\_gqFour}

### What is the importance of this requirement?

Institutional Response: {pgSeventeen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSeventeen\_range}

# CWA Requirement 4.4.1.8: Security management

Security Management: A security manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.

## Guiding Questions:

1. Has top management designated a security manager to manage and develop a facility security plan encompassing all aspects of facility security, including physical security, information security, transport security, personnel security, and material control and accountability?

Institutional Response: {pgEighteen\_gqOne}

1. Has top or senior management assigned and communicated other relevant biorisk management-related responsibilities to the security management based on the security manager's role?

Institutional Response: {pgEighteen\_gqTwo}

1. Does the security manager possess adequate knowledge of laboratory and facility security?

Institutional Response: {pgEighteen\_gqThree}

1. Does the security manager contribute to risk assessments from a security perspective?

Institutional Response: {pgEighteen\_gqFour}

1. Does the security manager regularly assess and document facility security programme performance?

Institutional Response: {pgEighteen\_gqFive}

1. Does the facility manager have adequate resources to execute his or her responsibilities?

Institutional Response: {pgEighteen\_gqSix}

1. Does the security manager communicate and coordinate with other stakeholders on facility security issues, including the biorisk management advisor and the biorisk management committee?

Institutional Response: {pgEighteen\_gqSeven}

1. Is the security manager a member of the facility's biorisk management committee?

Institutional Response: {pgEighteen\_gqEight}

### What is the importance of this requirement?

Institutional Response: {pgEighteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgEighteen\_range}

# CWA Requirement 4.4.1.9: Animal handling

Animal Handling: In laboratories where animals are maintained, an animal care manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.

## Guiding Questions:

1. Has an animal care manager been designated in laboratories or other facilities where animals are housed or maintained?

Institutional Response: {pgNineteen\_gqOne}

1. Has top or senior management assigned and communicated other relevant biorisk management-related responsibilities to the animal care manager based on the animal care manager's role?

Institutional Response: {pgNineteen\_gqTwo}

1. Does the animal care manager possess adequate knowledge and expertise with respect to the use and safety of laboratory animals, including related laboratory facilities and equipment?

Institutional Response: {pgNineteen\_gqThree}

1. Is the animal care manager familiar with animal and zoonotic diseases and the risks they pose?

Institutional Response: {pgNineteen\_gqFour}

1. Does the animal care manager contribute to facility risk assessments from an animal care and use perspective?

Institutional Response: {pgNineteen\_gqFive}

1. Does the animal care manager contribute to planning and implementation of biorisk control measures, including safe and secure animal handling?

Institutional Response: {pgNineteen\_gqSix}

1. Does the animal care manager coordinate with other personnel, including but not limited to the biorisk management advisor, to implement appropriate biorisk management measures related to animal care and use?

Institutional Response: {pgNineteen\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgNineteen\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgNineteen\_range}

# CWA Requirement 4.4.2: Personnel training, awareness and competence

The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience. The organization shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency.

## Guiding Questions:

1. Does the organization have a training program in biorisk management to ensure the competence of personnel to carry out assigned responsibilities?

Institutional Response: {pgTwenty\_gqOne}

1. Does the organization have a list of goals/training skills that are necessary for each type of work or job responsibility?

Institutional Response: {pgTwenty\_gqTwo}

1. Does the organization keep records on their employees' previous education, training and experience in order to help determine competence for specific responsibilities or tasks?

Institutional Response: {pgTwenty\_gqThree}

1. Does the organization define and record the responsibilities and associated competency levels for biorisk management?

Institutional Response: {pgTwenty\_gqFour}

1. Does the organization monitor their training program, including through the collection of training and training evaluation data?

Institutional Response: {pgTwenty\_gqFive}

1. Does the organization evaluate their training program and proactively identify areas for improvement?

Institutional Response: {pgTwenty\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgTwenty\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwenty\_range}

# CWA Requirement 4.4.2.1: Recruitment

The organization shall ensure that qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process.

## Guiding Questions:

1. Does the organization personnel qualifications and experience in the recruitment process?

Institutional Response: {pgTwentyOne\_gqOne}

1. Does the institution have a formal selection process for recruiting its personnel, based on risk?

Institutional Response: {pgTwentyOne\_gqTwo}

1. Does the organization consider health conditions required to perform responsibilities, where appropriate?

Institutional Response: {pgTwentyOne\_gqThree}

1. Does the organization re-evaluate the qualifications, experience and competencies of an employee when transferred to a different job responsibility?

Institutional Response: {pgTwentyOne\_gqFour}

1. Has the organization developed procedure(s) for implementing biorisk management developed for recruitment and personnel management?

Institutional Response: {pgTwentyOne\_gqFive}

1. Does the organization consider local laws pertaining to discriminatory recruitment practices in its recruitment process?

Institutional Response: {pgTwentyOne\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgTwentyOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyOne\_range}

# CWA Requirement 4.4.2.2: Competence

The organization shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.

## Guiding Questions:

1. Does the organization have periodic review processes in place in order to determine personnel are competent to work safely and securely in their job functions?

Institutional Response: {pgTwentyTwo\_gqOne}

1. Does the organization's review process allow for a measurable output that can be demonstrated to external agencies, if applicable and necessary for the organization?

Institutional Response: {pgTwentyTwo\_gqTwo}

1. Does the organization supervise new, inexperienced or visiting personnel?

Institutional Response: {pgTwentyTwo\_gqThree}

1. Does the organization have a time-line to re-assess competence?

Institutional Response: {pgTwentyTwo\_gqFour}

1. Does the organization have documentation that competence was assessed according to the timeline to re-assess competence?

Institutional Response: {pgTwentyTwo\_gqFive}

1. Does the organization have procedures that to identify and define the specific competency needs of personnel?

Institutional Response: {pgTwentyTwo\_gqSix}

1. Does the organization have procedures that ensure the completion of required training based on competency needs of personnel?

Institutional Response: {pgTwentyTwo\_gqSeven}

1. Does the organization have procedures that address demonstration of the ability to perform task under supervision and unsupervised?

Institutional Response: {pgTwentyTwo\_gqEight}

1. Does the organization have mechanisms in place to ensure that personnel who are not competent to carry out specific procedures are not permitted to do so alone?

Institutional Response: {pgTwentyTwo\_gqNine}

1. Does the organization apply internal policies and procedures for evaluating competence evenly throughout its organization?

Institutional Response: {pgTwentyTwo\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgTwentyTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyTwo\_range}

# CWA Requirement 4.4.2.3: Continuity and succession planning

The organization shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.

## Guiding Questions:

1. Does the organization identify roles and individuals and ensure that the integrity of any aspect of the facility's biorisk management system is not compromised through short or long-term absence?

Institutional Response: {pgTwentyThree\_gqOne}

1. Has the organization completed succession planning for personnel (technical, management and scientific, including contractors) to ensure that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of an individual's departure or unavailability?

Institutional Response: {pgTwentyThree\_gqTwo}

1. Does the organization integrate continuity succession planning into the business continuation strategy of the organization?

Institutional Response: {pgTwentyThree\_gqThree}

1. Has the organization identified back-up roles and individuals for work practices in the event of a short or long-term absence?

Institutional Response: {pgTwentyThree\_gqFour}

### What is the importance of this requirement?

Institutional Response: {pgTwentyThree\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyThree\_range}

# CWA Requirement 4.4.2.4: Training

The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained.

## Guiding Questions:

1. Does the organization regularly deliver initial and periodic biorisk training to ensure safe and secure performance of tasks?

Institutional Response: {pgTwentyFour\_gqOne}

1. Does the organization design, develop, implement and maintain a training program that equips staff with the knowledge and tools to identify hazards and manage biosafety and biosecurity risk?

Institutional Response: {pgTwentyFour\_gqTwo}

1. Does the organization establish and document training requirements for staff, based on the competencies required for their job functions?

Institutional Response: {pgTwentyFour\_gqThree}

1. Does the organization establish and document training requirements for staff based on facility-specific risk assessments?

Institutional Response: {pgTwentyFour\_gqFour}

1. Does the organization regularly assess its biorisk-related training program using measurable markers of success that can be reported to and used by management?

Institutional Response: {pgTwentyFour\_gqFive}

1. Does the organization regularly monitor and evaluate its biorisk-related training program?

Institutional Response: {pgTwentyFour\_gqSix}

1. Does the organization periodically review the training program to determine areas for improvement and modification to address current competence requirements?

Institutional Response: {pgTwentyFour\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgTwentyFour\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyFour\_range}

# CWA Requirement 4.4.3: Consultation and communication

The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be documented. Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization.

## Guiding Questions:

1. Has the organization documented and implemented mechanisms to ensure that relevant, adequate and up-to-date biorisk information relating to its activities is communicated to all relevant internal and external stakeholders (e.g. employees, community)?

Institutional Response: {pgTwentyFive\_gqOne}

1. Has the organization documented and implemented mechanisms to consult organizational staff on biorisk management issues?

Institutional Response: {pgTwentyFive\_gqTwo}

1. Are employees consulted concerning biorisk issues, including hazard identification, risk assessment, objectives of the biorisk management programme, and biorisk controls?

Institutional Response: {pgTwentyFive\_gqThree}

1. Has the organization implemented mechanisms to ensure the effective and timely delivery of relevant and current information with the potential to affect workers or others at the organization?

Institutional Response: {pgTwentyFive\_gqFour}

1. Is current information on the specific biorisks of the organization, facility and/or unit that have the potential to affect personnel or visitors available to all relevant personnel?

Institutional Response: {pgTwentyFive\_gqFive}

1. Has the organization established methods to identify technologies and information relating to laboratory biosafety and biosecurity, and to ensure this information is shared with relevant staff through appropriate communication mechanisms?

Institutional Response: {pgTwentyFive\_gqSix}

1. Is a review and approval process in place to ensure the appropriate external release of biorisk information?

Institutional Response: {pgTwentyFive\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgTwentyFive\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyFive\_range}

# CWA Requirement 4.4.4: Operational control

The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The organization shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.

## Guiding Questions:

1. Has the organization established comprehensive operational controls that meet all of the sub-requirements under Section 4.4.4 of CWA 15793:2011?

Institutional Response: {pgTwentySix\_gqOne}

1. Has the organization developed means to monitor the implementation of the operational controls, to ensure activities are undertaken in accordance with established procedures and specified conditions?

Institutional Response: {pgTwentySix\_gqTwo}

1. Are operational controls regularly reviewed against current risks to ensure their continued contribution to risk management including continued effectiveness?

Institutional Response: {pgTwentySix\_gqThree}

### What is the importance of this requirement?

Institutional Response: {pgTwentySix\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentySix\_range}

# CWA Requirement 4.4.4.1: General safety

The organization shall ensure that a formal process is in place to identify and manage risk associated with general safety.

## Guiding Questions:

1. Does the organization have a formal process in place that includes a preventative and proactive approach to managing safety risk and providing protection of workers from the direct hazards associated with their work, including physical, chemical, radiological, electrical, ergonomic, and other identified hazards?

Institutional Response: {pgTwentySeven\_gqOne}

1. Have measures been identified and implemented to detect, alert response personnel, respond and recover from incidents and emergencies?

Institutional Response: {pgTwentySeven\_gqTwo}

1. Do the measures identified and implemented to detect, mitigate and respond to incidents and emergencies take into consideration the control of biological agents?

Institutional Response: {pgTwentySeven\_gqThree}

1. Are the following safety issues addressed in the organization's general safety plan: general laboratory safety, fire safety, electrical safety, radiation safety, chemical safety, use of gasses, hot work and cold work, equipment under pressure, laboratory animal care and use, general housekeeping, and environmental safety?

Institutional Response: {pgTwentySeven\_gqFour}

1. Does the biorisk management system include references and links to the management systems related to other risks present in the work place, where appropriate?

Institutional Response: {pgTwentySeven\_gqFive}

1. Is there an ergonomics program in place, including measures to address ergonomic needs of individual workers?

Institutional Response: {pgTwentySeven\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgTwentySeven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentySeven\_range}

# CWA Requirement 4.4.4.2: Biological agents and toxin inventory and information

The organization shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained. It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision. It shall ensure that transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of risk.

## Guiding Questions:

1. Does the organization keep an accurate inventory of all biological agents and toxins that are stored and/or currently in use?

Institutional Response: {pgTwentyEight\_gqOne}

1. Does the inventory list identify a specific person accountable for the material, how and what it is being used for and location of its use and storage?

Institutional Response: {pgTwentyEight\_gqTwo}

1. Does the organization retain contact information for responsible personnel with access to biological materials?

Institutional Response: {pgTwentyEight\_gqThree}

1. Is the inventory of specific biological agents periodically checked against the actual physical inventory at regular intervals based on risk?

Institutional Response: {pgTwentyEight\_gqFour}

1. Has the organization determined which biological materials should be subject to inventory controls, and what information is to be included in the inventory for these materials?

Institutional Response: {pgTwentyEight\_gqFive}

1. Are biosecurity measures in place to protect biological materials according to risk, with more stringent controls in place to protect high risk materials?

Institutional Response: {pgTwentyEight\_gqSix}

1. Has the organization developed and maintained a reliable sample labelling and identification system?

Institutional Response: {pgTwentyEight\_gqSeven}

1. Are biological materials segregated and stored based on a facility-specific risk assessment?

Institutional Response: {pgTwentyEight\_gqEight}

1. Does the organization identify personnel with a demonstrative, legitimate need to access to the inventory system, biological agents or toxins, and limit access to biological agents only to those personnel?

Institutional Response: {pgTwentyEight\_gqNine}

1. Does the organization have an inventory of biological materials that have been sent and received, including materials consumed, destroyed or removed from the facility where appropriate according to risk?

Institutional Response: {pgTwentyEight\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgTwentyEight\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyEight\_range}

# CWA Requirement 4.4.4.3: Work programme, planning and capacity

The organization shall ensure that the programme of work for the facility is defined, documented and reviewed. The organization shall establish criteria for work that requires prior approval. It shall ensure there is sufficient resource capacity and capability to manage workflow, whether planned or unplanned.

## Guiding Questions:

1. Does the organization have a defined program of work for the facility that includes the scope, roles, biological materials in use, and extent of the work that is authorized to be conducted?

Institutional Response: {pgTwentyNine\_gqOne}

1. Does this program include the scope and extent of the work to be conducted?

Institutional Response: {pgTwentyNine\_gqTwo}

1. Does the program address the identified hazards including the biological toxins/agents in use?

Institutional Response: {pgTwentyNine\_gqThree}

1. Does this program include processes and procedures to be performed?

Institutional Response: {pgTwentyNine\_gqFour}

1. Does this program include consideration of the results of workplace health risk assessments?

Institutional Response: {pgTwentyNine\_gqFive}

1. Does this program include number and type of personnel required for the scope of the procedures and processes to be conducted?

Institutional Response: {pgTwentyNine\_gqSix}

1. Does this program include working with proper leadership and decision makers to ensure the resources needed to implement and maintain the biorisk management system and continually improve its effectiveness should be determined and provided?

Institutional Response: {pgTwentyNine\_gqSeven}

1. Is the organization's program of work periodically reviewed to assess for any changes needed?

Institutional Response: {pgTwentyNine\_gqEight}

1. Are all activities associated with the work programme specified and supported by formal SOPs approved in accordance with the requirements for controlled documents as defined by this standard?

Institutional Response: {pgTwentyNine\_gqNine}

1. Are any changes to the programme of work subject to a formal change management process?

Institutional Response: {pgTwentyNine\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgTwentyNine\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgTwentyNine\_range}

# CWA Requirement 4.4.4.4: Change management

The organization shall ensure that all changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.

## Guiding Questions:

1. Does the organization have a process for ensuring any changes associated with the design, operation and maintenance of the facility and for modifying any aspect of biorisk management are subject to a defined and documented change management process before changes are implemented?

Institutional Response: {pgThirty\_gqOne}

1. When executing a change management process, are roles and responsibilities related to the change management process defined?

Institutional Response: {pgThirty\_gqTwo}

1. Is there a method established for communicating all relevant changes to the design operation and maintenance of the facility to all relevant personnel?

Institutional Response: {pgThirty\_gqThree}

1. Are risk assessments performed or reviewed when there are proposed changes to the design, operation and maintenance of the facility to determine the effect of the changes on the risk assessment?

Institutional Response: {pgThirty\_gqFour}

### What is the importance of this requirement?

Institutional Response: {pgThirty\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirty\_range}

# CWA Requirement 4.4.4.5.1: Good microbiological technique

The organization shall ensure that all personnel handling biological agents and toxins are competent in good microbiological techniques and that appropriate resources (including time and equipment) are available to ensure such practices can be adhered to effectively.

## Guiding Questions:

1. Does the organization have training and mentoring programs that emphasize good microbiological technique?

Institutional Response: {pgThirtyOne\_gqOne}

1. Are appropriate resources including time, equipment, and consumables available to ensure good microbiological technique can be adhered to effectively?

Institutional Response: {pgThirtyOne\_gqTwo}

1. Are there monitoring controls in place to ensure that employees are competent to perform tasks using good microbiological technique?

Institutional Response: {pgThirtyOne\_gqThree}

1. Has the organization established standard procedures to support good microbiological technique?

Institutional Response: {pgThirtyOne\_gqFour}

1. Does the organization provide training to laboratory personnel on standard procedures to support good microbiological technique?

Institutional Response: {pgThirtyOne\_gqFive}

1. Does the organization promote good microbiological technique through the organization's communication process?

Institutional Response: {pgThirtyOne\_gqSix}

1. Does the organization check for contamination of personnel, product, environmental following laboratory procedures, if warranted from a biorisk or quality control perspective?

Institutional Response: {pgThirtyOne\_gqSeven}

1. Are procedures in place to address risks associated with animal handling?

Institutional Response: {pgThirtyOne\_gqEight}

1. Are procedures in place to address risks associated with centrifugation?

Institutional Response: {pgThirtyOne\_gqNine}

1. Are procedures in place to address risks associated with control of needles and sharps?

Institutional Response: {pgThirtyOne\_gqTen}

1. Are procedures in place to address risks associated with correct use of vacuum pumps?

Institutional Response: {pgThirtyOne\_gqEleven}

1. Are procedures in place to address risks associated with culture, purification and storage techniques?

Institutional Response: {pgThirtyOne\_gqTwelve}

1. Are procedures in place to address risks associated with minimization/containment of aerosols?

Institutional Response: {pgThirtyOne\_gqThirteen}

1. Are procedures in place to address risks associated with pipetting?

Institutional Response: {pgThirtyOne\_gqFourteen}

1. Are procedures in place to address risks associated with sonication and other mechanical forms of cell/tissue disruption?

Institutional Response: {pgThirtyOne\_gqFifteen}

1. Are procedures in place to address risks associated with the use of BSCs?

Institutional Response: {pgThirtyOne\_gqSixteen}

1. Are procedures in place to address risks associated with disinfectants, including spill control, routine decontamination, hand washing and showering?

Institutional Response: {pgThirtyOne\_gqSeventeen}

1. Are procedures in place to address risks associated with proper management of generated biowastes?

Institutional Response: {pgThirtyOne\_gqEighteen}

1. Are procedures in place to address risks associated with other techniques in addition to those listed above or that are unique to the organization?

Institutional Response: {pgThirtyOne\_gqNineteen}

### What is the importance of this requirement?

Institutional Response: {pgThirtyOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyOne\_range}

# CWA Requirement 4.4.4.5.2: Inactivation of biological agents and toxins

The organization shall establish and maintain procedures to ensure that appropriate methods for disinfection and decontamination are chosen and implemented effectively. The organization shall ensure that all contaminated or potentially contaminated waste items have been identified and documented (including those that may result from an emergency), and that effective procedures are put in place to devise effective decontamination and other appropriate treatments.

## Guiding Questions:

1. Does the organization consider the following sources of contamination in their inactivation of biological agents and toxins plan: personnel, clothing and PPE, glassware, equipment, cultures and associated materials, spill clean-up materials and equipment, infectious microorganisms and contaminated materials, paper and plastic waste, needles/syringes/sharps, waste water including that from showers and sinks, air, filters for air handling systems, discarded equipment in the facility, animals exposed to biological agents or toxins, animal carcasses and bedding, and facilities?

Institutional Response: {pgThirtyTwo\_gqOne}

1. Does the organization have validated procedures for the inactivation of biological agents, toxins and waste products, based on documentation and data to demonstrate that the method of decontamination is capable of inactivating the biological agents and toxins under the specific conditions encountered in the facility?

Institutional Response: {pgThirtyTwo\_gqTwo}

1. In determining the validation measures for decontamination does the organization consider the nature of the material being treated and the specific conditions of the disinfection protocol, such as contact time?

Institutional Response: {pgThirtyTwo\_gqThree}

1. In determining the validation measures for decontamination does the organization consider material compatibility issues between disinfectant and equipment or facilities?

Institutional Response: {pgThirtyTwo\_gqFour}

1. In determining the validation measures for decontamination does the organization consider the potential health hazards associated with the disinfectant?

Institutional Response: {pgThirtyTwo\_gqFive}

1. In determining the validation measures for decontamination does the organization consider the need to maintain the required level of active compound for disinfection?

Institutional Response: {pgThirtyTwo\_gqSix}

1. Are all potential waste streams and other modes of contamination identified and documented?

Institutional Response: {pgThirtyTwo\_gqSeven}

1. In planning and conducting decontamination does the organization ensure that all disinfectants used contain sufficient active compound throughout the disinfection process to address the specific working conditions employed?

Institutional Response: {pgThirtyTwo\_gqEight}

1. In planning and conducting decontamination does the organization ensure methods are available for effective decontamination of mixed waste?

Institutional Response: {pgThirtyTwo\_gqNine}

1. In planning and conducting decontamination does the organization ensure that methods are available for decontamination of sensitive equipment that is not suitable for autoclaving?

Institutional Response: {pgThirtyTwo\_gqTen}

1. In planning and conducting decontamination does the organization implement monitoring measures to ensure effectiveness of decontamination?

Institutional Response: {pgThirtyTwo\_gqEleven}

1. In planning and conducting decontamination does the organization decontaminate protective clothing by appropriate means prior to PPE leaving the facility?

Institutional Response: {pgThirtyTwo\_gqTwelve}

1. In planning and conducting decontamination does the organization ensure adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside of the facility?

Institutional Response: {pgThirtyTwo\_gqThirteen}

1. In planning and conducting decontamination does the organization ensure all relevant personnel are trained in the use of the decontamination protocols?

Institutional Response: {pgThirtyTwo\_gqFourteen}

### What is the importance of this requirement?

Institutional Response: {pgThirtyTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyTwo\_range}

# CWA Requirement 4.4.4.5.3: Waste management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

## Guiding Questions:

1. Are roles and responsibilities for waste management defined and documented?

Institutional Response: {pgThirtyThree\_gqOne}

1. Is the nature of the waste defined and documented?

Institutional Response: {pgThirtyThree\_gqTwo}

1. Are the appropriate decontamination processes defined and documented?

Institutional Response: {pgThirtyThree\_gqThree}

1. Are the local and environmental waste management policies identified and incorporated?

Institutional Response: {pgThirtyThree\_gqFour}

1. In the organization's waste management policy do they ensure that there is a programme in place to minimize waste production?

Institutional Response: {pgThirtyThree\_gqFive}

1. Does the organization effectively retain records and other documentation related to waste management?

Institutional Response: {pgThirtyThree\_gqSix}

1. Does the organization provide adequate facilities and procedures for the storage of waste, including short term storage?

Institutional Response: {pgThirtyThree\_gqSeven}

1. Does the organization ensure there are procedures to ensure effective segregation of waste?

Institutional Response: {pgThirtyThree\_gqEight}

### What is the importance of this requirement?

Institutional Response: {pgThirtyThree\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyThree\_range}

# CWA Requirement 4.4.4.5.4: Clothing and personal protective equipment

The organization shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility.

## Guiding Questions:

1. Is correct and properly-fitted PPE made available to all employees with a work-related need, at no cost to the employee?

Institutional Response: {pgThirtyFour\_gqOne}

1. Has the organization developed and documented a process for the identification of appropriate PPE, that includes ensuring sufficient information about selecting PPE and basing PPE selection on a risk assessment process?

Institutional Response: {pgThirtyFour\_gqTwo}

1. Are measures in place to ensure that all personnel who need to use PPE are identified? (Note: this includes employees and non-employees.)

Institutional Response: {pgThirtyFour\_gqThree}

1. Is the organization aware of and compliant with all relevant laws, regulations and policies (national, provincial, local) pertaining to the use of PPE?

Institutional Response: {pgThirtyFour\_gqFour}

1. Does the process for the identification of appropriate PPE include an evaluation of work tasks and input from personnel performing these tasks?

Institutional Response: {pgThirtyFour\_gqFive}

1. Does the process for the identification of appropriate PPE include consideration and evaluation of potential medical conditions of staff (for example, fitness to wear a respirator, allergic reactions)?

Institutional Response: {pgThirtyFour\_gqSix}

1. Does the process for identification of appropriate PPE include consideration of the effects of other non-biological hazards (for example, chemicals)?

Institutional Response: {pgThirtyFour\_gqSeven}

1. Are standard procedures for donning and doffing PPE documented and implemented throughout the facility?

Institutional Response: {pgThirtyFour\_gqEight}

1. Are personnel provided training on the selection, donning, doffing, proper use, and maintenance of PPE?

Institutional Response: {pgThirtyFour\_gqNine}

1. Are personnel trained on which areas in the facility PPE should be used, and on which areas in the facility PPE should not be used?

Institutional Response: {pgThirtyFour\_gqTen}

1. Is the selection, proper use (including donning and doffing), and maintenance of PPE incorporated into relevant SOPs?

Institutional Response: {pgThirtyFour\_gqEleven}

1. Is there a process in place to ensure an adequate supply of PPE at all times, including during abnormal working conditions?

Institutional Response: {pgThirtyFour\_gqTwelve}

1. Are there measures in place to assess the competence of personnel in the selection, proper use (including donning and doffing), and maintenance of PPE?

Institutional Response: {pgThirtyFour\_gqThirteen}

1. Is a maintenance program established to conduct routine checks and maintenance of PPE?

Institutional Response: {pgThirtyFour\_gqFourteen}

1. Is a program for conducting proper and periodic respirator fit testing established?

Institutional Response: {pgThirtyFour\_gqFifteen}

1. Are procedures established to safely decontaminate and dispose of disposable (one-time use) PPE?

Institutional Response: {pgThirtyFour\_gqSixteen}

1. Are procedures established to safely decontaminate and clean reusable PPE?

Institutional Response: {pgThirtyFour\_gqSeventeen}

1. Does the facility take steps to ensure that personnel do not take PPE home (for example, for laundering)?

Institutional Response: {pgThirtyFour\_gqEighteen}

1. Does the organization make available PPE for both normal circumstances and abnormal (emergency) circumstances?

Institutional Response: {pgThirtyFour\_gqNineteen}

### What is the importance of this requirement?

Institutional Response: {pgThirtyFour\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyFour\_range}

# CWA Requirement 4.4.4.6: Worker health programme

The organization shall ensure that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively including prevention and protection measures. The requirements of the health surveillance programme shall be determined by a defined health hazard identification and risk assessment process involving all relevant personnel.

## Guiding Questions:

1. Does the organization have documentation of the health hazards that may be encountered in work areas?

Institutional Response: {pgThirtyFive\_gqOne}

1. Does the organization conduct a health risk assessment for all relevant personnel at the facility?

Institutional Response: {pgThirtyFive\_gqTwo}

1. Does the organization have a mechanism to identify personnel within the organization considered to have significant risk of exposure to hazardous biological materials?

Institutional Response: {pgThirtyFive\_gqThree}

1. Does the organization conduct an assessment of the healthcare needs of personnel at risk of exposure to hazardous biological materials, including vaccination, PPE and emergency measures such as isolation/testing in the event of an exposure?

Institutional Response: {pgThirtyFive\_gqFour}

1. Does the organization have documentation that individuals who are associated with the facility, including contractors and visitors, receive a level of protection in line with the risk of the activities that they will perform?

Institutional Response: {pgThirtyFive\_gqFive}

1. Does the organization have documentation of consultation with relevant personnel such as biorisk management advisors, veterinary and animal care staff, occupational health professional etc.?

Institutional Response: {pgThirtyFive\_gqSix}

1. Does the organization have documentation of the health and immune status of an individual as part of the health risk assessment and health surveillance processes?

Institutional Response: {pgThirtyFive\_gqSeven}

1. Has the organization established appropriate work conditions with periodic checks of the work areas?

Institutional Response: {pgThirtyFive\_gqEight}

1. Does the organization consider and take action to address other health conditions that could impact the health of personnel associated with the facility?

Institutional Response: {pgThirtyFive\_gqNine}

1. Does the organization have procedures in place to protect the sensitive, confidential information generated in a worker health programme?

Institutional Response: {pgThirtyFive\_gqTen}

1. Does the organization take steps to provide access for all individuals to healthcare consultations and that they are informed of any treatments/vaccinations and the inherent risks and benefits of these treatments/vaccinations?

Institutional Response: {pgThirtyFive\_gqEleven}

1. Does the organization have documented medical response plans for all hazardous biological materials the facility handles or stores?

Institutional Response: {pgThirtyFive\_gqTwelve}

1. Does the organization document that the staff of the facility are aware of the risks associated with their work and/or the biological material they are working with, including potential consequences of exposure and medical preventative measures and treatment?

Institutional Response: {pgThirtyFive\_gqThirteen}

### What is the importance of this requirement?

Institutional Response: {pgThirtyFive\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyFive\_range}

# CWA Requirement 4.4.4.6.1: Vaccination of personnel

Based on risk, the need for vaccination shall be identified and shall cover groups identified as being potentially exposed to biological agents or toxins. The organization shall ensure that a vaccination policy be defined and implemented, and that access to laboratories or work is controlled for individuals until they comply with the policy.

## Guiding Questions:

1. Does the organization document that the staff of the facility are aware of the risks associated with their work or the agent they are handling and the likely consequences?

Institutional Response: {pgThirtySix\_gqOne}

1. Does the organization have a list of the biological agents and the available vaccines that the facility works with?

Institutional Response: {pgThirtySix\_gqTwo}

1. Does the organization have information on vaccine efficacy and safety data?

Institutional Response: {pgThirtySix\_gqThree}

1. Does the organization have a list of personnel to be vaccinated based upon risk assessment of their work activities and the biological materials they handle?

Institutional Response: {pgThirtySix\_gqFour}

1. Is there a policy in place for pre-employment vaccination?

Institutional Response: {pgThirtySix\_gqFive}

1. Is there a policy in place for pre- or post-exposure vaccination?

Institutional Response: {pgThirtySix\_gqSix}

1. Is there a policy for individuals with a low titer/response to the vaccine (including measures to identify non-responders to vaccination when needed) and for those unable to receive the vaccine?

Institutional Response: {pgThirtySix\_gqSeven}

1. Is there a policy for the use of vaccines in early stages of clinical development for selected infectious agents (where the medical consequences are severe if exposure goes undetected)?

Institutional Response: {pgThirtySix\_gqEight}

1. Does the organization have documentation for individuals who are considered unfit for work in the facility or laboratories within the facility, and a method by which they are prevented from accessing areas where there are risks of exposure?

Institutional Response: {pgThirtySix\_gqNine}

1. Are the areas requiring vaccination for entry identified and posted?

Institutional Response: {pgThirtySix\_gqTen}

1. Is there documentation that vaccinations have been given and certificates are valid?

Institutional Response: {pgThirtySix\_gqEleven}

1. Does the organization have documentation that required or recommended vaccines are made available for concerned personnel?

Institutional Response: {pgThirtySix\_gqTwelve}

### What is the importance of this requirement?

Institutional Response: {pgThirtySix\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtySix\_range}

# CWA Requirement 4.4.4.7: Behavioral factors and control of workers

The organization shall establish and maintain a programme to address risk associated with human behavior, including the management of how workers interact with the facility and its equipment.

## Guiding Questions:

1. Does the organization have SOPs to address incidents of work place violence?

Institutional Response: {pgThirtySeven\_gqOne}

1. Does the organization train managers to recognize human factor considerations and observe their signs with their personnel?

Institutional Response: {pgThirtySeven\_gqTwo}

1. Has the organization established measures that discourage a "blame culture" and enhance willingness to report incidents or unsafe/insecure conditions?

Institutional Response: {pgThirtySeven\_gqThree}

1. Does the organization have a method to ensure employees are adhering to SOPs?

Institutional Response: {pgThirtySeven\_gqFour}

1. Has the organization put in place conflict management and resolution procedures?

Institutional Response: {pgThirtySeven\_gqFive}

1. Do individuals have the authority to stop work if there are unsafe or unsecure practices or circumstances occurring?

Institutional Response: {pgThirtySeven\_gqSix}

1. Is there an ergonomics program in place, including measures to address ergonomic needs of individual workers?

Institutional Response: {pgThirtySeven\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgThirtySeven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtySeven\_range}

# CWA Requirement 4.4.4.7.1: Personnel reliability

The organization shall ensure that a personnel reliability policy is defined and implemented and that access to facilities or work is controlled for individuals according to the policy.

## Guiding Questions:

1. Does the organization have a documented personnel reliability policy?

Institutional Response: {pgThirtyEight\_gqOne}

1. Does the personnel reliability policy incorporate different levels of personnel screening, where lawful and appropriate based on a risk assessment, for different levels of job responsibilities?

Institutional Response: {pgThirtyEight\_gqTwo}

1. Is the personnel reliability policy reviewed on a regular basis?

Institutional Response: {pgThirtyEight\_gqThree}

1. Is access to facilities, defined areas, or work controlled for certain individuals according to the personnel reliability policy, based on facility-specific risk assessments?

Institutional Response: {pgThirtyEight\_gqFour}

1. Are personnel aware of the personnel reliability policy?

Institutional Response: {pgThirtyEight\_gqFive}

1. Is the personnel reliability policy consistent with local and national legal and regulatory frameworks?

Institutional Response: {pgThirtyEight\_gqSix}

1. Have risk assessments been performed and documented for each job responsibility?

Institutional Response: {pgThirtyEight\_gqSeven}

1. Are job responsibilities reviewed periodically?

Institutional Response: {pgThirtyEight\_gqEight}

1. Are the requirements of the personnel reliability screening consistent, transparent, and documented?

Institutional Response: {pgThirtyEight\_gqNine}

1. Are the results of the personnel reliability screening process treated as sensitive information and protected to an appropriate level?

Institutional Response: {pgThirtyEight\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgThirtyEight\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyEight\_range}

# CWA Requirement 4.4.4.7.2: Contractors, visitors and suppliers

The organization shall ensure that suppliers, contractors, visitors and sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility.

## Guiding Questions:

1. Does the organization's biorisk management policy include processes and procedures for contractors, visitors and suppliers who enter or work in the facility to ensure safety and security of the facilities materials and operations?

Institutional Response: {pgThirtyNine\_gqOne}

1. Does the organization have written SOPs based on facility-specific risk assessment for how contractors, visitors and suppliers access specific areas of the facility or equipment?

Institutional Response: {pgThirtyNine\_gqTwo}

1. Does the SOP designate locations where contractors, visitors and suppliers have access and where they have access if escorted by a facility employee?

Institutional Response: {pgThirtyNine\_gqThree}

1. Does the organization identify employees that can serve as escorts?

Institutional Response: {pgThirtyNine\_gqFour}

1. Are the escorts trained?

Institutional Response: {pgThirtyNine\_gqFive}

1. If contractors, visitors and suppliers are able to be escorted to high-risk areas, does the organization have training in place for them?

Institutional Response: {pgThirtyNine\_gqSix}

1. Are organizational procedures related to the management of facility access for contractors, visitors, and suppliers clearly communicated to employees?

Institutional Response: {pgThirtyNine\_gqSeven}

1. Are suppliers, contractors, visitors and sub-contractors made aware of hazards specific to certain areas of the organization where they will visit?

Institutional Response: {pgThirtyNine\_gqEight}

1. Are these procedures documented?

Institutional Response: {pgThirtyNine\_gqNine}

### What is the importance of this requirement?

Institutional Response: {pgThirtyNine\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgThirtyNine\_range}

# CWA Requirement 4.4.4.7.3: Exclusion

The organization shall ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility where deemed necessary through risk assessment.

## Guiding Questions:

1. Does the organization have a security system in place to exclude individuals who do not have legitimate access?

Institutional Response: {pgForty\_gqOne}

1. Does the organization have a procedure for removing legitimate access of individuals that present a security risk?

Institutional Response: {pgForty\_gqTwo}

1. Does the organization have a procedure for removing legitimate access to information relating to the facility i.e. documentation, computerized records and data?

Institutional Response: {pgForty\_gqThree}

1. Are consequences for violating certain criteria, to include exclusion from the facility, clearly communicated to contractors, visitors, suppliers and employees?

Institutional Response: {pgForty\_gqFour}

1. Does the organization have SOPs that clearly define exclusion process for unauthorized individuals?

Institutional Response: {pgForty\_gqFive}

1. Are the exclusion SOPs for unauthorized visitors communicated to all staff and those visiting the facility?

Institutional Response: {pgForty\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgForty\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgForty\_range}

# CWA Requirement 4.4.4.8: Infrastructure and operational management

The organization shall ensure that facilities, equipment and processes are designed and run in a safe and secure way with respect to biorisk management.

## Guiding Questions:

1. If the organization is planning to design or redesign a biological facility, has an analysis of biosafety and biosecurity risks been performed and documented?

Institutional Response: {pgFortyOne\_gqOne}

1. Does the facility perform a risk assessment as part of the process of selection, procurement and installation of a new piece of equipment?

Institutional Response: {pgFortyOne\_gqTwo}

1. Does the facility incorporate risk assessment into the development of new processes or modification of existing processes?

Institutional Response: {pgFortyOne\_gqThree}

1. Does the facility retain documentation pertaining to the facility design (for example: relevant national and international standards, design drawings and specifications, commissioning and decommissioning documentation, facility maintenance records)?

Institutional Response: {pgFortyOne\_gqFour}

1. Does the facility retain documentation pertaining to equipment (for example: operator logs, maintenance logs, validation logs, manuals, incident and failure reports)?

Institutional Response: {pgFortyOne\_gqFive}

1. Are costs associated with ongoing operation and maintenance of facilities and equipment documented, and adequately covered in the operational budget of the facility?

Institutional Response: {pgFortyOne\_gqSix}

### What is the importance of this requirement?

Institutional Response: {pgFortyOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyOne\_range}

# CWA Requirement 4.4.4.8.1: Planning, design, and verification

The organization shall ensure that a formal planning, design and redesign process is adopted for the facility, based upon an assessment of risk associated with the materials to be used and activities undertaken. The design process shall identify and incorporate all relevant legislative requirements, together with information from recognized standards, guidelines, industry good practices and facility-specific risk assessments. The design process shall identify and consult all relevant parties associated with the facility and its operation. All design features, construction techniques, materials and equipment selected shall be documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification. The organization shall ensure that a new construction and physical facility modifications are carried out according to an approved plan.

## Guiding Questions:

1. Has a risk assessment been performed to determine the needs of the facility?

Institutional Response: {pgFortyTwo\_gqOne}

1. Are the engineering and operational solutions consistent with the risk posed by the properties of materials that are stored and handled in the facility and the nature of the work?

Institutional Response: {pgFortyTwo\_gqTwo}

1. Is the physical space of the facility configured so that equipment can be properly maintained, moved, or removed?

Institutional Response: {pgFortyTwo\_gqThree}

1. Has the organization retained records of staff consultation on the design, construction, inspection and verification of the new facility?

Institutional Response: {pgFortyTwo\_gqFour}

1. Did the organization make budget plans to ensure adequate resources for construction?

Institutional Response: {pgFortyTwo\_gqFive}

1. Were the legal requirements and codes of practice reviewed and included in the design process?

Institutional Response: {pgFortyTwo\_gqSix}

1. Was a project committee formed to help define facility-specific design needs, consisting of some or all of the following representatives, as appropriate based on the project: management, scientific leaders, lab tech staff, maintenance engineers, biosafety staff, designers commissioning agents and financial staff?

Institutional Response: {pgFortyTwo\_gqSeven}

1. Did the institution consult with appropriate external parties such as constructors, materials and equipment suppliers, pest management consultants, certifiers, regulators, medical and first responders, community representatives, and others identified in the risk assessment?

Institutional Response: {pgFortyTwo\_gqEight}

1. If justified based on the work of the facility, was a peer review process involving independent and competent third parties conducted to ensure the design specification is in line with accepted building and engineering practices?

Institutional Response: {pgFortyTwo\_gqNine}

1. If justified based on the work of the facility, was a peer review process involving independent and competent third parties conducted to ensure the design specification incorporates features capable of providing assurance for the control storage and security of biological agents and toxins?

Institutional Response: {pgFortyTwo\_gqTen}

1. If justified based on the work of the facility, was a peer review process involving independent and competent third parties conducted to ensure the design specification ensures relevant legislative requirements, standards and risk assessment findings have been incorporated into the design?

Institutional Response: {pgFortyTwo\_gqEleven}

### What is the importance of this requirement?

Institutional Response: {pgFortyTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyTwo\_range}

# CWA Requirement 4.4.4.8.2: Commissioning and decommissioning

The organization shall ensure that there is a formal process for initial commissioning of new facilities and the final decommissioning of existing ones.

## Guiding Questions:

1. Was the commissioning process started at the design phase, such as at the first stage of science programme definition?

Institutional Response: {pgFortyThree\_gqOne}

1. Was the commissioning plan developed in parallel with the design concepts to ensure the expectations for the building are measurable?

Institutional Response: {pgFortyThree\_gqTwo}

1. Does the commissioning plan identify all steps in the commissioning process from beginning to end, including conditions of acceptance before moving to the next step?

Institutional Response: {pgFortyThree\_gqThree}

1. In developing the facility's commissioning process, were written procedures on integrated system testing considered?

Institutional Response: {pgFortyThree\_gqFour}

1. In developing the facility's commissioning process, were written procedures on equipment testing considered?

Institutional Response: {pgFortyThree\_gqFive}

1. In developing the facility's commissioning process, were written procedures on components testing considered?

Institutional Response: {pgFortyThree\_gqSix}

1. In developing the facility's commissioning process, were written procedures on verification of the structural integrity of the facilities according to acceptable criteria or local building regulations considered?

Institutional Response: {pgFortyThree\_gqSeven}

1. Is the commissioning report documented and retained?

Institutional Response: {pgFortyThree\_gqEight}

1. Does the decommissioning process identify the decontamination procedures and any biosecurity-related measures associated with decontamination?

Institutional Response: {pgFortyThree\_gqNine}

1. Does the decommissioning process describe the standards of acceptance when decommissioning procedures are performed?

Institutional Response: {pgFortyThree\_gqTen}

1. Are there clearance certificates or permits to work that identify when and under what conditions the decommissioned facility can be re-entered?

Institutional Response: {pgFortyThree\_gqEleven}

1. Did the organization consider having an independent third party perform the commissioning and decommissioning of the facilities?

Institutional Response: {pgFortyThree\_gqTwelve}

1. Is there documentation of the decommissioning plan and verification that the decommissioning process has been completed safely?

Institutional Response: {pgFortyThree\_gqThirteen}

### What is the importance of this requirement?

Institutional Response: {pgFortyThree\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyThree\_range}

# CWA Requirement 4.4.4.8.3: Maintenance, control, calibration, certification, and verification

The organization shall establish and maintain documented procedures to ensure equipment and elements of the physical plant that may impact on biorisk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the biorisk management programme.

## Guiding Questions:

1. Is there a facility maintenance program established that applies to all aspects of the physical structure, grounds and equipment at the institution?

Institutional Response: {pgFortyFour\_gqOne}

1. Is a documented process and procedure in place to ensure all materials and equipment that are used in the facility meet predetermined specifications?

Institutional Response: {pgFortyFour\_gqTwo}

1. Is maintenance performed in accordance with the facility's maintenance plan, and manufacturers' recommendations where appropriate?

Institutional Response: {pgFortyFour\_gqThree}

1. In developing a maintenance plan, did the organization consider how to maintain the physical integrity of the facility and its fixtures and fittings?

Institutional Response: {pgFortyFour\_gqFour}

1. In developing a maintenance plan did the organization consider how to ensure maintenance activities are performed by competent individuals and that risks associated with the work have been subjected to a risk assessment?

Institutional Response: {pgFortyFour\_gqFive}

1. In developing a facility maintenance plan did the organization consider identifying and recording maintenance requirements at the time of construction, and determine predictive maintenance requirements and associated indicators?

Institutional Response: {pgFortyFour\_gqSix}

1. In developing an equipment maintenance plan did the organization consider identifying and recording maintenance requirements at the purchase acquisition of equipment, and determine predictive maintenance requirements and associated indicators?

Institutional Response: {pgFortyFour\_gqSeven}

1. In developing a maintenance plan did the organization consider establishing a maintenance register for all applicable equipment?

Institutional Response: {pgFortyFour\_gqEight}

1. In developing a maintenance plan did the organization identify and plan maintenance activities at appropriate frequency based on predictive maintenance requirements and associated indicators and monitors?

Institutional Response: {pgFortyFour\_gqNine}

1. In developing a maintenance plan did the organization ensure adequate provision of resources for unplanned maintenance?

Institutional Response: {pgFortyFour\_gqTen}

1. In developing a maintenance plan did the organization set aside resources to procure essential spare parts?

Institutional Response: {pgFortyFour\_gqEleven}

1. In developing a maintenance plan did the organization consider a pest control programme?

Institutional Response: {pgFortyFour\_gqTwelve}

1. In developing a facility-specific equipment plan did the organization identify equipment in line with identified work needs?

Institutional Response: {pgFortyFour\_gqThirteen}

1. In developing an equipment control plan did the organization control the purchase/acquisition/transfer of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel?

Institutional Response: {pgFortyFour\_gqFourteen}

1. In developing a facility-specific equipment plan did the organization establish a system to document equipment, material and waste, including establishing a records system for audit?

Institutional Response: {pgFortyFour\_gqFifteen}

1. In developing an equipment control plan did the organization establish and maintain an inventory of all facility and scientific equipment including spare parts and consumables?

Institutional Response: {pgFortyFour\_gqSixteen}

1. For equipment certification activities did the organization identify and record certification requirements at the time of purchase and include relevant and current standards?

Institutional Response: {pgFortyFour\_gqSeventeen}

1. For equipment certification activities did the organization ensure competent and independent certifiers were used?

Institutional Response: {pgFortyFour\_gqEighteen}

1. For equipment certification activities did the organization ensure certification was scheduled, conducted, and recorded in line with manufacturers requirements, equipment relocation, and other specified intervals as identified by a risk assessment?

Institutional Response: {pgFortyFour\_gqNineteen}

1. In performing equipment validation did the organization identify and record validation requirements at time of purchase?

Institutional Response: {pgFortyFour\_gqTwenty}

1. In performing validation did the organization identify the standards/tests that will be used to ensure the equipment is correctly validated?

Institutional Response: {pgFortyFour\_gqTwentyOne}

1. In performing equipment validation did the organization ensure validation is scheduled, conducted, and recorded (for example, in an equipment validation register for each piece of equipment) in line with manufacturer’s requirements or as identified by a risk assessment?

Institutional Response: {pgFortyFour\_gqTwentyTwo}

1. In performing equipment validation did the organization ensure competent and independent validation companies are used, if required for proper validation?

Institutional Response: {pgFortyFour\_gqTwentyThree}

1. In performing equipment validation did the organization perform the required tests for the validation?

Institutional Response: {pgFortyFour\_gqTwentyFour}

1. For certification activities did the organization ensure re-certification is performed at the required intervals?

Institutional Response: {pgFortyFour\_gqTwentyFive}

1. In performing validation did the organization identify and record validation requirements at time of purchase?

Institutional Response: {pgFortyFour\_gqTwentySix}

1. In performing validation did the organization identify the standards/tests that will be used to ensure the equipment is correctly validated?

Institutional Response: {pgFortyFour\_gqTwentySeven}

1. In performing validation did the organization create a documented, up-to-date validation register for equipment?

Institutional Response: {pgFortyFour\_gqTwentyEight}

1. In performing validation did the organization ensure validation is scheduled and conducted in line with manufacturer’s requirements or as identified by a risk assessment?

Institutional Response: {pgFortyFour\_gqTwentyNine}

1. In performing validation did the organization ensure competent and independent validation companies are used?

Institutional Response: {pgFortyFour\_gqThirty}

1. In performing validation did the organization perform the required tests for the validation?

Institutional Response: {pgFortyFour\_gqThirtyOne}

### What is the importance of this requirement?

Institutional Response: {pgFortyFour\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyFour\_range}

# CWA Requirement 4.4.4.8.4: Physical security

The organization shall ensure that the controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained.

## Guiding Questions:

1. Has a biosecurity risk assessment been conducted and documented?

Institutional Response: {pgFortyFive\_gqOne}

1. Is the facility's physical security system designed based on a biosecurity risk assessment, including security scenarios?

Institutional Response: {pgFortyFive\_gqTwo}

1. Is the physical security system designed to protect relevant assets (hazardous materials, sensitive information, critical systems or equipment)?

Institutional Response: {pgFortyFive\_gqThree}

1. Is the physical security system designed to address the security risks posed by biohazardous waste?

Institutional Response: {pgFortyFive\_gqFour}

1. Is the facility perimeter well-defined and intact?

Institutional Response: {pgFortyFive\_gqFive}

1. Does the physical security system effectively limit access to areas where assets are stored or used to those personnel who have a need to access those areas?

Institutional Response: {pgFortyFive\_gqSix}

1. Is the physical security system designed using a "graded" approach in which high risk areas are secured to a greater degree than lower risk areas?

Institutional Response: {pgFortyFive\_gqSeven}

1. Does the physical security system design incorporate the principles of "detection," "assessment," "delay," and "response?”

Institutional Response: {pgFortyFive\_gqEight}

1. Does the physical security system enable authorized personnel to access secured areas to which they have access, and prevent unauthorized access to non-authorized personnel?

Institutional Response: {pgFortyFive\_gqNine}

1. Are personnel trained on proper use of the physical security system?

Institutional Response: {pgFortyFive\_gqTen}

1. Is the physical security system designed to provide an immediate notification to a response force in case of a security incident?

Institutional Response: {pgFortyFive\_gqEleven}

1. Does the facility have a response plan in place in case of a biosecurity incident (for example, an unauthorized intrusion)?

Institutional Response: {pgFortyFive\_gqTwelve}

1. Does the physical security system design account for relevant biosafety and worker safety requirements?

Institutional Response: {pgFortyFive\_gqThirteen}

1. Is the performance of the physical security system regularly checked, tested, verified?

Institutional Response: {pgFortyFive\_gqFourteen}

1. Is a maintenance program established to conduct routine checks and maintenance of physical security equipment?

Institutional Response: {pgFortyFive\_gqFifteen}

1. Is the effectiveness of the physical security system regularly reviewed?

Institutional Response: {pgFortyFive\_gqSixteen}

### What is the importance of this requirement?

Institutional Response: {pgFortyFive\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyFive\_range}

# CWA Requirement 4.4.4.8.5: Information security

The organization shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to control access to such information.

## Guiding Questions:

1. Does the facility have a policy and procedure in place to protect sensitive information?

Institutional Response: {pgFortySix\_gqOne}

1. Are roles and responsibilities for maintaining information security assigned and communicated?

Institutional Response: {pgFortySix\_gqTwo}

1. Is a process in place to identify sensitive information?

Institutional Response: {pgFortySix\_gqThree}

1. Are procedures in place to ensure sensitive information is appropriately marked and/or labeled?

Institutional Response: {pgFortySix\_gqFour}

1. Is a process in place to determine which personnel may access specific sensitive information, including consideration of the "need to know" principle?

Institutional Response: {pgFortySix\_gqFive}

1. Are procedures in place to ensure sensitive information storage areas are secured in a "graded" manner based on the risk posed by the unauthorized release of sensitive information?

Institutional Response: {pgFortySix\_gqSix}

1. Are procedures in place to manage the communication of sensitive information?

Institutional Response: {pgFortySix\_gqSeven}

1. Are procedures in place for transmitting sensitive information internally and externally, including through electronic and telephonic means?

Institutional Response: {pgFortySix\_gqEight}

1. Has the facility adopted network security measures?

Institutional Response: {pgFortySix\_gqNine}

1. Are procedures established to protect sensitive electronic information stored on electronic devices, including computers, laptops, tablets, or other devices (for example, password protection of user accounts and sensitive files)?

Institutional Response: {pgFortySix\_gqTen}

1. Are any off-site information storage locations (physical or electronic) secured to an appropriate degree based on risk?

Institutional Response: {pgFortySix\_gqEleven}

1. Are procedures established for the review and approval of information before release to the public or other external groups?

Institutional Response: {pgFortySix\_gqTwelve}

1. Is sensitive information that is no longer needed securely destroyed before disposal?

Institutional Response: {pgFortySix\_gqThirteen}

1. Are facility personnel trained on their information security responsibilities?

Institutional Response: {pgFortySix\_gqFourteen}

1. Are information security measures regularly tested and updated to ensure continued effectiveness?

Institutional Response: {pgFortySix\_gqFifteen}

1. Is there a procedure in place for personnel to report a potential information security incident?

Institutional Response: {pgFortySix\_gqSixteen}

1. Has the facility developed a process to investigate potential information security incidents?

Institutional Response: {pgFortySix\_gqSeventeen}

1. Is the effectiveness of the information security system regularly reviewed?

Institutional Response: {pgFortySix\_gqEighteen}

### What is the importance of this requirement?

Institutional Response: {pgFortySix\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortySix\_range}

# CWA Requirement 4.4.4.8.6: Control of supplies

The organization shall ensure that purchases (including services) conform to specified requirements. Controls shall be applied depending on potential impact on the biorisk involved. The organization shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this standard. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

## Guiding Questions:

1. Does the organization have a process in place to select, evaluate, and re-evaluate suppliers to ensure they meet the requirements of safety and security and the biorisk programme of the facility?

Institutional Response: {pgFortySeven\_gqOne}

1. Does the organization have a process in place to evaluate all purchases to ensure they meet the requirements of safety and security, and which is dependent on the potential biorisks involved?

Institutional Response: {pgFortySeven\_gqTwo}

1. Is the evaluation of suppliers based on documented procedures for the procurement of supplies and services, including taking into account legal and permit requirements?

Institutional Response: {pgFortySeven\_gqThree}

1. Are the necessary actions taken arising from the review documented and maintained as records?

Institutional Response: {pgFortySeven\_gqFour}

1. Do the reviews take into account the risks associated with the materials and services that are intended to be purchased?

Institutional Response: {pgFortySeven\_gqFive}

### What is the importance of this requirement?

Institutional Response: {pgFortySeven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortySeven\_range}

# CWA Requirement 4.4.4.9: Transport of biological agents and toxins

The organization shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.

## Guiding Questions:

1. Does the organization ensure transport requirements are identified and implemented, including legal requirements and national and international guidelines for the transport of dangerous goods?

Institutional Response: {pgFortyEight\_gqOne}

1. Does the organization ensure adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transportation process?

Institutional Response: {pgFortyEight\_gqTwo}

1. If applicable, does the organization select a reliable, trustworthy carrier that is qualified to handle the package safely and securely?

Institutional Response: {pgFortyEight\_gqThree}

1. Does the organization determine whether a request for biological agents and toxins or material that may contain viable biological agents is being made by an approved facility for a legitimate reason and appropriate risk controls are applied to importation of material to the facility?

Institutional Response: {pgFortyEight\_gqFour}

1. Does the organization determine and ensure that formal transfer documents will be signed by the responsible management representative authorizing movement of materials?

Institutional Response: {pgFortyEight\_gqFive}

1. Does the organization implement document control that allows traceability of material movements, both internally and externally?

Institutional Response: {pgFortyEight\_gqSix}

1. Does the organization identify and implement adequate and proportionate emergency response and contingency plans associated with transportation, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-offs?

Institutional Response: {pgFortyEight\_gqSeven}

1. Does the organization identify and train a transport safety advisor who should be aware of the specific carrier requirements for a biological agent shipment?

Institutional Response: {pgFortyEight\_gqEight}

1. Does the organization receive an acknowledgement by the receiving organization that the material was delivered and in a safe and secure condition?

Institutional Response: {pgFortyEight\_gqNine}

1. Has the organization received a written acknowledgement or confirmation from carrier that they have an appropriate security plan for the materials being transported?

Institutional Response: {pgFortyEight\_gqTen}

1. Does the organization retain documentation of staff training in shipping and/or transport of biological agents?

Institutional Response: {pgFortyEight\_gqEleven}

1. Does the organization have documentation describing requirements for transportation of biological materials (shipment, verification, responsible personnel)?

Institutional Response: {pgFortyEight\_gqTwelve}

1. Are individuals responsible for receiving and sending materials authorized to have access to biological agents?

Institutional Response: {pgFortyEight\_gqThirteen}

### What is the importance of this requirement?

Institutional Response: {pgFortyEight\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyEight\_range}

# CWA Requirement 4.4.5: Emergency response and contingency planning

The organization shall establish and maintain plans and procedures to identify the potential for incidents and emergency situations involving biological agents, toxins and materials, to prevent their occurrence, to respond to emergency situations and to limit the likely illness or other damage that may be associated with them. Emergency planning shall cover all aspects of biorisk and include general safety, security and medical issues.

## Guiding Questions:

1. Does the organization have risk assessment data necessary to begin the emergency response planning process?

Institutional Response: {pgFortyNine\_gqOne}

1. Does the organization identify and assign roles to and responsibilities of staff members in the event of an emergency?

Institutional Response: {pgFortyNine\_gqTwo}

1. Does the organization identify roles and responsibilities of people involved in emergency management?

Institutional Response: {pgFortyNine\_gqThree}

1. Does the organization identify and list (inventory) readily accessible emergency equipment, including location and maintenance status?

Institutional Response: {pgFortyNine\_gqFour}

1. Does the organization assess the availability of local emergency responders?

Institutional Response: {pgFortyNine\_gqFive}

1. Does the organization maintain a list of regulatory bodies to report to, depending on the level of emergency?

Institutional Response: {pgFortyNine\_gqSix}

1. Does the organization maintain information from consultation and planning sessions with local emergency responders?

Institutional Response: {pgFortyNine\_gqSeven}

1. Does the organization record and preserve experience from previous accidents or incidents at the facility or from similar facilities?

Institutional Response: {pgFortyNine\_gqEight}

1. Does the organization record and preserve accident and incident investigation reports (lessons learned)?

Institutional Response: {pgFortyNine\_gqNine}

1. Does the organization review emergency drills and exercises?

Institutional Response: {pgFortyNine\_gqTen}

1. Does the organization provide informational signage related to emergency response such as evacuation routes, exit signage, location of emergency response equipment, etc.?

Institutional Response: {pgFortyNine\_gqEleven}

1. Does the organization develop emergency plan(s) (see 4.4.5.2)?

Institutional Response: {pgFortyNine\_gqTwelve}

1. Does the organization identify necessary emergency equipment provided to responders and periodically test its suitability?

Institutional Response: {pgFortyNine\_gqThirteen}

1. Does the organization have procedures for reviewing and capturing lessons learned following each incident or emergency response event in order to improve future performance?

Institutional Response: {pgFortyNine\_gqFourteen}

1. Does the organization have procedures for coordinating response plan processes and resources across organizational, municipal, governmental levels, etc.?

Institutional Response: {pgFortyNine\_gqFifteen}

1. Do emergency plans include an operational continuity plan?

Institutional Response: {pgFortyNine\_gqSixteen}

1. Does the organization provide training to staff in indigenous languages?

Institutional Response: {pgFortyNine\_gqSeventeen}

### What is the importance of this requirement?

Institutional Response: {pgFortyNine\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFortyNine\_range}

# CWA Requirement 4.4.5.1: Emergency scenarios

The organization shall ensure that all credible and foreseeable emergency scenarios that may impact the organization’s biorisks have been identified. In order that emergency planning can take place, it is necessary to consider all credible emergency scenarios. It is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, the rationale as to why issues were dismissed.

## Guiding Questions:

1. Does the organization identify all credible potential accident and emergency scenarios in order to develop and validate planned responses?

Institutional Response: {pgFifty\_gqOne}

1. Do emergency scenarios include an infected/potentially infected worker or other contact (e.g. family member, emergency responder or community member?

Institutional Response: {pgFifty\_gqTwo}

1. Do emergency scenarios include accident or illness to workers and need for evacuation?

Institutional Response: {pgFifty\_gqThree}

1. Do emergency scenarios include fire?

Institutional Response: {pgFifty\_gqFour}

1. Do emergency scenarios include flood?

Institutional Response: {pgFifty\_gqFive}

1. Do emergency scenarios include breach of security?

Institutional Response: {pgFifty\_gqSix}

1. Do emergency scenarios include explosion?

Institutional Response: {pgFifty\_gqSeven}

1. Do emergency scenarios include potential loss of biological agents or toxins through theft or any other reason?

Institutional Response: {pgFifty\_gqEight}

1. Do emergency scenarios include chemical spill?

Institutional Response: {pgFifty\_gqNine}

1. Do emergency scenarios include unexpected virulence (unknown biological agents or biological agents expected to be virulent)?

Institutional Response: {pgFifty\_gqTen}

1. Do emergency scenarios include theft or spill of radioactive materials?

Institutional Response: {pgFifty\_gqEleven}

1. Do emergency scenarios include physical facility and equipment failure, including control system failure?

Institutional Response: {pgFifty\_gqTwelve}

1. Do emergency scenarios include failure of disinfection regime?

Institutional Response: {pgFifty\_gqThirteen}

1. Do emergency scenarios include utility failure including electricity, gas, steam and water supplies?

Institutional Response: {pgFifty\_gqFourteen}

1. Do emergency scenarios include major spillage/aerosol release?

Institutional Response: {pgFifty\_gqFifteen}

1. Do emergency scenarios include environmental release?

Institutional Response: {pgFifty\_gqSixteen}

1. Do emergency scenarios include natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.)?

Institutional Response: {pgFifty\_gqSeventeen}

1. Do emergency scenarios include acts of terrorism or deliberate vandalism?

Institutional Response: {pgFifty\_gqEighteen}

1. Do emergency scenarios consider the potential for intense media attention?

Institutional Response: {pgFifty\_gqNineteen}

1. Do emergency scenarios consider the potential for loss of communication systems?

Institutional Response: {pgFifty\_gqTwenty}

### What is the importance of this requirement?

Institutional Response: {pgFifty\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFifty\_range}

# CWA Requirement 4.4.5.2: Emergency plans

The organization shall ensure that biorisks are taken into account when preparing and implementing emergency plans. The organization shall ensure a system is established to effectively manage medical and/or environmental emergencies, including, but not limited to, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers. The organization shall also ensure that control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency. Emergency plans shall be effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations.

## Guiding Questions:

1. Do emergency response plans include identification of the location of hazardous materials and the emergency action required?

Institutional Response: {pgFiftyOne\_gqOne}

1. Do emergency response plans include risk assessments data?

Institutional Response: {pgFiftyOne\_gqTwo}

1. Do emergency response plans include lessons learned from previous emergency response activities to improve effectiveness of response procedures?

Institutional Response: {pgFiftyOne\_gqThree}

1. Do emergency response plans include information from consultation and planning sessions with local emergency responders?

Institutional Response: {pgFiftyOne\_gqFour}

1. Do emergency response plans include identifying measures to control environmental impacts?

Institutional Response: {pgFiftyOne\_gqFive}

1. Do emergency plans include evacuation procedures?

Institutional Response: {pgFiftyOne\_gqSix}

1. Do emergency plans include maps?

Institutional Response: {pgFiftyOne\_gqSeven}

1. Do emergency response plans include making relevant information available during the emergency (building layouts, location and nature of hazardous materials data where examples include material safety data sheets, laboratory containment level, and contacts information?

Institutional Response: {pgFiftyOne\_gqEight}

1. Do emergency response plans include information from emergency and practice evacuation drills?

Institutional Response: {pgFiftyOne\_gqNine}

1. Do emergency plans include identification of people in charge during the emergency (chain of command in accordance with the level of the emergency)?

Institutional Response: {pgFiftyOne\_gqTen}

1. Do emergency plans include designation of authority of people with specific roles during the emergency (wardens, first aid staff, spill teams, maintenance, interaction with first responders, etc.)?

Institutional Response: {pgFiftyOne\_gqEleven}

1. Do emergency plans include involvement of relevant management levels depending on the type of emergency?

Institutional Response: {pgFiftyOne\_gqTwelve}

1. Do emergency plans include the need to respond during out-of-hours emergencies as well as those that occur during normal working hours?

Institutional Response: {pgFiftyOne\_gqThirteen}

1. Do emergency plans include provision for periods of reduced staff availability (e.g. during weekends and holiday periods)?

Institutional Response: {pgFiftyOne\_gqFourteen}

1. Do emergency plans include identification of those responsible for devising, implementing and testing the control measures specified?

Institutional Response: {pgFiftyOne\_gqFifteen}

1. Do emergency plans include identification, roles and availability of police and security services?

Institutional Response: {pgFiftyOne\_gqSixteen}

1. Do emergency plans include identification, roles and availability of fire services?

Institutional Response: {pgFiftyOne\_gqSeventeen}

1. Do emergency plans include identification, roles and availability of ambulance and local hospitals/healthcare providers?

Institutional Response: {pgFiftyOne\_gqEighteen}

1. Do emergency plans include identification, roles and availability of transport providers/couriers?

Institutional Response: {pgFiftyOne\_gqNineteen}

1. Do emergency plans include identification, roles and availability of local and national government officials, including environmental officials?

Institutional Response: {pgFiftyOne\_gqTwenty}

1. Do emergency plans include documenting contact information and making it available to personnel responsible for coordinating the emergency response activity?

Institutional Response: {pgFiftyOne\_gqTwentyOne}

1. Do emergency plans include informing and educating external services in their roles and any risk exposures they may face and ensure their actions will not unnecessarily increase the risk associated with the emergency (e.g., uncontrolled use of water for suppressing fire)?

Institutional Response: {pgFiftyOne\_gqTwentyTwo}

1. Do emergency plans include reviewing options to sign a memorandum of understanding or agreements with key responders?

Institutional Response: {pgFiftyOne\_gqTwentyThree}

1. Do evacuation plans include emergency access/exit, including the ability to override access controls as appropriate?

Institutional Response: {pgFiftyOne\_gqTwentyFour}

1. Do evacuation plans include emergency exit routes that avoid evacuating people through areas of greater biosafety or biosecurity?

Institutional Response: {pgFiftyOne\_gqTwentyFive}

1. Do evacuation plans include provision for safe removal, transport, transfer, treatment, and accommodation of contaminated persons, objects, etc.?

Institutional Response: {pgFiftyOne\_gqTwentySix}

1. Do emergency plans include procedures to address worker health needs in the event of an accident or emergency, including first responders and their families and members of the broader community?

Institutional Response: {pgFiftyOne\_gqTwentySeven}

1. Do emergency plans include procedures to address environmental conditions that may have been affected by the incident?

Institutional Response: {pgFiftyOne\_gqTwentyEight}

1. Do emergency plans include the identification of emergency scenarios, including infected worker/family members?

Institutional Response: {pgFiftyOne\_gqTwentyNine}

1. Do emergency plans include necessary support measures (e.g., liaison with emergency services/local authorities), provision of equipment and other resources required to manage the emergency (e.g., prophylaxis, post exposure treatment, disinfectants, isolation requirements, vaccines, etc.)?

Institutional Response: {pgFiftyOne\_gqThirty}

1. Are necessary plans and other materials for managing medical emergencies prepared, tested, and maintained?

Institutional Response: {pgFiftyOne\_gqThirtyOne}

1. Do emergency plans include the assurance of adequacy of first aid provision in relation to credible accident scenarios identified during risk assessment?

Institutional Response: {pgFiftyOne\_gqThirtyTwo}

1. Do emergency plans address the need for adequate provision of trained personnel and their availability, as well as equipment and other materials that may be required in the provision of treatment?

Institutional Response: {pgFiftyOne\_gqThirtyThree}

1. Do emergency plans include identification of additional available competent medical support (e.g., hospitals, isolation units, etc.)?

Institutional Response: {pgFiftyOne\_gqThirtyFour}

1. Do emergency plans identify personnel knowledgeable in risk communication who is responsible for communicating on behalf of the facility with the general public and the community, the authorities, and the employees?

Institutional Response: {pgFiftyOne\_gqThirtyFive}

1. Do emergency plans include developing communication plans and procedures for communicating specific actions to be taken by personnel at the site of the emergency, including contractors and visitors?

Institutional Response: {pgFiftyOne\_gqThirtySix}

1. Do emergency plans include informing and educating external services in their roles and any risk exposures they may face to ensure their actions will not necessarily increase the risk associated with the emergency (e.g. uncontrolled use of fire water, receipt by hospital emergency of patients possibly infected with biological agents)?

Institutional Response: {pgFiftyOne\_gqThirtySeven}

1. Do emergency plans include determining the needs for purchase of emergency equipment such as alarm systems, emergency lighting and power, means of escape, safe refuges, critical isolation valves, firefighting and first aid equipment, safety, security and backup power equipment, communication facilities?

Institutional Response: {pgFiftyOne\_gqThirtyEight}

1. Do emergency plans include testing, storage in a safe and accessible location, and documentation (inventory) of emergency equipment?

Institutional Response: {pgFiftyOne\_gqThirtyNine}

### What is the importance of this requirement?

Institutional Response: {pgFiftyOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyOne\_range}

# CWA Requirement 4.4.5.3: Emergency exercises and simulations

The organization shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.

## Guiding Questions:

1. Does the organization actively test its emergency plans with exercises involving all pertinent employees and staff in order to provide an assurance that plans are complete and effective and to learn from any lessons that arise?

Institutional Response: {pgFiftyTwo\_gqOne}

1. Does the organization include external organizations or agencies (e.g. local fire-fighters, police department, and county or state emergency management teams) during practice drills?

Institutional Response: {pgFiftyTwo\_gqTwo}

1. Are emergency exercises and simulations based on emergency plans and considerations developed under section 4.4.5.2?

Institutional Response: {pgFiftyTwo\_gqThree}

1. Are emergency exercises and simulations (e.g. desktop exercises, mock exercises, practice drills), realistic representations of the events they are designed to simulate in order to provide greater assurance that the actions planned are effective in the event of a real emergency?

Institutional Response: {pgFiftyTwo\_gqFour}

1. Do emergency exercises and simulations include conducting exercises under controlled conditions so they are not allowed to become a source of risk in their own right?

Institutional Response: {pgFiftyTwo\_gqFive}

1. Do emergency exercises and simulations include evaluating results from exercises and drills, including security drills, after each exercise?

Institutional Response: {pgFiftyTwo\_gqSix}

1. Do organizations have a process for learning from emergency exercises, and for identifying and implementing modifications to emergency plans to ensure effectiveness and completeness?

Institutional Response: {pgFiftyTwo\_gqSeven}

1. Do emergency exercises and simulations include providing feedback to appropriate personnel on performance?

Institutional Response: {pgFiftyTwo\_gqEight}

1. Do emergency exercises and simulations include recording any actions that have arisen and allocate to named individuals?

Institutional Response: {pgFiftyTwo\_gqNine}

1. Do emergency exercises and simulations include ensuring that changes to the plans based on the outcomes of the exercises and simulations are implemented?

Institutional Response: {pgFiftyTwo\_gqTen}

1. Do emergency exercises and simulations include determining the frequency and type of emergency exercises and simulations, including security drills based on the likelihood of the event?

Institutional Response: {pgFiftyTwo\_gqEleven}

### What is the importance of this requirement?

Institutional Response: {pgFiftyTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyTwo\_range}

# CWA Requirement 4.4.5.4: Contingency plans

The organization shall ensure that in the event of an emergency, adequate contingency measures shall be in place to ensure the safety and security of continued operations.

## Guiding Questions:

1. Are contingency plans developed by the organization?

Institutional Response: {pgFiftyThree\_gqOne}

1. Do contingency plans include identification of possible emergencies considered under section 4.4.5.2?

Institutional Response: {pgFiftyThree\_gqTwo}

1. Do contingency plans include availability of vital records and equipment and ensuring their protection?

Institutional Response: {pgFiftyThree\_gqThree}

1. Does the process for the development of contingency plans consider risk assessment data?

Institutional Response: {pgFiftyThree\_gqFour}

1. Do contingency plans include lessons learned from past events?

Institutional Response: {pgFiftyThree\_gqFive}

1. Do contingency plans include identifying individuals who should be notified if the contingency plan is activated, the best method for contacting them, and their contact information?

Institutional Response: {pgFiftyThree\_gqSix}

1. Do contingency plans include consideration of alternate storage areas for critical or high-risk materials?

Institutional Response: {pgFiftyThree\_gqSeven}

1. Do contingency plans include a list of equipment and systems that would be affected by an emergency or unforeseen events that may cause a partial or full disruption of normal working conditions?

Institutional Response: {pgFiftyThree\_gqEight}

1. Do contingency plans include identification of critical areas and systems for priority response?

Institutional Response: {pgFiftyThree\_gqNine}

1. Do contingency plans include identification and prioritization in terms of likelihood, based on risk assessment, of the possible reasons for a partial or full disruption to normal operating conditions?

Institutional Response: {pgFiftyThree\_gqTen}

1. Do contingency plans include procedures for complete, safe and secure shutdown of all operations, if circumstances require?

Institutional Response: {pgFiftyThree\_gqEleven}

1. Do contingency plans include procedures for identifying affected areas, including physical locations and functions? These may include identification of the warning indicators. For a power failure, indicators may include lights and electrical equipment.

Institutional Response: {pgFiftyThree\_gqTwelve}

1. Do contingency plans include establishing a recovery time objective (minutes, hours, days, etc.) to determine when the plan should be activated to prevent major interruptions?

Institutional Response: {pgFiftyThree\_gqThirteen}

1. Do contingency plans include checking and monitoring the status of backup resources in priority order (generator, UPS devices, access to document storage etc.) and documenting this information during each monitoring event?

Institutional Response: {pgFiftyThree\_gqFourteen}

1. Do contingency plans include recovery of backup resources, in priority order, listing the backup resources available?

Institutional Response: {pgFiftyThree\_gqFifteen}

1. Do contingency plans include review of the potential to start work in a different location?

Institutional Response: {pgFiftyThree\_gqSixteen}

### What is the importance of this requirement?

Institutional Response: {pgFiftyThree\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyThree\_range}

# CWA Requirement 4.5.1: Performance measurement and analysis of data

The organization shall ensure that appropriate data are determined, collected and analyzed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.

## Guiding Questions:

1. Does the organization develop and implement methods to measure proactively and reactively, as appropriate, the effectiveness of its biorisk management programme and to determine if any improvements are required, including assigning responsibilities for these tasks?

Institutional Response: {pgFiftyFour\_gqOne}

1. Does the system to measure and analyze data include identification of information appropriate for biorisk management, e.g., data from performance measurements from staff, equipment and training?

Institutional Response: {pgFiftyFour\_gqTwo}

1. Does the system to measure and analyze data include results of walk-through inspections and audits, both internal and external?

Institutional Response: {pgFiftyFour\_gqThree}

1. Does the system to measure and analyze data include reported accidents, injuries and near misses and the actions taken to prevent reoccurrence?

Institutional Response: {pgFiftyFour\_gqFour}

1. Does the system to measure and analyze data include quality control, performance results and calibration of the equipment (e.g. safety and security equipment and systems testing)?

Institutional Response: {pgFiftyFour\_gqFive}

1. Does the system to measure and analyze data include environmental sampling?

Institutional Response: {pgFiftyFour\_gqSix}

1. Does the system to measure and analyze data include results of security and emergency response exercises?

Institutional Response: {pgFiftyFour\_gqSeven}

1. Does the system to measure and analyze data include analysis of documentation and records (e.g. review of biological material inventories)?

Institutional Response: {pgFiftyFour\_gqEight}

1. Does the system to measure and analyze data include employee surveys?

Institutional Response: {pgFiftyFour\_gqNine}

1. Does the system to measure and analyze data include unanticipated events which were not considered during the risk assessment?

Institutional Response: {pgFiftyFour\_gqTen}

1. Does the system to measure and analyze data include response to non-conformities resulting from an inspection or a biorisk management system audit or job hazard assessments?

Institutional Response: {pgFiftyFour\_gqEleven}

1. Is a biorisk management system performance analysis conducted at least annually and more often if justified by the risks and the scope of operations?

Institutional Response: {pgFiftyFour\_gqTwelve}

1. Are the results of the performance analysis applied in management review?

Institutional Response: {pgFiftyFour\_gqThirteen}

### What is the importance of this requirement?

Institutional Response: {pgFiftyFour\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyFour\_range}

# CWA Requirement 4.5.2: Records, document and data control

The organization shall ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this standard and that they remain legible, readily identifiable and retrievable.

## Guiding Questions:

1. Has the organization established a document control programme to demonstrate that its biorisk management programme meets the requirements of the CWA 15793:2008?

Institutional Response: {pgFiftyFive\_gqOne}

1. Is a procedure established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records, including assuring that information is accessible only to people who need it?

Institutional Response: {pgFiftyFive\_gqTwo}

1. Is a procedure established to define the controls needed to approve documents prior to issue or public release to ensure sensitive information is not inadvertently released?

Institutional Response: {pgFiftyFive\_gqThree}

1. Are procedures established to define the controls for review, revision, update and re-approval of documents?

Institutional Response: {pgFiftyFive\_gqFour}

1. Are controlled documents subject to version control, including establishing periods of validity, review and revision dates?

Institutional Response: {pgFiftyFive\_gqFive}

1. Has the organization established a defined process for determining which documents are subject to control (controlled documents), based in part of biorisk?

Institutional Response: {pgFiftyFive\_gqSix}

1. Has the organization conducted a review of documentation and information needs, considering legal and other requirements related to documentation, data and record management?

Institutional Response: {pgFiftyFive\_gqSeven}

1. Has the organization assigned responsibility for documentation and maintenance of the information, including retention periods and disposal?

Institutional Response: {pgFiftyFive\_gqEight}

1. Has the organization carefully considered and determined in what medium various types of protected information will be recorded and stored, including considering issues related with electronic repositories (document versioning, electronic records, software, etc.)?

Institutional Response: {pgFiftyFive\_gqNine}

### What is the importance of this requirement?

Institutional Response: {pgFiftyFive\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyFive\_range}

# CWA Requirement 4.5.3: Inventory monitoring and control

The organization shall ensure that a review of the inventory is conducted at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner. The organization shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.

## Guiding Questions:

1. Does the organization ensure that the inventory of all biological agents and toxins within the facility is well maintained and reviewed on a regular basis?

Institutional Response: {pgFiftySix\_gqOne}

1. Does the organization take steps to destroy or otherwise safely dispose of biological materials that are no longer useful?

Institutional Response: {pgFiftySix\_gqTwo}

1. Is the nature of the inventory and associated controls based upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse?

Institutional Response: {pgFiftySix\_gqThree}

1. Does the organization demonstrate proactive measures toward the reduction of risk through elimination, substitution or minimization of volumes/quantities of biological agents and toxins used, and the number of manipulations conducted?

Institutional Response: {pgFiftySix\_gqFour}

1. Are procedures in place to investigate potentially missing biological agents appropriate for the level of risk?

Institutional Response: {pgFiftySix\_gqFive}

1. Do the components of an inventory management system include measures or systems to facilitate tracking and review of the inventory, including tubes and box numbering?

Institutional Response: {pgFiftySix\_gqSix}

1. Has the organization established a rationale for the minimizing of the quantity of biological agents held by the organization, such as through the creation of an inventory control plan?

Institutional Response: {pgFiftySix\_gqSeven}

1. Has the organization established a process for a periodic review of the inventory?

Institutional Response: {pgFiftySix\_gqEight}

1. Has the organization established protocols for investigating record discrepancies and tracing missing biological agents that are appropriate for the level of risk?

Institutional Response: {pgFiftySix\_gqNine}

1. Has the organization established a well-defined system of audit or control of inventory?

Institutional Response: {pgFiftySix\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgFiftySix\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftySix\_range}

# CWA Requirement 4.5.4.1: Accident/incident investigation

The organization shall establish and maintain documented procedures to define, record, analyze and learn from accidents and incidents involving biological agents and toxins.

## Guiding Questions:

1. Are procedures set in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel, and may include events of exposure and accidental release?

Institutional Response: {pgFiftySeven\_gqOne}

1. Does the accident/incident investigation process include identifying those responsible for maintaining the accident/incident reporting system?

Institutional Response: {pgFiftySeven\_gqTwo}

1. Does the accident/incident investigation process include defining what constitutes an accident/incident, and what triggers recording and reporting?

Institutional Response: {pgFiftySeven\_gqThree}

1. Does the accident/incident investigation process include specifying required documentation to support the system?

Institutional Response: {pgFiftySeven\_gqFour}

1. Does the accident/incident investigation process include identifying the reports that will be generated, their frequency and distribution?

Institutional Response: {pgFiftySeven\_gqFive}

1. Does the accident/incident investigation process include ensuring analysis of trends?

Institutional Response: {pgFiftySeven\_gqSix}

1. Does the accident/incident investigation process include identifying root causes using individuals trained in investigation techniques?

Institutional Response: {pgFiftySeven\_gqSeven}

1. Does the accident/incident investigation process include providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learned result in action to avoid the repeat of such events and/or minimize their potential impact?

Institutional Response: {pgFiftySeven\_gqEight}

1. Does the accident/incident investigation process include identifying where it may be appropriate or necessary for security professionals to coordinate with law enforcement?

Institutional Response: {pgFiftySeven\_gqNine}

1. Does the accident/incident investigation process include management participation in investigations of major events?

Institutional Response: {pgFiftySeven\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgFiftySeven\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftySeven\_range}

# CWA Requirement 4.5.4.2: Control of nonconformities

The organization shall ensure that situations that do not conform to the requirements of this standard are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.

## Guiding Questions:

1. Are authorities, controls, and related responsibilities for dealing with non-conforming situations well defined?

Institutional Response: {pgFiftyEight\_gqOne}

1. Is there a systematic approach for addressing nonconformities?

Institutional Response: {pgFiftyEight\_gqTwo}

1. Does the organization's approach to addressing nonconformities include procedures to identify, investigate and correct nonconformities taking into account audit and inspection reports, and root cause analysis of nonconformities identified?

Institutional Response: {pgFiftyEight\_gqThree}

1. Does the organization's approach to addressing nonconformities include reviews of operations to prevent anticipated re-occurrence?

Institutional Response: {pgFiftyEight\_gqFour}

1. Does the organization's approach to addressing nonconformities include analysis of the impact of the nonconformity on other aspects of the biorisk management and correction of potential effects?

Institutional Response: {pgFiftyEight\_gqFive}

1. Does the organization's approach to addressing nonconformities include revision of the biorisk management and documentation of the changes made?

Institutional Response: {pgFiftyEight\_gqSix}

1. Does the organization's approach to addressing nonconformities include communication of relevant nonconformities and corrective and preventive actions to impacted individuals?

Institutional Response: {pgFiftyEight\_gqSeven}

### What is the importance of this requirement?

Institutional Response: {pgFiftyEight\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyEight\_range}

# CWA Requirement 4.5.4.3: Corrective action

The organization shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this standard in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

## Guiding Questions:

1. Does the organization have a programme for the review and elimination of potential causes of nonconformities and for preventing their reoccurrence?

Institutional Response: {pgFiftyNine\_gqOne}

1. Has the organization defined requirements for reviewing the nonconformities?

Institutional Response: {pgFiftyNine\_gqTwo}

1. Has the organization defined procedures for determining the cause of nonconformities?

Institutional Response: {pgFiftyNine\_gqThree}

1. Has the organization defined requirements and procedures for evaluating the need for corrective action to ensure that nonconformities do not recur?

Institutional Response: {pgFiftyNine\_gqFour}

1. Has the organization defined requirements for determining needed corrective action plans including identification, prioritization, and implementation of corrective measures?

Institutional Response: {pgFiftyNine\_gqFive}

1. Has the organization defined requirements for recording results of corrective action taken?

Institutional Response: {pgFiftyNine\_gqSix}

1. Has the organization defined requirements for reviewing corrective actions taken to ensure their proper implementation and effectiveness?

Institutional Response: {pgFiftyNine\_gqSeven}

1. Does the organization consider reports and recommendations of inspections, reviews, and audits when establishing corrective action plans?

Institutional Response: {pgFiftyNine\_gqEight}

1. Does the organization consider accident and incident investigations when establishing corrective action plans?

Institutional Response: {pgFiftyNine\_gqNine}

1. Does the organization consider evaluation of risk assessment results when establishing corrective action plans?

Institutional Response: {pgFiftyNine\_gqTen}

### What is the importance of this requirement?

Institutional Response: {pgFiftyNine\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgFiftyNine\_range}

# CWA Requirement 4.5.4.4: Preventative action

The organization shall ensure action is taken to identify and eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential nonconformities.

## Guiding Questions:

1. Does the facility have an established preventative programme aimed at eliminating the root causes of potential nonconformities?

Institutional Response: {pgSixty\_gqOne}

1. Has the organization established procedures for determining the potential non-conformities and their causes?

Institutional Response: {pgSixty\_gqTwo}

1. Has the organization established procedures for evaluating the need for action to prevent occurrence of non-conformities, using all available and relevant information?

Institutional Response: {pgSixty\_gqThree}

1. Has the organization established procedures for determining and implementing routine action needed (e.g., equipment QC, personnel training)?

Institutional Response: {pgSixty\_gqFour}

1. Has the organization established procedures for recording of the results of preventive action taken?

Institutional Response: {pgSixty\_gqFive}

1. Has the organization established procedures to continuously reviewing preventive action taken to ensure proper implementation and effectiveness?

Institutional Response: {pgSixty\_gqSix}

1. Does the organization consider reported accidents, incidents and near-misses and their investigation records when establishing preventive action plans?

Institutional Response: {pgSixty\_gqSeven}

1. Does the organization consider changes in the facility that may affect the biorisk management programme when establishing preventive action plans?

Institutional Response: {pgSixty\_gqEight}

1. Does the organization consider audit, inspection and walk-through reports when establishing preventive action plans?

Institutional Response: {pgSixty\_gqNine}

1. Does the organization consider results of medical surveillance and preventative medical programmes when establishing preventive action plans?

Institutional Response: {pgSixty\_gqTen}

1. Does the organization consider results of periodic personnel and facility reviews and advice from employees when establishing preventive action plans?

Institutional Response: {pgSixty\_gqEleven}

1. Does the organization consider the potential for equipment malfunctions when establishing preventive action plans?

Institutional Response: {pgSixty\_gqTwelve}

### What is the importance of this requirement?

Institutional Response: {pgSixty\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSixty\_range}

# CWA Requirement 4.5.5: Inspection and audit

The organization shall ensure that a programme of inspection and audit is conducted which is appropriate to the risk associated with the facility. Inspections and audits shall be conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and to the requirements of this standard, and that it is effectively implemented and maintained. Management responsible for the area being inspected / audited shall ensure that any actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities arising shall include the verification of the actions taken and the reporting of verification results.

## Guiding Questions:

1. Does the organization utilize internal audits and inspections, as well as third-party external audits, to review and evaluate the conformity and effectiveness of their biorisk management programme?

Institutional Response: {pgSixtyOne\_gqOne}

1. Do inspections include frequent checks on specific areas conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels/concentrations and air exchange rates/ maintenance of directional air flow) and more extensive but less frequent inspections of laboratories, facilities or other operations?

Institutional Response: {pgSixtyOne\_gqTwo}

1. Does the organization conduct random, unannounced inspections and inventory checks?

Institutional Response: {pgSixtyOne\_gqThree}

1. Are audits and inspections performed by competent and independent individuals with knowledge and experience in biorisk management systems, the organization's operations and the scope of work and general facility design within the operational legal framework?

Institutional Response: {pgSixtyOne\_gqFour}

1. Are the personnel conducting audits and inspections (internal and external) sufficiently independent of the procedures, processes, and/or facilities being assessed?

Institutional Response: {pgSixtyOne\_gqFive}

1. Are records maintained of findings of inspections/audits, including action taken to close out any non-conformities or improvement opportunities?

Institutional Response: {pgSixtyOne\_gqSix}

1. Does the organization's inspection and audit programme include informal physical inspections of work areas?

Institutional Response: {pgSixtyOne\_gqSeven}

1. Does the organization's inspection and audit programme include inventory audits (announced and unannounced)?

Institutional Response: {pgSixtyOne\_gqEight}

1. Does the organization's inspection and audit programme include document reviews?

Institutional Response: {pgSixtyOne\_gqNine}

1. Does the organization's inspection and audit programme include a review of the results of data generated by facility personnel, including maintenance and usage logs, self-inspection reports, etc.?

Institutional Response: {pgSixtyOne\_gqTen}

1. Does the organization's inspection and audit programme include review of incident and accident reports?

Institutional Response: {pgSixtyOne\_gqEleven}

1. Does the organization's inspection and audit programme include routine or random equipment performance evaluations?

Institutional Response: {pgSixtyOne\_gqTwelve}

1. Does the organization's inspection and audit programme include routine or random facility systems evaluations or recertification, e.g., HVAC (heating, ventilating and air conditioning) system and airflow analysis, and filter system integrity reviews?

Institutional Response: {pgSixtyOne\_gqThirteen}

1. Does the audit and inspection programme determine the scope of audit or inspection prior to the audit or inspection?

Institutional Response: {pgSixtyOne\_gqFourteen}

1. Does the organization ensure that the team performing the audit has been assigned defined roles and responsibilities and be selected through an agreed, documented process?

Institutional Response: {pgSixtyOne\_gqFifteen}

1. Has the organization established internal agreement on the procedure for audits/inspections which may include check-lists, and written scope?

Institutional Response: {pgSixtyOne\_gqSixteen}

1. Does the audit or inspection team determine whether relevant personnel should be interviewed; or determine if all personnel will be subject to interviews?

Institutional Response: {pgSixtyOne\_gqSeventeen}

1. Does the organization's audit and inspection program include measures to ensure that all relevant documentation will be examined, including policy, objectives, emergency procedures, permits, training records, etc.?

Institutional Response: {pgSixtyOne\_gqEighteen}

1. Does the audit and inspection program include procedures to reach agreement on how results of the inspection or audit will be measured and reported and who would receive the report?

Institutional Response: {pgSixtyOne\_gqNineteen}

1. Has the organization considered the frequency of audits based on the facility's risk (determined by risk assessment), and if additional audits may be conducted after an incident?

Institutional Response: {pgSixtyOne\_gqTwenty}

1. Has the organization determined whether unannounced audits and inspections may be performed under specific circumstances?

Institutional Response: {pgSixtyOne\_gqTwentyOne}

1. Do audit and inspection reports include documentation about the audit process, scope, and auditing team?

Institutional Response: {pgSixtyOne\_gqTwentyTwo}

1. Do audit and inspection reports include assessments of the effectiveness of biorisk management procedures and practices?

Institutional Response: {pgSixtyOne\_gqTwentyThree}

1. Do audit and inspection reports include detailed assessments of levels of compliance with procedures and practices?

Institutional Response: {pgSixtyOne\_gqTwentyFour}

1. Do audit and inspection reports include recommendations for corrective or preventive procedures where nonconformities are identified, or potential nonconformities anticipated?

Institutional Response: {pgSixtyOne\_gqTwentyFive}

1. Are audit and inspection reports shared with relevant personnel, as appropriate?

Institutional Response: {pgSixtyOne\_gqTwentySix}

1. Are reports shared with relevant personnel, as appropriate?

Institutional Response: {pgSixtyOne\_gqTwentySeven}

### What is the importance of this requirement?

Institutional Response: {pgSixtyOne\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSixtyOne\_range}

# CWA Requirement 4.6.1: Biorisk management review

Top management shall review the organization's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the system, procedures, policies and objectives. Records from the management review shall be maintained.

## Guiding Questions:

1. Does the organization regularly conduct a biorisk management review at pre-defined intervals?

Institutional Response: {pgSixtyTwo\_gqOne}

1. Is the review conducted at least once per year, or more frequently based on risk?

Institutional Response: {pgSixtyTwo\_gqTwo}

1. Is the process for conducting the review documented?

Institutional Response: {pgSixtyTwo\_gqThree}

1. Are roles and responsibilities related to the review clearly defined, including who will participate in the review and who will receive the final review?

Institutional Response: {pgSixtyTwo\_gqFour}

1. Does the review cover all aspects of the system, for example planning, implementation and resource allocation, monitoring and corrective action?

Institutional Response: {pgSixtyTwo\_gqFive}

1. Does the review evaluate information and results in relation to documented goals and objectives for the biorisk management system?

Institutional Response: {pgSixtyTwo\_gqSix}

1. Does the review account for changes that could impact the effectiveness of the system?

Institutional Response: {pgSixtyTwo\_gqSeven}

1. Is the review based on all available sources of data, such as previous reviews, investigation reports, audit results, etc.?

Institutional Response: {pgSixtyTwo\_gqEight}

1. Has top management regularly led and actively participated in the biorisk management system review?

Institutional Response: {pgSixtyTwo\_gqNine}

1. Does the review include an analysis of opportunities to improve the biorisk management system (continual improvement)?

Institutional Response: {pgSixtyTwo\_gqTen}

1. Does top management take decisions on improving the system, including resource allocation, based on the review?

Institutional Response: {pgSixtyTwo\_gqEleven}

1. Are the decisions made by top management following a review effectively implemented?

Institutional Response: {pgSixtyTwo\_gqTwelve}

1. Is there a documented mechanism to communicate relevant results of the review to affected parties in the organization?

Institutional Response: {pgSixtyTwo\_gqThirteen}

### What is the importance of this requirement?

Institutional Response: {pgSixtyTwo\_prty}.

### As a percent, how well does your lab meet this requirement?

Institutional Response: {pgSixtyTwo\_range}