



**ASSOCIATION
OF SOUTHEAST
ASIAN NATIONS**

ASEAN Regional Forum Workshop on Biorisk Management

Best Practices for Implementation of A Biorisk Management System

Background

The 2010 ASEAN Regional Forum Workshop on Biorisk Management held from 28-30 September 2010 in Manila, Philippines, shared technical information and experiences on approaches to biorisk management followed by member states. The workshop discussed basic set of principles that are necessary for effective laboratory biosafety and biosecurity. It highlighted the value of adopting best practice strategies to biorisk management based on the CEN Workshop Agreement (CWA) 15793:2008 Laboratory Biorisk Management Standard. The workshop recognized that it is not possible to apply a ‘one size fits all’ solution to biosecurity and biosafety issues and that the CWA 15793:2008 provides for local solution of local problems. It encouraged member states to adapt their own guidelines to suit their own individual circumstances. To this end, participants recommend the below list of best practices as guidance for implementation of a biorisk management system. This list of best practices can be a useful tool for national governments, assistance providers, and the ARF in their respective implementation of national biorisk policies and regional cooperation.

“Best Practices”

- **Establish and Implement Biorisk Management System**
- **Develop Biorisk Management Policy that covers laboratory biorisk (biosafety and biosecurity)**
 - Raising awareness of building Biorisk Management Expertise
 - Promoting public awareness on biorisk is necessary, as risk perception and people’s attitudes are important

- Identifying gaps in current practices
- Policy should be commensurate to nature and scale of the risk of the activities at a facility
- Defines objectives of the system
- Defines risk communication methods
- Defines financial responsibility
- Role of professional organizations
- **Establish, implement, and maintain a Biorisk Assessment Process**
 - Identify, implement, and maintain suitable, reproducible and scientifically based biorisk assessment methodology.
 - Define roles and responsibilities (Management, Biorisk committee, Biosafety & Biosecurity, Scientists/Researchers, Occupational Health, Facility management, etc.)
 - Certification/Accreditation is optional and preceded by a comprehensive self-audit system
 - Consider what factors trigger the need for a biorisk assessment (timing)
 - Consider what factors bind the scope of the biorisk assessment needed
 - Risk communication and the adoption of clear “acceptable risk” decision making
 - Biorisks associated with proposed work should be identified and documented (including responsibility to identify biohazards, qualifications, mode of action of the biological agents, accident/incident reporting, etc.)
 - Biological agents and toxin inventory and information
- **Establish operational practices commensurate with level of research being conducted to include:**
 - Biological agents and toxin inventory and information.
 - Biosafety and biosecurity
 - Work program, planning, standard operation procedures, and capacity
 - Information security
 - Good microbiological practices and techniques
 - Decontamination, disinfection, and sterilization
 - Transport procedures
 - Waste disposal procedures

- **Establish maintenance practice commensurate with level of research/work being conducted to include:**
 - Materials management
 - Equipment and maintenance
 - Facility requirements
 - Physical and personnel security

- **Establish emergency response and contingency plans to include:**
 - Possible emergency scenarios
 - Emergency plans
 - Emergency exercises and simulations
 - Contingency plans to address changes in the laboratory scenarios

- **Establish performance metrics to include:**
 - Establishing control, assurance and improvement processes and objectives
 - Conduct performance measurements and analyze data
 - Data, records, and document control
 - Institute an inventory monitoring and control system
 - Risk management and risk mitigation measures

- **Establish/test accident and incident investigation methodology to include:**
 - Identification of non-conformance to operational procedures
 - Identify corrective and preventive action for risk mitigation
 - Inspections and audits
 - Review of biorisk assessments including management review

- **Address human resources needs to include:**
 - Organizational capacity
 - Personal protective equipment (PPE)
 - Vaccinations and employee health monitoring
 - Human factors: behavioral factors
 - Succession planning
 - Curriculum development and certification to increase professionalism

- Personnel training and competency assessment, that training is tiered for different stakeholders and effectively implemented in the local language
- **Develop a Formal certification process**
 - A recognized certification scheme supported by accredited certifiers should be developed
 - Identify a non-profit, non-government, independent accreditation body to take responsibility for the certification process (i.e. Biosafety or other professional organizations)
 - Ensure certification costs are built into existing programs
- **National policy**
 - Determine political culture, opportunities and barriers
 - Identify policies that support or hinder implementation of the biorisk management system
 - Conduct a national survey of pathogens, ensuring appropriate information security. The survey would inform priorities and identify gaps in implementing biorisk management.
 - Conduct gap analysis
 - Identify existing national laws and legislation with a view to analyze potential gaps between the obligations under international treaties/conventions and the current legislation
 - Leverage international organizations
 - Raise awareness and identify the concerns of stakeholders
 - Identify responsibility and authorities
 - Applicable across all sectors and all types of laboratories
 - Raising awareness of building biorisk management expertise
- **Leverage biosafety associations that can assist in:**
 - Promoting biorisk management
 - Providing technical support
 - Supporting and promulgating the CEN standard