



# Documentation Management

***Biorisk Management Training Course***  
**International Biological Threat Reduction Program**  
**National Institutes of Virology**  
**October 2009**

SAND No.

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
for the United States Department of Energy's National Nuclear Security Administration  
under contract DE-AC04-94AL85000.



# 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

- **Biosafety plans are procedures and mitigation strategies ultimately designed to protect persons in the lab, persons outside the lab and the environment from accidental exposure to biological materials**
- **Biosecurity plans are procedures and mitigation strategies ultimately designed to protect biological materials and related valuable assets against unauthorized access, theft, etc.**
- **Incident response plans describe methods by which facilities respond to various incidents**
  - Natural
  - Medical
  - Safety
  - Security
- **Based on facility-wide risk assessment**
- **Coordinate with facility-wide plans and procedures**



# 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





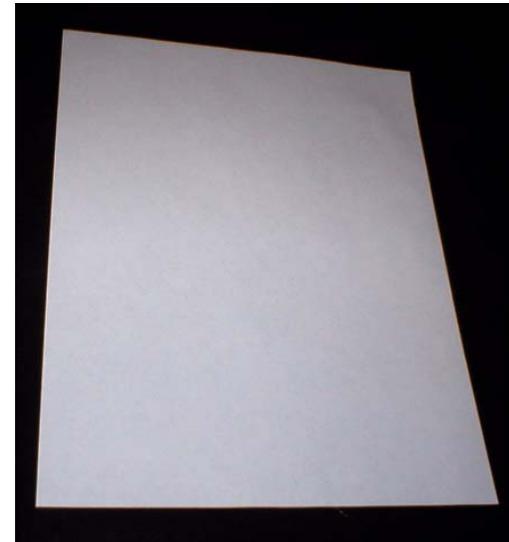
# Purpose of SOPs

- **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