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Development of a tool to perform systematic gap analysis of Biosafety program based on Biorisk Management System (CWA15793: 2008)

By

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An abstract of
A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
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in Environmental Health
2010

Abstract

Development of a tool to perform systematic gap analysis of Biosafety program based on Biorisk Management System (CWA15793: 2008)

By: Kalpana Rengarajan

The European Committee for Standardization (CEN) Workshop Agreement (CWA) is a Management System Standard which has been utilized for identification and management of biorisks. This management systems approach implies identifying, understanding and managing a system of interrelated processes for a given objective, improves the organization's safety effectiveness and deficiency. This standard CWA 15793:2008 was developed, adopted and published in 2008 with 76 participants from 24 countries actively involved. A Management System is a framework integrating best practices and procedures frequently built around the Plan-Do-Check-Act cycle. This standard is not a technical document, rather it is performance oriented.

This study aims to develop a "Gap Analysis Tool" - generating a series of questions based on the CWA 15793:2008 requirements. The CWA 15793:2008 standard has multiple components. Based on this standard, specified questions increase institution capacity to analyze the gaps present in the existing biosafety programs. Once gaps are identified, institutions may develop solutions to fill the gaps, and become more effective in safety program performance. The overall objective of the CWA 15793:2008 is to support and promote good biorisk practices including self regulation.

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My special thanks to my family members without whose unconditional support I would have completed this.

I would like to dedicate this work to my parents.

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Introduction

Management systems approach

Laboratory biosafety describes the containment principles, technologies and practices implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release [(1)]. **Biorisk** is the probability or chance, a particular adverse event like accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release, possibly leading to harm, will occur. **Biorisk assessment is** the process to identify acceptable and unacceptable risks (e.g. risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release) and their potential consequences. Biorisk encompasses biosafety and biosecurity, where the hazards are biological agents and its toxins [(2)].

Regulations require institutions to set safety controls aimed at minimizing personnel exposure to pathogenic organisms by limiting, and managing the release of biological agents in the community or the environment. Biosafety must be embedded in core activities which involve a variety of aspects making it necessary to organize preventive and protective measures in a structured and integrated manner. One way of organizing a number of various measures efficiently is using **management systems.** A management system is a proven framework for managing and continually improving your organization's policies, procedures and processes [(3)].

Many institutions have implemented such systems, using standards like the ISO 9000 series and others for quality, ISO 14001 for environmental management or OHSAS 18001 for occupational safety. The first internationally recognized management standard, CWA 15793:2008 'Laboratory Biorisk Management Standard', specifically addresses

biological hazards, allows the same approach in the fields of biosafety and biosecurity. Besides integrating biosafety and biosecurity, CWA 15793:2008 presents the advantage of being fully compatible with the other management standards.

This CWA 15793:2008 laboratory biorisk management standard is based on the management system approach. The goal of a management system approach is to increases an organization's effectiveness and efficiency in identifying, understanding and managing a system of interrelated process for a given objective [(4)]. An effective management system approach is built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions an organization undertakes to meet goals. This is known as the **PDCA** cycle based on (Plan-Do-Check-Act) principle [(5)] (Appendix 1). Improvement of biorisk management programs requires individuals within the organization to identify causes of non-conformities and recognize undesirable events. Systematic identification, recognition, and correction of system deficiencies lead to improved performance and increased control of biorisks. The systems approach outlined above has been successfully adopted by the International Organization for Standardization (ISO). CWA 15793:2008 biorisk management standard is compatible with the EN ISO 9001:2000 (Quality), EN ISO 14001:2004 (Environmental) and OHSAS 18001:2007 (Occupational Health and Safety) management systems standards, in order to facilitate the integration of all such management systems of an organization.

The requirements of this standard are intended to be applicable to organizations handling biological agents and/or toxins, regardless of type, size and biological agents being handled. The risk based approach does not employ biological agent risk

classification or laboratory safety/containment levels, although such approaches can be entirely compatible with this standard. Biosafety levels are based on a composite of the design features, construction, containment facilities, equipment, practices and operational practices required for working with agents from the various risk groups. The Biosafety levels do not equate to the risk groups of the organisms in each risk group.

Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any safety program. Where any part of this standard is in conflict with any legal requirement, the conflicting part of the standard may be eligible for exemption if the legal requirement meets or exceeds the intent of this standard. Example, in United States to work with Select Agents and toxins, an individual or entity should be compliant with 42 CFR 73.12 (code federal regulations).

All organizations face challenges in putting the management system requirements of this standard in place. Challenges faced include but are not limited to limited resources, increased costs involved and difficulty in understanding and applying the standard. The more challenging requirement clauses in this respect may be the ones related to continual improvement. The organization should regard this as a recurring, step-by-step activity. When opportunities for improvement are identified, and justified, the organization needs to decide how they are to be implemented based on the available resources. The justification should be founded on an analysis of the potential gains in terms of improved control of risk [(6)].

Typically, the setting of a biorisk management program includes a review of the activities and practices (**Gap analyses**), the proposal of an overall concept, the

development of the solution and its implementation. Implementation of the CWA 15793:2008 involves three steps:

Step 1: Development of a tool to perform systematic gap analysis of Biosafety program.

Step 2: Implementation of the gap analysis tool, compare and analyze the existing processes and systems in place.

Step 3: Based on the results obtained from the gap analysis and comparing with CWA 15793:2008 requirements, process has to be defined for implementation of CWA 15793:2008 "Laboratory Biorisk Management Standards" at Emory University.

The current study has developed and proposed a "TOOL" (**Step 1** listed above) to perform the gap analysis based on the CWA 15793:2008 "Laboratory Biorisk Management Standards".

This effort has produced a tool which can be utilized by organizations to perform **Step 1: Systematic Gap Analysis.**

Methods

CEN Workshop Agreement is a technical agreement, developed by an open workshop structure through consensus within the framework of CEN. CWA 15793:2008 is a comprehensive management blueprint for Biosafety and Biosecurity (biorisk) program. In 2007, 76 participants from 24 countries developed a management system approach to biosafety and biosecurity (biorisk) in the laboratory. This Standard is voluntary and not intended to replace any national or sub national regulatory requirements that may apply to a research laboratory or facility. The standard is used for improving overall laboratory biorisk performance; increasing effective management of complex laboratory safety and security processes as they relate to biosafety and biosecurity; and facilitating international laboratory collaboration and safety harmonization within and between organizations.

Laboratories in all major regions of the world expressed a strong need for more guidance and help in the interpretation and implementation of the CWA 15793:2008. As a result 55 participants from 19 countries met to develop the guidance document. The objective of this CEN Workshop 55 is to develop a guidance document to facilitate the implementation of the Biorisk Management program internationally.

In order to effectively implement the CWA 15793:2008, any institution has to compare and analyze the existing processes and systems in place based on the CWA 15793:2008 requirements. Thus a systematic gap analyses is required to achieve this. Gap analysis is the technique for determining the steps to be taken in moving from a current state to a desired future-state. The Gap Analysis is intended as a living and evolving document to identify and prioritize those areas of digitization that fall within the scope of this Initiative, and that are: a) not currently defined within existing agency

guidelines; or b) not adequately addressed by those guidelines. Thus gap analysis is a good way to determine what the current situation is, and where action is critically needed [7]. It begins with (1) listing of characteristic factors (such as attributes, competencies, performance levels) of the present situation ("what is"), (2) cross-lists factors required to achieve the future objectives ("what should be"), and then (3) highlights the 'gaps' that exist and need to be 'filled.' In order to develop a gap analysis tool (**Step 1**) the basic elements that constitute the CWA 15793:2008 were identified.

Based on the CWA 15793:2008, the following major components were used to build the gap analysis tool: Biorisk Management System, Policy, Planning, Implementation and Operation, Checking and corrective action, Review. An institutional biosafety program review, encompassing the above components would result in a comprehensive outcome (gap analysis) facilitating further planning to improve the program.

Based on the CWA 15793:2008 and the guidance document, a series of questions have been developed to identify organizational risks caused by gaps which exist in the current process. The Gap Analysis Checklist (Appendix 2) provides elements of the CWA 15793:2008 requirements in the form of a checklist.

Results

Appendix 2 details a list of questions developed based on the methods described. A total of 391 questions were developed based on the six main components of the CWA 15793:2008.

4.1 Biorisk Management System :

This section includes 8 questions which identify whether:

- an institution has established a biorisk managements system.
- the management confirms legal requirements take precedence to the standard's requirements.
- the organization strives to continue to develop and refine systems in place to ensure that further opportunities to improve are identified and implemented.

4.2 Policy:

Policy section has 11 questions. This section confirms the institution has biorisk policy in place. The policy should clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance.

4.3 Planning:

Planning section with 44 questions addresses planning and resource availability for hazard identification, risk assessment and risk management. The approach is to ensure risk assessment is defined with respect to its scope, nature and timing, so that it is proactive rather than reactive.

4.4 Implementation and Operation:

Implementation and operation component is the largest element of the standard. This section has a total of 245 questions. These questions address the following:

1. Roles and responsibilities of the management which includes the Top management, senior management, the biorisk committee, Biosafety officer, occupational health, facility management, security management and animal handling. It is extremely vital that the roles and responsibilities are well defined for each key player for implementation of the program.
2. Personnel training, awareness and competency are the next aspect that is addressed here. The questions are focused on the importance of personnel training and competency in order to perform their duties safely to mitigate risk.
3. Consultation and communication is important as relevant biorisk information relating to its activities should be communicated to and from employees.
4. Operational control aspects include several items like general safety, inventory information on biological agents and toxins, work practices including decontamination methods, waste management, personal protective equipment, worker health program, vaccinations, contractors/visitors policy, equipment maintenance, facility

infrastructure and emergency response. Security questions include physical security, personal security and information security.

4.5 Checking Corrective Action:

Checking and corrective action is a vital part of the PDCA cycle. This section has 71 questions mainly addressing the suitability and effectiveness of the biorisk management system and evaluate where continual improvement of the system can be made. Results of the analysis should be applied in the management review.

4.6 Review:

Review section has 12 questions. This section focuses on the importance of the organization's role to ensure continued sustainability, and effectiveness of the biorisk management program. Different aspects like importance of evaluating opportunities for improvement need for a change to the system, objectives, policies and procedures is emphasized in this section.

Overall the tool developed provides a comprehensive set of questions to analyze the gap in the existing program based on the CWA 15793:2008 biorisk management system.

Discussion

Organizations are increasingly concerned with achieving and demonstrating sound biosafety and biosecurity performance by controlling the biorisks in a manner consistent with their own biorisk policy and objectives. This is based on increasing concerns expressed by several stakeholders in any country and by the internal regulatory systems that is becoming more stringent.

Several institutions conduct biorisk reviews in the form of laboratory inspections, or audits to assess the performance. Most of these inspections or audits are based on regulatory requirements and the results are discussed are compliance based. What is lacking in most places when an inspection or audit is done is an assurance provided to the organization its performance not only meets, but will continue to meet, its legal and policy requirements. Thus to be effective such inspections and follow ups need to be conducted within a structured management system that is integrated within the organization.

CWA 15793:2008 specifies requirements to biorisk management system to enable an organization to develop and implement a policy and objectives which take into account legal requirements and information about biorisks. The CWA 15793:2008 is performance based and is suitable to any type, size of institution as well as can be implemented in any country.

In order to implement the CWA 15793:2008 biorisk management system, we need to primarily understand or analyze where an institution currently stands based on the standards - gap analysis. Once the gaps are identified, it becomes easier to plan as to what would be the next step to implement to close the gaps. The current tool developed can be

used by any institution to analyze their program gaps prior to implementation of the CWA 15793:2008 biorisk management system. The current tool shows six major components with number of questions varying in each section. The advantage of this tool is, it is simple, generic and can be used to analyze the gaps based on the standard either at the department level or institution level. Though this is a simple tool, it can be further expanded. As a next step if each of the questions is ranked based on a scale of 0-5 (nothing in place to a robust situation), it will facilitate the biosafety manager to prioritize the needs of the program, and help the management to understand the need for additional resources, etc to establish an overall robust program.

At Emory University, as a next step this tool will be used to identify program gaps. A rankings system will be used to place the institution's position based on each component. Based on the ranking, prioritization and resources available, the significant gaps will be addressed and corrected. The overall process for further use is described below.

- Assign a rank
- List remedial actions to fill gaps
- Assign remedial action to appropriate stake holder
- Document procedures used to fill gaps and time taken to complete
- Once all remedial actions have been performed and implemented, system will be CWA 15793: 2008 compliant

Though the gap analysis tool looks simple, there are certain challenges to be faced. This tool has not been tested so far and hence the validity of the tool can be further evaluated only after it is rolled out. As explained earlier, if a grading has to be given, the

question is on what basis we do it. Different institutions may prioritize their program needs based on several factors like resources available, institutional vision and regulatory requirements. Thus the advantage of the tool is it can be used according to the needs of an institution, need not be used in any specific sequence. The tool also will facilitate to identify low hanging items to be fixed easily. The tool ultimately facilitates to constantly evaluate the existing program and constantly improve it.

Safety Management Systems (SMS) is a term used to refer to comprehensive systems designed to manage the workplace safety, health, environmental and general risk aspects of any institution. CWA 15793:2008 is compatible with the ISO 9001:2008 (Quality) [(7),] ISO 14001:2004 (Environmental) [(8)] and OHSAS 18001:2008 (Health and Safety) [(9)] management system standards, in order to facilitate the integration of quality, environmental, occupational health and safety biorisk management systems by organizations, should they wish to do so. Gap analysis followed by implementation of the biorisk management system is a systematic approach to improve not only the worker health and safety in an institution, but also improve the environment. Thus CWA 15793:2008 biorisk management system provides a structured, systematic approach to negotiate biorisk issues and have two key components: integration of management of biorisk issues in daily operations and improvement (performance)-oriented practices.

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4. EN ISO 9000:2005, Quality Management Systems-Fundamentals and vocabulary (ISO 9000:2005)
5. EN ISO 9001:2000, Quality Management Systems-Requirements (ISO 9001:2000)
6. CWA 15793:2008, Laboratory biorisk management standard.
7. EN ISO 9001:2008, Quality Management Systems-Requirements (ISO 9001:2008)
8. EN ISO 14001:2004, Environmental Management Systems-Requirements with guidance for use (ISO 14001:2004)
9. OHSA 18001:2007, Occupational Health and Safety Management Systems-Requirements.

Appendices

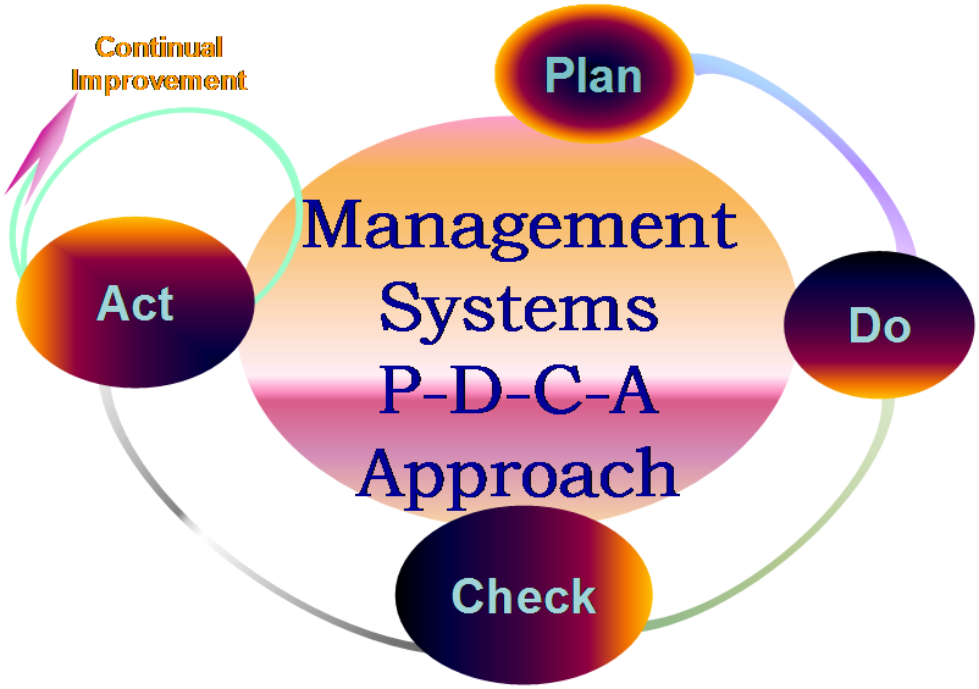
Appendix 1: PDCA Cycle

Plan: Planning, including identification of hazard and risk and establishing goals,

Do: Implementing, including training and operational issues,

Check: Checking, including monitoring and corrective action,

Act: Reviewing, including process innovation and acting to make needed changes to the management system.



Appendix 2: Development of a Gap Analysis Tool based on CWA 15793:2008

4 Biorisk Management Systems	
4.1 General Requirements	
1	Has a Laboratory Biorisk Management System that complies with CWA15793 standard been established by the organization?
2	Are the policy and objectives of the institution included in the Biorisk Management system?
3	Are the legal requirements considered prior to establishing the Biorisk Management system?
4	Is the historical and current performance by the organization evaluated for establishing the Biorisk Management system?
5	Was the input from organizations' employees, contactors and other external personnel evaluated for establishing the Biorisk Management system?
6	Are the resources required to establish a Biorisk Management system been evaluated by the organization?
7	Are the Integrations with the specific requirements of other management systems e.g. ISO 9001, ISO 14001, ISO 17025, ISO/IEC 27001, ISO 22000, ISO/IEC 20000 and OHSAS 18001 been evaluated by the organization?
8	Are resources and procedures to continually improve the effectiveness of Biorisk management system been evaluated by the organization?

4.2 Policy	
4.2.1 Biorisk Management Policy	
9	Is the Biorisk management policy authorized and signed by organization's top management?
10	Are the institutional mission, vision, core values and beliefs been included in the development of the Biorisk management policy by the organization?
11	Are the biohazards specific to the organization clarified and defined to be included in Biorisk Management policy?
12	Are the legal and other requirements related to biohazards been defined by the organization?
13	Is the policy defined to reflect activities reducing risk of unintentional release of or exposure to hazardous biological materials?
14	Is the policy defined to reflect reducing risk to an acceptable level of unauthorized intentional release of hazardous biological materials?
15	Is the policy defined to reflect complying with all legal requirements applicable to handling of biological agents and toxins?
16	Is the policy defined to accommodate the scale of institutional activities and functions?
17	Is the policy defined to include views of interested stakeholders?
18	Is the policy defined to include organization's communication to all employees and relevant third parties including contactors?
19	Is the policy defined to be made available to the public?

4.3 Planning	
4.3.1 Planning for Hazard Identification, Risk Assessment and Risk Control	
20	Is the Senior management included for review and continual improvement process?
21	Are actions initiated to prevent or reduce adverse effects of risk?
22	Are actions initiated to control further mitigation of risk until the level of risk becomes acceptable?
23	Have established procedures to identify and conduct risk assessments of activities, products, and services been established?
24	Are procedures in place to initiate, recommend, or provide solutions through designated channels?
25	Does process flow include consultations internally and externally as appropriate?
26	Are procedures evaluated prior to commencement of new work or changes to existing work practices including introduction of new biological agents or change in work flow volume?
27	Are procedures evaluated prior to new constructions/modifications to laboratories, equipments or its operation?
28	Are plans in place for introduction of altered and unplanned staffing arrangements (including contractors, visitors, and other non-core personnel)?
29	Are procedures in place for significant alterations to Standard Operating Procedures (SOPs) or working practices including waste management, exit/entry procedures?
30	Are planned activities in place when unexpected events occur that may have relevance for the management of biorisks such as changes in the security threat environment?
31	Are procedures in place when actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or an incident)?
32	Are defined plans in place when considering emergency response and contingency planning requirements?
33	Are resources available as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency)?

34	Is the entire work team and input from organizational experts included for hazard identification?
35	Are biological hazards evaluated in relation to human, animals and environment?
36	Are local needs as well as risk groups based on international classifications evaluated when considering hazards for materials used?
37	Are external legislations, rules, and requirements considered while performing risk assessments?
38	Are properties of microorganisms evaluated?
39	Are laboratory procedures, equipment, and controls used for biological agents evaluated?
40	Are personnel qualifications, training, and reliability checked prior to commencement of work?
41	Are environmental conditions, including endemic pathogens and external threats included in risk assessment?
42	Is management committed to manage and mitigate risk?
43	Are results of the risk assessments made available?
44	Are level of risk tolerance identified based on relation to the institution?
45	Are results of internal and external monitoring and evaluations documented?
46	Are resources available to be utilized (e.g. personnel, funding)?
47	Is a time line defined for implementation?
48	Are details of the mechanism and frequency of review of compliance with the plan been defined?
4.3.2	**Conformity and Compliance**
49	Is an organizational policy in place describing commitment to compliance legislation, including statutes, regulations and codes of practice?
50	Is an organizational policy in place describing commitment to orders and “regulatory” guidelines issued by regulators; permits, licenses or other forms of authorization; treaties, conventions, protocols?

51	Is an organizational policy in place describing non-regulatory guidelines?
52	Is an organizational policy in place describing voluntary principles, best practices or codes of practices?
53	Is an organizational policy in place describing agreements with health authorities?
4.3.3	**Objectives, Targets, and Program**
54	Is a policy established based on objectives relevant to the organizational needs?
55	Is the effectiveness of the program evaluated based on technological options, financial and operational and business needs?
56	Is the effectiveness of the program evaluated based on analysis of previous records of biorisk nonconformities and incidents?
57	Is the effectiveness of the program evaluated based on employee consultation?
58	Is the effectiveness of the program evaluated based on results of hazard identification, risk assessments and existing controls?
59	Is the effectiveness of the program evaluated based on need for availability of resources?
60	Is the effectiveness of the program evaluated based on management review?
61	Has controls and processes for monitoring effectiveness of the controls been established?
62	Are audits conducted audits and corrective action reporting used?
63	Are incidents investigated and reports used for improvement and evaluate availability of resources?

4.4 Implementation and Operation	
4.4.1 Roles, Responsibilities and Authorities	
64	Are resources including financial and personnel needed to support Biorisk Management system provided by the management?
65	Are resources provided based on nature and volume of biological agents stored or handled?
66	Are technologies available related to tasks performed?
67	Are security/biosecurity threats faced by the organization evaluated?
68	Are the infrastructure and equipment information systems available based on eth needs?
69	Are training and specialized skills provided to increase expertise?
70	Have the roles, responsibilities, and authorities in the implementation of management system clearly defined?
71	Has an individual been appointed to assume the role of *management representative*?
72	Has the management representative been given the responsibility and the authority to *establish* a Biorisk Management system that complies with this CWA 15793 standard?
73	Has the senior management representative been given the responsibility and the authority to implement a Biorisk Management system that complies with this CWA 15793 standard?
74	Has the senior management representative been given the responsibility and the authority to report to management?
75	Has a biorisk management committee been established?
76	Has the committee been entrusted to develop institutional biorisk policies and codes of practice?
77	Has the committee been entrusted to approve proposals for new work or significant modifications to the potential risk associated with existing activities?
78	Has the committee been entrusted to review and approve protocols and risk assessments for work involving biological agents and toxins?

79	Has the committee been entrusted to review information relating to significant accidents/incidents, data trends, associated local/organizational actions and associated communication needs?
80	Has a biorisk management advisor with authority to report to senior manager been appointed?
81	Does the biorisk management advisor participate in the reporting, investigation and follow up of accidents/incidents, and when appropriate report to the management committee?
82	Does the biorisk management advisor ensure that all relevant information is available to scientific and other required personnel?
83	Does the biorisk management advisor advice on management issues within organization?
84	Does the biorisk management advisor contribute to development and or delivery of training activities?
85	Does the biorisk management advisor ensure that all relevant activities are performed in compliance within regulations?
86	Has a scientific manager been designated with responsibilities to manage within the facility?
87	Does the scientific manager ensure that all work is conducted in accordance with established policies and guidelines?
88	Does the scientific manager supervise workers and ensure that only competent personnel can enter and work in facility?
89	Does the scientific manager ensure that adequate staffing, time, space and equipments are available?
90	Does the scientific manager ensure that all required risk assessments have been performed, reviewed and approved prior to initiation of work?
91	Does the scientific manager ensure that all at risk employees have been informed of risk assessments and provisions of recommended medical practices?
92	Does the organization have access to occupational health expertise?
93	Does the organization have an established occupational health program commensurate with activities and risks of the facility?

94	Does the organization have a facilities manager with designated responsibilities in accordance with requirements set out in this standard?
95	Does the organization have a security manager with designated responsibilities in accordance with requirements set out in this standard?
96	Does the organization have an animal care manager designated responsibilities in accordance with requirements set out in this standard?
97	Does eth animal care manager have in depth knowledge of animal handling, zoonotic diseases and occupational health issues?
98	Does the animal care manager liaise with biorisk management advisor, veterinarian, and occupational health professional for implementation of program?
99	Does the animal care manager provide input into risk assessment?
100	Does the animal care manager determine which animal species exist in the facility and what risks are posed?
101	Does animal care manager participate in the Institutional Animal Care and Use Committee (IACUC)?
102	Does the animal care manager provide input for site visitations like AALAC?
4.4.2	**Personnel Training, Awareness and Competencies**
103	Are the training requirements defined by the organization to perform different types of work?
104	Are competent trainers selected to render training?
105	Is the training defined based on hazard identification, risk assessment risk mitigation results?
106	Is the employee performance evaluated?
107	Are personnel recruited based on technical expertise, experience?
108	Are health conditions that may put employee at risk in the laboratory evaluated?
109	Are personnel integrity and reliability to work safely evaluated?
110	Are procedures in place to ensure that all employees are competent to perform their tasks safely?

111	Are procedures in place to periodically re-examine employees?
112	Are competency requirements defined based on facility and work that is measurable?
113	Is the competency assessment process defined and documented?
114	Is a process in place for continuous professional development for supporting staff including initial and periodic follow up training?
115	Are procedures in place to ensure that adequate back-up and contingency measures are in place to address need for continuity and succession planning?
116	Are procedures in place to determine what documents should be available to evaluate succession planning?
117	Are roles and responsibilities for continuity and succession planning defined?
118	Are employee duties clearly defined to evaluate training program?
119	Are safety and security competencies at different levels evaluated for training requirements?
120	Is frequency of training requirement defined by the organization?
121	Is an awareness program available for contractors, temporary workers and visitors?
122	Is the appropriate method of training evaluated-e.g. web based, instructor led, and hands on training?
123	Are all trainings documented?
4.4.3	**Consultation and Communication**
124	Does the organization have mechanisms in place for communicating to internal employees and external regulatory agencies?
125	Are objective defined for the need and requirements for communication?
126	Are formal employee consultations encouraged?
127	Are public and community based meetings held to discuss relevant information to all impacted and interested groups?

4.4.4	Operational Control
128	Are operations and activities associated with possible biological risk and relevant control measures to be applied defined?
129	Are the procedures reviewed on regular basis for suitability and effectiveness?
130	Are risk assessments reviewed regularly?
131	Is a formal process in place to evaluate risk associated with general safety?
132	Are measures taken to identify and implement issues related to fire safety, chemical safety, electrical safety, radiation safety etc?
133	Are processes in place to evaluate use of gasses, hot work/cold work, and equipment under pressure?
134	Are processes in place to evaluate use of laboratory animal care and use?
135	Is an up to date inventory system for biological agents and toxins established?
136	Is an up to date inventory system for infected tissues, cultures established?
137	Is restricted access in place by permitting only individuals authorized to access agents?
138	Is an effective security measure in place - e.g. locks, alarms, access controls?
139	Is a sample identification system in place?
140	Are biological agents and toxins segregated and stored according to risks?
141	Are materials to be controlled identified and documented?
142	Is the program of work for the facility defined by the organization?
143	Does the program define criteria for work that requires prior approval?
144	Is sufficient resource and capability to manage workflow evaluated by the organization?
145	Is the scope of work defined?
146	Are hazards identified?
147	Are results of workplace health risk assessments evaluated?

148	Are sufficient personnel available to implement all processes?
149	Are changes associated with design, operation and maintenance of facility defined and documented as a change management process?
150	Are changes associated with SOPs documented?
151	Are changes associated with modifications of entry/ exit procedures, personnel and visitor policies, etc subject to change management policy?
152	Are modifications to disinfection, waste disposal procedures etc subject to change management policy?
153	Are modifications to PPE provision and use subject to change management policy?
154	Are standard microbiological techniques to handle biological agents and toxins defined and documented?
155	Are the standards and expectations communicated to all users?
156	Are procedure sin place to monitor the practices?
157	Are procedures in place to assess personnel, product, environment contamination following laboratory procedures?
158	Are procedures established and maintained to ensure appropriate methods of disinfection and decontamination?
159	Are procedures in place to ensure that all contaminated or potentially waste items have been identified and documented?
160	Do procedures for verification of contamination include personnel, PPE, glassware, equipment, cultures used, etc?
161	Are specific procedures in place to ensure that waste is managed and disposed of in a safe and cost effective manner?
162	Are role sand responsibilities defined for waste management process?
163	Are local and environmental waste management policies reviewed periodically?
164	Are waste disposal documentations in place?
165	Are procedures in place to segregate mixed wastes: e.g. infected animals that have received radioactive materials?

166	Is adequate storage facility available to store waste?
167	Are decontamination procedures defined based on specification of waste?
168	Are appropriate packaging material used to maintain integrity during storage and transportation?
169	Are records of waste disposal documented and waste audit trails maintained?
170	Are PPE available, used and maintained appropriately within the facility?
171	Is PPE requirement determined based on risk assessment - agents, procedures used, controls available?
172	Are resources evaluated prior to making appropriate PPE available?
173	Is appropriate PPE training provided-e.g. donning/doffing, fit testing?
174	Are medical conditions associated with PPE evaluated?
175	Is a worker health program in place?
176	Does the worker health program include biorisk management advisor, occupational health professional, facility personnel, employee representative, biorisk mismanagement committee members, veterinary and animal care facility staff, human resources representative, communicable disease specialist, scientific management?
177	Is agent inventory and type of techniques used documented for this worker health program purpose?
178	Are updated medical histories of staff available?
179	Are adequate financial resources available for the program?
180	Are workflows defined and documented?
181	Is vaccinations required identified based on risk assessment of agents used by the organization?
182	Is a vaccination policy been defined, documented and implemented by the organization?
183	Is an inventory of vaccines available?
184	Is vaccine efficacy and safety data available?

185	Is policy for pre-employment vaccination defined?
186	Is a policy for pre and post exposure vaccination defined?
187	Is a policy in place to determine work policy for individuals with low titer/responses to the vaccine?
188	Is a policy in place for the use of vaccines in early stages of clinical development for selected infectious agents?
189	Is a program established to address risk associated with human behavior?
190	Are SOPs in place to maintain effective measures related to human behavior, specifically to control biological, chemical, physical and ergonomic risks?
191	Is a personnel reliability policy defined and established by the organization?
192	Is risk assessment evaluations included in the reliability assessment measures?
193	Is personnel reliability system based on applicable local and national legal and regulatory requirements? (E.G. immigration status, criminal records, drug screening)
194	Is personnel reliability system based on organizational human resource hiring practices and employment requirements?
195	Is personnel reliability system based on organizational occupational health and medical requirements?
196	Are periodic reviews conducted to assess changes in job responsibility?
197	Is a biorisk management policy in place to ensure all suppliers, contractors, visitors work in the facility without compromising safety and security of the facility?
198	Is the policy based on agents used, service contracts required for equipment maintenance?
199	Are specific employees identified to escort contractors, visitors and suppliers?
200	Are procedures communicated to facility employees, contractors and suppliers?
201	Is a policy in place for removal and exclusion of temporary and permanent employee from the facility when necessary based on risk assessment?
202	Is security system in place to exclude individuals that do not require legitimate access to the facility?

203	Are visitors, contractors, suppliers communicated that violation to procedures of facility shall be dismissed?
204	Is a comprehensive access control system in place?
205	Is the access control system updated regularly?
206	Is the infrastructure (facilities, equipment and process) of the organization reviewed and maintained for safe operation including biorisks?
207	Is the use and function of the facility documented?
208	Is the facility designed based on national and international standards, regulations and guidelines?
209	Are drawings and specifications of facility documented?
210	Is documentation in place for operation, maintenance, and calibration and validation history of the facility?
211	Is commissioning documentation in place for the facility?
212	Is the facility construction, equipment requirements planned based on use, function and biorisk management of the facility?
213	Are the roles and responsibilities of individuals responsible for the design, construction and inspection defined?
214	Is documentation in place for budget planning?
215	Are relevant legal requirements and codes of practice evaluated prior to designing the construction?
216	Is documentation in place for design, construction, inspection and verification of the new facility?
217	Are future facility stakeholders consulted on uses and needs?
218	Is a formal process in place for initial commissioning of new facilities and final decommissioning of existing ones?
219	Is a formal process in place when decommissioning an existing facility, including testing equipments, etc?
220	Is a process in place to ensure equipment and elements of the physical plant that may impact on biorisk?

221	Is documentation in place for purchase, control, calibration, certification, and validation of equipments and all aspects of the facility?
222	Are maintenance checks based on risk assessment of agents used?
223	Is a maintenance register available?
224	Are maintenance activities performed at planned times?
225	Is process in place for to manage any breakdown at eth facility?
226	Is a pest control program in place?
227	Are entry and exit of equipments to and from facility, including decontamination procedures documented?
228	Are equipment purchases approved by competent personnel based on risk assessments?
229	IS equipment use, material and waste generated documented for audit trail?
230	Is a complete inventory of all facility and scientific equipment, including critical spare parts and consumables available?
231	Are standards/tests to be used for calibration identified to ensure that equipment is correctly calibrated?
232	Is an up to date calibration register available for all equipments?
233	Are calibrations planned based on manufacturer’s specification s well as identified by risk assessment?
234	Are current standards compared prior to certifications?
235	Are competent and independent certifiers used for certification process?
236	Are validation requirements documented?
237	Are standards identified to be used to ensure proper validation?
238	Are required tests performed for validations?
239	Are security risk assessments done on possible theft of biological agents and toxins?
240	Are security risk assessments done for possible vandalism or tampering of materials?

241	Are security risk assessments done for possible labor issue and disputes?
242	Are security risk assessments done for weather related emergencies-e.g. earthquake, flood, tornado, hurricane?
243	Are security risk assessments done for work place violence?
244	Are security risk assessments done for utilities failure?
245	Are security risk assessments done for screening and isolation of suspected packages?
246	Are security risk assessments done for possible acts of terrorism?
247	Is a policy in place to identify sensitive information, control access to secured information?
248	Are all sensitive written records and data, including electronic data secured?
249	Are robust firewalls and encryption protocols in place for computer security?
250	Are policies in place regarding PCs' laptop computers, storage media, and cameras entering/exiting the facility?
251	Are policies in place for destruction of unwanted electronic files and paper files to be discarded?
252	Are policies for information security based on risk and threat assessments?
253	Are suppliers to the facility evaluated and selected based on their ability provide products, that meet the requirements of this standard?
254	Are legal requirements associated with procurement - e.g. shipping documents, permits, evaluated?
255	Are adequate credentials of the suppliers and services evaluated?
256	Are transportation requirements for biological materials identified and implemented?
257	Are legal requirements, national and international guidelines reviewed when reviewing transport requirements?
258	Is a transport safety advisor identified by the organization?

259	Are packaging systems, labels, PPE in place for proper transportation of biological materials?
260	Is documentation for audit trail available?
261	Is document control in place for traceability of material movements?
262	Is a policy in place to provide personal security support services to staff and when appropriate provide security awareness training?
4.4.5	**Emergency Response and Contingency Plan**
263	Are risk assessment data used to begin the emergency response planning process?
264	Are roles and responsibilities for staff members assigned in the event of an emergency?
265	Is a list (inventory) of readily accessible emergency equipment, including location and maintenance status available?
266	Are local emergency responders available?
267	Is a list of regulatory bodies available to report to, depending on level of emergency?
268	Is information from consultation and planning sessions with local emergency responders available?
269	Is experience from previous accidents and incidents at the facility or from similar facilities utilized while evaluating emergency plans?
270	Are emergency drills and exercises reviewed?
271	Is informational signage related to emergency response such as evacuation routes, exit signage, location of emergency response equipment, etc. clearly defined?
272	Are emergency scenarios considered while making contingency emergency plans- example Infected / potentially infected worker or other contact (e.g. family member, emergency responder or community member);
273	Are in plans in place when an accident or illness to worker requires evacuation?
274	Are in plans in place to handle Fire, flood, explosion, earthquake, extreme weather conditions, disease pandemics, breach of security?
275	Are plans in place to handle Potential loss of biological agents or toxins through theft or any other reason?
276	Are plans in place to handle unexpected virulence (unknown biological agents or biological agents expected to be avirulent)?

277	Are plans in place to handle Physical facility and equipment failure, including control system failure, Utility failure including electricity, gas, steam and water supplies?
278	Are plans in place to handle failure of disinfection regime?
279	Are plans in place to handle Major spillage / aerosol release or environmental release?
280	Are plans in place to handle Act of terrorism or deliberate vandalism?
281	Are plans in place to respond to intense media attention?
282	Are the responsible personnel identified by the organization to devise, implement and test the control measures?
283	Are procedures in place to respond to emergency situations during out of hours and normal business hours?
284	Are procedures in place to handle reduced staff availability during weekends or holidays?
285	Are procedures in place for emergency access by overriding access controls as appropriate?
286	Are procedures in place to evacuate people avoiding higher biosecurity areas during emergency?
287	Are procedures in place for safe removal, transport, treatment and accommodation of contaminated people or objects?
288	Are external agencies like police department, security services, fire services, ambulance and local hospitals consulted while planning emergency procedures?
289	Are structured, emergency exercises and simulations planned?
290	Are lessons learned from previous emergency exercises evaluated?
291	Are response plan and SOPs for emergency situations used for the drills?
292	Are the results of such drills documented?
293	Is feedback provided to personnel on their performance?
294	Is training provided in use of emergency equipments?
295	Is the frequency of drills determined based on the likelihood of the events?

296	Are results from the drills reviewed and used for continuous improvement of the process?
297	Are contingency plans evaluated by the organization in the event of an unforeseen event resulting in disruption of normal operations?
298	Are contingency plans made based on risk assessments, previous incidents and lessons learned?
299	Is a contact list for relevant staff in place?
300	Are specific individuals identified to be notified in the event of a contingency plan needs to be activated?
301	Are warning indicators like power failure indicators, etc evaluated?
302	Is a recovery time determined as to when the contingency plan should be activated?
303	Are backup resources listed and prioritized?
304	Are back up sources regularly checked?
305	Are critical materials stored in two different locations?
306	Is a plan in place to protect vital records and equipments?
307	Is a plan in place to start work potentially in a different location?
308	Is a list describing possible reasons for partial or full disruption of normal operating conditions available?

4.5 Checking and Corrective Action	
4.5.1	**Performance Measurement and Analysis of Data**
309	Are the matrices for biorisk management been identified by the organization- E.g. data from performance measurement from staff, equipment, training etc.
310	Are results of risk assessments periodically analyzed?
311	Are results of audits and inspections analyzed periodically?
312	Are reports of accidents, incidents and near misses analyzed periodically?
313	Are results of corrective actions resulting from inspections periodically analyzed?
314	Are results of equipment performances/maintenance evaluated periodically?
315	Are routine security and emergency response exercises performed regularly?
316	Are results from non-conformances resulting from an inspection or job hazard assessment evaluated?
4.5.2	**Records, Documents and Data Control**
317	Are risk assessments performed, standard operating procedures (SOPs), and safety manuals documented, and readily available?
318	Are results of audits and inspections documented?
319	Are training records documented?
320	Is certification of equipments in containment facilities documented?
321	Are design records and commissioning/test plans, maintenance plans and associate data documented?
322	Are job hazard analyses and charts of authority documented?
323	Are medical and health surveillance records documented?
4.5.3	**Inventory Monitoring and Control**
324	Is a functional and complete inventory of all biological agents and toxins maintained that allows the organization to keep track of pathogens and toxins in the facility?

325	Is a time table established to review the inventory periodically?
326	Has a responsible been designated to review the inventory?
327	Has a standard method been defined for maintenance of inventory-e.g. tubes/box numbering?
328	Is a process in place for solving discrepancies (i.e. when number of tubes do not correspond to the list) and identify the reason, responsible individual, etc?
329	Are proactive measures taken 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?
330	Are procedures in place to investigate missing biological agents that is appropriate for the level of risk?
331	Is documentation maintained on decisions made on inventory reduction?
332	Has a defined system of audit or control of inventory been established?
4.5.4	**Accident and Incident Investigation, Non-conformity, Corrective and Preventive Actions**
333	Are responsible identified for maintaining accident/incident reporting system?
334	Are parameters constituting an accident / incident, been defined to ensure recording and reporting?
335	Is documentation required to support the system defined?
336	Is the frequency and distribution of reports defined?
337	Is a trend analysis of accidents/incidents performed?
338	Is a root cause analysis of accidents/incidents performed using individuals trained in investigation techniques?
339	Is feedback obtained at regular intervals and action tracking mechanisms ensure that lessons learned result in action to avoid the repeat of such events and / or minimize their potential impact?
340	Are interviews conducted regularly with relevant personnel to analyze accident/investigations?
341	Is the management involved management in the investigation of major events?

342	Are procedures identified as appropriate or necessary to coordinate with security professionals and law enforcement?
343	Are procedures in place to investigate and correct nonconformities?
344	Are procedures reviewed to prevent anticipated recurrence?
345	Is the impact of nonconformity on other aspects of biorisk management analyzed?
346	Are the nonconformities and the impact communicated to the impacted individuals?
347	Are responsibilities, authority and steps to be taken defined?
348	Are reports and recommendations of inspections and audits reviewed as a corrective action?
349	Is corrective action plans identified, prioritized and implemented?
350	Are records of actions taken documented?
351	Are corrective actions taken continuously reviewed?
352	Is safety walkthrough conducted proactively?
353	Are suggestions from employees evaluated?
354	Are results from medical surveillance or preventive medical programs in place?
355	Are equipment malfunctions identified through routine maintenance programs?
356	Are announced and unannounced safety walkthroughs performed?
357	Are self inspections performed by investigators?
358	Are results of informal walkthroughs, self inspections and validation walkthroughs analyzed?
359	Are corrective actions plans, implementation time lines defined?
4.5.5	**Inspection and Audit**
360	Do audits include both internal and external inspections and reviews?
361	Do inspections include informal walk-through?

362	Do audits include announced and unannounced inspections?
363	Are routine and random equipment performance evaluations included as part of the audit?
364	Are routine and random facility systems evaluations performed-e.g. HVAC system check, airflow analysis, etc?
365	Are results of self inspections evaluated?
366	Are documents pertaining to inspections and corrective actions documented?
367	Are procedures evaluated and the need for action to prevent nonconformities established?
368	Is the documentation process changed whenever corrective actions make this necessary?
369	Is the documentation process changed whenever preventive actions make this necessary?
370	Are Biorisk Management records established?
371	Do records document results and achievements?
372	Are records identifiable?
373	Do records remain identifiable?
374	Are records traceable?
375	Does the internal audit program take the results of previous audits into consideration?
376	Are audit requirements and responsibilities clearly defined?
377	Is the internal audit process impartial?
378	Are auditors selected that are impartial?
379	Are internal audit results reported to organization’s management?

4.6 Review	
4.6.1 Biorisk Management Review	
380	Has a defined process been established by the organization to periodically review the organization's Biorisk management system?
381	Does the organization examine results of internal audit results?
382	Does the organization review the institutional compliance to Standard operating procedures (SOP) and other work instructions?
383	Does the organization review status of risk assessment activities?
384	Does the organization review status of previous corrective actions?
385	Does the organization review status of previous preventive and corrective actions recommended?
386	Does the organization review follow up actions of previous management reviews?
387	Does the organization review results of accident/incident investigations?
388	Does the organization recommend changes that could affect the system?
389	Does the organization review recommendations for improvement?
390	Does the organization generate decisions and actions to change or improve the elements of Biorisk Management system?
391	Does the organization generate decisions and actions to change your Biorisk Management policy?