

INTRODUCTION TO BIORISK MANAGEMENT

ADMINISTRATIVE CONTROLS

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INTRODUCTION

This lecture has been designed and developed to introduce you to the **Administrative Controls (AC)** which govern the safe working operation of a containment facility. ACs constitute the cornerstone of biorisk management and are the first set of controls which must be developed prior to commencement of the design, development and operation of a containment facility.



LEARNING OBJECTIVES

The objectives of this lecture are:

1. To introduce you to the **concept** of administrative controls.
 2. To assist you in the development of your first standard operating procedure (**SOP**).
 3. To provide guidance on development of your own unique administrative control: **laboratory biosafety manual**.
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LEARNING OUTCOMES

Upon completion of this module you should demonstrate the ability to:

1. **Describe** the various types of Administrative Controls (AC).
 2. **Design and develop** a basic Standard Operating Procedure (**SOP**).
 3. **Understand** how administrative controls must be used concurrently with PPEs.
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ADMINISTRATIVE CONTROLS

- Administrative controls are work procedures such as
 - Written safety policies,
 - Rules
 - Schedules
 - Training
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GOAL OF AC

Reducing the duration, frequency, and severity of exposure to biological agents and biological hazards.



INTERNAL AND EXTERNAL AC



ADMINISTRATIVE CONTROLS

- ✓ Biorisk Management Program
 - ✓ Committees – IBC, IACUC, IRB
 - ✓ Staff
 - ✓ Education and Training
 - ✓ Risk Assessment
 - ✓ Practices and Techniques
 - ✓ Safety Manuals and SOPs
 - ✓ Signs & Labeling
 - ✓ Registration and Inventory Control
 - ✓ Medical Surveillance Program
 - ✓ Inspections/Audits/Certifications
 - ✓ Documentation
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BIORISK MANAGEMENT PROGRAM

A framework of organizational structure, policies, practices, and biosafety/biosecurity guidance instituted and supported by management

- that provides procedures and accountability
 - for preventing occupationally-acquired infections
 - or release of harmful organisms to the environment
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STAFF & PERSONNEL

- Education
 - Training
 - Competency
 - Prior experience
 - Medical surveillance
 - Health history review
 - Prophylactic immunizations
 - Mental screening?
 - Psychology ?
 - Behavioral ?
 - Security screening?
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EDUCATION AND TRAINING

- Ensure that the right people are doing the job
 - Education should be up to date and refreshed as necessary
 - Training should occur as needed
 - New task, situation, equipment, animal species, etc.
 - Must be site and situation specific
 - Re-training at least annually or as needed
 - Document the training!
 - Competency – needs to be demonstrated
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GOOD WORK PRACTICES

- Good Laboratory Practices
 - Aseptic Techniques
 - Code of Conducts
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- Awareness
 - Training
 - Observations
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SAFETY MANUALS

- Create operations manual (write or buy)
 - Basic ones:
 - Biosafety manual
 - Animal biosafety manual
 - Biosecurity manual
 - Incidence/emergency response manual
 - Facilities operation manual(s)
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STANDARD OPERATING PROCEDURES

- A **standard operating procedure** is a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness.
 - Standard Operating Policies and Procedures can be effective catalysts to drive performance and improving organizational results.
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SIGNAGE AND LABELLING

- Signage is important to communicate the potential hazard
 - Post a biohazard warning sign when immunizations or use of respirators is needed for entry
 - Provide contact information
 - Persons at increased risk of infection should not enter infected animal rooms
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INVENTORY CONTROL

- Inventory everything to the level required by the risk assessment
 - Animals
 - Pathogens
 - Genetically Modified Organisms (GMOs)
 - Record of use/ logbook
 - Record of access

 - What is there ? Where is it stored ?
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MEDICAL SURVEILLANCE

- Process of evaluating the health of personnel as it relates to their potential occupational exposures to Biohazardous agents, monitoring exposure results and arranging / monitoring post exposure prophylaxis.
 - Pre-employment Physical
 - Annual Physical
 - Emergency Care
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AUDITS, INSPECTIONS AND CERTIFICATION

- Audits - check that procedures and SOP are correctly followed
 - Inspections – check that facilities are functioning according to design
 - Certification – check that equipments etc are functioning within the required parameters
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DOCUMENTATION

- A necessary part of good practices
 - “If you didn’t document it you didn’t do it”
 - Electronic or paper or both
 - Confirmation/verification
 - Log books/paper in labs?
 - Version control
 - Archive? Retention time?
 - Access control to documents – biosecurity!
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SUMMARY

- Admin controls are implemented through-out
 - Are vital to ensuring a successful program
 - Does not cost that much

 - Prone to human error
 - Often forgotten or overlooked or ignored
 - Frequently not well documented
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GOAL OF AN SOP

- Different people
 - Doing the same thing
 - Getting the same result
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INSTRUCTIONAL DOCUMENT

- Instructional documents teach a reader to:
 - Understand a rule or principle.
 - Envision a process or workflow.
 - Perform a task.
 - Use a tool.
 - Instructional documents are **READER-CENTERED** (rather than rule-centered)
 - **ENGAGE** the end users when writing SOPs
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INSTRUCTIONAL DOCUMENT

- Policy:
 - A plan or guiding principle that influences other actions
 - Program Plan:
 - A set of tasks or actions, performed in a specified sequence or manner, that achieves a particular result.
 - Procedure:
 - A specific task, work instruction, or action. Procedures may include steps or actions
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POLICY DOCUMENTS

- *Dispose of biologically contaminated waste according to local regulations.*
 - Who writes this document?
 - Who is the audience?
 - What is the intended purpose?
-



PROGRAM PLAN

- In order to dispose of contaminated waste appropriately, the following must be in place (for example):
 - Method of final decontamination and disposal
 - Method of transport from point of generation to point of final decontamination and disposal
 - Labeled waste containers
 - Labeled (or colored) waste bags
 - Training for all roles involved in waste disposal
 - etc.
 - Along with the details required for each of the above to be in place and effective.
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PROCEDURES

- To dispose of contaminated laboratory waste, take the following actions:
 - Step 1.
 - Step 2
 - Step 3, etc.
 - Who writes this document?
 - Who is the audience?
 - What is the intended purpose
 - SOPs are (generally) designed to **achieve a single, or small, outcome**
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SOP: SECTIONS

- Conditions
 - Context
 - Actions
 - Documentation
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CONDITIONS

- Who should use the SOP?
 - When should it be used?
 - Why should the SOP be used?
 - Where should it be used?
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CONTEXT

- Basic process:
 - Input + Actions = Output
 - Input
 - Output
 - Preparation: What is presumed to be ready (as part of input) when actions begin?
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ACTIONS

What steps must be taken to move from the INPUT to the OUTPUT?



DOCUMENTATION

- Cross-references
 - Regulatory sources
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IMPLEMENTATION: TESTING SOP

- Did you understand the SOP?
 - Could you physically do what the SOP asked?
 - Was the outcome the intended outcome?
 - Did different individuals achieve the same outcome?
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VALIDATING SOP

Behavioral Observation Data (BOD)

- A question about an observed behavior that can be answered “yes” or “no”.
 - Example: Is Pat’s lab coat buttoned? YES or NO
 - Useful in validating SOPs
-



VALIDATING SOP

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BEHAVIOURAL OBSERVATION DATA

- Useful for checking and validating SOPs
 - Objective assessment

 - Observers will also improve.
 - When expected behavior is standardized and well-communicated, it is easier to see when behaviors change.
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BEHAVIOURAL OBSERVATION DATA

- Just one tool used in safety industry (and others).
 - MUST not stand alone.
 - Critical to involve those who will be observed when the BOD questions are developed.
 - MUST be used consistently for all.
 - Use as “self-audit” (as well as in observation) will help reduce self-consciousness in those observed.
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REVISION AND REVIEW OF SOP

- How often?
 - When?
 - How?

 - Look at the procedure you brought with you.
 - Is there any sign it has been reviewed or revised?
 - How would you undertake a review or revision?
 - What needs to happen before you could review or revise the document?
 - What are obstacles to getting the document revised?
 - What are solutions for routinely reviewing and revising SOPs?
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KEY MESSAGES: SOP

- SOPs are instructional documents designed to guide “different people doing one thing the same way and **achieving the same outcome.**”
 - SOPs are (generally) designed to **achieve a single, or small, outcome**
 - There are many acceptable ways to write and SOP; however, there are **key components** that can comprise an effective SOP.
 - SOPs must be **evaluated and validated** to assure that individuals can understand and physically accomplish the procedure and that all individuals are accomplishing the intended outcome of the SOP.
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