Biosafety, Biosecurity and the Evaluation of Biohazards

Course Facilitators' Manual

YALE CENTER FOR
PUBLIC HEALTH PREPAREDNESS

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Acknowledgements

This facilitators' manual has been developed from the wealth of information, knowledge and practical experience accumulated by Mr. Ben Fontes, MPH, CBSP, who serves as the Biological Safety Officer at Yale University and works in the Office of Environmental Health and Safety. Mr. Fontes has been providing biosafety training to Yale researchers, staff, students, and visitors since arriving on campus in 1995 where he has served as a member of the Yale Biological Safety Committee. Ben received the MPH degree from the University of Michigan (Occupational Health/Industrial Hygiene) and is a Certified Biological Safety Professional. He is a member of the American Biological Safety Association (ABSA) and has previously served as the Chair of their Training and Education Committee. Prior to joining Yale, Ben was with the Harvard University's Environmental Health and Safety Office as an Associate Biosafety Officer and Health Physics Technician. Mr. Fontes is a recipient of the prestigious John H. Richardson Special Recognition Award in 2002 and the Outstanding Means of Communication Citation granted by the ABSA to formally acknowledge high-impact and original non-commercial training materials. Mr. Fontes serves as the instructor and has been teaching the Biosafety and Biohazard Evaluation course at the Yale School of Public Health since 1999.

The facilitators' manual was designed and edited by Dr. Srdjan Stakic. Srdjan serves as a coordinator with the Yale Center for Public Health Preparedness. As part of a national network of Centers for Public Health Preparedness funded by the CDC, the Yale Center for Public Health Preparedness, based at the Yale School of Public Health, works to ensure that frontline public health workers are prepared to respond to public health emergencies including natural disasters, acts of terrorism, and disease outbreaks. Over the course of his career, Dr. Stakic has developed facilitators' manuals and training-of-trainers tools on various health related topics for agencies of the United Nations system, Ministries of Health throughout Eastern Europe, Central Asia, and Sub-Saharan Africa and for the US Centers for Disease Control and Prevention.

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Course Overview and Introduction

Introduction

This Facilitators' Manual is designed to support offering the Biosafety and Biohazard Evaluation Course in its entirety in graduate schools of public health or related institutions or programs. In addition, the Facilitators' Manual provides the opportunity for various segments of the course or Modules to be offered as stand-alone educational programs. These may be most appropriate for continuing education initiatives for professionals in various disciplines.

Contents

The Facilitators' Manual is comprised of the following:

1. Information on how to prepare, plan and organize each module independently and the entire course as a whole
2. Educational tools, such as presentation slides, handouts, videos, site visit and assignment recommendations
3. Assessment tools, such as pre- and post-tests
4. Training tools, such as tips on scheduling, training activities and time management

Adapting the Manual

Teaching and learning are complex processes. Knowing a specific topic is only the first step in a teaching process. Knowing your audience and their expectations and needs is equally important. In addition, individual teaching styles differ. Although this Manual has been based upon the basic principles of adult learning outlined below, you are encouraged to adapt any aspect of the Manual to best suit your teaching style and the needs of your audience.

Thus, this Manual provides recommendations for offering a course or specific modules within it. It will be your personal changes to the suggested activities in this publication that will individualize the course or training session and thus most closely fulfill the needs of your participants.

Offering the course or modules

Familiarize yourself with this Facilitators' Manual and identify any requirements of your host institution. Carefully plan each one of the training / teaching sessions following the recommendations in the Manual, while feeling comfortable to make changes as necessary to best suit the needs of your participants / learners. Make sure that you know the needs and expectations of your participants, and that you clearly and accurately explain the scope of the course or training sessions to them.

In brief: Principles of adult learning

Although this might differ across cultures and personal preferences, in general, adults learn best as active participants rather than passive recipients of information. This Manual is designed to provide you with recommendations on how to incorporate scientific information and present it in an entertaining and educational manner, couples with specifically designed exercises and assessments that will enhance the learning process. You will note that the Manual will incorporate use of presentations with small group activities, case study analyses, large group discussions, interactive and other media, and site visits. As the

instructor, you will be responsible for choosing the optimal set of possible exercises (or adapting the recommended ones) to best suit your participants' needs.

Course Description

This course will provide an overview of the field of biological safety and its application to the control biohazards in a wide variety of settings for students at all levels who are interested in the epidemiology of microbial diseases.

Students will review biohazards associated with occupational laboratory acquired infections, and examine select case studies to identify critical biosafety lapses. The course will teach participants how to perform a comprehensive qualitative risk assessment for biohazards and learn how to employ the control strategies to appropriately manage these risks. Course concepts can be applied to the control of biohazards during the review of proposed research involving biohazards, along with emphasizing protective measures when addressing incidents involving biohazards, such as emergency spills or bioterrorism related events. The course will provide multiple opportunities to gain direct hands-on experience and review key course concepts through interactive exercises, case studies and site visits.

Course Pre-Requisites

There are no specific pre-requisites. However, some background in microbiology and molecular biology will help the students.

Course Objectives

By the end of the course, students will be able to:

- Apply biohazard control measures to a variety of settings, including emergency response events;
- Perform an indoor air quality evaluation to assess exposure to bioaerosols; and
- Conduct a biohazard risk assessment and select the appropriate combination of protective equipment and work practices to minimize the potential for exposure.

Course Instructor

This course was offered by a Biosafety Officer with comprehensive practical experience in the field. However, professionals with related but different backgrounds may serve as course instructors. We encourage any course instructor to partner with practitioners with diverse backgrounds related to biosafety and biohazard evaluation in order to enhance students' learning experience.

Suitable adjunct faculty to provide assistance with the course include: a microbiology professor, the chair of an institution's biological safety committee, an industrial hygienist, a representative from the building services group at an institution, a representative from the local public health department, leaders from the institution's police, fire and safety emergency response teams, local town or city emergency responders, and a representative from an institution's animal care and use committee or animal resources center.

Audience

This course has been geared towards:

- Graduate students with a background in microbiology or molecular biology who are interested in exploring Biosafety as a profession;
- Students who have handled or will handle hazardous biological agents in an occupational or emergency response setting; and

- Public health students or current professionals who may be interested in exploring the range of biohazards and their control mechanisms.

The course may be easily adapted to suit other audiences, such as undergraduate students, first responders, etc., thus this Manual will use the terms students and participants interchangeably throughout the text.

Course Length

Number of credits: 2 to 3 credit hours

Course duration: 14 weeks (2 hours per week)

This course could be offered as an intensive course over a month.

Also, many of the lectures can be offered as stand alone seminars. The following lectures lend themselves to this feature:

- Risk Assessment
- Personal Protective Equipment
- Facility Design
- Bioaerosols and Indoor Air Quality
- Biosafety Level 3 Programs
- Animal Biosafety
- Human Gene Transfer
- Food Sanitation
- Emergency Response
- Regulations, Standards & Guidelines
- Program Management
- Shipping, Transport of Regulated Biological Materials
- Bloodborne Pathogens
- Work Practices & Personal Protective Clothing
- Effective Use of the Class II Biological Safety Cabinet

Course Format

The course consists of weekly lectures consisting of a variety of pedagogical tools, including presentations, in-class exercises, videos, and guest lectures. Field trips to various facilities will help further reinforce course concepts. Additionally, students will have an opportunity to work in a group format to participate in microbiological sampling in the field and in a team presentation exercise.

Estimated Work Load

Participants are expected to spend 7 – 10 hours per week on the course. This estimate includes time spent in class, on tours, reading, and completing assignments.

Student Expectations

Students are expected to:

- Attend course lectures and scheduled tours;
- Prepare for course lecture by completing assigned reading prior to the lecture;
- Participate in course interactive exercises;
- Join a small working group of fellow students for completion of a biological sampling project; and

- Work with a group of fellow students to prepare and deliver team presentation to complete an assigned course project.

Course Policies

Please follow your institution's policies. Some recommendations include:

- Deadlines for assigned projects may be extended with permission of the instructor.
- All assignments should be completed to receive credit for the course.
- Students who require accommodation or special needs shall be addressed in coordination with the school registrar.

Recommended Assignments

Each of the recommended assignments below have been designed to provide the students with an opportunity to practice what they learned in lecture or reinforce key concepts discussed during the course. Students will gain direct experience with pertinent biosafety evaluation methods in team and individual formats.

Risk Assessment Exercise

Students may produce a written report that researchers and documents the 5 P's of Risk Assessment and Risk Management (Pathogen, Procedures, Protective Equipment, Personnel, and Place), from one of 10 sample situations. Students may also select their own pathogen and scenario to complete the Risk Assessment Exercise, but should confirm the agent and proposed example with the course instructor.

Bioaerosol/Environmental Microbiology Sampling Exercise

For this exercise, the students should work in groups to develop a hypothesis about an environment (of potential concern) of their choice. Students should then develop a biological sampling strategy and work with the course instructor to collect samples to test the hypothesis. The group should analyze the data and work together to write and submit a formal written analysis of the condition or area sampled. Students may receive a team grade for the project that will be assessed on the group's participation in the project, the quality of the written report and the strength of the justification for the analysis and recommendations made by the group.

Point/Counterpoint Challenge

For this exercise participants may be asked to work in teams to debate a certain topic in a mock court setting with a jury of their peers. Students would be assigned to one side of a contentious biosafety argument and should work with their teams to research their assigned positions and develop a persuasive argument for presentation to a student jury for determination of the winning argument. Each team will receive a grade based on the depth of their research, strength of their argument and quality of their presentations.

Regulatory Policy Comparison Exercise

This is a homework exercise that requires the students to read one existing state biosafety regulation and compare it to proposed state biosafety regulation, developing an argument for which regulation would be the most effective at protecting workers.

Facility Commissioning Exercise

This in-course interactive exercise and tour may be part of the student's overall class participation grade. Students will visit an inactive BSL-3 laboratory to gain hands-on

experience with verification of physical facility function. The course instructor and a representative from the building services group should provide an orientation and training for the equipment utilized to perform the verification. After the orientation, students would work together to monitor room pressure, airflow and perform key containment calculations. Worksheets will be provided to guide the students through the facility verification.

Grading Policy

If you are offering the course for credit, follow your institution's grading policies and requirements. Below is a recommended breakdown of possible scoring for each exercise:

Assignment	**Weight**	**Notes**
Reading Assignments and Class Participation	5%	
Risk Assessment Exercise	25%	Individual grade
Bioaerosol/Environmental Sampling Exercise	20%	Team grade – all members of the team share the same grade
Point/Counterpoint Challenge	20%	Team grade – all members of the team share same grade
Regulatory Policy Commissioning Exercise	5%	Individual grade
Facility Commissioning Exercise	5%	Individual grade
Final Exam	20%	Individual grade
Total:		Honors = 91% – 100% High Pass = 81% – 90% Pass = 71% – 80%

Required Texts

Wilson, DL, Chosewood, LC., Editiors, 2007. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, U.S. Govt. Printing Office, Washington, D.C. 2007. Currently available online at: http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

Fleming, D.O., and Hunt, D.L., Biological Safety Principles and Practices, 4th Edition, ASM Press, Washington, D.C. 2006.

Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), Department of Health and Human Services, National Institutes of Health, April 2002. Available from the NIH Office of Biotechnology Activities (phone: 301-496-9838). Also available online at: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

The readings are referred to with following acronyms throughout the test:

- BSP&P – Biosafety: Principles and Practices
- BMBL – CDC/NIH Biosafety in Microbiological Laboratories
- RDNA – NIH Guidelines for Research Involving Recombinant DNA Molecules

Lecture 1

Course Introduction and Overview; Review of the Profession of Biological Safety; Laboratory-Acquired Infections; and Biosafety Resources

READING ASSIGNMENT:
BSP&P: Ch. 4 & 24
BMBL: Sec. I, II, & Appendix E

OBJECTIVES:

- Review semester lecture topics, tours, assignments, hands-on exercises, and grading policies
- Review course texts and major references and resources
- Identify student knowledge base (education and experience) in Biosafety, Microbiology and Molecular Biology
- Describe the Biosafety profession and its application
- Describe the knowledge, skills and abilities required of Biosafety professionals, including relevant education and experience
- Define and review laboratory-acquired infections
- Identify student interest and attempt to incorporate any special needs into the class

POWERPOINT LECTURE TITLE:
EMD545bLecture#1

STUDENT HANDOUTS:
Course syllabus
Course web page
NRM Biosafety Task List

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
None

ADDITIONAL REFERENCES:
None

Lecture 2

Biosafety Foundation: Risk Assessment, Routes of Exposure, Risk Groups and Biosafety Levels

READING ASSIGNMENT:
BSP&P Ch. 5
BMBL Sec. III, IV
RDNA: Sec. II, App. B

OBJECTIVES:
By the end of the class, students will be able to:

- Describe components of risk assessment and risk management as applicable to Biosafety
- Describe various groups of professionals, expertise, and resources required to conduct a risk assessment
- Outline the risk assessment pathway from development, review, and assignment of appropriate risk management factors
- Define the four Risk Groups

POWERPOINT LECTURE TITLE:
EMD545bLecture#2

STUDENT HANDOUTS:

1. ABSA Risk Group Tables http://www.absa.org/riskgroups/index.html

NIH Risk Group Classification of Etiologic Agents on the Basis of Hazard
http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm

2. Material Safety Data Sheets for Infectious Agents (Health Canada) http://www.phac-aspc.gc.ca/msds-ftss/index.html#menu?

IN-CLASS EXERCISES OR TOURS:
Class exercise: Finding Risk Groups for Hazardous Biological Agents

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
Risk Assessment/Risk Management Project. Students should select one of 10 biohazard proposals (or choose one of their own design) and prepare a written risk assessment for the agent and detail appropriate precautions to take.
Course Assignment #1: Risk Assessment Exercise
Risk Assessment Caution Statement: Students are asked to prepare a brief written "caution" statement that transmits the most salient risk features of the agent.
Class Homework Exercise #1: Risk Assessment Caution Statement

ADDITIONAL REFERENCES:
None

Lecture 3

Biosafety Program Management

READING ASSIGNMENT:
BSP&P: Ch 22, 25
BMBL: App. B
RDNA: Sec. I, IV

OBJECTIVES:
By the end of the class, students will be able to:

- Describe the components of a Biosafety program for a research institution
- Explain the importance of a comprehensive Biosafety program
- Discuss the roles and responsibilities of groups responsible for Biosafety at an institution

POWERPOINT LECTURE TITLE:
EMD545bLecture#3

STUDENT HANDOUTS:
Yale Biological Safety Manual
http://www.yale.edu/oehs/Documents/Bio/Biosafety%20Manual.pdf

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
None

ADDITIONAL REFERENCES:
None

Lecture 4

Regulations, Standards, and Guidelines Applicable to Biological Safety

READING ASSIGNMENT:
BSP&P: Ch. 18, 21, 23
BMBL: App. C
RNDA: Sec. III

OBJECTIVES:
By the end of the class, students will be able to:

- Describe the federal, state, and local regulations, codes that deal with biological safety
- Explain the prescriptive requirements of select regulations to demonstrate related program elements
- Define performance-based standards, guidelines and regulations applicable to biosafety and provide examples
- Identify the major compliance elements from key standards and guidelines in biological safety

POWERPOINT LECTURE TITLE:
EMD545bLecture#4

STUDENT HANDOUTS:

1. OSHA Bloodborne Pathogens Standard http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
2. NIH Guidelines for Research Involving Recombinant DNA Molecules http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
3. CT Department of Public Health Human Pathogen Registration and BSL3 Law

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
Compare/Contrast the State of CT (existing) and the State of MA (proposed) Biosafety regulations

ADDITIONAL REFERENCES:
None

Lecture 5

Controls in Biosafety I: Facility Design and Containment Equipment

READING ASSIGNMENT:
BSP&P: Ch. 14, 15, 16, & 17
BMBL: App. A

OBJECTIVES:
By the end of the class, students will be able to:

- Explain the four Biosafety Levels for the containment of biological agents
- Describe the laboratory design features for each biocontainment level
- Define the concepts of primary and secondary containment
- Understand engineering controls utilized as primary containment devices
- Outline the types, features, operation, effective use, and limitations of biological safety cabinets

POWERPOINT LECTURE TITLE:
EMD545bLecture#5

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
Containment Laboratory (Biosafety Level 3 Lab) Tour
To augment the BSL-3 Program course lecture, students may be toured through one of the campus (or local) containment laboratory locations with the course instructor along with facility management personnel. A review of the layout of the facility, key physical safety features, lab entry, use, exit, and security controls should be provided for those on the tour. Students may not be able to enter active BSL-3 research space, but would be able to view research laboratories from observation windows located in the anteroom and facility perimeter.

FILMS:

1. Biosafety Level 3 for Service and Maintenance Personnel
   http://www.yale.edu/oehs/biomoreinfo.htm

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
None

ADDITIONAL REFERENCES:

- NSF Standard #49: Class II Biohazard Cabinetry
- CDC/NIH Primary Containment for Biohazards: Selection, installation and Use of Biological Safety Cabinets, 2000
- WHO Lab Biosafety Manual and Health Canada's Laboratory Biosafety Guidelines (both available online under Biosafety Resources off the ABSA web page www.absa.org)

Lecture 6

Controls in Biosafety II: Work Practices and Personal Protective Equipment

READING ASSIGNMENT:
BSP&P: Ch. 19 & 20

OBJECTIVES:
By the end of the class, students will be able to:

- Describe best practices to follow when handling hazardous biological agents
- Define the foundational work practice used to protect researchers handling infectious agents
- Outline the range of protective clothing and equipment options available for worker protection
- Discuss respiratory protection and review the range of respirators worn to protect researchers against hazardous biological agents
- Review the selection, use, limitations, reprocessing and disposal of protective clothing and equipment

POWERPOINT LECTURE TITLE:
EMD545bLecture#6

STUDENT HANDOUTS:

1. Work Practice documents and posters:
    a. Biosafety Level 1 work practice poster, Biosafety Level 2 work practice poster
    b. Biosafety Level 3 work practice poster, Toxin Safety Guidelines
    c. Centrifuge Safety, Effective Use of the Biosafety Cabinet, Autoclave Safety, and
    d. On-campus Transport.
2. The course host institution's Institutional Biosafety Manual may serve as an alternate handout

IN-CLASS EXERCISES OR TOURS:

1. Biosafety Foundation Game
2. Student donning of protective clothing
3. Respirator Fit Testing practicum

Students would be given a description of the federally required elements of a respiratory protection program along with a hands-on opportunity to learn how to properly train, size, and qualitatively fit test a person for an air-purifying respirator.

Students would receive the opportunity to handle and wear air-purifying respirators, powered-air-purifying respirators and a self contained breathing apparatus (SCBA). This represents the full range of protective equipment that may be worn for protection against biohazards in both research and emergency response settings. Students would also have a chance to don additional emergency response protective clothing, such as booties, jump suits, gloves and Level B vapor tight protective suits.

FILMS:

1. Working Safely and Effectively in the Biological Safety Cabinet
   http://www.yale.edu/oehs/biomoreinfo.htm

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):

Level B protective suit, Tyvek jump suit, various gloves, booties, N-95 respirator, N-100 respirator, powered-air-purifying-respirator, self-contained breathing apparatus, and respiratory protection fit testing kit

HOMEWORK:

None

ADDITIONAL REFERENCES:

None

Lecture 7

Controls in Biosafety III: Decontamination & Emergency Response

READING ASSIGNMENT:
BSP&P: Ch. 19 & 20

OBJECTIVES:
By the end of the class, students will be able to:

- Define antisepsis, disinfection, decontamination, and sterilization
- Demonstrate chemical and physical methods used to inactivate hazardous biological agents
- Identify the situations and incidents that require decontamination
- List criteria for the selection of a disinfectant based on risk assessment
- Outline immediate response measures for occupational exposures to biological hazards
- Review documentation, monitoring and follow-up for occupationally exposed individuals
- Examine the initial steps and remediation procedures for addressing biohazard spills and releases

POWERPOINT LECTURE TITLE:
EMD545bLecture#7

STUDENT HANDOUTS:

1. WHO/NIH Table of Disinfectants

IN-CLASS EXERCISES OR TOURS:
None

FILMS:

1. Cleaning up a Blood Spill in a Laboratory (BSL2 Spill Response) http://www.yale.edu/oehs/biomoreinfo.htm

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):

HOMEWORK:

ADDITIONAL REFERENCES:

- EPA lists of Registered Disinfectants, Sterilants and Tuberculocidal Disinfectants (www.epa.gov/oppadd001/chemregindex.htm).
- NIH Laboratory Safety Monograph, 1978, p 104-105, (available from the NIH Office of Biotechnology Activities (301) 496-9838.
- Characteristics of Selected Disinfectants. Center for Food Security & Public Health, ISU (www.cfsph.iastate.edu/BRM/resources/disinfectants/characteristicsselecteddisinfectants.pdf);
- American Industrial Hygiene Association Biosafety Reference Manual. Heinson, Jacobs, and Concoby, 1995. pp. 104 – 106

Lecture 8

Bioaerosols and Indoor Air Quality

READING ASSIGNMENT:
None

OBJECTIVES:
By the end of the class, students will be able to:

- Define bioaerosols and provide an overview of indoor air quality issues associated with them
- Identify medical conditions related to indoor air quality
- Give examples of the range of microorganisms and biological materials usually linked with bioaerosols and indoor air quality issues
- Identify the conditions required for the growth, proliferation and dissemination of microorganisms in buildings
- Provide an overview of general building design and explain the components of a Heating Ventilation and Air Conditioning (HVAC) system
- Review preliminary assessment steps for conducting an indoor air quality investigation associated with microorganisms
- Outline bioaerosol monitoring equipment and sampling procedures for the identification and enumeration of viable microorganisms in building air and on surfaces
- Describe the typical remediation measures for building microbial problems and the control measures required to control the spread of bioaerosols

POWERPOINT LECTURE TITLE:
EMD545bLecture#8

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
The following two tours can be scheduled together to replace one full course lecture or maybe scheduled at alternate time when all students are available to meet with power plant and/or building management representatives. Participants must be provided with hard hats, safety glasses and any items of personal protective equipment required or entry into the power plant and/or building mechanical rooms.

Tour of Campus Power Plant
This tour should consist of a brief meeting for the students with a representative or the power plant and a representative from the water treatment management company. Students should be provided with an overview of power plant operation and the volume, distribution, use and flow of water within the facility. A description of the chemicals used to control microorganisms, the target chemical concentration range, and delivery mechanisms, and efficacy test procedures should also be provided to the students.

Tour of a Building Heating Ventilation and Air Conditioning (HVAC) System

A member of the institution's building maintenance group should select a building with an HVAC system that is easily accessible and accommodating of a group of up to 10 students. Outdoor air intake vents, exhaust stacks, exhaust and supply fans, heating and cooling coils, and condensate drip pans or drains. A description of the preventive maintenance program should be provided.

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):

- Anderson Sampler (2 Stage Cascade Impactor) and sample media plates
- Swabs for sampling surfaces
- Q-Trak Monitor (Temp., %RH, CO2, and CO)
- Dust-Trak Particulate Monitor
- Photo Ionization Detector (PID)

HOMEWORK:
Group Bioaerosol Sampling Project
The following exercise is normally conducted outside of the normal class meeting time. The instructor, students and any additional assistants must coordinate the dates/times for sampling. Transport of equipment, calibration, set-up, monitoring of both complaint and comparison areas, packaging samples, recalibration and equipment break down could take up to 4 hours.

Groups of 2 or more are recommended to identify a "complaint" area or an area of potential concern for evaluation using the equipment demonstrated in class. The group should tour the proposed sampling area, develop a sampling strategy, take the desired samples, participate in the packaging and shipment of the samples to the laboratory, review the results, and write a report outlining the findings of the evaluation and the group's recommendations.

ADDITIONAL REFERENCES:

- EPA Guide to Building Air Quality for Building Owners http://www.epa.gov/iaq/largebldgs/pdf_files/iaq.pdf
- Rao, C.Y., Burge, H.A., and Chang, J.C.S., "Review of Quantitative Standards and Guidelines for Fungi in Indoor Air," Journal of the Air & Waste Management Association, Vol. 46, Sept. 1996, 899-908.

Lecture 9

LECTURE #9:
Biological Terrorism and Biosecurity

READING ASSIGNMENT:

OBJECTIVES:
By the end of the class, students will be able to:

- Outline historical and recent bioterror events
- Provide an overview of the major microorganisms that have been utilized or studied for biowarfare
- Describe the preliminary response procedures for responding to reports of suspicious packages or suspicious materials
- List the notifications that must be made in a bioterrorism event
- Discuss the application of the hazardous material response to a bioterrorism event
- Provide a summary of the biosecurity elements outlined by the federal government for entities in possession of regulated potential biowarfare agents

POWERPOINT LECTURE TITLE:
EMD545bLecture#9

STUDENT HANDOUTS:
42 CFR Part 73 – The DHHS/CDC Select Agent Rule

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
A visiting lecturer from the institution's or region's law enforcement division or local fire department may be invited to the class to contribute to the lecture topic. A member of the group's Hazardous Materials Response Team or Bomb Squad is an ideal candidate to provide a first hand account of responding to hazardous materials incidents and potential bioterror events. Each state also has a biosecurity/ bioterrorism coordinator and the course could be augmented significantly with their involvement. Finally, if it can be coordinated, a bioterrorism expert from the regional Federal Bureau of Investigation's field office can be contacted to join the group and provide awareness of the coordinated response at the federal level.

HOMEWORK:
None

ADDITIONAL REFERENCES:

- The ABSA web page (www.absa.org) contains links to numerous websites with information on biological terrorism within the biosafety resources section
- CDC's Bioterrrorism web sitehttp://www.bt.cdc.gov/

- U.S.Army Medical Research Institute of Infectious Diseases (USARMRIID), Fort Detrick, MD http://www.usamriid.army.mil/
- Bioterrorism Readiness Plan - A Template for Health Care Facilities, APIC http://www.apic.org/educ/readinow.html
- Center for Biodefense Studies (John Hopkins University) http://www.hopkins-biodefense.org/
- Hawley, Robert J., PhD. "Biological Weapons - A Primer for Microbiologists", Annual Review of Microbiology and Human Genetics, 55:235-253. 2001. http://micro.annualreviews.org/cgi/content/full/55/1/235?ijkey=enEHjLfv2n34o&keytype=ref
- APIC Bioterrorism Readiness Plan: http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Bioterrorism/Bioterrorism.htm http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Bioterrorism/APIC_BTWG_BTRSugg.pdf
- Johns Hopkins Biodefense website: http://www.jhsph.edu/preparedness/
- University of Pittsburgh Center for Biodefense: http://www.upmc-biosecurity.org/

Lecture 10

Human Gene Transfer

READING ASSIGNMENT:
NIH Guidelines (April 2002), Appendix M

OBJECTIVES:
By the end of the class, students will be able to:

- Define the human gene therapy field and provide examples of previous and recent applications
- Provide an overview of the regulatory structure for the review and authorization of human gene transfer experiments in the United States
- Review gene transfer vector delivery mechanisms
- Discuss the risk factors that must be evaluated prior to the approval of a human gene transfer experiment
- Outline the requirements for the safe conduct and oversight of a human gene transfer experiment
- Describe the reporting requirements for adverse events associated with a human gene transfer experiment

POWERPOINT LECTURE TITLE:
EMD545bLecture#10

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
None

ADDITIONAL REFERENCES:
NIH Office of Biotechnology Activities http://www4.od.nih.gov/oba/
NIH Recombinant DNA and Gene Transfer http://oba.od.nih.gov/rdna/rdna_faq.html

Lecture 11

Animal Biosafety

READING ASSIGNMENT:
BSP&P: Ch 12, 28
BMBL 5th Edition: Sec. IV, VI, & App. D
RDNA: App. Q

OBJECTIVES:
By the end of the class, students will be able to:

- Provide an overview of the range of hazards unique to animal facilities for small or conventional research animals
- Review the signs and symptoms of laboratory animal allergy and outline the basic control methods to reduce or eliminate its occurrence
- Discuss the concept of risk assessment as it pertains to experiments involving research animals
- Review the biohazard containment and control mechanisms required for the safe housing and handling of naturally or experimentally infected research animals
- Outline administrative controls that may be utilized to control biohazards in animal research
- Give an overview of the regulatory and resource groups applicable to experiments involving laboratory animals used in research

POWERPOINT LECTURE TITLE:
EMD545bLecture#11

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
If possible, make arrangements in advance with your institution's Animal Care and Use Committee or Animal Resource Center representatives and schedule a visit to an active animal housing facility to get an opportunity to see the entry and exit stations, the animal room doors and required signage, a glimpse at the various containment and control equipment located within each room, the personal protective equipment utilized, the numerous support areas for supplies, the sanitation rooms, and associated storage locations. Although the tour does not have to include direct entry into animal rooms, all students must be cleared for entry by the host institution and escorted at all times during the tour within the facility.

FILMS:

1. Working Safely with Laboratory Animals: Animal Biosafety Levels 1 – 3 (ABSL1 & 2) http://www.yale.edu/oehs/biomoreinfo.htm

Also from: http://www.absa.org/restraining.html

2. Handling Non-Human Primates Safely (Available from the Elizabeth R. Griffin Research Foundation http://www.ergriffinresearch.org/

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
It is helpful to recruit representatives from the institution's Animal Care and Use Committee or the Animal Resources Center to provide a brief overview of an Animal

Care and Use Program to the students. This presentation can also discuss the relationship between the Animal Care and Use Program and the Environmental Health and Safety Program to ensure that hazards associated with research animals are addressed.
HOMEWORK: None
ADDITIONAL REFERENCES: None

Lecture 12

Biosafety Level 3 Containment

READING ASSIGNMENT:
None

OBJECTIVES:
By the end of the class, students will be able to:

- Identify risks involved with the use of Risk Group 3 agents in research
- List training and experience required by personnel conducting research at Biosafety Level 3 containment
- Outline the range of personal protective equipment options for BSL3 research
- Demonstrate the required BSL3 work practices for both cell culture and animal experiments
- Describe the facility entry and exit requirements, including the donning and doffing of personal protective equipment required for BSL3 research
- Outline disinfection and decontamination procedures for the termination of BSL3 research

POWERPOINT LECTURE TITLE:
EMD545bLecture#12

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
BSL-3 Facility Verification Tour/Exercise
Students may work with the course instructor and a representative from building services to test and verify the function of a BSL-3 containment laboratory. An overview of the verification process will be provided first along with a description of the monitoring equipment used to assess proper lab operation. Students will then gain direct experience with the airflow and pressure monitoring equipment to determine the exhaust and supply flow rates, airflow direction, strength of facility pressure differentials between rooms, and calculate the total number of air changes per hour of the facility. Upon completion of this exercise, students will have a firm understanding of the steps required for the annual verification and certification of BSL-3 containment laboratories.

FILMS:

1. Working Safely with Laboratory Animals: Animal Biosafety Level 1 – 3 (ABSL3 segment)) http://www.yale.edu/oehs/biomoreinfo.htm or : http://www.absa.org/restraining.html

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
BSL3 Facility Verification Checklist (can be completed by the student group within class during the tour)

ADDITIONAL REFERENCES:
None

Lecture 13

Food Sanitation

READING ASSIGNMENT:

OBJECTIVES:
By the end of the class, students will be able to:

- Outline the most significant organisms associated with food-borne illness in the US
- Identify groups at greatest risk of food-borne illness
- Explain the Hazard Analysis of Critical Control Points (HACCP) in the food safety industry
- Examine each of the critical control points in a food safety program and identify breaches that could elevate risk of food-borne illness

POWERPOINT LECTURE TITLE:
EMD545bLecture#13

STUDENT HANDOUTS:
None

IN-CLASS EXERCISES OR TOURS:
Invite a guest lecturer from your institution's Food Service division responsible for the sanitation program or a representative from the local Department of Public Health to give an overview of their respective programs to the students. The internal and/or external food inspection programs should be reviewed during the lecture.

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
None

HOMEWORK:
None

ADDITIONAL REFERENCES:

- Hazard Analysis of Critical Control Points (HACCP) documents on the website of the U.S. Food and Drug Administration (www.fda.org) and from State Public Health Department websites.
- FDA HACCP Website: http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm

Lecture 14

Point/Counterpoint (Judge & Jury) Team Debates

READING ASSIGNMENT:
Course Texts, Lectures, Notes, and Student Research

OBJECTIVES:
By the end of the class, students will be able to:

- Understand responsibilities of a Principal Investigator or lab group performing a Risk Assessment evaluation for a proposed research project involving a biohazardous agent
- Review project proposals, evaluating the risk, and determining the most appropriate containment level for the sample projects
- Experience difficulties faced by Biosafety Officers and Institutional Biosafety Committees in the Risk Assessment and Risk Management process

POWERPOINT LECTURE TITLE:
None

STUDENT HANDOUTS:
EMD545bPointCounterpointExercise
Suggested exercises are included in the class handout associated with this lecture. However, instructors are encouraged to use any cases, situations, or protocols from their own Institutional Biosafety Committees that involved a disagreement in either the Risk Group or Biosafety Level designation. A good source of potential topics are published reports of laboratory acquired infections, the agent summary statements from the CDC/NIH BMBL, and announcements from the NIH Office of Biotechnology Activities and minutes from the NIH Recombinant DNA Advisory Committee, where unique protocols from NIH funded institutions are discussed.

Examples Exercises used previously in the class are:

- BSL2 or BSL3 for experiments with Mycobacterium tuberculosis in mice?
- BSL2 or BSL3 for cell culture or animal (mice) experiments with Rabies virus?
- BSL3 or BSL2 for cell culture and animal (mice) experiments with LCMV?
- BSL4 or BSL3 for experiments with a multi-drug resistant strain of Mycobacterium tuberculosis that is resistant to 12 of the current available drugs.
- Funding for BSL3 safety program or BSL2 Bloodborne Pathogen training program in the aftermath of two laboratory acquired infections (assumption is that the institution must prioritize which program to fund immediately).

Other topics that could be utilized are:

- BSL3 or BSL2 for cell culture and animal (mice) experiments with HIV?
- BSL3 or BSL2 for cell culture experiments with Creutzfeld-Jacob Disease agent?
- BSL3 or BSL2 for cell culture experiments with Hepatitis C Virus?
- BSL4 or BSL3 for experiments involving 1918 Pandemic Influenza Virus?
- ABSL2 or ABSL3 for experiments with Ectromelia virus (mousepox) in mice?

IN-CLASS EXERCISES OR TOURS:
The entire class time may be reserved for the point/counterpoint presentation or combined with one of the existing lectures. The exercises, presentation assignments and student team roles should be determined at least 2 weeks before this lecture. Students are divided into three teams and presented with three proposed biohazard experiments. Each group must serve in each of the following roles for the exercises:

- Risk Group 3 Position (team presenting an argument that the proposed work must be conducted at Biosafety Level 3 Containment);
- Risk Group 2 Position (team presenting an argument that the proposed work can be safely conducted at Biosafety Level 2 Containment);
- Jury (team that serves as the IBC for each exercise and weighs the merits of each presentation and privately deliberates prior to presenting their decision).

The Assignment Matrix should look like this after the assignments have been made:

	Exercise	**Exercise**	**Exercise 3**
Team 1	Jury	RG3 argument	RG2 argument
Team 2	RG3 argument	RG2 argument	Jury
Team 3	RG2 argument	Jury	RG3 argument

When the student teams arrive in class, start with Exercise #1, flip a coin to determine which of the presentation teams (Team 2 or Team 3) will win the choice to present 1st of 2nd. This choice then rotates among the remaining teams for the next two Exercises. Thus, each Team must prepare two formal presentations of their assigned position in an argument and serve as Jury once. Although the Jury is not required to make a presentation on a topic, Jury members should read the Exercise they are judging before coming to class to have a perspective on what may be needed for the proposal.

FILMS:
None

CLASS DEMONSTRATION (EQUIPMENT/DEVICES):
Class lecture is devoted to student presentations and follow-up discussion after the completion of each exercise.

HOMEWORK:
None

ADDITIONAL REFERENCES:

- As determined by each student group for their respective exercises

Lecture 15

Final Exam

READING ASSIGNMENT:
None. Recommend allowing open book, open notes for students during the 2 hour final examination.

OBJECTIVES:
- To assess students' rational application of biosafety principles to situations likely to be encountered in the profession (not students' memorization ability)

POWERPOINT LECTURE TITLE:
None

STUDENT HANDOUTS:
EMD545bFinalExam

IN-CLASS EXERCISES OR TOURS:
None

FILMS:
Incorporating video or DVD into the final exam is strongly encouraged. Video editing technology makes taking video footage an incorporating it into presentations a simple project. Also, many institutions have Audio Visual Departments that can be contacted for assistance with small video projects.
Sample ideas for video footage for "real time" examination questions.

- Take footage of your staff cleaning up a "FAKE" spill of human blood or cell culture flask and ask them to make as many "mistakes" as they can. Show this to the class as one of the exam questions. Provides an opportunity to assess if they can identify poor work practices in an emergency response situation.
- Take footage of your existing researchers handling a RG2 agent under BSL2 containment conditions. Show a clip of them working at the biological safety cabinet performing cell culture work as an exam question, but ask students to assess their BSL3 work practices. The exam question could be "Is this researcher ready to start working with RG3 agents tomorrow? Yes/No, justify.
- Ask same group of BSL2 researchers to make mistakes during their work with "MOCK" cell cultures on purpose. Work with the researchers in advance to develop a list of "mistakes" and take footage of them recreating this list in their laboratories. The exam question posed to students watching the video is to find as many mistakes or opportunities for exposure or the dissemination of contaminants as they can find.
- One existing video that can be used for this purpose is available at a small cost from the American Biological Safety Association (www.absa.org). Contact them and ask to purchase the Job Hazard Analysis Risk Assessment Video (created by Gilian Norton). This has footage of researchers working with virus in cell culture at a biological safety cabinet and bacteria on the bench in a microbiology lab.

CLASS DEMONSTRATION (EQUIPMENT/DEVICES): None
HOMEWORK: None
ADDITIONAL REFERENCES: None

References and Resources for Biological Safety

Organizations

- **American Biological Safety Association (ABSA) www.absa.org**

ABSA Homepage:
Upcoming conferences, events and courses

ABSA Resources and Tools Link:
ABSA Publications
Anthology I: Perspectives on Lab Design
Anthology II: Facility Design Considerations
Anthology III: Application of Principles
Anthology IV: Issues in Public Health
Anthology V: BSL-4 Laboratories
Anthology VI: Arthropod Borne Diseases
Anthology VII: Biosafety Level 3
Anthology VIII: Evolving Issues in Containment
Anthology IX: Exploring the Performance Envelope for BSL-3 and BSL-4 Laboratories

Applied Biosafety Journal

Key Topics and Links (on ABSA web page Resources/Tools section)
Biosafety Guidelines
WHO Laboratory Biosafety Manual, 3rd Edition, 2004
NIH rDNA Guidelines, April 2002
CDC/NIH Primary Containment for Biohazards: Selection, installation and Use of Biological Safety Cabinets, 2000
CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, 1999. (Note: 5th Edition due in 2007)
Laboratory Centers for Disease Control
Laboratory Biosafety Guidelines, 3rd Edition, 2004

Rules, Regulations & Federal Agencies
OSHA www.osha.gov/
OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030
Needlestick Standard
NIH Office of Biotechnology Activities
NIH Guidelines
IBC Resources
FDA www.fda.gov/
USDA www.usda.gov/
APHIS www.aphis.usda.gov/
DHHS/CDC Select Agent Final Rule 42 CFR Parts 72 and 73
Friday March 18, 2005
USDA Select Agent Final Rule 9 CFR Part 121, 7 CFR Part 33
Friday March 18, 2005
World Health Organization (WHO) www.who.int/

ABSA Resources and Tools
Material Safety Data Sheets (MSDS) Infectious Substances
Laboratory Centers for Disease Control – Canada
Risk Group Classification for Infectious Agents
Bacteria – Viruses – Parasites – Fungi
Risk Group and Biosafety Level Definitions
Bioterrorism Links
Biosafety on the Internet
Belgian Biosafety Server
Office of Biosafety, Laboratory Centers for Disease Control – Canada
OHASIS, Office of Health & Safety Information Systems – CDC
Select Agents web site
International Veterinary Biosafety Workgroup
European Biosafety Association

International Biosafety Working Group (IBWG)

NIH Design Criteria for Laboratory Construction

Laboratory Centers for Disease Control
Laboratory Biosafety Guidelines, 3rd Edition, 2004

- **European Biosafety Association (EBSA)** http://www.ebsaweb.eu/

Resources
Biosafety References
LAI (Laboratory Acquired Infections Bibliography)
Archive EBSA Newsletters
Links
The Biosafety Institute

- **Eagleson Institute (www.eagleson.org/)**

Standard Training Programs:
Biological Safety Cabinets
Chemical Fume Hoods
Laboratory Design
Laboratory Ventilation
Laboratory Maintenance
Biological Safety
Design and Operation of Animal Facilities
Cleanrooms
Decontamination
Isolators and Glove Boxes
BSL-3 Facilities

Custom Classes

Videos and Software
Safe Use of Biological Safety Cabinets
Safe Use of Chemical Fume Hoods

Seminars (Annually)

Certification Workshops
HVAC Systems and Lab Design
Laboratory Commissioning and Controls
Safety BSL-3 Work Procedures and Practices

- **USDA ARS Facilities Design Standards**
  http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf

- **Yale University Office of Environmental Health & Safety www.yale.edu/oehs**
  Biosafety Requirements
    BL3 Laboratory Safety Manual
  Training (streaming videos)
    Effective and Safe Use of the Biosafety Cabinet
    BSL-3 Training for Service and Maintenance Personnel
    Animal Biosafety
    Spill Response Video

Annual Related Courses

- **Tradeline, Inc.** (http://www.tradelineinc.com/conferences/)
  International Conference on Biocontainment Facilities (annually)
  Conference on Animal Research Facilities (annually)

- **Harvard School of Public Health (www.hsph.harvard.edu/ccpe)**
  Guidelines for Laboratory Design: Health & Safety Considerations (annual short course)

- **Center of Public Health Preparedness and Research, Rollins School of Public Health (www.sph.emory.edu/CPHPR/biosafetytraining)**
  Biosafety Level 4 Science & Safety Training: Practice, Assessment, and Communication (periodic sessions, at least annually)

- **American Biological Safety Association (ABSA) www.absa.org**
  Principles and Practices of Biosafety (at least annually)
  ABSA Summer Seminar Series (annual series of courses)
  Annual ABSA Conference (20+ Pre-Conference Courses)

- **Eagleson Institute (www.eagleson.org)**
  BSL3 Seminar Series (annual courses related to BSL-3 lab design and work practices)

- **Centers for Disease Control/Dept. of Health and Human Services www.cdc.gov**
  Biennial International Symposium on Biosafety