

Biorisk Management Systems 101

Introduction to Biorisk Management Systems Implementation

Student workbook

*Sandia National Laboratories
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Course Goals:

- For you to understand a management systems applicability to all layers within an institution
- For you to see the nature and value of a management system
- To understand the concepts of the plan, do, check, and act cycle
- For you to know the key elements of the CWA 15793 Biorisk Management System Standard
- For you to be able to assess situations and identify problems and solutions based on resources outlined in the CWA 15793 Biorisk Management System Standard
- For you to become an advocate for Biorisk Management Systems
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This course will run for two days and has been designed to follow the International Biological Threat Reduction Departments Controlling Laboratory Biorisks Course.

Activity 1: Your Biorisk Concerns

Lesson Objective:

- For you to see the nature and value of management systems
- For you to become an advocate for Biorisk Management systems
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You will be assigned a specific roles and responsibility for a laboratory which works with infectious biological material. Based upon your role and responsibility you will identify as many concerns as you have regarding biological risks. (Both safety and security risks)

Put your concerns on the provided colored sticky notes, one concern per note.

When asked, you will move your concerns to the provided boards.

Biorisk Concerns

Biorisk Management System	Risk Assessment
Pathogen and Toxin Inventory and Information	General Safety
Personnel and Competency	Good Microbiological Technique
Clothing and Personal Protective Equipment	Human Factors

Health Care	Emergence Response and Contingency Planning
Accident / Incident Investigation	Facility Physical Requirements
Equipment and Maintenance	Decontamination, Disinfection and Sterilization
Transport Procedures	Security

Rubric:

Proficient: In your final listing of biorisk concerns, you should have at least one item in each category and the concerns are placed under these topics in a rational and defensible manner.

Nearly Proficient: If there are missing key concerns, concerns are not distributed across the categories, or concerns are miss categorized you may want to discuss your final listing further.

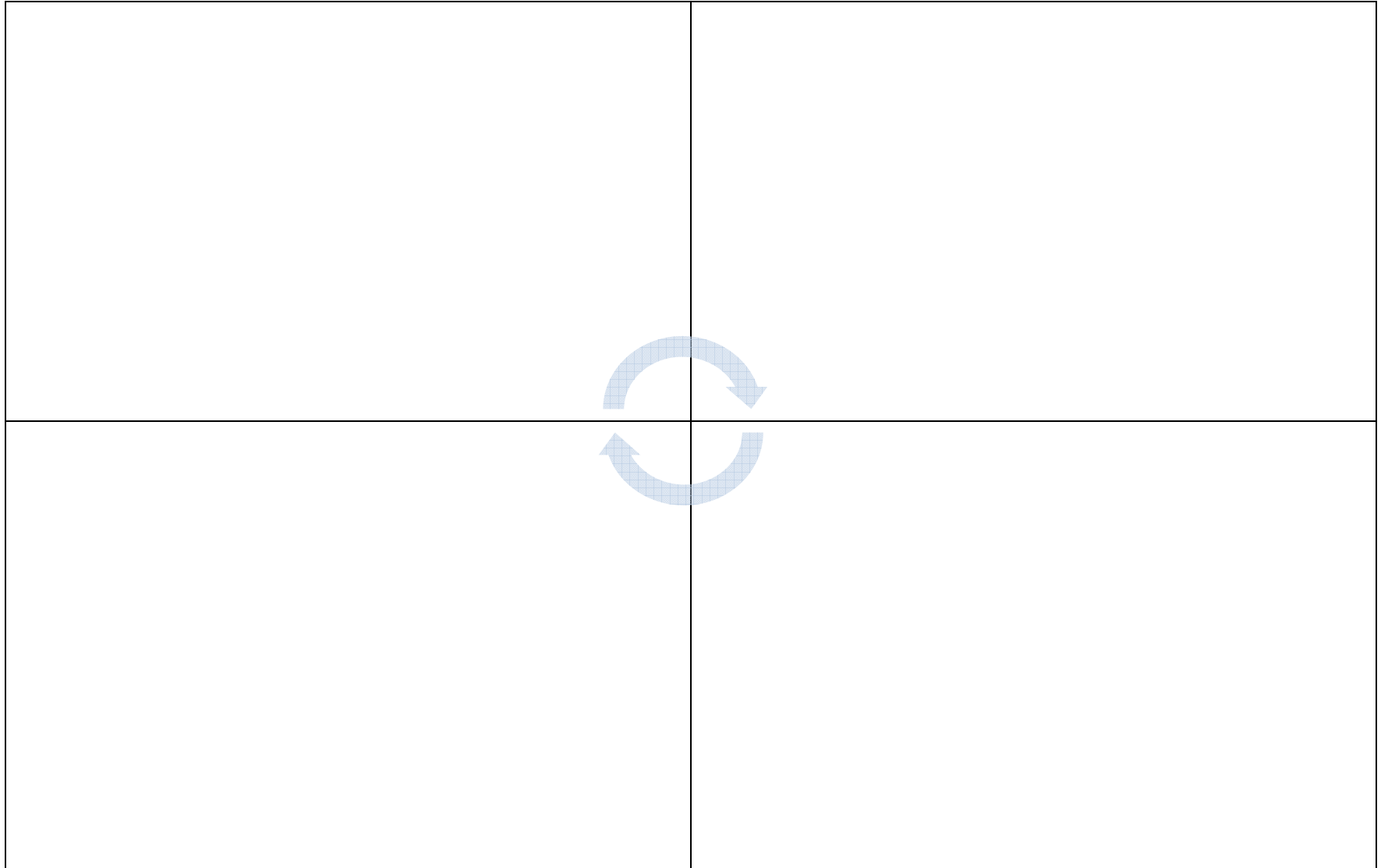
Activity 2: The Management System Cycle

Lesson Objective:

- For you to see the nature of a management system

In your group, you will work through the following activity (one step at a time as provided by your instructor).

The Management System Cycle



Rubric:

Proficient: The laboratory activity you documented showed steps which are complete, linear and items listed in each category are rational; acted upon items follow what was learned in the check, the check was based upon what was done and what was done was based upon what was planned.

Nearly Proficient: The laboratory activity you documented skipped some of the steps or ordered them in a manner which was not linear: acted upon items did not follow what was learned in the check, the check was not based upon what was done or what was done was not based upon what was planned.

Reference information on the Plan, Do, Check, Act Cycle:

The steps in each successive PDCA cycle are¹:

PLAN

Establish the objectives and processes necessary to deliver results in accordance with the expected output (the target or goals). By establishing output expectations, the completeness and accuracy of the specification is also a part of the targeted improvement. When possible start on a small scale to test possible effects.

DO

Implement the plan, execute the process, make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps.

CHECK

Study the actual results (measured and collected in "DO" above) and compare against the expected results (targets or goals from the "PLAN") to ascertain any differences. Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. Information is what you need for the next step "ACT".

ACT

Request corrective actions on significant differences between actual and planned results. Analyze the differences to determine their root causes. Determine where to apply changes that will include improvement of the process or product. When a pass through these four steps does not result in the need to improve, the scope to which PDCA is applied may be refined to plan and improve with more detail in the next iteration of the cycle.

¹ Moen and Norman. "Evolution of the PDCA Cycle"

Activity 3: Organizing the CWA 15793 Biorisk Management Standard

Lesson Objective:

- This lesson will help in your valuing and understanding of the CWA 15793 Biorisk Management Standard
- This lesson will help you see the nature of a management system, and to know the key elements of the CWA 15793 Biorisk Management Standard

For this activity, you will work with your group. As a group you will review sections of the CWA document and consider typical laboratory items (items physically in the laboratory as well as the records and other items used in laboratory management) and determine their relevance to the CWA. You will be asked to organize your ideas.

Organizing the CWA 15793 Biorisk Management Standard

	Laboratory Elements		Applicable CWA Elements
Example	Fire Extinguisher		<p><i>4.4.1.1 Top Management</i></p> <p><i>4.4.2.1 Recruitment</i></p> <p><i>4.4.2.4 Training</i></p> <p><i>4.4.4.1 General Safety</i></p> <p><i>4.4.4.5.2 Inactivation of Biological Agents and Toxins</i></p> <p><i>4.4.5.2 Emergency Plans</i></p> <p><i>4.4.5.4 Contingency Plans</i></p> <p><i>4.5.4.3 Corrective Action</i></p>
1	Training Records		<p>4.1.1 Biorisk Management Systems</p> <p>4.3.1.1 Planning and Resources</p> <p>4.3.1.3 Hazard Identification</p> <p>4.3.3.1 Biorisk Control Objectives and Targets</p> <p>4.4.1.7 Facility Management</p> <p>4.4.4.3 Work Programme Planning and Capacity</p> <p>4.4.4.5.3 Waste Management</p> <p>4.4.4.8.5 Information Security</p> <p>4.4.4.5.3 Emergency Exercises and Simulations</p> <p>4.5.3 Inventory Monitoring and Control</p>
2	Risk Assessments		<p>4.1.1 Biorisk Management Systems</p> <p>4.3.1.1 Planning and Resources</p> <p>4.3.1.3 Hazard Identification</p> <p>4.3.3.1 Biorisk Control Objectives and Targets</p> <p>4.4.1.7 Facility Management</p> <p>4.4.4.3 Work Programme Planning and Capacity</p> <p>4.4.4.5.3 Waste Management</p> <p>4.4.4.8.5 Information Security</p> <p>4.4.4.5.3 Emergency Exercises and Simulations</p> <p>4.5.3 Inventory Monitoring and Control</p>
3	Biohazard Labels		<p>4.1.1 Biorisk Management Systems</p> <p>4.3.1.1 Planning and Resources</p> <p>4.3.1.3 Hazard Identification</p> <p>4.3.3.1 Biorisk Control Objectives and Targets</p> <p>4.4.1.7 Facility Management</p> <p>4.4.4.3 Work Programme Planning and Capacity</p> <p>4.4.4.5.3 Waste Management</p> <p>4.4.4.8.5 Information Security</p> <p>4.4.4.5.3 Emergency Exercises and Simulations</p> <p>4.5.3 Inventory Monitoring and Control</p>

4	Hazard Awareness Document		4.1.1 Biorisk Management Systems 4.3.1.1 Planning and Resources 4.3.1.3 Hazard Identification 4.3.3.1 Biorisk Control Objectives and Targets 4.4.1.7 Facility Management 4.4.4.3 Work Programme Planning and Capacity 4.4.4.5.3 Waste Management 4.4.4.8.5 Information Security 4.4.4.5.3 Emergency Exercises and Simulations 4.5.3 Inventory Monitoring and Control
5	Audits		4.1.1 Biorisk Management Systems 4.3.1.1 Planning and Resources 4.3.1.3 Hazard Identification 4.3.3.1 Biorisk Control Objectives and Targets 4.4.1.7 Facility Management 4.4.4.3 Work Programme Planning and Capacity 4.4.4.5.3 Waste Management 4.4.4.8.5 Information Security 4.4.4.5.3 Emergency Exercises and Simulations 4.5.3 Inventory Monitoring and Control
6	Policy Statement -objectives -targets -roles and responsibilities -monitoring requirements		4.1.1 Biorisk Management Systems 4.3.1.1 Planning and Resources 4.3.1.3 Hazard Identification 4.3.3.1 Biorisk Control Objectives and Targets 4.4.1.7 Facility Management 4.4.4.3 Work Programme Planning and Capacity 4.4.4.5.3 Waste Management 4.4.4.8.5 Information Security 4.4.4.5.3 Emergency Exercises and Simulations 4.5.3 Inventory Monitoring and Control
7	Autoclave printout		4.1.1 Biorisk Management Systems 4.3.1.1 Planning and Resources 4.3.1.3 Hazard Identification 4.3.3.1 Biorisk Control Objectives and Targets 4.4.1.7 Facility Management 4.4.4.3 Work Programme Planning and Capacity 4.4.4.5.3 Waste Management 4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
8	Freezer logs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
9	Laboratory Order List		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
10	Dated Risk Assessment Reports		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
11	Risk Assessment Schedule		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
12	Risk Assessment Responsibilities Chart		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
13	List of Mitigation measures to be implemented		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
14	Fire Inspection Sticker		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
15	Environmental Health and Safety Compliance Report		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
16	Maintenance Logs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
17	Designated Scientific Manager		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
18	Contact List		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
19	Biorisk Management Committee Request Form		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
20	Urgent Care Sticker		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
21	Job Postings and Requirements		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
22	Curriculum Vitae		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
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			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
23	Mentor List		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
24	Designated Deputy Scientific Manager		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
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			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
25	NFPA Diamond		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
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			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
26	Material Safety Data Sheets (MSDS)		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
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			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
27	"Caution Hot" stickers		4.1.1 Biorisk Management Systems
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			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
28	High Pressure Stickers		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
		29	Biological Inventory
	4.3.1.1 Planning and Resources		
	4.3.1.3 Hazard Identification		
	4.3.3.1 Biorisk Control Objectives and Targets		
	4.4.1.7 Facility Management		
	4.4.4.3 Work Programme Planning and Capacity		
	4.4.4.5.3 Waste Management		
	4.4.4.8.5 Information Security		
	4.4.4.5.3 Emergency Exercises and Simulations		
	4.5.3 Inventory Monitoring and Control		
30	Biological Agent List		
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
		31	Laboratory Title
	4.3.1.1 Planning and Resources		
	4.3.1.3 Hazard Identification		
	4.3.3.1 Biorisk Control Objectives and Targets		
	4.4.1.7 Facility Management		
	4.4.4.3 Work Programme Planning and Capacity		
	4.4.4.5.3 Waste Management		
	4.4.4.8.5 Information Security		

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
32	Laboratory Standard Operating Procedures (SOPs)		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
33	Emergency Exit Map		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
34	Normal Entry/Exit Procedures		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
35	Personal Protective Equipment SOPs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
36	Sharps Containers		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
37	Disinfectants		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
38	Spill Kit		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
39	Autoclave		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
40	Biohazard Bags		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
41	Autoclave Tape		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
42	Bioindicators		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
43	Gloves		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
44	Laboratory Coats		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
45	Eye Protection		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
46	Vaccination Records		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
47	Personnel File		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
48	Visitor Badges		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
49	Visitor Logs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
50	Authorized Personnel Only Signs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
51	Employee Badges		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
52	Access Controls		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
53	Blue-prints		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
54	Commissioning Report		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
55	Biosafety Cabinet Certification Sticker		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
56	Autoclave Validation Sticker		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
57	Pipette Calibration Schedule		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
58	Biometrics-palm readers		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
59	Door Locks		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
60	Badge Swipe		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
61	Pin-pads		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
62	Locked Cabinets		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
63	Passwords on Computer		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
64	Sensitive Information Document Labels		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
65	General Maintenance Schedule		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
66	International Air Transport Authority (IATA) Guide		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
67	Shipping Boxes		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
68	Bomb Threat SOP		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
69	Emergency Exit Sign		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
70	Fire Alarm		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
71	Emergency Response SOPs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
72	Waste Handling SOPs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
73	Incident Reporting SOPs		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
74	Incident Reports		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
75	Biorisk Management Audit		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
76	Biosafety Cabinet		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
77	Sink		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
78	Inoculating Loops		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
79	Pipettes		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security

			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control
80	Loop Incinerator		4.1.1 Biorisk Management Systems
			4.3.1.1 Planning and Resources
			4.3.1.3 Hazard Identification
			4.3.3.1 Biorisk Control Objectives and Targets
			4.4.1.7 Facility Management
			4.4.4.3 Work Programme Planning and Capacity
			4.4.4.5.3 Waste Management
			4.4.4.8.5 Information Security
			4.4.4.5.3 Emergency Exercises and Simulations
			4.5.3 Inventory Monitoring and Control

Rubric:

Proficient: A proficient group of the CWA elements shows that groupings shall capture processes at a macro level to support implementation. The groupings unite common requirements which support implementation, and all assigned CWA elements where addressed.

Nearly Proficient: Elements applied to an item that does not represent the CWA category or major laboratory components have been over looked.

Activity 4: Assess a laboratory's compliance with the CWA (Gap analysis) and prioritize any elements not in compliance

Lesson Objectives:

- For you to see the value of the CWA 15793 Biorisk Management System Standard
- For you to become an advocate for the CWA, and for you to know the key elements of the CWA
- For you to see the nature of a management system and its valueFor you to be able to assess situations to identify problems and solutions based on resources outlined in the CWA

In your group, you will review a laboratory scenario provided and identify area in which the laboratory is in compliance fully with the CWA or areas in which the laboratory will need improvement to be in compliance. Please note, any CWA items which have been omitted from the scenario you can assume to be in compliance and ignore.

After determining the laboratory's level of compliance and specifically defining elements in which the laboratory will need improvement, your group will prioritize these elements based the funding resources you group has been provided.

Biorisk Management Scenario

Any laboratory management items not specifically identified, assume they are in compliance with the CWA, for details on any items mentioned in this scenario feel free to inspect those items in the laboratory or in the appropriate office

This facility is part of the human public health system of the country. The facility is responsible for conducting diagnostic work on any human diseases which the local clinics are unable to diagnosis. The facility is reviewing one of their diagnostic laboratories to determine if it is in compliance with the CWA 15793 Biorisk Management System Standard and if not to specifically identify any items in non-conformance. Any identified items will be prioritized to determine how best to make this laboratory compliant with the CWA.

Facility Health and Safety Policy

Our Facility is committed to providing and maintaining a safe and healthy workplace for all staff, and to providing the information, training and supervision needed to achieve this.

Our Facility will take responsibility for health and safety procedures, however, employees need to be aware of their responsibilities and comply with the business' health and safety policy.

Each employee is encouraged to play a vital and responsible role in maintaining a safe and healthy workplace through:

- *Being involved in the workplace health and safety system.*
- *Sticking to correct procedures and equipment.*
- *Wearing protective clothing and equipment as and when required.*
- *Reporting any pain or discomfort as soon as possible.*
- *Ensuring all accidents and incidents are reported.*
- *Helping new employees, trainees and visitors to the workplace understand the right safety procedures and why they exist.*
- *Telling your manager immediately of any health and safety concerns.*
- *Keeping the work place tidy to minimize the risk of any trips and falls.*

Your participation is much appreciated.

Organizational structure with roles and responsibilities

- The facility director is Dr. Elisa, all funding, hiring, and purchased must be approved by the director
- There is a biosafety office who is ultimately responsible for the safety of the laboratory workers
- The biosafety committee supports all work conducted in the facilities biosafety level 3 laboratory and is chaired by the director
- There is a facility health clinic for use in the event of a physical injury to any persons in the work force
- There is a lab manager who is responsible for keeping all laboratory records and maintaining the work environment
- The laboratory technicians conduct the bulk of the work inside the laboratory
- Additional administrative and support persons are not included in this conformance review.

CV's and References are checked for laboratory personnel prior to employment.

Summary of the laboratory

The laboratory which is currently being assessed to determine if it is in compliance with the CWA is a diagnostic laboratory focusing on a variety of food borne pathogens.

The laboratory conducted biosafety and biosecurity risk assessments for Salmonella and based upon this assessment defined the biosafety measures in the laboratory.

The laboratory is a relatively new facility that is located in an area known to have hurricanes. During the construction process of the facility this was taken into account for the structural integrity of the building.

Laboratory Layout

The laboratory is a standard modern laboratory containing easily cleanable work surfaces, a sink, a class II A2 biosafety cabinet, and a lockable door. There is an autoclave inside the laboratory space. The laboratory does not have directional airflow. There is no direct effluent treatment on the waste water from the sink, however liquid is captured in a container and both it and the solid waste are autoclaved before disposal. The laboratory is locked when not in use. The laboratory manager and PI have keys to the laboratory and will provide keys to laboratory technicians and maintenance personnel if requested. The after hour guard does not have laboratory access.

All equipment is certified/validated. The laboratory also has bench equipment like incubators and centrifuges. This equipment is on an annual maintenance cycle.

The facility has a biosafety program which includes introductory training to all new staff on biosafety and biosecurity practices. The training also includes proper use and storage of PPE, general good

laboratory practices which include inventory management and information protection. Waste handling is also trained. There is a formal biosafety manual for the facility and each laboratory has its own SOPs.

PPE for this laboratory includes lab coats (which are autoclaved and washed as needed); closed toe shoes are required, as are gloves.

Laboratory workers are trained on the diagnostic process and on general safety. Training Records are kept in the laboratory manager's office.

Badges should be worn by all staff.

The laboratory has a spill kit inside the laboratory.

The laboratory has fire evacuation SOPs in place.

The laboratory has procedures posted for what to do in the event of a bomb threat

Incident records are kept in the laboratory manager's office.

Laboratory Diagnostic Process

The primary laboratory technician, Fred, receives fecal samples from many of the clinics within the country. These samples arrive in small sealed plastic containers.



Fred then lists the arrival of the sample in his laboratory notebook with the time and date of arrival and a sample number. He lists the sample number on the container as well.

Fred then adds sterile water to the sample to make it liquid then extracts some of the sample using a pipette. He then adds the liquefied sample to several varieties of plates containing selective media and spreads the media. Fred uses standard sterile techniques. He labels the plates with the same sample number and puts them into the incubator. He places the original sample into a rack in the fridge.

The biosafety cabinet is used for any process which has a potential to generate an aerosol specifically the pipetting and plating of the sample.

Depending upon the growth requirements based upon the possible bacteria and media. Fred exams the plates and enumerates his findings. He lists these findings in the notebook. Fred also fills out a diagnostic report on the computer and emails it to the clinic.

All plates and the original sample are then autoclaved. At the end of each day, Fred grabs a bottle of disinfectant from the shelf and sprays down all the surfaces. After 2 minutes, Fred wipes down the surfaces with a cloth which he then puts into the biohazard container for reusable items.

Any unusual cultures are set to a reference laboratory. Fred provides another laboratory technician, George, the original sample in the closed plastic container. George then follows the shipping SOP to package and label the sample and arranges for transport to the reference laboratory.

Fred autoclaves the waste from each of the separate waste containers as needed. He places the waste bags into the autoclave with a temperature and pressure indicator strip, and once a month includes a bio-indicator. Upon completion of the waste cycle, Fred puts the waste in a corner of the laboratory. Since the autoclave is small, Fred often has to run one load before leaving and leave the waste in a corner of the laboratory, out of the way, until the morning when he can run another load.

An outside contractor comes into the laboratory to collect the waste for processing.

Rubric:

Proficient: All CWA elements are represented and are rationally placed according to the scenario. CWA elements are attributed to justify placement

Nearly Proficient: Some CWA elements are present, but others are missing or the CWA elements contradict the scenario. The attributes are made based upon assumption and incomplete understanding of the CWA

Prioritization of the Incomplete Biorisk Management Elements

Management system change to become in compliance with the CWA	Rationale for prioritization
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	

Rubric:

Proficient: All CWA elements are represented, and are rationally placed and can be justified by criticality or simplicity. Ideally, simple and critical should come first

Nearly Proficient: Some elements are present but others are missing. Rationalization based upon assumptions or critical elements are present, but misrepresented. List is prioritized but simple elements are overshadowed by more complex and less critical items.

Summary

Course Goals:

- For you to understand management systems applicability to all layer within the laboratory
- For you to be able to assess situations and identify problems and solutions based on resources outlined in the CWA 15793 Biorisk Management System Standard
- For you to become an advocate for Biorisk Management Systems
- For you to see the nature of a management system
- For you to know the key elements of the CWA 15793 Biorisk Management System Standard
- To understand the concepts of the plan, do, check, and act cycle

Individually, consider each of these course goals. Do you feel this course has helped you to achieve them? Based on this course, what are the one or two (or more) key ideas or concepts you would like to take home to your facility?

1.

2.