Introduction to Biorisk and the OIE Standard

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### OIE Specialist Commissions

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- Responsible for ensuring that the Code reflects current scientific information. |
| **Scientific Commission for Animal Diseases**    | - Assists in identifying the most appropriate strategies and measures for disease surveill., prevention, control.  
- Examines Members’ request regarding their official animal health status, for MCs that wish to be included on the OIE official list of countries or zones free from certain diseases. |
| **Aquatic Animal Health Standards Commission**   | - Compiles information on aquatic diseases and recommends appropriate prevention and control methods for these diseases.  
- Responsible for updating the *Aquatic Code and Manual*; and for proposing new standards for adoption by the World Assembly of Delegates. |
| **Biological Standards Commission**             | - Establishes/approves methods for:  
  - diagnostic of terrestrial animals diseases  
  - defining quality criteria of biological products (vaccines)  
- Oversees production and adoption of the Terrestrial *Manual*.  
- Advises the Director General in supervising the global network of OIE Reference Centers. |
Divided into 4 parts, presented in 2 volumes:

**Volume I**
- **Part 1** • General Standards - introductory chapters including horizontal chapters
- **Part 2** • OIE Listed Diseases and other diseases of importance

**Volume II**
- **Part 3** • Specific Recommendations
- **Part 4** • OIE Reference Experts and Disease index
OIE Terrestrial Manual

Content Part 1 General Standards

Horizontal chapters on

> Management of veterinary laboratories
> Collection, submission and storage of diagnostic specimens
> Transport of specimens of animal origin
> Biosafety and biosecurity: Standard for managing biological risk in the veterinary diagnostic laboratory and animal facilities
> Quality management in veterinary testing laboratories
> Principles and methods of validation of diagnostic assays for infectious diseases
> Standards for high throughput sequencing, bioinformatics and computational genomics
> Principles of veterinary vaccine production (include. diag. biologicals)
> Tests for sterility and freedom from contamination of biological materials intended for veterinary use
> Vaccine banks
INTRODUCTORY CHAPTERS OF MANUAL

Management of veterinary diagnostic laboratories (NB: Version adopted in May 2015)

Collection, submission and storage of diagnostic specimens (NB: Version adopted in May 2013)

Transport of specimens of animal origin (NB: Version adopted in May 2013)

Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (NB: Version adopted in May 2015)

Quality management in veterinary testing laboratories (NB: Version adopted in May 2017)

Principles and methods of validation of diagnostic assays for infectious diseases (NB: Version adopted in May 2013)

Standards for high throughput sequencing, bioinformatics and computational genomics (NB: Version adopted in May 2016)

Principles of veterinary vaccine production (NB: Version adopted in May 2015)

Tests for sterility and freedom from contamination of biological materials intended for veterinary use (NB: Version adopted in May 2017)

Vaccine banks (NB: Version adopted in May 2016)
Adopted in 2013

• Chapter 1.1.1 – Collection, Submission and Storage of Diagnostic Specimens (update of information, removed shipping information)

• Chapter 1.1.2 - Transport of Specimens of Animal Origin
  (new chapter: coordination with international regulations and requirements on packaging and shipping)

Adopted in 2014

• Chapter 1.1.3.a – Standard for Managing Biorisk in Veterinary Laboratories and Animal Facilities
  (inclusion of a biorisk analysis and management approach)
Conceptual Changes

Chapter 1.1.4. **Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities**

Provides a biorisk analysis and biorisk management approach:

— replaced “pathogen risk group” classification and assignment of specific agents to pre-designated containment levels;

— consolidated terminology and approaches consistent between animal health and public health for laboratory biosafety, biosecurity, biocontainment, and biorisk analysis.
Biosafety
The consistent application of safety measures to minimize or prevent exposure to the person handling a biological agent, laboratory and building occupants, the community and the environment.

Biosecurity
Maintaining a biological agent a secure way, either by physical or procedural means, so as to ensure it does not constitute a hazard to man or his environment.

Biorisk analysis
Biorisk analysis is the process of identifying and characterising health, safety, and security risks, followed by implementing, measuring the effectiveness of, and communicating the control measures used to reduce those risks to acceptable levels.
Historical biosafety levels and biorisk groups

Four biosafety levels:

- BSL1 = lowest; BSL4 = highest (precise definitions vary from country-to-country);
  - Designation defines the application of physical and procedural requirements, appropriate to each group.

Four biorisk groups (NIH):

- Risk Group 1 (RG1): agents are not associated with disease in healthy adults;
- Risk Group 2 (RG2): agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available;
- Risk Group 3 (RG3): agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available;
- Risk Group 4 (RG4): agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

BUT: there is always confusion when dealing with zoonotic pathogens

- May be designated in two different groups........also with different laws covering each!
- ............and what about genetically engineered agents....?
  Genetically modified organisms – use initial classification as the basis!

Risk-based approach

- Assessment of the work being undertaken as well as an assessment of the pathogen.
Reasons for revising the chapter

- The previous system, of applying categories, both to animal and zoonotic pathogens, was confusing;
- "A one size fits all approach": prescriptive requirements;
- Containment requirements based on endemicity instead of release potential;
- "Western" perspective assuming an abundance of energy, water, consumables, service and maintenance support;
- Without the required resources, safety systems can increase rather than a reduction in the risk;
- No alternatives for low resource settings that are endorsed at international level;
- Based on this risk assessment, a selection of requirements will be applied, proportionate to the risk.
A new chapter in the *Terrestrial Manual* was adopted as the current standard for member countries during the May 2015 General Session of the OIE:

**Chapter 1.1.4.:**

**Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities.**

- Chapter 1.1.1. “Management of Veterinary diagnostic laboratories” (Adopted May 2015)
- Chapter 1.1.3. “Transport of specimens of animal origin” (Adopted May 2013)
- Chapter 3.5. “Managing biorisk: examples of aligning risk management strategies with assessed biorisks” (Adopted May 2014)
A new chapter in the *Terrestrial Manual* was adopted as the current standard for member countries during the May 2015 General Session of the OIE:

**Chapter 1.1.4. Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities.**

Appendix 1.1.4.1 : Steps in Biological Risk Analyses
Appendix 1.1.4.2: Considerations used in evaluating and implementing biological risk control measures.
The new Chapter 1.1.4 provides:

1. Principles for managing biological risks based on risk assessment and steps to be followed in biological risk analysis;

2. Essential basic standards to be followed for all laboratory work;

3. Illustrative examples of risk assessments.
Chapter 1.1.4: Key functions of biological risk analysis

1. Biohazard identification
   - What can go wrong?

2. Biological risk assessment
   - How likely is the hazardous event to occur and how severe would be the harm?

3. Risk management
   - How can the risks be prevented or minimised to acceptable levels?

4. Risk communication
   - How was the risk identified, characterised and controlled?
Chapter 1.1.4: Key functions of biological risk analysis

1. Biohazard identification
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Risk Assessment

- Pathogenicity of material – disease incidence and severity
- Routes of transmission – parenteral, airborne or ingestion
- Agent stability – ease of decontamination
- Infectious Dose – LD50
- Concentration – infectious organisms/volume & working volume
- Gain of function
- Origin of material – wild type, exotic, primary cells
- Availability of effective prophylaxis
- Medical surveillance – exposure management
- Skill level of staff
Guideline 3.5. Managing Biorisks: Examples of aligning risk management strategies with assessed biorisks:

Provide working examples based on hypothetical scenarios of how the checklist and the risk assessment process can be used for specific infectious hazards to support the implementation of Chapter 1.1.4.

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/GUIDELINE_3.5_BIOL_AGENT_SPECIF_RA.pdf
Managing Biorisk: Anthrax / FMDV

Risk assessment: Human / animal risk – route of natural transmission
- Contact with bodily fluids/ carcases / infected animals
- Laboratory transmission - Necropsy / handling specimens

Risk Management (Admin): Communications plan / Accident reporting / H&S programme / assessment findings (Laboratory, economic, environmental, biosecurity)

Risk Management (Opps): SOPs / Response plan / Incident reporting

Risk Management (Engineering controls): Biocontainment / Equipment / Facility security

Risk Management (PPE): Dedicated laboratory clothing / Respiratory protection

Cutaneous anthrax
Principles of biocontainment: Laboratories

Primary containment - The cabinet or isolator

Secondary Containment - The building

The environment is protected

Personnel are protected
The building is primary containment.

The environment is protected.

Personnel are NOT protected.

The risk is therefore greater.

Principles of biocontainment: Animal facilities
• A risk-based approach
  • Not a zoonosis
  • Low risk
• If genotype or species not endemic
  • Risk of escape is the same but the consequences are greater
  • Up one or level
• Genetically modified agents
  • Generally move up one level
  • If pathogenicity likely greater – up two levels
Avian influenza in poultry

- A risk-based approach
  - Zoonosis
  - High risk
- Full PPE, airflow hoods, shower out
- Genetically modified agents
  - Generally move up one level
  - If pathogenicity likely greater – up two levels
Managing Biorisk: Risk communication, verification, corrective actions and continuous improvement

- Develop a communications message and identify responsible person(s) in the event of either (1) a laboratory accident and / or (2) deliberate release
- Periodic self-assessment;
- Review of SOPs;
- Reporting and documentation of biosafety and / or biosecurity incidents;
- Correct the problem and identify opportunities for improved laboratory practice and implementation of biorisk control measures.
The biological risk management approach is a mechanism to protect human and animal populations from inadvertent or intentional release of exposure to animal pathogens and provides guidance on practices used to minimise the risks of disease transmission and for possible release of biological materials from laboratories and animal facilities into the environment, in an evidence-based, transparent, economically viable and sustainable manner.
Thank you for your attention

Organisation mondiale
de la santé animale

World Organisation
for Animal Health

Organización Mundial
de Sanidad Animal