

ABSA



57th Annual Biological Safety Conference

Manchester Grand Hyatt • San Diego, California

October 3-8, 2014

www.absaconference.org



Preliminary Program

American Biological Safety Association

The American Biological Safety Association (ABSA) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. The Association's goals are to establish the global standard for biological safety, to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information.

ABSA accomplishes these goals through providing members and stakeholders expertise and resources through publications in the peer-reviewed journal *Applied Biosafety*, the ABSA web site, sponsoring an annual Biological Safety Conference, training programs to inform members of regulatory initiatives, hazard recognition and management issues, risk communications, current Biosafety publications, meetings and seminars, e-mail updates, training opportunities, and employment opportunities. Additionally, ABSA members receive "Members Only" web privileges where they have access to past issues of *Applied Biosafety*, and members can participate in a biosafety mentoring program.

What is Biosafety?

The concept of Biological Safety (or biosafety) has paralleled the development of the science of microbiology and its extension into new and related areas including tissue culture, recombinant DNA, animal studies, molecular biology, synthetic biology, and biotechnology. The knowledge and skill gained by microbiologists necessary to isolate, manipulate, and propagate pathogenic microorganisms required parallel development of containment principles, facility design, and practices and procedures to prevent occupational infections in the workplace or release of the organisms to the environment.

What is a Biosafety Professional?

A biosafety professional develops and participates in programs to promote safe microbiological practices, procedures, and proper use of containment equipment and facilities; stimulates responsible activities among workers; and provides advice on laboratory design.

Core Purpose

ABSA is dedicated to promoting and expanding biological safety experience.

Core Organizational Values

Leading the profession
Collaboration and community
Promote biosafety as a scientific discipline
Absolute integrity
High standards of excellence



57th Annual Biological Safety Conference

Special Event

The Tuesday evening banquet will be held at the Birch Aquarium, a public exploration center for the world-renowned Scripps Institution of Oceanography at UC San Diego. You will enjoy sunset views of La Jolla from a bluff overlooking the Pacific Ocean, discover more than 60 habitats of fishes and invertebrates from the cold waters of the Pacific Northwest to the tropical waters of Mexico and beyond, learn about research discoveries by Scripps scientists on climate, earth, and ocean science. A delicious dinner from The French Gourmet, a multi-award winner for finest catering service and best French restaurant will be served.

Award Presentations

Monday, 8:30 am—Arnold G. Wedum Memorial Lecture Award Presentation

Tuesday, 8:05 am—Griffin Lecture Award Presentation

Tuesday, 2:00 pm—Eagleson Award Presentation

Wednesday, 11:35 am—Arnold G. Wedum Distinguished Achievement Award

Wednesday, 11:35 am—Everett J. Hanel, Jr. Presidential Award

Wednesday, 1:30 pm—Richard Knudsen Award Presentation

Registration

The Registration Desk will be open Friday through Wednesday from 7:00 am - 5:00 pm.

New Member Reception

The reception for new members will be held Sunday from 5:30 - 6:30 pm.

Opening Reception

The Opening Reception will be held Sunday from 6:30 - 8:00 pm.

Hotel Information

Manchester Grand Hyatt San Diego

One Market Place

San Diego, CA 92101

619-232-1234

Confirmed room rate: \$219.00/night

Exhibit Hall

The exhibit hall will be open on Sunday 6:30 - 8:00 pm for the Opening Reception. It will also be open on Monday and Tuesday for continental breakfasts, lunches, and breaks.

New for 2014

ABSA will be offering "Exhibit Only" passes for those not attending the Scientific Program, but would like to preview the latest in biosafety and biosecurity products and services in the ABSA Exhibit Hall. For more information, please contact the ABSA office at info@absa.org.



The American Biological Safety Association has been approved as a provider of continuing education programs in clinical laboratory science by the American Society for Clinical Laboratory Sciences (ASCLS), Professional Acknowledgment for Continuing Education (P.A.C.E.®) program.

For each preconference course, contact hours will be based on 60 minutes of instructional time for each P.A.C.E.® contact hour. The maximum number of P.A.C.E.® contact hours to be credited for half day courses is 3.50 contact hours and for full day courses is 7.50 contact hours.

Preconference Courses

Please visit our web site for course availability.
www.absaconference.org

Friday, October 3, 2014

8:00 am - 5:00 pm

1. Intermediate Threat Assessment for Laboratory Biosecurity Programs

Ben Perman, PhD, RBP, Booz Allen Hamilton, Inc., Washington, DC

Patricia Delarosa, PhD, RBP, CBSP, Booz Allen Hamilton, Inc., McLean, VA

Lindsay Odell, PhD, Booz Allen Hamilton, Inc., McLean, VA

Jason Griffeth, Booz Allen Hamilton, Inc., Herndon, VA

With the recent implementation of suitability and reliability measures to the Select Agent Program, laboratories are recognizing the need for proactive measures in ensuring facilities and staff operates in a secure manner and is protected from insider and external threats. This course is a continuation of the Basic Threat Assessment course previously offered as a preconference course. The purpose of this course is to provide laboratory staff with intermediate assessment skills to identify and classify threats and effectively implement personnel security procedures that directly mitigate those threats at their institutions. This course targets laboratory staff, responsible officials, principal investigators, laboratory managers, research scientists, human resource administrators, and facility security officers responsible for developing and/or implementing effective biosecurity measures.

Objectives:

- Describe the application of intermediate threat assessment techniques in a laboratory biosecurity program and how threat assessment can be implemented in a successful insider threat mitigation program
- Characterize specific personal security vulnerabilities or indicators and link these vulnerabilities to threats
- Summarize the purpose and requirements of suitability, reliability and other personnel security programs and how to successfully integrate threat assessment into these programs
- Identify advanced capabilities from human resources, occupational health and wellness, and legal/compliance sectors that are relevant to the implementation of a mature threat assessment program in a microbiological laboratory setting

Suggested Background: Basic Threat Assessment

Target Audience: Laboratory Workers, All Biosafety Professionals

Audience Level: Intermediate

8:00 am - 5:00 pm

2. Implementing an Exercise Program for Select Agent Facilities

Diann Stedman, MS, George Mason University, Fairfax, VA

David Farris, MBA, George Mason University, Fairfax, VA

Select Agent Program regulations require entities to conduct annual drills and exercises to test incident response, biosafety, and security plans. In this course, participants will learn how to design and implement an exercise plan that meets Select Agent Program requirements and facilitates the identification and correction of programmatic weaknesses. Participants will be provided tools for developing a comprehensive training and exercise plan for their facility, designing and conducting exercises, documenting exercise outcomes, and program improvements. Strategies for overcoming challenges (obtaining necessary time and resources, engaging appropriate audiences, fostering positive interagency relationships, etc.) will be discussed. Examples of tabletop, functional, and full-scale exercises will facilitate group discussion, highlight lessons learned, and best practices.

Objectives:

- Demonstrate the knowledge necessary to develop a comprehensive emergency response training and exercise program for high-containment laboratories
- Summarize the various types of exercises and the benefits and challenges of each type
- Utilize tools for developing and implementing different types of exercises to include the critical steps of planning, conducting, and posting the exercise follow-up
- Employ the tools to facilitate documentation, recordkeeping, and tracking program improvements

Suggested Background: Basic understanding of Select Agent Program requirements and the design/operation of Regional Biocontainment Laboratories (RBL)

Target Audience: All Safety Professionals, All Biosafety Professionals

Audience Level: Basic

8:00 am - 5:00 pm

3. Advanced Risk Assessment

Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, NC

Anne-Sophie Brocard, PhD, RBP, CBSP, University of Texas Medical Branch—Galveston, Galveston, TX

Elizabeth Weirich, MS, CBSP, SM(NRCM), Centers for Disease Control and Prevention, Atlanta, GA

In this advanced and interactive course, participants will evaluate research projects as they evolve over time from basic to multifaceted *in vitro* and *in vivo* scenarios based on actual research protocol submissions. Participants will work in teams to conduct risk assessments on scenarios that will include multiple systems used in research as it progresses from cell culture to small animal models using recombinant materials, and clinical trials. Risk assessments will focus on the likelihood of exposure and the severity of consequences from exposure to the multitude of hazards encountered in increasingly complex research. Participants should have a thorough understanding of rDNA principles and the link between biosafety, risk assessment, and risk mitigation for this advanced course. There is an emphasis on the interactive nature of the risk assessment process and differing views of risk tolerance; participants should be prepared to participate in discussions and bring interesting or difficult examples from their entities to share with the class.

Objectives:

- Analyze complex scenarios by identifying hazards associated with components of the plan
- Prioritize risks based on the likelihood and consequences of an occurrence
- Assess the overall risk and determine mitigation strategies to minimize the risk
- Evaluate mitigation strategies for effectiveness, adjust strategies as warranted

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Micro/Molecular Biology 101, Principles & Practices of Biosafety

Target Audience: Experienced Biosafety Professionals, Laboratory Workers

Audience Level: Advanced

8:00 am - 5:00 pm

4. Shipping Infectious Substances Certification Course

Eric Cook, MPH, CBSP, Sandia National Laboratories, Albuquerque, NM

This course is appropriate for those who have some experience with infectious substance handling or shipping but may not have been certified within the past three years. The course utilizes several facilitated and class learning activities such as group discussions and interactive exercises focused on the essential areas of infectious substance shipping. Participants will have the opportunity to mark, label, package, and complete documentation for a variety of infectious substances shipments (Category A, Category B, and Exempt Patient Specimens). Participants will review applicable regulations with a focus on IATA. This course is appropriate for those responsible for packaging, marking, and labeling shipments of all categories of infectious substances, dry ice, and liquid nitrogen. A final written certification exam will be administered. Participants must score at least 80% in order to be certified.

Objectives:

- Summarize the various regulations that impact the shipment of infectious substances
- Using principles of risk assessment, classify biological materials for shipping purposes as either Category A, Category B, Exempt or not regulated
- Demonstrate how to package, mark, label, and document shipments of infectious substances, Category A, Category B, and dry ice
- Complete a written exam to qualify for infectious substance shipping certification

Suggested Background: None

Target Audience: All Safety Professionals, Laboratory Workers, New Biosafety Professionals

Audience Level: Basic

8:00 am - 5:00 pm

5. Laboratory Design Process

Jeffrey Owens, MPH, CSP, CBSP, SM(NRCM), HDR Architecture, Inc., Atlanta, GA

Mark Fitzgerald, HDR Architecture, Inc., Los Angeles, CA

Natasha Griffith, MS, University of California—Los Angeles, Los Angeles, CA

Vibeke Halkjaer-Knudsen, PhD, Sandia National Laboratories, Albuquerque, NM

This course will offer an understanding of the activities that should be carried out prior to and during the design process for a laboratory facility. Through guided discussion and interactive exercises, participants will learn the laboratory pre-design concepts such as conducting user interviews, setting goals for the project, recording program information, diagramming important relationships, and establishing the facility criteria that will form the basis for the design and budget of a laboratory facility. The course proceeds into laboratory design principles and introduce students to building zoning, operational efficiency, biosafety, and biosecurity factors supporting good lab protocols

and flexibility. Participants will participate in guided discussions, develop diagrams to illustrate best practice concepts, and analyze existing plans with respect to the design principles under discussion.

Objectives:

- Paraphrase the programming and design process as it applies to laboratory facilities
- Illustrate and participate in methods of design and analysis that promote good laboratory design
- Demonstrate how good design practice works to enhance both biosafety and biosecurity

Suggested Background: Fundamentals of Biosafety

Target Audience: All Biosafety Professionals, Architects, Engineers, Laboratory Planners

Audience Level: Intermediate

8:00 am - 12:00 pm

6. Biosafety Considerations with Human Gene Transfer

Chris Jenkins, PhD, MPH, RBP, CHMM, WIRB Copernicus Group Biosafety, Puyallup, WA

Since the late 1990s, human gene transfer research has teased the community with the promise of medical breakthroughs using targeted clinical applications with biological materials. Despite setbacks along the way, the field of human gene therapy has made significant advances in the last two decades. This course will provide an overview of human gene transfer research, risk assessment considerations for biosafety professionals and Institutional Biosafety Committees, and outline the regulatory environment for human gene transfer research. Case studies and group discussion will be used to amplify the take home messages.

Objectives:

- Recall the challenges past and present with human gene transfer research into human subjects
- Generate risk assessments with biological materials used in clinical environments
- Review the regulatory environment from the FDA and NIH perspectives for human gene transfer research

Suggested Background: Risk Assessment, Micro/Molecular Biology 101

Target Audience: All Biosafety Professionals, Clinical Professionals

Audience Level: Intermediate

1:00 pm - 5:00 pm

7. Drawing Review Course

Theodore Traum, PE, World BioHazTec Corporation, North Bethesda, MD

Juan Osorio, IE, World BioHazTec Corporation, North Bethesda, MD

Diego Osorio, CE, World BioHazTec Corporation, North Bethesda, MD

From a biosafety perspective, the drawing review process is different than a professional design review as the focus is on compliance with biosafety guidelines, administrative and engineering controls, as well as the specific scientific program requirements. When working with design documents and industry review standards in Acrobat PDF, the drawing review process can be completed more quickly and with greater accuracy by utilizing the principles to be presented in this course. Site, structural, architectural, electrical, plumbing, mechanical specifications, program requirements, and review comments can be compiled into a template document which tracks responses until resolution. This course will address all phases of the drawing review process and how it pertains to high and maximum containment laboratories. Process drawings, barrier drawings, airflow pressurization regimens drawings, control sequences for biosafety ventilation validation testing and electrical drawing one-line diagram review will be presented. Key design features for consideration will be presented for ease of maintenance of the facility and equipment. Commissioning specification requirements for conformance to ANSI Z9.14 will be also addressed. This course will instruct how to read drawings and make comments in an organized format easily understood by the designer, especially regarding biosafety issues. Interpretation of schematics, details, and schedules will be presented. Upon conclusion of this course, the participants will have the skill set and sufficient knowledge to review design drawings and provide meaningful comments.

Objectives:

- Interpret and understand design and construction documents
- Review drawings and specifications to identify biosafety issues in a nontraditional manner using common software search features
- Compose comments in a format that is concise, able to be tracked, and documented to resolution

Suggested Background: None

Target Audience: All Safety Professionals, All Biosafety Professionals

Audience Level: Basic

8:00 am - 5:00 pm

8. The Essentials of Health and Safety at the Boundaries of Biosafety

Robert Emery, DrPH, RBP, CBSP, University of Texas Health Science Center—Houston, Houston, TX

Bruce Brown, DrPH, CBSP, University of Texas Southwestern Medical Center, Dallas, TX

Rachel Gamble, DrPH, CBSP, University of Texas Health Science Center—Houston, Houston, TX

In actual practice, there is virtually no work setting where occupational risks are limited solely to biological agents. Fire safety, occupational safety, and chemical safety risks are ubiquitous in laboratory and production settings, and sources of radiation can be regularly encountered. Issues regarding insurance coverage and policy limitations can also arise. Given this diversity of possible risks, it is prudent for biosafety professionals to familiarize themselves with the essential aspects of these other specialty areas of loss control. This course is designed specifically to provide a baseline orientation to a series of parallel health and safety professions with which a biosafety professional commonly interacts. Each section begins with a discussion of the relative public health impact of a specialty area and ends with a description of the simple things a biosafety professional can do to assist in keeping the overall organization safe and compliant. Ample time will be allocated for questions, answers, and discussion.

Objectives:

- Describe the five recognized steps of risk management process, differentiating between risk control and risk transfer techniques, and why this is important for the biosafety profession
- Identify the basic elements of a fire and life system program, a chemical safety program, radiation safety program, and a comprehensive hazardous waste management program that can be easily assessed by a biosafety professional
- Summarize the risk represented by insider threats

Suggested Background: None

Target Audience: All Safety Professionals, New Biosafety Professionals, Professionals involved with biosafety

Audience Level: Basic

8:00 am - 5:00 pm

9. Building and Refining a Select Agent Program: Safety, Compliance, and Efficiency

Amy Vogler, PhD, RBP, Northern Arizona University, Flagstaff, AZ

Shelley Jones, MS, RBP, Northern Arizona University, Flagstaff, AZ

A successful Select Agent Program depends on ensuring personnel safety and maintaining regulatory compliance in an efficient manner. In the absence of efficiency, research can be unnecessarily hindered and regulatory compliance may become overly burdensome, which could lead to lapses that affect the success or failure of an entity's Select Agent Program. This course will explore strategies for implementing a successful Select Agent and/or Tier 1 Select Agent Program based upon the instructors' experience with their institution's Select Agent (including Tier 1) BSL-3 Program. Topics covered will include identifying site-specific needs; developing and reviewing plans and SOPs; promoting a safety and compliance culture; organizing and tracking inventory; training methods and recordkeeping; providing effective oversight; and preparing for, facilitating, and responding to inspections. Strategies presented will focus on organization, resource management, flexibility, and efficiency. This course will consist of presentations, group discussions, and exercises to assist participants in applying the strategies to the needs of their entities.

Objectives:

- Evaluate site-specific needs and expectations
- Design and implement effective and efficient policies, plans, and procedures compliant with the current CDC/USDA Select Agent and Tier 1 Select Agent Regulations
- Identify strategies for streamlining and integrating required documentation
- Describe inventory management techniques to ensure current and accurate inventory records

Suggested Background: None

Target Audience: All Safety Professionals

Audience Level: Basic

8:00 am - 5:00 pm

10. Engineering for the Biosafety Professional—Part II

Theodore Traum, PE, World BioHazard Corporation, North Bethesda, MD

Brynte Johnson, MS, RBP, CBSP, SM(NRCM), World BioHazard Corporation, North Bethesda, MD

Juan Osorio, IE, World BioHazard Corporation, North Bethesda, MD

Diego Osorio, CE, World BioHazard Corporation, North Bethesda, MD

In following-up to Engineering for the Biosafety Professional—Part I, this course demonstrates biocontainment engineering principles and their applications in the proper operation and sustainability of a biocontainment laboratory. Included in the discussion will be concepts such as understanding various types of traditional HVAC design and emerging green design, comprehension of the purpose and information available from a building automation system, troubleshooting airflow reversals, understanding HVAC schematics, identifying redundancy needs, determining methodology for HVAC decontamination, deconstruction, and decommissioning. These basic concepts assist the biosafety professional in their interaction with facility personnel and designers of new construction, renovations, and ceasing of BSL-3 facilities operations. The objective of this course is to explain these engineering concepts using real-life examples and how they apply to biocontainment laboratories. More advanced engineering fundamentals will be discussed including HVAC sequence of operations, ventilation risk assessment, developing failure scenarios, integration of energy conservation into the laboratory and compliance to Testing and Performance Verification Methodologies for Ventilation Systems for BSL-3 and ABSL-3 Facilities (ANSI/ASSE Z9.14-2014). Group exercises will be conducted for practical application of principles presented. Building on Engineering for the Biosafety Professional—Part I, this course will not be driven by theory but will integrate examples that show cause and effect in real-life scenarios.

Objectives:

- Interpret and identify HVAC schematics and the basics of HVAC control systems
- Explain decontamination at the room level and HVAC system level
- Analyze test data and develop a risk assessment for an airflow reversal
- Restate the decommissioning and deconstruction process

Suggested Background: Engineering for the Biosafety Professional—Part I, Engineering for the Biosafety Professional

Target Audience: All Safety Professionals, All Biosafety Professionals, Facilities Personnel

Audience Level: Basic

8:00 am - 5:00 pm

11. Biorisk Management—Large Animals

Robert Heckert, DVM, PhD, CBSP, SM (NRCM), Robert Heckert Consulting, Desert Hot Springs, CA

David White, DVM, PhD, United States Department of Agriculture, Ames, IA

Joseph Kozlovac, MS, RBP, CBSP, United States Department of Agriculture, Beltsville, MD

This course will cover important biosafety and biosecurity issues when working with large agricultural animals at various levels of biocontainment. Participants will discuss the elements of the new BSL-3Ag checklist and learn how it might be applied by USDA inspectors in registration of high-containment animal facilities from a former employee of the Federal Select Agent Program (FSAP). Through interactive exercise, this course will apply the principles of biosafety and biosecurity when working with large animals infected with pathogens.

Objectives:

- Conduct a risk assessment for working with agricultural animals at various levels of biocontainment
- Develop practices and procedures appropriate for mitigating the risk of working with animals infected with various pathogens
- Design and build facilities (ABSL-3, BSL-3Ag) appropriate for containing the agricultural animals infected with various pathogens
- Demonstrate how to work with foreign animal diseases to prevent agroterrorism

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Biosafety Level 3-Design and Operations, Principles & Practices of Biosafety

Target Audience: Experienced Biosafety Professionals, Animal Caretakers, All Safety Professionals

Audience Level: Basic

8:00 am - 5:00 pm

12. Risk Assessment and Containment for Plant Research

Dann Adair, BS, Controlled Environments Inc., North Branch, MN

M. Malendia Maccree, University of California—Davis, Davis, CA

Kirk Martin, DPM, CBSP, SM(NRCM), United States Department of Agriculture, Beltsville, MD

Research on plants and their associated organisms routinely conducted in laboratories, greenhouses, growth chambers, growth rooms, and screen houses is “in containment” versus research conducted in the field or natural ecosystem. This presents a range of challenges and opportunities for conducting quality research while meeting any regulations or guidelines. Due to the limited guidance on the topic and the relatively smaller niche of plant biosafety, participants are presented a unique opportunity. The course will cover the fundamentals of plant pathology, plant pest interactions, and molecular technologies used in plants necessary to inform risk assessment for research. It will also explore various design and construction techniques, equipment, and management concepts needed to meet

programmatic and regulatory requirements. USDA ARS, APHIS, NIH, and selected international guidelines and regulations will be referenced. Case studies and interactive exercises will provide an opportunity to apply knowledge and skills gained in the course.

Objectives:

- Apply risk assessment methodology to plant-based research
- Describe plant research facility design and equipment (greenhouses, growth chambers, inoculation rooms, seed and plant handling)
- Identify regulations and guidelines which apply to plant research
- Summarize the similarities and differences between plant containment and human biohazard containment

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Principles & Practices of Biosafety

Target Audience: All Safety Professionals, Laboratory Workers, Facility and Greenhouse Managers

Audience Level: Intermediate

8:00 am - 5:00 pm

13. Implementing Personnel Security in Laboratory Biosecurity Programs

Ben Perman, PhD, RBP, Booz Allen Hamilton, Inc., Washington, DC

Lindsay Odell, PhD, Booz Allen Hamilton, Inc., McLean, VA

Jason Griffeth, Booz Allen Hamilton, Inc., Herndon, VA

Personnel security is comprised of security measures focused on people and behaviors rather than typical physical barrier approaches. Personnel security can be thought as the administrative controls in any advanced security program. This course will teach administration, management, and research staff the basic principles of threat assessment and introduce participants to the role of comprehensive personnel security in a laboratory biosecurity program. The course is intended to give participants a basic toolkit that will allow them to implement successful comprehensive insider threat mitigation strategies using personnel security approaches at their home institutions and to convey concepts in personnel security to their colleagues. Participants will learn through case studies about relevant threats in the biomedical and health sectors. Through case study analysis, participants will learn how to identify threats, link threats to vulnerabilities, and most importantly, address specific personnel security vulnerabilities. Participants will learn all aspects of personnel security including: suitability, reliability, training, peer and self-reporting strategies, threat assessment, OPSEC, INFOSEC, and an introduction to elicitation, manipulation and surveillance awareness. Key aspects of personnel security will be practiced as part of the course in challenging, fun interactive exercises that illustrate how adversaries can defeat weak personnel security measures. Regulatory issues relevant to implementation of personnel security management programs, in particular changes to the Select Agent Regulations pertaining to Tier 1 Agents, will also be discussed. Theoretical concepts will be put into practice in conceptual personal security program developed through direct participant input using a realistic laboratory security problem that draws on the material presented in the lecture and case studies.

Objectives:

- Identify the types of threats posed to biomedical research, public health, and clinical diagnostic facilities and institutions and the resources and legal/regulatory controls relevant to personnel security programs
- Describe the tools used to assess threats, how each mitigates the threats, and the unique role personnel security programs play in insider threat mitigation
- Explain the main components of laboratory security programs
- Summarize the purpose, requirements, and major components of personnel security programs

Suggested Background: None

Target Audience: All Safety Professionals, Laboratory Workers

Audience Level: Basic

8:00 am - 12:00 pm

14. A BSO's Guide for Understanding Research Compliance Regulations

Ted Myatt, ScD, RBP, University of Rhode Island, Kingston, RI

This course will enhance the participant's range of understanding in research compliance areas, regulations, and the guidance that underpins these areas which can be beneficial to biosafety officers and environmental health and safety (EH&S) professionals. For example, research typically encountered by biosafety officers, Institutional Biosafety Committees (IBC), and EH&S groups may also require Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) review and oversight. Comprehension of the regulations and guidance governing research involving human and animal subjects, export controls, and financial conflicts of interest will expand a course participant's area of expertise, potentially leading to new opportunities within an institution's overall research compliance structure. This knowledge can be used to develop best practices at your institution and reduce the regulatory burden on investigators. This course will consist of a mixture of didactic lecture, case studies, and interactive exercises.

Objectives:

- Describe the major regulations and guidance governing research involving human subjects (IRB) and animal subjects (IACUC)
- Compare and contrast IBC governance with IRB and IACUC governance
- Summarize when review by both the IRB and/or IACUC are required for research requiring IBC review
- Identify strategies to effectively manage IBCs and best practices for coordination of review and oversight for research requiring review from multiple committees

Suggested Background: None**Target Audience:** Experienced Biosafety Professionals, All Safety Professionals**Audience Level:** Intermediate**1:00 pm - 5:00 pm****15. Full-Length Clones are Just the Beginning: Working Safely on Risk Group 3 and 4 Viruses at BSL-2***Nancy P. Hoe, PhD, CBSP, National Institutes of Health, Hamilton, MT**Megan Morgan, Lieutenant, United States Public Health Service, Hamilton, MT*

Work with Risk Group (RG) 3 and 4 viral agents requires the use of high and maximum containment laboratories. Due to the prohibitive cost or lack of access to such facilities, scientists rely on molecular methods such as full-length clones, mini genomes, or viral-like particles to enable work with virally-derived genetic material at lower containment. As a biosafety professional, you must be knowledgeable about the biology of these viruses, the current molecular techniques that allow the safe study of viral life cycles and pathogenesis, and the regulatory restrictions on such work. This course will present these topics along with the specific biosafety, biosecurity, and regulatory requirements for working with full-length cloned viral cDNA of RG4 viral agents at BSL-2.

Objectives:

- Paraphrase the biology of Risk Group 3 and 4 RNA viruses
- Describe the molecular techniques used to study viral life cycles and pathogenesis
- Explain what can and cannot be worked with at lower containment
- Describe the facility and regulatory requirements to safely work with full-length clones of RG4 agents of the order Mononegavirales

Suggested Background: Fundamentals of Biosafety, Micro/Molecular Biology 101**Target Audience:** Laboratory Workers, Experienced Biosafety Professionals**Audience Level:** Intermediate

Sunday, October 5, 2014

8:00 am - 5:00 pm**16. Advanced BSL-3 Facility Operations***Miguel Grimaldo, M. Eng, University of Texas Medical Branch—Galveston, Galveston, TX**J. Paul Jennette, MS, PE, RBP, Cornell College of Veterinary Medicine, Ithaca, NY**John R. Henneman, MS, RBP, Pennsylvania State University, University Park, PA*

This course is a follow-up to the BSL-3 Facility Operations and Management course focusing on detailed aspects of biocontainment operations of BSL-3, ABSL-3, and enhanced BSL-3 laboratories. It will cover risk assessments for biocontainment facilities; facility operations and maintenance SOPs; maintenance personnel training requirements; solid and liquid waste decontamination equipment, procedures, validations and cycle developments; area decontamination methodologies, procedures and validations; filtration systems and validation and testing process; ventilation control methodologies and ventilation equipment configuration; facility testing during normal and failure conditions of the ventilation system; test documentation and recordkeeping.

Objectives:

- Explain the facility verification process in detail, including recommended test methodologies
- Restate the training requirements for facility personnel accessing the biocontainment areas
- Identify methodologies for decontamination of areas, equipment, filters, and waste
- Describe elements of biocontainment facility risk assessments

Suggested Background: Fundamentals of Biosafety, Biosafety Level 3-Design and Operations, Principles & Practices of Biosafety**Target Audience:** All Safety Professionals, Experienced Biosafety Professionals**Audience Level:** Advanced

8:00 am - 5:00 pm

17. How to Develop an Export Management and Compliance Program, Including the I-129 for Deemed Exports

Deborah Howard, MPH, CBSP, Bayer CropScience, Morrisville, NC

Constance Birden, BS, University of North Carolina—Chapel Hill, Chapel Hill, NC

How are you handling certification regarding the release of controlled technology or technical data to foreign persons in the United States? This course targets individuals who manage the shipping and exporting program, including deemed exports, at universities and biotech companies. Participants will learn about the fundamental research exclusion and the impact deemed exports have on your organization. Do you have foreign nationals in the workplace? Ship biological materials (or genetic elements) out of the U.S.? Export Select Agents? Ship items that cost more than \$2,500 out of the U.S.? Is your software controlled? Do you have controlled “development” technical research? Participants will learn to understand the six terms of use as they relate to foreign nationals in the workplace. There is more to shipping than classification, labeling and marking. When shipping anywhere outside the U.S., including Puerto Rico, there also are licensing, under-invoicing, and ITN numbers from the U.S. Census Bureau to consider. During this workshop, participants will learn about the SNAP-R Program, visual compliance, and how the International Traffic and Arms (ITAR) Regulations fit into exporting. Troublesome clauses in contracts will be covered. This course will discuss which pathogens and lab equipment require a license when exporting, how to obtain a license, Census Bureau requirements, recordkeeping, and much more.

Objectives:

- Describe the exporting agencies and what items and technology they regulate
- Recommend strategies for implementing an export management plan
- Discuss the I-129 Deemed Export Attestation and how it affects your organization
- Recognize situations where export controls apply

Suggested Background: None

Target Audience: All Safety Professionals, Experienced Biosafety Professionals

Audience Level: Intermediate

8:00 am - 5:00 pm

18. Advanced Principles and Practices of Working in an ABSL-3

Belinda Rivera, BS, University of Texas Medical Branch—Galveston, Galveston, TX

This course will provide information to individuals who are currently working, plan on working, or audit ABSL-3 facilities. Working in an ABSL-3 facility has unique hazards and requires input from animal care staff, researchers, and biosafety professionals to perform collaborative risk assessments. Personnel working in these facilities need to be informed of the hazards and trained to work safely and appropriately with the species and agents being handled. Topics will include personal protective equipment (PPE), animal handling procedures using pictures and videos, husbandry procedures, caging options, waste management, and emergency response procedures. Institutions with ABSL-3 facilities need to involve animal care and research staff along with safety personnel to ensure that proper work procedures and safety protocols are in place and followed to maintain a safe and productive work environment.

Objectives:

- Identify proper PPE and disinfection practices
- Restate examples of techniques used to manipulate animals safely
- Explain the process of waste (cages, carcasses) management
- Summarize emergency and exposure response

Suggested Background: Principles & Practices of Biosafety

Target Audience: All Safety Professionals, Animal Caretakers

Audience Level: Advanced

8:00 am - 5:00 pm

19. Applied Risk Assessment Methodologies

Paul Huntly, PhD, Riskren, Singapore, Singapore

The area of risk management is one of growing interest to those designing and operating laboratories around the world. Despite the requirement for risk assessment in many standards and guidelines, the adoption of good practice in relation to workable and flexible methodologies is still relatively challenging for many. This course will describe the principles underlying the risk assessment approach, using two recognized and practical methodologies; the Structured What-if Technique (SWIFT) and BowTie analysis. Interactive exercises will be conducted to help participants better understand these proactive risk based tools and how they can be applied to a range of scenarios relating to facility design and tasks within the laboratory environment. The course will include the provision of templates and other tools to help participants get started in a practical and applied manner.

Objectives:

- Describe the practices and principles of risk assessment as it can be applied a laboratory setting
- Express practical, flexible, and applied methodologies for use within laboratory settings
- Review practical experiences and views in relation to challenges faced conducting risk assessment and risk management activities

Suggested Background: None**Target Audience:** All Safety Professionals, Laboratory Workers, Animal Caretakers, Laboratory Designers and Managers**Audience Level:** Intermediate**8:00 am - 12:00 pm****20. Understanding Biosafety and Laser Safety in Advanced Optoelectronics and Microscopy Core Facilities***Vinod Jyothikumar, PhD, George Washington University, Washington, DC*

Imaging core facilities at academic institutions are well established, providing services using advanced laser launchers from diode to Ti:sapphire lasers, sorting and other applications. This heterogeneous nature of core facilities, leads to multiple level of safety awareness for the investigator as well as to the facility managers. In core facilities evaluating laser hazards and outlining the necessary precautions involves a challenging combination of optical engineering design and human behavior. This course will outline the biophysical basis for emission and exposure limits; describe the biological effects of the laser radiation; and include laser components, types, classification, and practical tools for laser safety and traps to avoid. Good laboratory practice must be observed in core facility laboratories which are associated with live cell imaging, whole animal imaging, sample preparation, cell biology, and microbiology related research. This course is an essential component for any core facility providing service to the inter-disciplinary researchers. Participants will be able to raise key questions regarding the project, experimental design, and define the appropriate biosafety level to be shared by the users and core facility managers. This course will provide an overview on how to build a biosafety SOP for sample preparation to minimize the generation of infectious/chemical aerosols and prevent laboratory-acquired infections. This heterogeneous nature of the core facility structure leads to define multiple levels of safety awareness to be observed by the facility managers and the users. There are an ever increasing number of core facilities handling biologics, analysis, and sample sorting at varying biosafety levels, some performing complex biohazard experiments. This course will aid in setting up safety protocols for shared advanced optoelectronics and core facilities that keep up with the challenging demands for serving the research community.

Objectives:

- Compile and organize appropriate safety knowledge (laboratory assessments including imaging technologies)
- Recognize a clear concept of advance optoelectronics and its applications in research
- Illustrate the importance of the integrating biosafety and laser safety methods in the context of work in core facilities
- Develop safety awareness evaluation tools for practice classroom presentation techniques and training delivery skills for core facility managers

Suggested Background: Fundamentals of Biosafety, Micro/Molecular Biology 101**Target Audience:** All Biosafety Professionals, All Safety Professionals**Audience Level:** Intermediate**8:00 am - 12:00 pm****21. Biosafety Considerations for RNA Interference (RNAi): MicroRNAs with Microbes and siRNA Therapeutics***Thomas Cremer, PhD, Atlanta, GA*

RNA interference (RNAi) is a field of study within molecular biology that has only been known since the mid-1990s and has expanded into numerous areas of biomedical research with major advances in the mid- to late-2000s. While the research has rapidly advanced, little is reported about the biosafety implications associated with this work; there is a lack of guidance on how to approach risk assessments. This course will cover microRNAs and small interfering RNAs (siRNAs) with particular emphasis on the risk assessment of manipulating microRNAs in viruses by case studies of recently published reports. MicroRNAs have been shown to be important for immunity and viral fitness; siRNAs have been used in basic research, though are being advanced into clinical trials as novel antimicrobials. The course will provide a fundamental understanding of RNAi and highlight tools that can be used to facilitate risk assessment of work done in this field.

Objectives:

- Explain emerging topics in molecular biology within the biosafety community
- Examine dual use research of concern issues among recent publications with RNAi experiments
- Identify tools and resources for facilitating risk assessment of RNAi experiments
- Describe novel therapeutics based on RNAi technology and fundamental concepts in the emerging field

Suggested Background: Risk Assessment, Micro/Molecular Biology 101**Target Audience:** Experienced Biosafety Professionals, Laboratory Workers**Audience Level:** Advanced

8:00 am - 12:00 pm

22. IBC Basics: An Introduction to the NIH Guidelines

Kathryn Harris, PhD, RBP, National Institutes of Health, Bethesda, MD

Ryan Bayha, National Institutes of Health, Bethesda, MD

IBC Basics is a course on the history, function, and administration of Institutional Biosafety Committees (IBCs). Delivered by expert staff from the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA), IBC Basics will promote the professional development of those associated with IBCs by providing an opportunity to learn about the NIH OBA, the content of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, the history of IBCs, understand the range of responsibilities that IBCs have under the NIH Guidelines, and examine the relationship of IBCs to IACUCs and IRBs in terms of their respective purviews, roles, and responsibilities.

Objectives:

- Summarize the content of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules
- Restate the requirements for IBCs under the NIH Guidelines
- Identify the need for IBCs, IRBs and IACUCs to work together to promote coordination and collaboration in the oversight of research subject to the NIH Guidelines
- Describe how to implement an effective program of oversight for research subject to the NIH Guidelines, learn about common challenges, and possible solutions

Suggested Background: None

Target Audience: New Biosafety Professionals, IBC Support Staff, and new IBC Members

Audience Level: Basic

8:00 am - 12:00 pm

23. High Speed Cell Sorter Selection, Biosafety, and Aerosol Containment

Geoffrey Lyon, MPH, Yale University, New Haven, CT

High speed cell sorting is a very common research tool utilized by universities, biotechnology companies, and hospitals. High speed cell sorters allow users to separate tens of millions of cells per hour with purities of >99%. This makes cell sorting one of the most effective method of separating cell populations from a heterogeneous mixture. High speed cell sorters are also capable of generating massive aerosols in the event of a clog or deflection. This course will help biosafety professionals understand the potential risk associated with cell sorters. We will discuss safety features of various machines and highlight aspects of each that should be considered when making a purchase. High speed cell sorting is also utilized by people who want to sort cells that are infected with various agents and pathogens. This course will focus on the safety considerations that are required when creating a BSL-3 cell sorting facility, the creation of SOPs, facility requirements, and the risk assessment process for sorting BSL-3 materials. Different methods used in assessing the containment of aerosols for cell sorters will also be examined. The overall goal of this course is to provide biosafety professionals with a background to help them make decisions on safety and containment for high speed cell sorters, particularly in a BSL-3 setting.

Objectives:

- Determine the level of containment needed for high speed cell sorters and the guidelines to use in evaluating cell sorters for RG3 cell sorting
- Identify the different methods used in evaluating and testing the aerosol containment of high speed cell sorters
- Explain the topics needed to develop emergency response to catastrophic failures of high speed cell sorters
- Identify the topics needed to develop SOPs and risk assessments for cell sorters

Suggested Background: Risk Assessment, Biosafety Level 3-Design and Operations, Principles & Practices of Biosafety

Target Audience: All Safety Professionals, Laboratory Workers, Experienced Biosafety Professionals

Audience Level: Intermediate

1:00 pm - 5:00 pm

24. Large-Scale Biosafety

Brian Petuch, MA, RBP, CBSP, Merck, West Point, PA

This course will review the biosafety involved for working at large-scale, which the NIH *Guidelines for Research Involving Recombinant DNA Molecules* defines as >10L. This course will review Appendix K from the NIH Guidelines to BSL-3-LS, with a focus on primary and secondary containment. Basic bioprocessing steps, such as fermentation/cell culture and purification technologies will be reviewed, examples of classic and newer single use technologies will be provided, and the pearls and pitfalls of the various technologies will be discussed. A review of risk assessment techniques used for large-scale bioprocesses will also be discussed during this course.

Objectives:

- Recognize large-scale bioprocessing technologies, the inherent risks, and how to perform and document risk assessments
- Restate the advantages and disadvantages of single use biotechnology equipment
- Develop a plan for issues of waste disposal and emergency response
- Recall the components of the NIH rDNA Guidelines Appendix K and how implement them for large-scale bioprocessing projects

Suggested Background: Fundamentals of Biosafety, Risk Assessment**Target Audience:** All Biosafety Professionals, All Safety Professionals**Audience Level:** Basic/Intermediate**1:00 pm - 5:00 pm****25. Virus-based Gene Transfer Vectors***Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, NC*

This intermediate course will examine the molecules, processes, and techniques involved in recombinant gene expression. Participants will explore the technology of how viruses are converted into vector systems for the transfer of gene expression constructs. Common viral vector systems, including retroviruses, lentiviruses, adenoviruses, poxviruses, herpesviruses, alphaviruses, and baculoviruses will be discussed with an emphasis on the biosafety characteristics of the vectors derived from these viruses. This course is targeted for the biosafety professional who is not actively conducting laboratory research, yet requires a basic understanding of recombinant DNA methodology.

Objectives:

- Describe processes of recombinant gene expression
- Discuss concepts of viral vector technology and biosafety features
- Recognize characteristics of vector systems unique to specific viruses
- Apply knowledge of recombinant gene expression and viral vector principles to risk assessments

Suggested Background: Micro/Molecular Biology 101**Target Audience:** Laboratory Workers, All Safety Professionals**Audience Level:** Advanced**1:00 pm - 5:00 pm****26. Molecular Biology 101***James Klenner, MSc, MPH, MPA, RBP, CBSP, Indiana University-Purdue University at Indianapolis, Indianapolis, IN*

This course is intended for those professionals that participate in protocol review, facilities planning, and other risk assessment activities but lack a basic understanding of molecular biology and techniques. Following this course, participants will be able to use the new understanding of the principles of molecular biology in various situations at their institution. This course will cover topics such as the chemistry of nucleic acids, DNA replication, RNA transcription, and protein translation, the central dogma of biology, DNA cloning, transfection of prokaryotic and eukaryotic cells, restriction enzymes, and recombinant DNA lab methodologies (including PCR, DNA fingerprinting, sequencing, and detection protocols). This course will not turn you into a molecular biologist, however, it will give the participant enough background information to understand the nature and manipulation of genetic material and hopefully unveil the mystery of deoxyribonucleic acid.

Objectives:

- Summarize the central dogma of molecular biology
- Explain the differences and chemistry of nucleic acids
- Define general molecular biology techniques
- Demonstrate an understanding of the principles of molecular biology used to develop recombinant DNA technology and to show how these technologies are used to study biological phenomena

Suggested Background: None**Target Audience:** All Safety Professionals, New Biosafety Professionals, Animal Caretakers**Audience Level:** Basic**1:00 pm - 5:00 pm****27. Flipping Biorisk Management Training***LouAnn Burnett, MS, CBSP, Sandia National Laboratories, Albuquerque, NM*

Flipped classrooms provide more lecture-based materials in a self-study mode (pre-assigned reading, slides, or videos) and reserves classroom time for active work on case studies, projects, and activities previously considered homework. Significant gains in the understanding and retention of subjects taught in flipped classrooms have been

reported, as well as advantages for better utilizing diverse expertise and perspectives. This course will serve as a flipped model. Participants will receive materials to review prior to the course and will come into the course ready to begin working actively on case studies and projects, with a basic understanding of key principles of flipped classrooms and experiential learning. This course will be highly interactive and participatory, requiring approximately 60 minutes of self-study prior to arrival at the course (to be provided two weeks prior to the course or upon registration, whichever is later).

Objectives:

- State the definitions, models, and options for experiential learning and flipped classrooms
- Define how traditional biosafety training can be flipped and the options for overcoming obstacles and objections that arise as a new model of training is introduced
- Explain the use of flipped training as an option for biorisk management training
- Design a flipped training agenda

Suggested Background: Participants who have actively conducted biosafety training

Target Audience: Experienced Biosafety Professionals, Trainers

Audience Level: Advanced



Scientific Program

Monday, October 6, 2014

7:00 - 5:00 pm	Registration
7:00 - 8:00 am	Continental Breakfast in Exhibit Hall
7:00 - 4:00 pm	Vendor Exhibits
8:00 - 8:05 am	Welcome Master of Ceremonies Paul J. Meechan, PhD, RBP, CBSP, Centers for Disease Control and Prevention, Atlanta, GA
8:05 - 8:10 am	Local Arrangements Committee Welcome Sylvie Blondelle, PhD, Sanford Burnham Medical Research Institute, La Jolla, CA
8:10 - 8:15 am	Scientific Program Committee Welcome Shelley Jones, MS, RBP, Northern Arizona University, Flagstaff, AZ
8:15 - 8:30 am	ABSA President's Address Paul J. Meechan, PhD, RBP, CBSP, Centers for Disease Control and Prevention, Atlanta, GA
Session I	Wedum Lecture Award Presentation
8:30 - 9:30 am	Introduction: Darlene Ward, RBP, Florida Atlantic University, Boca Raton, FL Nucleic Acid Based Therapeutics Mark Kay, MD, PhD, Stanford University, Stanford, CA
Session II	Laboratory-Acquired Infections
9:30 - 9:50 am	Moderator: Betty Kupskey, RBP, University of Minnesota, Minneapolis, MN Neisseria Meningitidis Fatality Investigation Channing Sheets, MEd, RBP, California Department of Public Health, San Francisco, CA
9:50 - 10:10 am	A Mycobacterium Marinum Occupational Exposure Case Study Speaker: TBD
10:10 - 10:30 am	A University's Response to a Meningitis Outbreak Jacqueline Wagner, CIH, Princeton University, Princeton, NJ
10:30 - 11:00 am	Exhibits, Posters, and Coffee Break
Session III	Laboratory Safety Aspects
11:00 - 11:20 am	Moderator: Cynthia Pressman Schwartz, PhD, RBP, Lunenfeld-Tanenbaum Research Institute, Toronto, Ontario, Canada Proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern Kathryn L. Harris, PhD, RBP, National Institutes of Health, Bethesda, MD
11:20 - 11:40 am	Keep Calm and Be Prepared—Lessons Learned from an NIH OBA Site Visit Kalpana Rengarajan, PhD, RBP, Emory University, Atlanta, GA
11:40 - 12:00 pm	Changing Safety Culture in the Laboratory: Practical Steps to Making Real Improvements James Gibson, PhD, University of California—Los Angeles, Los Angeles, CA
12:00 - 1:30 pm	Exhibits, Posters, and Lunch
Session IV	Poster Session
12:30 - 1:30 pm	Presenters must be available during the session.

Session V	Invited Paper
1:30 - 2:30 pm	Introduction: Francine Rogers, RBP, CBSP, University of Tennessee Health Science Center, Memphis, TN <i>Yersinia pestis</i> and the Plague of Justinian 541—543 AD: A Genomic Analysis David Wagner, PhD, Northern Arizona University, Flagstaff, AZ
2:30 - 3:00 pm	Exhibits, Posters, and Coffee Break
Session VI	Resolution 1540 and the <i>Biological Weapons Convention</i>
3:00 - 3:30 pm	Introduction: Paul J. Meechan, PhD, RBP, CBSP, Centers for Disease Control and Prevention, Atlanta, GA Obligations Under Resolution 1540 and the <i>Biological Weapons Convention</i> Speaker: TBD (United Nations Group of Experts Member)
Session VII	Roundtable I—Occupational Health and Medical Surveillance
	Moderator: TBD
3:30 - 3:50 pm	Title: TBD Speaker: TBD
3:50 - 4:10 pm	Title: TBD Speaker: TBD
4:10 - 4:30 pm	Treatment of Lentiviral Vector Exposures Gary Fujimoto, MD, Palo Alto, CA
4:30 - 5:00 pm	Questions and Discussion
5:00 - Close	Members' Business Meeting (<i>Door prizes will be awarded—must be present to win.</i>)

Tuesday, October 7, 2014

7:00 - 5:00 pm	Registration
7:00 - 8:00 am	Continental Breakfast in Exhibit Hall
7:00 - 4:00 pm	Vendor Exhibits
8:00 - 8:05 am	Welcome Master of Ceremonies Marian Downing, RBP, CBSP, Biosafety Consultant, Kemah, TX
Session VIII	Griffin Lecture Award Presentation
8:05 - 8:20 am	Introduction: Caryl Griffin, MSN, MDiv, Elizabeth R. Griffin Research Foundation, Kingsport, TN
8:20 - 9:20 am	Title: TBD Ambassador Bonnie Jenkins, PhD, JD, LLM, MPA, United States Department of State, Washington, DC
Session IX	Biosafety Risk Assessment
	Moderator: Anil Saxena, RBP, American Red Cross, Rockville, MD
9:20 - 9:40 am	Lessons Learned from a Near-Miss Exposure to HIV Cara Leitch, RBP, George Mason University, Fairfax, VA
9:40 - 10:00 am	Assessing the Biological Safety Profession; Evaluation and Control of Risks Associated with the Field Collection of Potentially Infectious Specimens Scott J. Patlovich, DrPH, CBSP, CHMM, Texas Biomedical Research Institute, San Antonio, TX
10:00 - 10:20 am	Characterizing the Challenges of Biological Material Transport on Campus at Emory University Using the Zurich Hazard Analysis Method Meagan P. Fitzpatrick, Georgia Institute of Technology, Atlanta, GA

10:20 - 10:50 am	Exhibits, Posters, and Coffee Break
Session X	Roundtable II—Flow Cytometry
10:50 - 11:10 am	Moderator: Jacqueline Wagner, CIH, Princeton University, Princeton, NJ Cell Sorting Biosafety: Policies and Practices Kevin Holmes, PhD, National Institutes of Health, Bethesda, MD
11:10 - 11:30 am	What is the Effective Life Span of UPLA Filters in Cell Sorter Aerosol Management Options? Althea Capul, PhD, National Biosafety & Biocontainment Training Program, Bethesda, MD
11:30 - 11:50 am	Cross Training, Collaboration, and Partnership: The Path to a Comprehensive Campus Cell Sorting Biosafety Program Ben Fontes, MPH, CBSP, Yale University, New Haven, CT
11:50 - 12:20 pm	Questions and Discussion
12:20 - 2:00 pm	Exhibits, Posters, and Lunch
Session XI	Poster Session
1:00 - 2:00 pm	Presenters must be available during the session.
Session XII	Eagleson Lecture Award Presentation
2:00 - 3:00 pm	Introduction: Mary Ann Sondrini, Eagleson Institute, Sanford, ME Influenza, Gain-of-Function Studies and Biosafety: “A Tempest in Tea Pot or a Crisis Waiting to Happen?” Michael T. Osterholm, PhD, MPH, University of Minnesota, Minneapolis, MN
3:00 - 3:30 pm	Exhibits, Posters, and Coffee Break
Session XIII	Training and Outreach
3:30 - 3:50 pm	Moderator: Francis Novembre, PhD, RBP, Scott & White Healthcare, Temple, TX Shipping Recommendations for Select Agent Toxins Sarah Ziegler, PhD, National Biosafety & Biocontainment Training Program, Bethesda, MD
3:50 - 4:10 pm	The Sky is Falling—Myths, Realities, and How the Biosafety Community Can Engage with the DIYBIO Community Todd Kuiken, PhD, Woodrow Wilson Center, Washington, DC
4:10 - 4:30 pm	Can I Push You Off a Ladder Tomorrow? Rescue Drills in a Containment Facility Margaret Juergensmeyer, PhD, RBP, Institute for Food Safety and Health, Bedford Park, IL
4:30 - 4:50 pm	Meeting the Challenges of BSL-2+: When to Use It and How to Adapt It to Your Facility Elizabeth Gilman Duane, MS, RBP, CBSP, Environmental Health & Engineering, Inc., Needham, MA
5:30 - 10:00 pm	Banquet at Birch Aquarium at Scripps Institution of Oceanography, University of California—San Diego, La Jolla, CA

Wednesday, October 8, 2014

7:00 - 5:00 pm	Registration
7:00 - 8:15 am	Continental Breakfast
8:15 - 8:20 am	Welcome Master of Ceremonies

Session XIV		
Start Time	U.S. Regulatory Issues Moderator: James Klenner, MSc, MPH, MPA, RBP, CBSP, Indiana University-Purdue University at Indianapolis, Indianapolis, IN	International Biosafety Moderator: Claudia Gentry-Weeks, PhD, CBSP, Colorado State University, Fort Collins, CO
8:20 am	Incident Reporting Under the NIH Guidelines—A Review of Trends Kathryn L. Harris, PhD, RBP, National Institutes of Health, Bethesda, MD	Laboratory Waste Management Issues and Challenges: Where Are We Now in Africa? Atef M. ElGendy, RBP, African Biological Safety Association, Cairo, Egypt
8:40 am	The CDC Import Permit Program Vondgaurus McClee, MS, Centers for Disease Control and Prevention, Atlanta, GA	Biological Risk Assessment and Human Factors David Bryant, Animal Health and Veterinary Laboratories Agency (UK), Weybridge, United Kingdom
9:00 am	A Survey of Tier 1 BSAT Personnel Suitability and Occupational Health Programs David Gillum, MS, RBP, Arizona State University, Tempe, AZ	Novel GMO-Based Vaccines Against Tuberculosis: State of the Art and Biosafety Considerations Amaya Leunda, PhD, Scientific Institute of Public Health, Brussels, Belgium
9:20 am	Soil Permits: It's Not a Dirty Word Betsy Matos, PhD, RBP, Iowa State University, Ames, IA	Environmental Risk Assessment for Placing the Gene Therapy Product Glybera on the Market Ursula Jenal, Jenal & Partners Biosafety Consulting, Rheinfelden, Switzerland

9:40 - 10:10 am Coffee Break

Session XV		
Start Time	Containment Facilities Moderator: Philip Hauck, MS, MSHS, CIH, CBSP, SM(NRCM), Icahn School of Medicine at Mount Sinai, New York, NY	Animal Biosafety Moderator: Kelly Flint, RBP, CBSP, SM(NRCM), National Institutes of Health, Fort Detrick, MD
10:10 am	What If It Doesn't Work? Post Construction Troubleshooting the UCLA Global Bio Lab Natasha Griffith, MS, University of California—Los Angeles, Los Angeles, CA	Keeping Them In or Out? Case Study—Control of Aerosols in Loose Housed Versus Caged Laboratory Research Animals for HPAI Studies Henriette Schubert, NNE Pharmaplan A/S, Gentofte, Denmark
10:30 am	Failure to Launch: A Case Study of a Facility Turnaround Michael Clements, MBA, PE, Merrick & Company, Decatur, GA	Detection of Viral Vector Sequences in Animal Excretions Dawn P. Wooley, PhD, RBP, CBSP, SM(NRCM), Wright State University, Dayton, OH
10:50 am	Addressing Communication Challenges Within a Multi-Suite BSL-3 Facility Kathryn F. Board, MS, University of Pittsburgh, Pittsburgh, PA	Addressing Challenges Associated with Consolidation and Decommissioning of ABSL-3 Facilities Molly S. Stitt-Fischer, PhD, SM(NRCM), CPH, University of Pittsburgh, Pittsburgh, PA
11:10 am	Criteria in Considering Barrier Options in High-Containment Heather Sheeley, MSc, Public Health England, Salisbury, United Kingdom	The Implementation and Expansion of a Formal Biorisk Management Program at the Algerian National Institute of Veterinary Medicine Amel Blaha, DVM, Institut National de la Médecine Vétérinaire, El Tarf, Algeria

11:35 - 1:30 pm	<p>Honor Awards and Special Recognition Luncheon Presenter: Paul J. Meechan, PhD, RBP, CBSP, Centers for Disease Control and Prevention, Atlanta, GA Arnold G. Wedum Distinguished Achievement Award Everett J. Hanel, Jr. Award Presentation John H. Richardson Special Recognition Award International and National Poster Awards Recognition of Certified Biosafety Professionals and Registered Biosafety Professionals Presenters: Betty Kupskey, MS, RBP, University of Minnesota, Minneapolis, MN Krista Murray, RBP, CBSP, University of Delaware, Newark, DE</p>
Session XVI 1:30 - 2:30 pm	<p>Knudsen Award & Lecture Moderator: Judy LaDuc, RBP, University of Massachusetts, Amherst, MA Title: TBD Speaker: TBD</p>
Session XVII 2:30 - 3:00 pm	<p>Public Health Agency of Canada Moderator: Dawn P. Wooley, PhD, RBP, CBSP, SM(NRCM), Wright State University, Dayton, OH Evaluation of a National Biosafety Framework/Canada's Human Pathogens and Toxins Act Sandra Fry, Director General for the Centre for Biosecurity for the Public Health Agency of Canada, Ottawa, Ontario, Canada</p>
3:00 - 3:30 pm	Coffee Break
Session XVIII 3:30 - 3:50 pm	<p>Roundtable III—Facilities, Operations, and Equipment Moderator: Bruce Whitney, PhD, Texas A&M University System, College Station, TX Directional Airflow—What, Where, and When J. Paul Jennette, MS, RBP, PE, Cornell College of Veterinary Medicine, Ithaca, NY</p>
3:50 - 4:10 pm	<p>Containment Laboratory Operations: Further Comments on Competency from Outside the Box John R. Henneman, MS, RBP, Pennsylvania State University, University Park, PA</p>
4:10 - 4:30 pm	<p>Lessons Learned in the Operation of BSL-3/BSL-4 Laboratory Facilities Miguel A. Grimaldo, MEng, University of Texas Medical Branch—Galveston, Galveston, TX</p>
4:30 - 4:50 pm	<p>Annual Performance Verification for ABSL-3 and BSL-3 Facilities Daniel Frasier, PE, CCP, Cornerstone Commissioning, Boxford, MA</p>
4:50 - 5:00 pm	Questions and Discussion
5:00 pm	<p>Close of Conference Master of Ceremonies Marian Downing, RBP, CBSP, Biosafety Consultant, Kemah, TX</p>

Registration Form

57th Annual Biological Safety Conference October 3-8, 2014

ABSA Member ID Number: _____ Nonmember

Last Name: _____ First Name: _____
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Conference Fees	Pre Sept. 12	Post Sept. 12	Amount
ABSA Member	\$760	\$810	\$ _____
Nonmember	\$995	\$1,045	\$ _____
Member of ABSA Affiliate	\$875	\$925	\$ _____
Discount Code: _____			
One-day Member (day: _____)	\$255	\$280	\$ _____
One-day Nonmember (day: _____)	\$350	\$400	\$ _____
Emeritus Member	\$385	\$435	\$ _____
2014 Individual ABSA Dues	\$210	\$210	\$ _____

Registration includes: continental breakfasts, breaks, lunches, Opening Reception, and banquet. One-day registration does not include the banquet.

Dietary Restrictions: _____
 Additional lunch tickets (\$65 each) \$ _____
 Additional banquet tickets (\$125 each) \$ _____
 Total from course(s) \$ _____
 Total amount enclosed or to be charged: \$ _____

Registration is not complete without payment or credit card information. Purchase Orders are not accepted. Check must be made payable to "ABSA" and bank drafted in U.S. dollars or it will be returned.

Visa MasterCard American Express Check Enclosed
 Card #: _____ Exp. Date: _____
 Signature: _____

Course space is limited. No course substitutions or changes prior to the conference. Please visit the ABSA web site at www.absaconference.org for course availability and online registration. **Registration forms must be faxed to the ABSA Office to receive Affiliate Member discount.** Mail to: ABSA, 1200 Allanson Road, Mundelein, IL 60060-3808 or fax to 847-566-4580.

Preconference Courses

Friday, October 3, 2014	Member	Nonmember	Amount
1. Intermediate Threat Assessment for Laboratory Biosecurity Programs	\$590	\$640	\$ _____
2. Implementing an Exercise Program for Select Agent Facilities	\$590	\$640	\$ _____
3. Advanced Risk Assessment	\$590	\$640	\$ _____
4. Shipping Infectious Substances Certification Course	\$590	\$640	\$ _____
5. Laboratory Design Process	\$590	\$640	\$ _____
6. Biosafety Considerations with Human Gene Transfer	\$330	\$380	\$ _____
7. Drawing Review Course	\$330	\$380	\$ _____

Saturday, October 4, 2014

8. The Essentials of Health and Safety at the Boundaries of Biosafety	\$590	\$640	\$ _____
9. Building and Refining a Select Agent Program	\$590	\$640	\$ _____
10. Engineering for the Biosafety Professional—Part II	\$590	\$640	\$ _____
11. Biorisk Management—Large Animals	\$590	\$640	\$ _____
12. Risk Assessment and Containment for Plant Research	\$590	\$640	\$ _____
13. Implementing Personnel Security in Laboratory Biosecurity Programs	\$590	\$640	\$ _____
14. A BSO's Guide for Understanding Research Compliance Regulations	\$330	\$380	\$ _____
15. Full-Length Clones are Just the Beginning	\$330	\$380	\$ _____

Sunday, October 5, 2014

16. Advanced BSL-3 Facility Operations	\$590	\$640	\$ _____
17. Export Management and Compliance	\$590	\$640	\$ _____
18. Advanced Principles and Practices Working in an ABSL-3	\$590	\$640	\$ _____
19. Applied Risk Assessment Methodologies	\$590	\$640	\$ _____
20. Understanding Biosafety & Laser Safety	\$330	\$380	\$ _____
21. Biosafety Considerations for RNA Interference (RNAi)	\$330	\$380	\$ _____
22. IBC Basics: An Introduction to the NIH Guidelines	\$330	\$380	\$ _____
23. High Speed Cell Sorter Selection, Biosafety, and Aerosol Containment	\$330	\$380	\$ _____
24. Large-Scale Biosafety	\$330	\$380	\$ _____
25. Virus-Based Gene Transfer Vectors	\$330	\$380	\$ _____
26. Molecular Biology 101	\$330	\$380	\$ _____
27. Flipping Biorisk Management Training	\$330	\$380	\$ _____

Registration for two 4-hour courses on the same day will include lunch.

Cancellation Policy: Cancellations received before September 2, 2014—90% refund; cancellations received between September 2-9, 2014—50% refund; cancellations received after September 9, 2014—no refund.



ABSA Biosafety Buyer's Guide

www.biosafetybuyersguide.org

ABSA recently launched the Biosafety Buyer's Guide to connect supplier partners with ABSA members and biosafety professionals. The Guide features biosafety and biosecurity related companies, services, and consultants. The Biosafety Buyer's Guide offers biosafety professionals easy access to ABSA partners' products and services. The Guide offers Basic Listings (company contact information), Highlighted Listings (company contact information and logo), and Banner Ads. Listings and Banners are posted for 12 months.

Biosafety Buyer's Guide
brought to you by the
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