

DLS ECHO Biosafety Session: June 25, 2024

Support: Communication and Documented Information



Marian Downing, RBP, CBSP, SM(NRCM)

Independent Biosafety Consultant
Kemah, TX



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Independent Biosafety Consultant
Galveston, TX



Agenda

- Speaker Introduction
- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders



Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.



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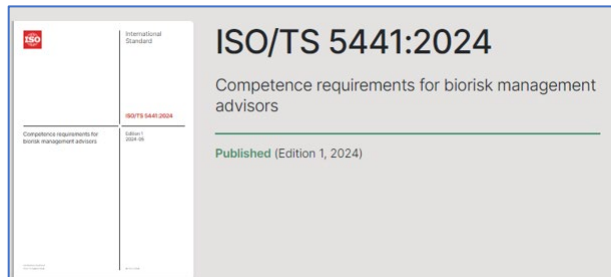
June 25, 12:00 PM ET

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ISO/AWI TS 7446

ISO 35001

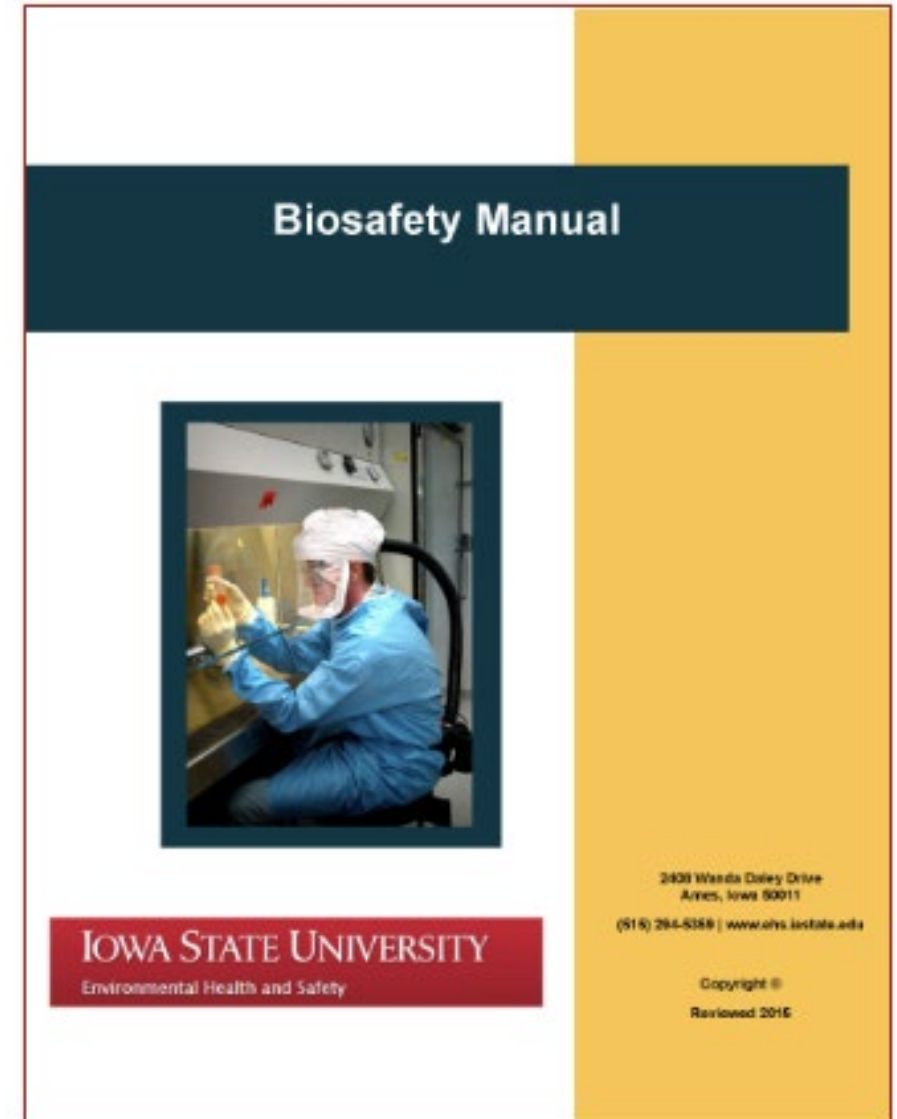
Biorisk management for laboratories and other related organisations

Implementation guidance

Status : Under development



Communication

- Top management commitment
 - **Communicate** biosafety and biosecurity policy
 - Want to see this policy as a written document in the Biosafety Manual
 - Commit to continuous improvement, compliance with local/state/national regulations, maintaining a safe workplace for employees, reducing risks to environment/families/community, etc.



Biorisk Management Roles

ISO 35001:2019

 									
Profession	BIOLOGICAL SAFETY PROFESSIONAL (BSP) also referred to as Biological Safety Officer (BSO)								
Competency Definition	Ability to identify, assess, and control occupational health risks associated with exposure to biohazardous agents and materials and to develop programs to manage these risks. Biohazardous agents are infectious agents that include: bacteria, viruses, fungi, protozoa, multicellular parasites, prions (proteins), and certain types of recombinant DNA. Biohazardous materials include: human and/or other animal blood, body fluids, tissues that contain biohazardous agents; <i>in vitro</i> cell or tissue cultures of biohazardous agents, and toxins that cause disease in humans and/or other animals and are derived from various biological sources including certain biohazardous agents.								
<table border="1"> <thead> <tr> <th>DEVELOPING BSO</th> <th>BSO CORE COMPETENCIES</th> </tr> </thead> <tbody> <tr> <td> Actively engages in the following activities: <ul style="list-style-type: none"> Prepares and maintains a biosafety manual and site exposure control plan (ECP) Reviews project proposals and provides advice on biosafety issues Advices on occupational health programs for persons working with biohazardous agents and materials Provides and interprets biosafety regulations, guidelines, resources and reference information Provides and interprets institutional biosafety compliance programs and audits their effectiveness Institutes, evaluates and documents biosafety training Identifies biohazardous agents and materials in his/her institution and maintains an inventory Develops and implements an infectious-medical waste management program Provides technical information and advice on new technologies impacting biological safety Develops and recommends biosafety practices Interacts with other safety areas such as chemical safety or radiation protection Inspects/maintains Personal Protective Equipment (PPE) and emergency response equipment Plans for biological emergencies and develops procedures to address them Conducts risk assessments to determine how to work safely with biohazardous agents and materials and mitigate biosafety and biosecurity risks Prepares biohazardous agents and materials for shipping/receiving in accordance with import/export regulations </td> <td> A "Competent BSO" can effectively do the following: <ul style="list-style-type: none"> Design and implement biohazardous agent programs to meet current regulatory and institutional requirements Identify and manage biosecurity risks Provide appropriate resources to ensure adequate biosafety program management Assess risk of occupational exposure and infection associated with handling biohazardous agents/materials Assess effectiveness of existing exposure controls and advises on different control methodologies Develop and deliver training on exposure control strategies Support investigations of biohazard-related injuries and illnesses Provide technical support to health surveillance program managers Manage technical aspects of 3rd party providers, (e.g. laboratories, consultants) Provide input to biohazard emergency response plans and pandemic planning & preparedness Critically analyze occupational exposure data at site and advise senior management Provide advice on choice of appropriate inactivation methods for biohazardous agents and materials and the potential hazards (explosive, flammable, corrosive, carcinogenic, and irritating) associated with various disinfectants and sterilants </td> </tr> <tr> <td> Knowledge Requirements: <ul style="list-style-type: none"> A Bachelor's degree in biological sciences Successful completion of several microbiology related courses (e.g., General Micro., Virology) </td> <td> Requirements: <ul style="list-style-type: none"> A Bachelor's degree in biological sciences; an advanced degree is desirable Successful completion of several microbiology related courses (e.g., Gen. 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<https://absa.org/wp-content/uploads/2018/05/OSHABSOcompetencyFactSheet.pdf>

- “roles, responsibilities, and authorities related to biorisk management are defined, documented, and **communicated** to those who manage, perform, and verify work associated with biological materials”
 - Top to bottom understanding of roles and responsibilities when working with biologicals
 - Workers, managers, supervisors, quality, etc.
 - SOPs to cover use of disinfectants, autoclave, waste disposal, BSC, use of PPE, etc. (with written training documentation)
 - Door signage includes agent info, PPE, vaccinations, respiratory protection, etc. (BMBL)

Biorisk Management Roles (continued)



The screenshot shows the Government of Canada website with the following content:

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Health > Health risks and safety > Biosafety and biosecurity > Pathogen Safety Data Sheets

Pathogen Safety Data Sheets: Infectious Substances – Measles virus

PATHOGEN SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: Measles virus

SYNONYM OR CROSS REFERENCE: MV, measles, morbilli, rubella, pneumonia, measles inclusion body encephalitis, encephalomyelitis, atypical measles, subacute sclerosing panencephalitis, red measles, 5 or 10-day measles, hard measles

CHARACTERISTICS: Measles virus is a negative-sense, single stranded RNA virus, which belongs to *morbillivirus* genus in the *Paramyxoviridae* family. It consists of a helical nucleocapsid, 100-300 nm in diameter, surrounded by an envelope. The envelope is lined by matrix proteins and carries transmembrane hemagglutinin and fusion glycoproteins which are the virulence factors.

SECTION II - HAZARD IDENTIFICATION

PATHOGENICITY/TOXICITY: The Measles virus may cause measles, a systemic infection starting in the respiratory epithelium of the nasopharynx. Measles may lead to severe complication and can cause death. After an incubation period of 8-12 days, fever (approximately 38.3°C) and malaise develop over 24 hours. These symptoms are followed by cough, coryza (inflammation of the nasal mucous membranes) and conjunctivitis. After 2-3 days of cough, coryza and conjunctivitis, Koplik spots (white and granular lesions in the lateral buccal mucosa) appear. On the fourth day, a macropapular rash appears on the head and neck, behind the ears. The rash then spreads to the rest of the body and persists for 3-5 days before fading. Other symptoms include anorexia and dyspnea. Subjective improvement can begin 2-4 days after the rash first appears. Infants, pregnant women, immunocompromised and malnourished patients are at a greater risk of developing complications, and experience more severe illness. Historically, males have had a higher mortality rate than females, but this difference has tended to decrease with modernization of healthcare in western countries. Measles is a leading cause of death in children under 5 years of age in developing countries. Measles is a leading cause of middle ear infection in 1,000 cases or death (15%).



- Recommend laboratory employees included in Management Safety Committee discussions and as members of the IBC (Institutional Biosafety Committee)
- Training includes info on agents handled in the lab, modes of transmission, PPE, vaccine, pregnancy and immune suppression risks
- “Laboratory directors or principal investigators should consider the use of competency assessment(s) to train and retrain new staff to the point where aseptic techniques and safety precautions become second nature.” (BMBL pg.18)
 - *The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment. (BMBL pg. 40)*



Poll Question #1

Multiple Choice

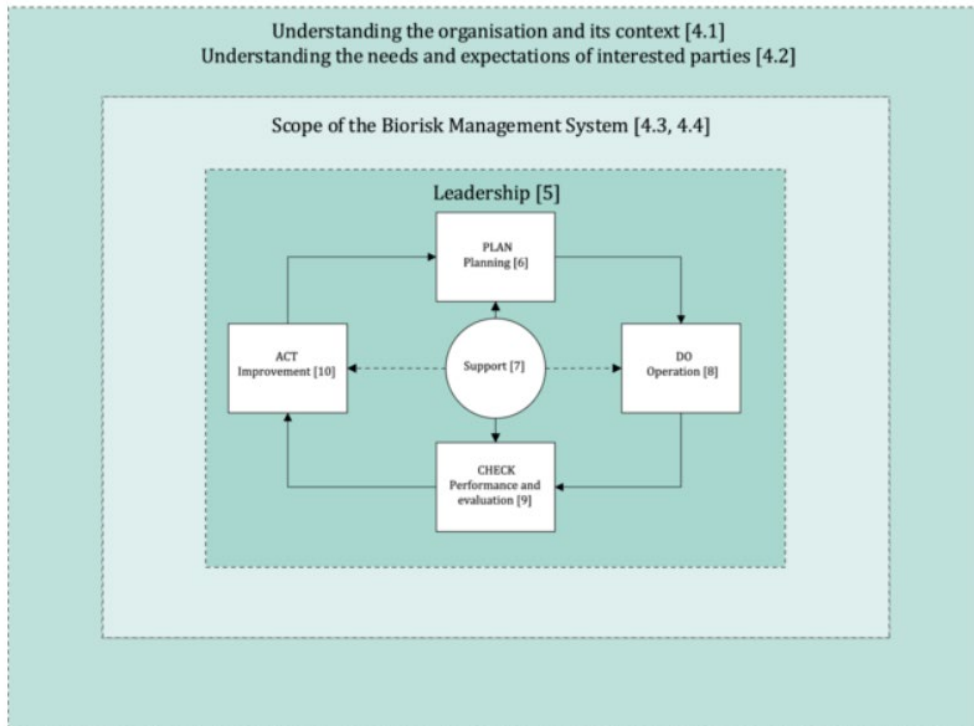
How does your institution ensure that a worker can “demonstrate proficiency” for microbiological practices for BSL-2 work?

- Hands-on 3/4 step process with trainer
- Manager/supervisor observation
- Co-worker mentors and approves employee
- Written test
- Quiz after training
- Other?

Communicate Goals of the BRM Program

Do you have a written Biosafety Policy?

Biorisk Management System Model
[Top - Down Pyramid View]



- Biorisk management objectives are **communicated**

- Potential topics:

- reduce waste and protect environment,
- mitigate risks to lowest level,
- comply with local, state, federal regulations,
- 100% training compliance,
- reduce incidents, increase reporting
- define whistleblower policy,
- emergency response expectations,
- risk assessment process improvements,

Communicate Goals of the BRM Program



- Regular performance evaluation of the biorisk program
 - Lab evaluations, training reviews, SOP review, incident trends are all involved
 - “shall be **communicated** to those members of the organization whose work may be affected by the biorisks, and reviewed by all relevant ... leadership”
 - Room for improvement shared with laboratorians, upper management, waste handlers, emergency personnel, facility engineering, Occupational Health, security personnel, relevant contractors and suppliers, etc.
 - Employee performance evaluation can include biorisk management factors (wearing PPE, reporting incidents, washing hands, disinfection practices, etc.)

Communication Basics

All determined/documentated in advance

- Internal and external **communications** determined
 - WHAT will be covered (policy, expectations, basic laboratory operations, spills, exposures, illnesses, etc.)
 - WHEN the information will be communicated (employees, NIH, state/local authorities, after diagnosis of disease, etc.)
 - NIH immediate notification of incident, investigation report within 30 days
 - WHO will do the official notification
 - IBC Chair, BSO, EHS lead, PI, Compliance Chair

**RESTRICTED AREA
NO UNAUTHORIZED PERSONNEL**

HUMAN BIOHAZARD

Exposure Date: _____ JACUC Log #: _____
(For Animal Rooms Only) (For Animal Rooms Only)

Biosafety Level: BSL1 BSL2 BSL3 BSL4

Building: _____ Room#: _____

Agent Information: _____

Room Entrance Protocol (Checked items **must** be worn to enter):

Boots Clean Coveralls Head Cover Eye Protection

Gloves Face Shield Rain Suit

Face Mask (specify type) _____

Other (specify) _____

Additional Instructions: _____

Emergency Contacts:

	Name	Work Phone	Home Phone	Office Location
1st:				
2nd:				
	Department of Public Safety	294-4428 (24 hour contact)	N/A	N/A



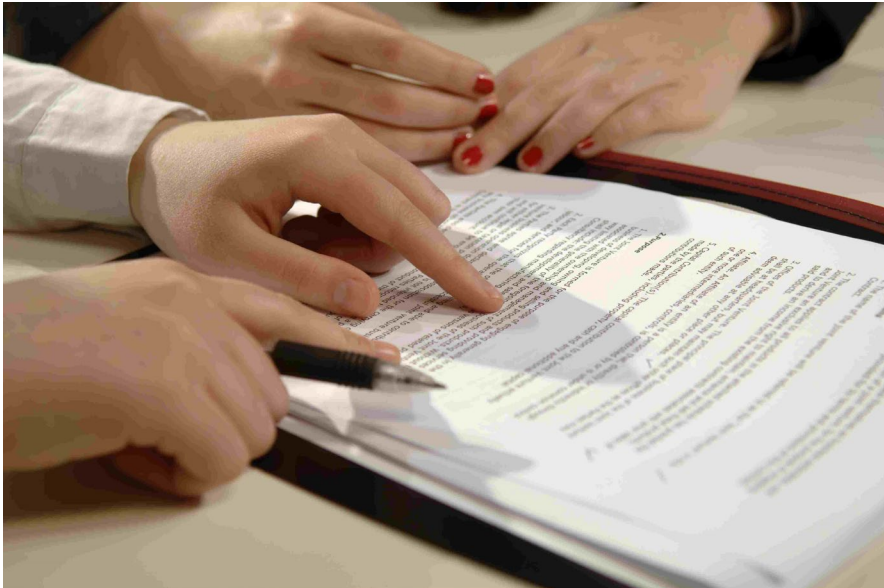
Poll Question #2

Multiple Choice

- How does your institution ensure that the root causes of biosafety incidents are communicated (without identifying those involved) with all lab staff?
 - Annual training
 - Annual Bloodborne Pathogen training
 - Newsletter, poster
 - Computer notice, blog
 - Other?



Communication Basics (continued)



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- WHO will be included in the notification
 - Internally (laboratorians, safety, quality, legal, public relations)
 - Externally (government agencies, local public health, local police and fire, community liaisons)
 - Others (news outlets, watchdog groups, etc.)
- HOW to **communicate** (identify communication channels)
 - verbal (training, team meeting, safety committees, conference/Zoom call, Town Hall)
 - Non-verbal (signage, document circulation, newsletter, formal letter for outside organization)

Poll #3

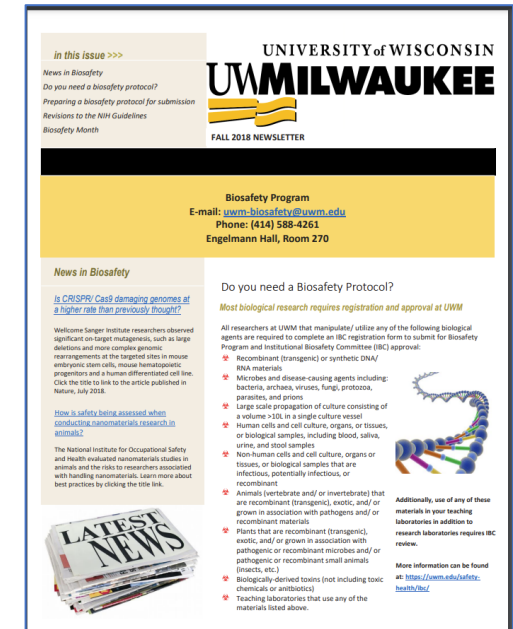


- Do you have a written procedure for any mandatory reporting of incidents or spills?
 - Yes
 - No
- Does it include a clear explanation of timing, who is responsible for investigating, who will make the actual phone call or sign the formal submission, who will follow up?
 - Yes
 - No

Note: You do NOT want 2 individuals calling NIH or another agency about the same incident!

The organization shall ensure:

- **Effective communication** is established within the facility with consideration of the organization's information security program
 - FOI parameters are determined in advance
 - Consideration of exposed worker confidentiality for incidents
- Ensure **2-way communication**; workers have access to most current info on biorisks
 - Effective training and proactive ability to express concerns about workplace
 - Safety committee meetings, anonymous tip box

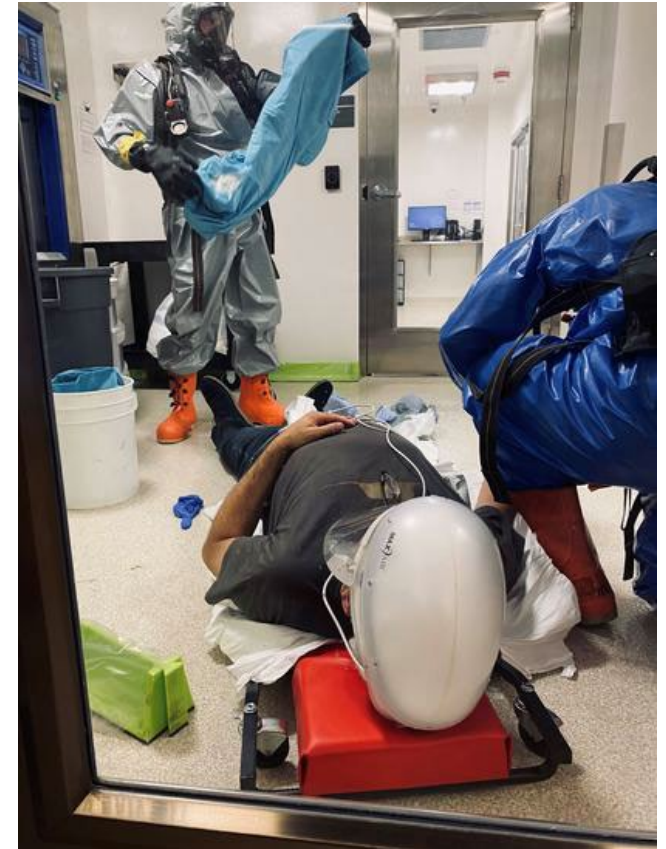


<https://uwm.edu/safety-health/wp-content/uploads/sites/405/2018/09/Biosafety-Fall-2018-Newsletter.pdf>



The organization shall ensure:

- **Communication** process in place for relevant workers on roles, responsibilities, needs
 - Emphasizing the significance of the BRM program
 - Annual training even if no changes in the workplace
 - Didactic training increases likelihood of questions and interactions
 - Use regular lab inspections to increase awareness
- Internal/external communication plans/training are in place for emergency response
 - Fire, police, local public health departments, other emergency responders
- A record of all **communications** and meetings is kept
 - Written minutes for all safety meetings, including upper-level management safety discussions
 - Written training and documentation of reading SOPs, work instructions, etc.



UC, Riverside
<https://insideucr.ucr.edu/stories/2021/08/30/campus-holds-major-biosafety-drill>

Documentation

“The Biorisk management system shall include:

- Documented information required by this document including but not limited to policies, plans, procedures, protocols and records; and
- Any other documented information determined by the organization as being necessary for the effectiveness of the Biorisk management system.”

From ISO 35001:2019



Documentation

“The extent of documented information for a Biorisk management system can differ from one organization to another due to:

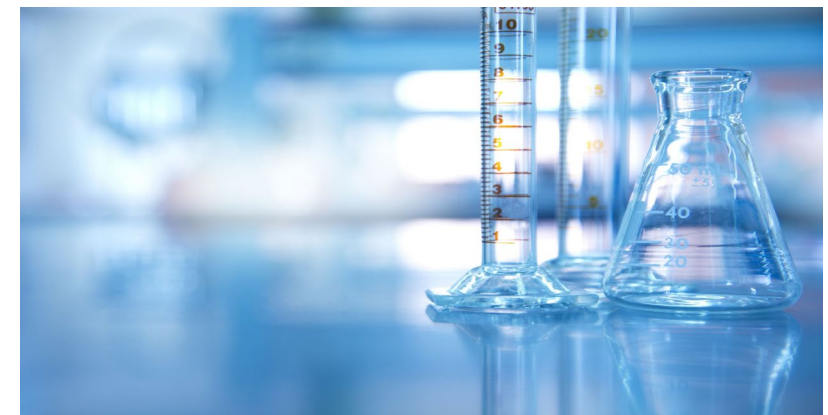
- the size of organization and its type of activities, processes, products and services;
- legal or other requirements;
- the complexity of processes and their interaction; and
- competence of persons.”



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Creating and Updating

- “Identification and description (e.g., a title, date, author, or reference number);
- Format (e.g., language, software version, graphics) and media (e.g. paper, electronic);
- Review and approval for suitability accuracy and adequacy;
- Review and approval for suitability for public release; and
- Security and protection of sensitive information.”



A background image of a laboratory setting with various glassware, bottles, and equipment on a bench.

Poll Question #4

Short Answer

- What department has been identified as the keeper of your documents and who has the authority to update and make changes to your documents?
- Biosafety manual?
- Accident investigation and root cause analyses documents?

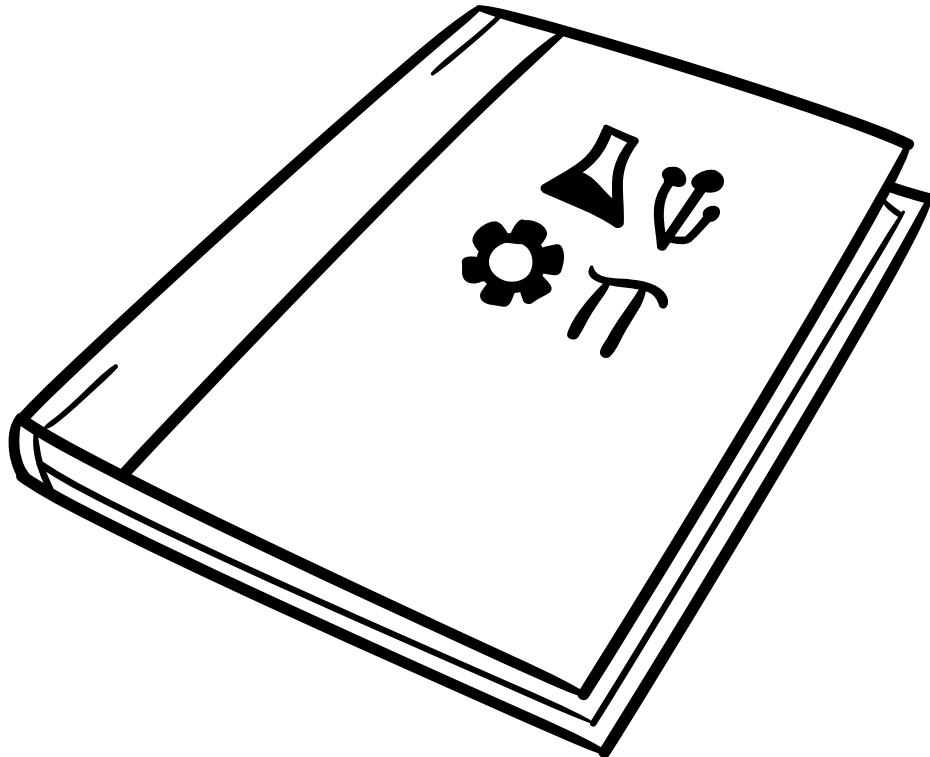
A background image of a laboratory setting with various glassware, bottles, and equipment on a bench.

Control of Documented Information

“Documented information required by the Biorisk management system and by this document shall be controlled to ensure:

- it is available and suitable for use, where and when it is needed;
- It is adequately protected (e.g., from loss of confidentiality, improper use or loss of integrity);
- it reflects the most current policies, plans, procedures, protocols, records, and other information associated with the Biorisk management system.”

Control of Documented Information



“The organization shall address the following activities as applicable:

- distribution, access retrieval, and use based on risk;
- storage and preservation, including preservation of legibility;
- control of changes (e.g., version control) and status (e.g., draft, interim final);
- retention and disposition.”

Poll #5

Multiple and Single Choice

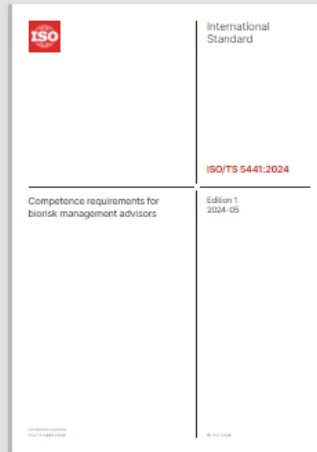
- How does your organization track training on SOP/policy, etc. revisions?
 - Computer
 - Paper copy (dated) of training on changes
 - Other?
- Do you require training (documented reading/understanding/application) of a revision to a controlled document for:
 - Change only
 - Entire document
 - Neither
 - Other?
- Are your SOPs and Biosafety Manual controlled the same way as policies?
 - Yes
 - No
 - Not sure

Access

“Access can imply a decision regarding the permission to view the documented information only or the permission and authority to view and change the documented information.”



Just out!
May 2024



[Read sample](#)

ISO/TS 5441:2024

Competence requirements for biorisk management advisors

Published (Edition 1, 2024)

ISO/TS 5441:2024

Format

PDF + ePub

Language

English

CHF **194**

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Abstract

This document defines the requirements for competence of individuals who provide advice, guidance, and assurance on processes to identify, assess, control, and monitor the risks associated with hazardous biological materials in a laboratory or other related organization that handles, stores, transports, or disposes of biological materials that can be potentially hazardous for people, animals, plants and the environment.

General information

Status : Published

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Stage : International Standard published [60.60]

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Number of pages : 62

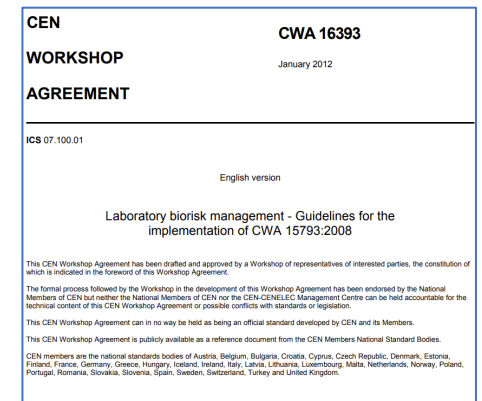
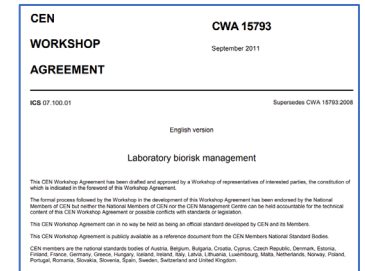
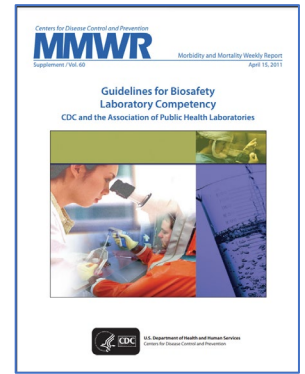
Technical Committee : ISO/TC 212

ICS : 07.100.01 11.100.01

[RSS updates](#)

References

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Thank you!



Post-session Surveys

June Survey

- 2 min to complete; helps improve ECHO and Community of Practice
- Participation is voluntary, responses are anonymous, and feedback is summarized in aggregate
- Today's session is eligible for 0.125 ABSA Credentialing Maintenance points
 - Screenshot the submission page as your certificate of attendance for the session

Six-Month Survey

- Will be sent in mid to late July



Scan here to take the
June survey

DLS ECHO Biosafety Session: August 27, 2024

Operations: Planning and Maintaining

Esmeralda Meyer, MD, JM, RBP (ABSA), CBSP (ABSA), BRM (IFBA), CPIA (PRIMR)

Director, Institutional Animal Care and Use Committee

Office of Research Compliance and Regulatory Affairs, Emory University

Atlanta, GA

