

Documentation Management

*Biosafety and Biosecurity Awareness Training
For Afghan and Pakistani Bioscientists*

December 7 – 9, 2009

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Biorisk Documentation

- **After the risk assessment has been conducted, it is the responsibility of management to decide which risks must be mitigated and to allocate resources in a graded manner to meet those needs.**
- **Once decisions have been made, it is imperative that management create a laboratory biorisk plan, an incident response plan, and other documents (SOP) necessary for successful operation of the laboratory.**
- **Such a plan helps ensure the overall functioning of the lab biorisk program.**



Biorisk Plan : Discussion

- **What types of documentation should a facility have for a biorisk program?**

- **How many of the above documents does your facility have?**



BioRisk Plan Contents

- **Summary of Risk Assessment**
 - Site-specific
 - Agent-specific
 - Facility wide
 - Summarize hazards, threats, vulnerabilities, consequences

- **Plan language**
 - Refers to the assessments and conclusions
 - Identify and elaborate on resulting mitigation measures

- **Detailed descriptions of procedures and protocols necessary to mitigate unacceptable risks to protect valuable materials**

- **Incident Response Plans**



Standard Operating Procedures

- **Standard Operating Procedures (SOPs)**
 - Written instructions that document a routine or repetitive activity
 - Detail of processes necessary to perform a job safely and properly
 - Specific to an organization or laboratory





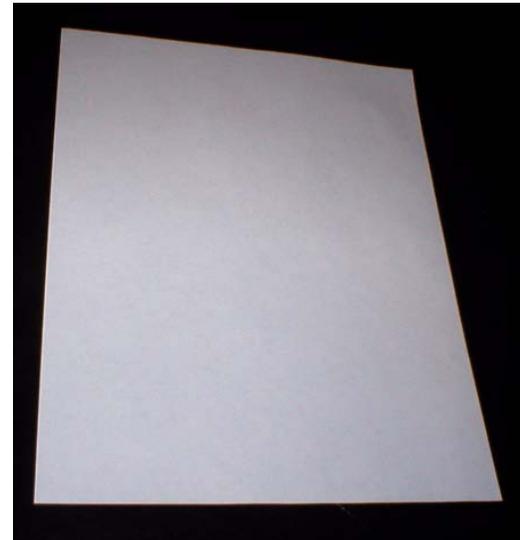
Purpose of SOPs

- **Ensure all relevant individuals understand the process**
- **Document how activities shall be performed**
- **Types of SOPs**
 - **Repetitive technical activities**
 - Sample receipt and processing
 - Diagnostic test procedures
 - **Administrative procedures**
 - The process for proper documentation of training
 - Laboratory Access Authorization
 - **Response Activities**
 - Building evacuation
 - Suspicious individuals and activities
 - Medical emergencies



Please follow this SOP

1. Take a piece of paper
2. Fold paper in half
3. Fold paper in half
4. Tear one corner
5. Unfold paper
6. Hold up in air





Sections

- **Title Page**
- **Table of Contents**
- **Required Controls**
 - Limited Access
 - Containment
- **Required Training**
 - Personal Protective Equipment
 - Equipment
- **Body**
 - Brief description of the procedure
 - Risks
 - Definitions
 - Procedures
- **Emergency Response Measures**
- **References**
 - Other relevant SOPs
 - Relevant Guidelines and Regulations
- **Contact Information**
 - Principle Investigator
 - Responsible Official
 - Biosafety Officer
 - Engineering and Maintenance





Documentation

- **Documentation**
 - Retention times should be determined for all types of documentation
 - Methods of documentation should be determined for each type of information
 - Maintain control of documentation containing potentially sensitive information
 - The plan should describe methods of control for potentially sensitive documentation
 - Samples of all forms should be included in an appendix of the plan