Concept of Biorisk Management

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INTRODUCTION

The World Assembly of Delegates adopted a new chapter on **Laboratory Biorisk Management**, Chapter 1.1.3a, during the May 2014 General Session of the OIE.

Chapter 1.1.3a is in coordination with chapter 1.1.3 on **Laboratory Biosafety and Biosecurity**.

At the May 2015 General Session the Biological Standards Commission will propose adopting a merged version of Chapter 1.1.3 and 1.1.3a.
All laboratories are responsible for biosafety and biosecurity that protects their workers, animal populations, and the environment from exposure or spread of pathogens.

This important function is accomplished by:
• not handling the specified biorisk in their facility,
  
or
• by identifying, implementing and maintaining appropriate biosafety and biosecurity measures.
**Laboratory Biosafety** describes the containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, and to prevent their accidental release.

**Laboratory Biosecurity** describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.
Laboratory Biorisk Management / Biorisk Controls

- Administrative Controls
- Operational Controls
- Engineering Controls
- Personal Protective Equipment
Administrative Control Examples

- Laboratory policies and management programmes;
- Qualified, trained, and competent personnel;
- Training in the safe & secure handling of biological agents & toxins;
- Health and safety programmes (e.g. health care, vaccinations);
- Incident and accident investigation programmes; emergency response and contingency plans;
- Biological agents and toxin inventory management requirements (e.g. access, storage, transfer, destruction, and audit);
- Waste management policies;
- Security policies (e.g. facility security, visitor access, personnel security, access to biological agents and toxins, data security).
Operational Control Examples

- Standard Operating Procedures for all safety and laboratory biosecurity-relevant processes;
- Good Microbiological Technique and Laboratory Safety practices;
- Use of appropriate disinfection and decontamination practices;
- Transportation procedures for potentially infectious materials and specimens;
- Specimen and reagent handling and storage practices;
- Accident/incident reporting, response, and review protocols;
- Emergency exercise drills.
Engineering Control Examples

- Facility ventilation and air-flow;
- Barrier walls and shields for separation of incompatible activities;
- Biological Safety Cabinets, Glove boxes;
- Equipment, including equipment maintenance, calibration, and certification;
- Physical security: access restrictions, security guards, perimeter fences, facility and equipment locks with associated key control protocols, badge readers, detectors and sensors, biometric devices.
Personal Protective Equipment Examples

- Eye protection (safety glasses, face shields),
- Respiratory protection (face masks, N95 respirators, face shields, hoods, PAPRS),
- Hand protection (gloves);
- Body protection (laboratory coats, uniforms, coveralls, surgical scrubs, rubber boots, disposable shoe covers).
Biorisk Management Systems include:

1) biohazard identification,

2) biorisk assessment,

3) biorisk management, and

4) biorisk communication.
Identify the biologic agent or toxin, including:

- The amount (volume, concentration) of the agent expected to be handled in the laboratory.

- The laboratory procedures to be used (e.g. centrifugation, sonication, isolation and amplification in culture, animal inoculation).

- Storage and archive volumes of the agent or toxin expected for the laboratory.
Identify the possible biological risks, including:

- Characteristics of the Agent:
  - Zoonotic potential, ease of transmission, availability of prophylaxis and treatment.

- Health and economic consequences of an exposure or release from the facility:
  - Susceptible species, impact on access to food and fiber, trade implications.

- Available laboratory infrastructure and resources.
Biorisk Assessment

1) Identify the likelihood and the potential consequences (severity of harm) associated with exposure to or release of the agent:

- human disease (probability and severity)
- animal disease (probability and severity)
  - susceptible species in the vicinity
  - environmental factors in the vicinity (routes of transmission)
- economic consequences of the disease and associated disease control costs.
- potential for theft, misuse, or deliberate release.

2) Decide if the risk of handling the agent in the laboratory can be controlled and is the cost justifiable.
Biorisk Management

• The process requires documentation of timelines for action, assignment of responsible persons, and completion of the associated local/national reporting and approval requirements.

• The laboratory manager works with a biorisk management advisor to identify which risk control measures are appropriate and feasible for use in their laboratory.
Biorisk Management Approach

(1) Identify appropriate control measures for the **agent**:
   • Administrative, Operational, Engineering, and PPE.

(2) Identify appropriate control measures for your **laboratory**:
   a) Determine if suitable control measures currently exist in the laboratory.
   b) Identify additional control measures that the laboratory can implement based on fiscal resources and available infrastructure.
   c) Implement the control measures.
Biorisk management is an ongoing process in which:

• specific laboratory biorisk control measures are regularly monitored, and

• when warranted the control measures are corrected to ensure they are working as expected.
Biorisk communication is the interactive transmission and exchange of information and opinions throughout the risk analysis process about risk, risk-related factors and risk perceptions among risk managers, risk communicators, the general public, and other impacted parties.
Biorisk **communication** format and language is tailored to the intended audiences, including policy-makers, disease control authorities, animal care providers, and the public.

The information is provided in a clear and understandable manner, including:

— the identification of the biohazard (agent or toxin)
— the benefits to the stakeholder gained by the laboratory working with the biohazard
— information indicating that a biorisk analysis was performed and is documented
— information indicating that the laboratory has control measures in place to mitigate against accidental or intentional release of the biological agent or toxin.
Health standards

• *Terrestrial Animal Health Code, Aquatic Animal Health Code*

• *OIE Quality Standard & Guidelines for Veterinary Laboratories:*
  — Management Requirements, Technical Requirements

• *Manual of Diagnostic Tests for Aquatic Animals*

• *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
  — *Chapter 1.1.1* - Collection and Storage of Diagnostic Specimens
  — *Chapter 1.1.2* - Transport of Specimens of Animal Origin
  — *Chapter 1.1.3* and 1.1.3a
  — Individual Agent and Disease chapters

OIE Biosafety and Biosecurity Resources
http://www.oie.int/publications-and-documentation/general-information
OIE Reference Materials and Handbooks

- **Handbook on Import Risk Analysis for Animals and Animal Products**
  - Introduction and qualitative risk analysis (v.1)
  - Quantitative Risk Assessment (v.2)

- **OIE Biological Threat Reduction Strategy**

- **Atlas of Transboundary Animal Diseases**
OIE Periodicals

- *Scientific and Technical Review*

- *OIE Bulletin*

- *Disease Information* (available on the [WAHID](http://www.oie.int/publications-and-documentation/general-information) interface)

- *World Animal Health (Annual Global Disease Summary)*
• **Laboratory Biorisk Management Standard**

• European Committee for Standardization CEN Workshop Agreement CWA 15793(2011) – A *management systems approach to Laboratory Biosafety.*

• **Safe and Secure Biomaterials: Matching resources to reality. Chatham House** (2012)
  http://www.chathamhouse.org/events/view/182665

• **Guidelines for safe work practices in human and animal medical diagnostic laboratories** (2012)
  http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm
Current efforts by animal health and public health are focused on sharing approaches and terminology with the aim of reducing biological threats by strengthening, enhancing, and cross-linking existing health systems.
“A world that is safe and secure from the accidental or deliberate release of animal pathogens, including zoonoses.”