SAND2012-4757P

Course:

Identifying Legal Requirements that Impact Biorisk Management

Design Document

Sandia National Laboratories

International

BIOLOGICAL THREAT REDUCTION

CBEP

Cooperative Biological Engagement Program

Part I: Course Overview

Course Description

Overview

Identifying Legal Requirements that Impact Biorisk Management is designed for managers and leaders to identify the international, national, and local requirements that impact biorisk management at the organizational level. Although it is designed for managers and leaders, it can also be used for any worker that influences or impacts biorisk management to provide an opportunity to think through and to catalog these requirements.

Note: Presenting this course will require extensive preparation on the instructor's part. The course materials provide only the framework of this exercise – it cannot anticipate all possible responses to the exercise based on the localities where it may be presented and, thus, anticipated responses are, in general, not provided.

Scope

See above

Learning Level
based on Bloom's taxonomy

- ✓ knowledge
- ✓ comprehension
- ✓ application
- synthesis
- evaluation

Length of Course

4 hours

Course Objectives

At the end of this Course, Students will be able to:

Organizational Objectives

- Understand that legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management

Instructional Objectives

- Identify the legal requirements that impact biorisk management (i.e. lab & equipment design, lab & equipment operation, laboratory mission, deliverable, staff, agents and supplies)
- Understand how to align legal requirements with biorisk management
- Understand how to conduct gap analysis

Personal Objectives

Know

- How to identify legal requirements that impact biorisk management (BRM)
- How to align legal requirements with BRM
- What is involved in performing a gap analysis
- How to perform a gap analysis

Feel	• Confident in identifying and understanding legal requirements that impact BRM
Do	• Identify legal requirements that impact BRM • Determine how legal requirements affect BRM • Perform a gap analysis to determine if the organization and BRM system/program is in alignment with all legal requirements
Key Messages	1. Legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management 2. A best practice to determine alignment with legal requirements is to conduct a gap analysis 3. Legal requirements are not the only drivers for biorisk management

Evaluation Strategy

Level 1 (satisfaction):	Students will complete a satisfaction survey about their experience with the course
Level 2 (learning):	Students will complete a "learning contract" for the next steps needed to begin biorisk management implementation
Level 3 (behavior):	Desired behavior is for students to participate in additional learning opportunities on BRM – this behavior will be evaluated three to six months post-training and may encompass additional training courses
Level 4 (organizational change):	A repeat of the training needs assessment will be performed at least annually – this annual assessment can be compared to the baseline assessment to determine improvements in biorisk management performance

Learner Description (for Course design purposes)

Number of Students:

10 to 25; small groups of 5 people each

Biorisk Management Role:

- ✓ Policy Makers
- ✓ Top Management
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
- Workforce

Audience Assumptions:

(assumed range is indicated by shaded cells)

		Novice		Practi-tioner		Expert
Education	Scientific	1	2	3	4	5
	BRM*	1	2	3	4	5
Expertise	Scientific	1	2	3	4	5
	BRM	1	2	3	4	5
Competence	Scientific	1	2	3	4	5
	BRM	1	2	3	4	5
BRM = "biorisk management". See definitions for terms in Resources section						

Language of instruction; translation or interpretation anticipated:

English (for design purposes)

Prerequisites

Orientation to Biorisk Management

Pre- or post-work required for completion

None

Certificates or documents of completion:

Certificates of completion will be provided

Preparation for future coursework

This course is part of the policy, planning and assessment module under the Management and Leadership Track.

Anticipated next steps

Students will participate in learning tracks, as defined by the local training needs assessment and other subject matter expert (SME) recommendations.

Instructional Environment

Number of Instructors/Staff required:	TBD depending on number of Students – optimal ratio is 1 Instructor per no more than 12 Students
Instructor Qualifications:	Instructors must have completed the Global Biorisk Management Curriculum (GBRMC) orientation, including this course, and be enrolled in the GBRMC training network.

Learning Environment

Media:	Instructor-led course.
Exercises & Activities	
Experience (Activists)	Students will be asked to consider their experiences in regard to identifying legal requirements that impact BRM and if any of their past experience included in how to align legal requirements with BRM and performing a gap analysis
Reflection (Reflectors)	Students will be asked to reflect on those experiences to help develop a model how they would review a legal requirements and its impact on BRM; Students will be asked to reflect on the next steps for working towards in identifying legal requirements and performing a gap analysis
Models (Theorists)	Students will be introduced to a real world scenario in which a review was completed in which they can analyze the situations and evaluate how the process was undertaken
Practice (Pragmatists)	Students will be given the real world scenario as a case study to see how the topics discussed are practiced in real life

On-Site Specifics

Location	TBD
Room organization	Clusters of tables to facilitate small group (no more than 5 Students per group
Dress code and/or important cultural considerations	TBD

Instructional Materials

Equipment & Supplies	Large flip charts Markers (enough for up to 5 groups plus instructor(s)) 6 x 8 inch Post-it notes (no lines) Student binders (1" or less) and tabs Pens

	Laptop computer with powerpoint files loaded Projector Easels (1 per group) Name tags/lanyards or Tent Cards Certificates Notepads
Student Handouts	Course agenda and schedule Student notes Glossary CWA 15793 Hippocratic Oath

Resources

Dependencies	
Authorities	
References	CWA 15793 CEN WS 55, 53 WHO Laboratory Biosafety Manual Laboratory Biosecurity Handbook IBTR Training – Information Security and MC&A (SAND No. 2004-4555P, SAND No. 2005-3288 C) DTRA BSL-2 Training – Hazard Crtieria and Categorization DTRA BSL-3 Training – Bioethics and Biosecurity CDC/WHO Laboratory Quality Management System Training Toolkit Biosecurity Plan template (in development) Glossary of terms (in development)

Terms used in this document

- Knowledge – remembering the material in the same form as it was taught
- Comprehension – student's ability to understand the material by (for example) explaining or summarizing key messages
- Application – ability to use the material in a new or given situation
- Synthesis – ability to put together learning material in a new whole entirety. For example, using the material to create a new program or plan.
- Evaluation – ability to judge the value of the material presented as a peer (to be able to critically advise or judge others on their application and synthesis of this learning material).
- Novice – a person who is new to the circumstances, work, etc. in which s/he is placed; beginner
- Practitioner – a person engaged in the practice of a profession; a person who practices something specified
- Expert – a person who has special skill or knowledge in some particular field; specialist; authority; trained by practice
- Education – the act of acquiring particular knowledge or skills, as for a

profession

- Expertise – the process of personally observing, encountering or undergoing something; knowledge or practical wisdom gained from what one has observed, encountered, or undergone
- Competence – Possession of a suitable or sufficient skill, knowledge, experience, etc. for some specified purpose; properly qualified

Part II: Course Outline/Schedule							
Day	**Segment time (min)**	**Time**	**Topic**	**Instructional Method**	**Slide #**	**KM #**	**T/F**
1							
KM = key messages ; T/F = teaching versus facilitation (instructor-based versus learner-based)							