Implementing the European CWA Laboratory Biorisk Management Standard

An assessment of the CWA document compiled to assess its impact on BRC operations, carried out by the GBRCN Demonstration project secretariat. The document is intended to be a voluntary standard in the ISO suite and is written to be compatible with ISO 9001:2000 (Quality), ISO 14001: 2004 (Environmental) and OHSAS 18001 (Occupational Health and Safety) management systems standards in order to facilitate the integration of all such management systems of an organisation. As such it impacts on Biological Resource Centre (BRC) requirements. It addresses the safe handling of pathogens and/or toxins in microbiological containment laboratories regardless of type, size and pathogens/toxins handled. It does not cite normative references, these are still to be identified but it cites two central guidance documents for biorisk management and the development of the standard the WHO Laboratory Biosafety Manual, third edition (WHO/CDS/CSR/LYO/2004.11, 2004) and the WHO Biorisk Management Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006). In principle all laboratories in Europe that have procedures to comply with the European Directive and National Laws implementing the directive should already be implementing the requirements of this draft standard.

Comments, non-compliances and anomalies identified

Planning: The sections on planning resources and assessment timing may need a more rigorous risk identification. In the provided notes it states that it is advisable that biological hazards are identified and assessed in relation to their potential damage to human, domestic animals, wildlife, flora and the environment. The risk assessments normally used cover human and plant pathogens quite well, animals less well and the environment even less so. The inherent risk assessment uses a consequence and likelihood tables and plotting results on a matrix.
Risk assessment as described in the standard:

Consequence:
Catastrophic: (death, long term environmental damage, political or public outrage resulting in closure)
Major: extended absence from work due to incident, major political or public reaction, major financial loss
Moderate temporary absence, minor financial loss, public or political concern
Minor: First aid treatment, minor public concern
Insignificant
Likelihood:
Almost certain
Likely: history of occurrence, may expect several times a year
Probable (cited possible but typo) Has occurred before, might be expected to occur in the next few years
Possible: might be expected to occur but not often
Unlikely: not expected to occur but possible that it could

The inherent risk is assessed by making a judgement on the consequences and likelihood If the consequences are always catastrophic then the inherent risk is always high, despite the likelihood being rare. A moderate consequence but almost certain event will also be a high inherent risk. BRCs should review its risk assessment with this in mind. The risk assessment process should have senior management sign off. An objectives and targets programme should be in place, establishing, implementing and maintaining documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organisation. Additionally, management shall establish monitoring 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. This is normally addressed in a process of review of

risk assessment which is usually annual or triggered by change or an incident. This may need to a more formal approach.
Implementation and operation: Biorisk management supervision; normally, a safety committee covers the responsibilities but the CWA standard recommends the establishment of a biorisk committee. The format and constituent members of the biorisk committee is focussed only on biological risks. In BRCs it maybe unwarranted to have a separate biological safety committee, the responsibilities could be implemented by a subgroup of the safety committee. The standard requires an occupational health professional to be appointed and a security manger responsible for security relating to biological materials and toxins.

Continuity and succession planning is emphasised ensuring back-up and contingency measures are in place to address the need for continuity and succession planning. A biological agents and toxin inventory and information must be established and maintained.

A worker health programme is required for those who may be exposed to pathogens and/or toxins. Personnel must be screened for reliability factors e.g. identity and immigration status, membership of organisations hostile to biological research, criminal records and financial probity.

Most content is covered both by OECD best practice and European Directives implemented nationally in Europe. Further analysis is needed for countries outside Europe.

What is the Laboratory Biorisk Management Standard?

This Laboratory Biorisk Management Standard is based on a management system approach. This implies that identifying, understanding and managing a system of interrelated processes for a given objective, improves the organisation's effectiveness and efficiency. Application of the management systems approach principle leads to the following actions:

- Defining the system by identifying or developing the processes that affect a given objective,
- Structuring the system to achieve the objective in the most effective manner,
- Understanding the interdependencies among the processes of the system,
- Continually improving the system through measurement and evaluation, and,
- Establishing resource constraints prior to action.

The systems approach outlined above has been successfully adopted by the International Organisation for Standardization (ISO). The management system approach enables an organisation to effectively identify, monitor and control the laboratory biosafety and biosecurity aspects of its' activities. An effective management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that an organisation undertakes to meet goals.

Keys to a successful biorisk management system:

Some of the key factors in establishing and implementing a successful biorisk management system include:

Commitment by top management:

- Providing adequate resources, prioritisation and communication of safety and security policy;
- Integration of biorisk management throughout the organisation;
- Identifying opportunities for improvement and prevention, determining root causes and
- preventing recurrence.

Focus on continual improvement:

- Making continual improvement an objective for every individual in the organisation;
- Using periodic assessment against established risk-criteria to identify areas for potential improvement;

- Continually improving the effectiveness and efficiency of processes;
- Promoting prevention activities;
- Providing personnel in the organisation with appropriate education and training including the methods and tools of continual improvement;
- Establishing measures and goals for improvement;
- Recognising improvement.
- Management system integration

This Laboratory Biorisk Management Standard is compatible with the ISO 9001:2000 (Quality), ISO 14001:2004 (Environmental) and OHSAS 18001 (Occupational Health and Safety) management systems standards, in order to facilitate the integration of all such management systems of an organisation.

Application
The requirements of this standard are generic and are intended to be applicable to all organisations handling pathogens and/or toxins, that is, microbiological containment laboratories, regardless of type, size and pathogens/toxins handled.

Scope of standard
The scope of the biorisk management system standard is to set requirements necessary to control risks associated with activities in microbiological containment laboratories, i.e., laboratories where biological agents and toxins are handled.

The standard will enable organisations to:
- Establish and maintain a biorisk management system to control or minimise risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;
- Provide assurance that the requirements are in place and implemented effectively;
- Seek and achieve certification or verification of the biorisk management system by an external third party;
- Provide a framework that can be used as the basis for training and raising awareness of biosafety and laboratory biosecurity guidelines and best practices within the scientific community.
- The standard is performance-based and sets out requirements and places responsibility on organisations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.

Informative references
Two central guidance documents for biorisk management and the development of this standard are the WHO Laboratory Biosafety Manual, Third Edition (WHO/CDS/CSR/LYO/2004.11, 2004) and the WHO Biorisk Management: Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006).

Biorisk management system requirements
General Requirements
Biorisk Management System
The organisation shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this laboratory biorisk management standard.
Continual Improvement
The organisation 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 preventive actions and the management review.

NOTE: The organisation should not be content that performance has reached a point whereby no further improvements can be made, but should strive to continue to develop and refine the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved through goal setting and targets placed upon those working within the facility, and monitoring progress to ensure the goals are achieved.

Policy

Biorisk Management Policy

The organisation's top management shall develop, authorise and sign a policy concerning the management of biosafety and laboratory biosecurity (biorisk). 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 protecting all who come in contact with the work, reduce risk, comply with legislation, effective communication and improving biorisk management performance:

Planning

Planning for Hazard Identification, Risk Assessment and Risk Control

Planning and Resources

The organisation 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 the organisation's institutional biosafety committee and to management for review and as a basis for improvement. The organisation 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.

Assessment Timing and Scope

The organisation shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that that it is proactive rather than reactive.

Risk Identification

The hazards (or risks) associated with the proposed work shall be identified and documented . The biological agents being handled are not the only risks associated with the work. All source, need to be considered including mechanical (plant), radiation, fire and explosion, temperatures, hazardous environments, electrical, biological, chemical and hazardous substances, gases and personnel. A hazard is defined as something with the potential for causing harm. It may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting) or a material (in the case the principal hazard most likely to be a pathogen or toxin, but others will include chemicals 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.

Inherent Risk Assessment

The initial assessment is to clearly state the task or activity, and then identify the specific hazard or hazards. The inherent risk is then assessed, where controls are not in place .
The inherent risk is assessed by making a judgement on the consequences and likelihood and if the consequences are catastrophic, then the inherent risk will always be high, despite the likelihood being rare. A moderate consequence but almost certain event will also be a high inherent risk.

Identification of Treatment Options (or controls)

Treatment options to control the hazards identified in the assessment of the inherent risk shall be identified and documented. The process by which the controls will be applied and who is responsible, together with adequate allocation of resources, must also be documented

The Hierarchy of Controls
The use of the hierarchy of controls is a recognised means of risk management. These controls start with the elimination of the risk. This is the most effective control. If this is not possible, then the substitution of a process with a lower risk is one alternative. In many cases in microbiology, it is not possible to work with an agent other than a serious pathogen. Other controls need to be introduced to reduce the level of residual risk.
a) Elimination
b) Substitution
c) Isolation
d) Engineering controls
e) Administrative controls
f) Personal Protective Equipment (PPE)

Residual Risk
The residual risk shall be established after applying the controls that have been identified. The residual is used to determine whether the work can safely proceed and the level of monitoring that is required of the controls. This process needs to be fully documented.

Legal Requirements
The organisation shall ensure that all relevant legal requirements are identified within the biorisk management system.
Objectives, Targets and Programme
Biorisk Control Objectives and Targets
The organisation shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organisation.
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

Implementation and Operation
Roles, Responsibilities and Authorities
Top management shall ensure that roles, responsibilities and authorities related to biorisk management are defined and documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins. Top management is accountable for the organisation's biorisk management decisions and policy
Senior Management
A member of senior management shall be designated with overall responsibility for overseeing the system for management of biorisk.
Functions 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 organisation;
d. Instituting review, audit and reporting measures to provide assurance that the requirements of this Standard are being implemented and maintained effectively.

Biorisk Management Supervision
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.
A biorisk committee shall be constituted to act as an independent review group for biorisk issues.

Occupational Health
An occupational health professional shall be appointed to provide advice and guidance on worker health and related issues, including the establishment of an occupational health programme commensurate with the activities and risks of the facility.
NOTE: The occupational health professional would normally be a medical doctor or occupational health nurse with experience working in a laboratory environment, and with specific knowledge of the biological agents and toxins that are handled within the facility.

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.

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

Personnel Training, Awareness and Competence
The organisation shall ensure that personnel that have responsibilities and perform tasks that may impact biorisk management in the workplace are competent on the basis of appropriate education, training and experience.
The organisation shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency.

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

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

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

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

Consultation and Communication
The organisation 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 organisation.

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

General Safety
The organisation shall ensure that a formal process is in place to identify and manage risk associated with general safety. NOTE: The organisation should adopt a preventive and proactive approach to managing such sources of risk,

Biological Agents and Toxin Inventory and Information
The organisation 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 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 nature of the risk.

Work Programme, Planning and Capacity
The organisation shall ensure that the programme of work for the facility is defined, documented and reviewed.
The organisation 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.

Change Management
The organisation 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.

Inactivation of Pathogens and Toxins
The organisation shall establish and maintain procedures to ensure that appropriate methods for disinfection and decontamination are chosen and implemented effectively.
The organisation 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.

Clothing and Personal Protective Equipment (PPE)
The organisation shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility.

Worker Health Programme
The organisation 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.

Vaccination of Personnel
The organisation shall ensure that access to laboratories or work is controlled for individuals until they have been appropriately vaccinated and / or are under a defined medical surveillance programme. The need for vaccination shall be identified on the basis of risk and shall cover groups identified as being potentially at risk of exposure to biological agents or toxins.

Human Factors and Control of Workers
The organisation shall establish and maintain a programme to address risk associated with human factors, including the management of behaviour and how workers interact with the facility and its equipment.

Personnel Reliability
The organisation shall ensure that personnel are screened for adverse reliability factors. Where lawful and appropriate as determined by risk assessment, screening may include such checks as identity and immigration status, membership of organisations hostile to biological research, criminal records and financial probity

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

Exclusion
The organisation 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.

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

Planning, Design and Verification
The organisation 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 and activities planned. The design process shall identify and incorporate all relevant legislative requirements, together with information from recognised 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 specified and documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification. The organisation shall ensure that new construction and physical facility modifications are carried out according to an approved plan.

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

Maintenance, Control, Calibration, Certification and Validation
The organisation shall establish and maintain documented procedures to ensure equipment 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 program.
The organisation shall ensure procedures:
- for maintenance of the facility and its equipment;
- for the control, calibration and validation of the equipment relevant to biorisk management;
- for the certification of relevant equipment; are established and maintained.

Physical Security
The organisation 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.

Control of Supplies
The organisation shall ensure that purchases (including services) conform to specified requirements. Controls shall be applied depending on potential impact on the risk involved. The organisation 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.

Transport of Biological agents and Toxins
The organisation shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained.

Information Security
The organisation shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to determine whether such information may be released. The organisation shall ensure that sensitive information is identified and controlled, as part of the risk assessment process.

Emergency Response and Contingency Plans

The organisation shall establish and maintain plans and procedures to identify the potential for incidents and emergency situations involving biological agents 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 and medical issues.

Emergency scenarios
The organisation shall ensure that all credible and foreseeable emergency scenarios that may impact on the organisation's biorisks have been identified.
Scenarios considered should include:
a. Infected / potentially infected worker or other contact (e.g. family member, emergency responder or community member);
b. Accident or illness to worker and need for evacuation;
c. Fire;
d. Flood;
e. Breach of security;
f. Explosion;
g. Potential loss of biological agents or toxins through theft or any other reason;
h. Unexpected virulence (unknown biological agents or biological agents expected to be avirulent);
i. Physical facility and equipment failure, including control system failure;
j. Failure of disinfection regime;
k. Utility failure including electricity, gas, steam and water supplies;
l. Major spillage / aerosol release;
m. Environmental release;
n. Natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.);
o. Act of terrorism or deliberate vandalism;
p. Intense media attention.

Emergency Plans
The organisation shall ensure that biorisks are taken into account when preparing and implementing emergency plans. The organisation shall ensure a system is established to effectively manage medical emergencies, including the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers

The organisation will 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.

Emergency Exercises and Simulations
The organisation 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.
NOTE: Exercises and simulations should be conducted in order to provide an assurance that plans are effective and to learn from any lessons that arise. Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. However, such activities must also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of the exercise should be documented and reviewed for lessons learned, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, allocated to named individuals and measures set in place to ensure they are closed out effectively.

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

Checking and Corrective Action

Performance Measurement and Analysis of data
The organisation shall ensure that appropriate data is determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.

Records, Document and Data Control
The organisation 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.

Inventory Monitoring and Control
The organisation 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 organisation shall ensure that the measures are put in place to minimise the quantities of biological agents and toxins that make up the inventory.
NOTE: The nature of the inventory and associated controls should be based upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse. For many biological agents and toxins the checks may be of a lower frequency and stringency than for others with greater potential for causing harm. Such measures may include numbered sequences of tubes, periodic inspections and crosschecks with records of materials held. The organisation should demonstrate proactive measures towards the reduction of risk through elimination, substitution or minimisation of volumes / quantities of biological agents and toxins used, and the number of manipulations conducted. Procedures should be in place to investigate potentially missing biological agents appropriate for the level of risk.

Accident and Incident Investigation, Non-conformances, Corrective and Preventive Actions
Accident / Incident Investigation
The organisation shall establish and maintain documented procedures to define, record, analyse and learn from accidents and incidents involving biological agents.

Control of non-conformities
The organisation shall ensure that situations that do not conform to the requirements of this Standard are identified and controlled to prevent undesirable effects. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.

Corrective action
The organisation 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 non-conformities encountered.

Preventive action
The organisation shall ensure action is taken to identify and eliminate the causes of actual and potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the non-conformities encountered.

Inspection and Audit
The organisation 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.

Management Review
Biorisk Management Review
Top management shall review the organisation'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.
NOTE: The management review should be conducted at a defined frequency determined by the needs of the organisation, but at least annually.
The review input should include information on:
a. Results of audits;
b. Compliance to SOPs and work instructions;
c. Status of risk assessment activities;
d. Status of preventive and corrective actions;
e. Follow-up actions from previous management reviews;
f. Changes that could affect the system;
g. Recommendations for improvement;
h. Results of accident / incident investigations.
The review output should include decisions and actions related to:
i. Improvement of the effectiveness of the biorisk management system;
j. Improvement related to the requirements and risk assessments;
k. Resource needs.

Glossary: Terms and definitions

acceptable risk - risk that has been reduced to a level that that can be tolerated by the organisation having regard to its legal
accident - undesired event giving rise to harm; an accident is an incident that resulted in harm.
audit - systematic, independent and documented process for obtaining "audit evidence" and evaluating it objectively to determine the extent to which "audit criteria" are fulfilled NOTE: Independent does not necessarily mean external to the organisation. In many cases, particularly in smaller

organisations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

biohazard - potential source of harm from biological agents

biological agent - any microorganism, including those which have been genetically modified, genetic elements and materials derived from microrganisms (e.g. toxins, allergens, prions, cell-cultures and parasites), which may be able to cause an infection, create or provoke an allergy or exhibit toxicity in humans animals or plants or have an adverse effect on the environment

biorisk - combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence (in terms of accidental infection, toxicity or allergy or unauthorised access, loss, theft, misuse, diversion or release of biological agents or VBMs) of such an exposure

biorisk assessment - process of evaluating the biorisk(s) arising from biohazard(s) or VBMs, taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable

biorisk committee (IBC) - institutional committee of competent individuals versed in the subject of biorisk control, and other representatives as appropriate

biorisk management system - part of an organisation's management system used to develop and implement its biorisk policy and manage its biorisks

biorisk officer (BSO) or biorisk advisor - a staff member of an institution who has expertise in the biohazards encountered in the organisation and is competent to advise top management and staff on biorisk management issues

biorisk performance - measurable results of an organisation's management of its biorisks

biosafety - laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release

biosecurity - laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorised access, or intentional release

calibration - the correlation of the performance of equipment (e.g. readings of an instrument) to a standard

certification - systematic, documented process to ensure a system qualification, calibration, validation or revalidation has been performed appropriately and that results are acceptable

competence - appropriate education, training, skills and experience

containment - system for confining microorganisms or organisms or other entity within a defined space

corrective action - action to eliminate the cause of a detected nonconformity or other undesirable situation

decontamination - procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects

disinfection - process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms

genetically modified microorganism (GMM) - a microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

good microbiological techniques - working methods applied to eliminate or minimize exposure to biological agents via e.g. aerosols, splashes, and accidental inoculation

harm - adverse effect on the health of people, animals or plants, on the environment or on property

hazard - source, situation, or act with a potential for harm

incident - event with a potential to cause harm

nonconformity - non-fulfilment of a requirement; NOTE A non-conformity can be any deviation from: relevant work standards, practices, procedures; legal requirements etc; biorisk management system requirements.

personal protective equipment (PPE) - material, including clothing (e.g. gown, gloves, respirators, safety glasses), used to prevent contamination of a person by chemical or biological matter
preventive action - action to eliminate the cause of a potential nonconformity or other undesirable potential situation
risk - the product of the likelihood of an adverse event and the severity of possible adverse consequences (see also biorisk)
risk assessment - process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the risk(s) is acceptable
safety - conditions and factors that affect, or could affect, the health and safety of employees, temporary workers, students, contractor personnel, visitors and any other person in the workplace
toxin - a substance, produced by a biological system, which produces an adverse effect in humans, animals or plants. This definition includes substances and materials which may be contaminated with toxins (see also biohazard)
validation - documented procedure for obtaining, recording and interpreting the results needed to show that a process will constantly yield a product complying with predetermined specifications