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Standards for Laboratory Accreditation

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Mission Statement

The purpose of the ABSA accreditation program is to accredit the biosafety management programs of U.S. based entities with high containment research laboratories relative to technical and operational competence compatible with applicable regulations, guidelines, and standards.

Vision Statement

The accreditation program shall promote and provide an opportunity for U.S. based entities conducting research in high containment laboratories to demonstrate a culture of responsibility and safety.

Introduction

This accrediting body will accredit entities that own/operate high containment laboratories through a formal process known as “accreditation. “ The entity’s biosafety management system will ensure that these containment laboratories/vivaria (laboratories hereafter) shall be designed, maintained and operated in such a manner that they ensure the highest attention to safeguards that will protect the worker, public health, agriculture and the environment. This accreditation is a voluntary process for each laboratory entity. All data and information about accredited entities will remain confidential.

Entities applying for accreditation must be in compliance with all applicable local, state, federal regulations, international standards and guidelines and current standards of the industry prior to applying for ABSA International

accreditation. Entities that are applying for accreditation should seek guidance from the CEN Workshop Agreement 15793 for management guidance. For detailed technical biosafety information and guidance, see Appendix B. High Containment Facilities are laboratories that are defined as Biosafety Level 3 (BSL-3) or all vivaria that are defined as Animal Biosafety Level 3 (ABSL-3), according to the guidelines set forth in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, See Appendix A).

Outside the scope of the accreditation program are non-research activities that take place in diagnostic and treatment (non-research) facilities such as hospitals, clinics, veterinary, and food diagnostic laboratories. Non-research activities in most licensed biomedical production facilities and mobile field analytical laboratories also lie outside the scope because they vary markedly from those of facilities engaged in high containment research. Such entities are already licensed or accredited by other organizations.

Terminology

Biosecurity

Recognizing that laboratory biosecurity is an integral part of biosafety, throughout this document the use of the term biosafety includes laboratory biosecurity (Appendix A).

Accreditation

Accreditation is confirmation that the entity has established, documented, implemented and maintained a risk management system that oversees the operation of a high containment laboratory, and that the design, maintenance and operational regulations, guidelines, and standards have been met.

Guidance

Each entity will be provided guidance through the Accreditation Board, including standards, assessment protocols and references (see Appendices A, B, and C) so that the entity may determine if they wish to participate in the voluntary accreditation program. Entities applying for accreditation can review the accreditation application before applying (see Appendix D). Each entity must designate an official of the entity as the point of contact for the accreditation process. This person may be the biosafety officer, select agent responsible official or may serve the entity in another capacity.

Goals

The goals of the Accreditation Program are:

- To promote the safe and responsible conduct of science within entities utilizing high containment research laboratories
- To foster quality biosafety programs by providing a mechanism for objectively accrediting high containment laboratories through an independent, non-biased review process
- To continuously emphasize the importance of maintaining a standard of excellence in biosafety and laboratory biosecurity in ~~high~~ high-containment laboratories
- To assist entities to meet or exceed all applicable U.S. regulations, guidelines, and standards pertaining to biosafety

• To promote competency and adequate training of laboratory staff and biosafety professionals
• To encourage appropriate construction and maintenance of facilities suitable and adequate to provide high containment

Classification

There will be three outcomes of the accreditation process: accredited, provisionally accredited, not accredited.

1 An accredited entity is one that meets all of the requirements of the accreditation program.

2. A provisionally accredited entity is one that does not fully meet all of the requirements but shows intent to do so. A provisionally accredited laboratory shall be given a specified period of time to correct identified deficiencies.

3. An entity is not accredited if it fails to meet the requirements of the accrediting body. An entity may re-apply for accreditation after the deficiencies have been addressed or corrected.

Accreditation Management Structure

Accreditation Board

The Accreditation Board will be responsible for the oversight of the Accreditation Program. It is responsible for managing the budget and the overall direction of the Accreditation Program. The Board will make the final decisions on strategy, standards, and policy. The Board will make the final decision on any appeals by entities denied accreditation. The Board will oversee and coordinate the efforts of the committees within the Accreditation Program.

Standards Committee

The Standards Committee will develop and implement effective methods for identifying, reviewing and adopting regulations and other pertinent guidelines or best practices that impact the standards referenced or used by the ABSA Laboratory Accreditation Board in its laboratory accreditation process. To develop and implement effective methods for identifying, reviewing, and updating checklists used in laboratory accreditation process and communicating that information to affected Committees.

Accreditation Committee

The Accreditation Committee will determine whether an entity can be accredited based on the complete and final inspectors' report.

Inspectors Committee

The Inspectors Committee will select and train inspectors for the Laboratory Accreditation

program, conduct entity inspections, and to provide a completed inspection report to the Accreditation Committee.

The committee shall ensure that inspectors are trained, up to date on the standards, and are objective when performing assessments. The Inspectors Committee will review and evaluate any potential conflict of interest or competitor issues when assigning inspection teams. The Inspectors Committee shall have a system to evaluate inspectors to improve the quality and consistency of the inspection process.

Inspector Requirements:

All inspectors must be credentialed biosafety professionals or have equivalent experience, and are selected by the Inspectors Committee. All inspectors must be trained on the accreditation process and assessment protocols and must have the technical knowledge to perform assessments. The inspectors assigned to an entity inspection must disclose any conflict of interest [financial or other association] with the entity.

Rights and Responsibilities of Accredited Entities

Accredited entities are required to submit annual self-assessment reports using the accreditation assessment protocols s in years that they are not being visited by inspectors. Entities are encouraged to offer suggestions or comments about the accreditation process and site visits. Upon successful completion of the process the entity will receive a certificate of accreditation. Entities must report any significant problems, violations of applicable regulations, guidelines, standards, or any significant research related accidents and illnesses.

Timeline for Accreditation Process

All entities seeking laboratory accreditation will submit an application and required documentation (see Appendix D). Incomplete applications will result in significant delay.
The Accreditation Committee will review applications and determine suitability for inspection.
This inspection will be conducted by a team appointed by the accreditation body.
The following timeline is to be used as a guideline for the average amount of time to complete the process.

Accreditation process timeline	Time allotted	Estimated days after application receipt
Application received and inspectors assigned	1-20 days	1-20 days
Document review and inspection	10-30 days	20-50 days
Assessment results submitted by inspectors	1-20 days	50-70 days
Assessment results processed	5-15 days	70-80 days
Decision by Accreditation Committee	1-10 days	80-90 days
Entity notification	1-5 days	90-95 days

Provisional Accreditation

When deficiencies are noted, a corrective action plan must be submitted within 30 calendar days of the inspection report. Failure to fully respond to deficiencies found during the entity's

inspection may result in further delay or termination of the application. Extensions may be granted on a case-by-case basis.

Entities Not Granted Accreditation

Entities that are not granted accreditation will have the opportunity to formally appeal through an appeals process.

Appeals Process:

Any denial of accreditation may be appealable by the applicant one time per application as follows:

1. If an entity receives a denial of accreditation from the Accreditation Committee, the entity may submit written notice to the Committee for reconsideration. If the applicant is not satisfied with the Committee's response, they may submit written notice to the Accreditation Board within 10 working days to request an appeal if the appeal is based on a factual and or procedural issue with regard to the review and denial. No other issues or matters shall be so appealable.
2. The Accreditation Board will be provided with the necessary information to conduct an appeal review. The review will take place during an Accreditation Board meeting with a quorum of Accreditation Board members present. The Accreditation Board shall only consider the factual and or procedural issues stated within the written notice.
3. If the Accreditation Board confirms the denial, the decision is final and no other appeal process shall be available to the applicant. If the denial is not confirmed, the Accreditation Board shall remit the matter to the Accreditation Committee with recommendations on addressing any factual or procedural issues, along with instructions to conduct a re-review. If the Accreditation Committee again denies the applicant, the decision is final and no further appeal is available.

Amendments

Within the three year accreditation period, if significant changes occur (e.g., new or renovated facilities, new processes, large scale, large animals) an amendment must be submitted to the Accreditation Committee. The committee will review the amendment and determine if an inspection is needed.

Accreditation Maintenance

To maintain accreditation, an entity must submit a renewal application three years after the accreditation approval date. Renewal applications must be submitted no less than 120 days prior to the expiration of the accreditation.

Biosafety Standards for the High Containment Research Laboratory

The following are core elements of a comprehensive biosafety management program:

A. Institutional Policy

The entity has established a written policy addressing management commitment to occupational health and safety.

The policy shall commit to:

1. Protecting staff, contractors, visitors, community and the environment from biological agents and toxins stored or handled within the facility
2. Reducing the risk of unintentional release of, or exposure to biological agents and toxins
3. Reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials
4. Complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard
5. Ensuring that the need for effective biosafety management shall take precedence over all non "health and safety" operational requirements
6. Effectively informing all employees and relevant third parties and communicating individual obligations with regard to biosafety to those groups
7. Continually improving the biosafety management system

B. Management/Governance

A clear reporting structure shall be documented for the entity. Top management ensures that roles, responsibilities, and authorities related to biosafety management are defined, documented, and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins. Management shall document a clear reporting structure, responsibility, and mechanism to report unsafe conditions and implementation of corrective action.

C. Risk Assessment

Each entity must have a documented risk assessment process. Adequacy of risk assessments will be evaluated as part of the assessment process. The risk assessment process can take many forms e.g., biosafety officer review, Institutional Biosafety Committee (IBC) or related committee applications, IBC meeting minutes, or other related evidence that documents hazards of proposed agent, facility design, and laboratory equipment.

D. Biosafety Program Management

Entities must have a written biosafety program. The program elements shall include but not be limited to:

- Employee competencies and training
- Personal protective equipment
- Safe work practices
- Engineering controls
- Safety plans and other documents pertinent to the safe use of the agent(s)
- Medical surveillance program
- Animal care and handling, if appropriate
- Agent inventory – a list of agents located at the entity

- Disinfection, decontamination, and sterilization
- Waste management
- Evidence of corrective actions from incident investigations

1. Quality Assurance

Entities shall demonstrate evidence of an assurance program to verify that policies and standard operating procedures are being followed. The program should also document continued risk assessments, standard operating procedure review, work practices, document control and other issues related to the continued safe use of the agent(s) and continued improvement of the program.

2. Corrective and preventive action

The entity shall have a written policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the biosafety or biosecurity systems have been identified. The policy and procedures shall ensure:
a) Designation of authorities responsible for implementation of corrective action(s)
b) Implementation of investigative procedures to determine the root cause(s) of the problem and analyze for trends
c) Implementation of corrective action(s)
d) Documentation of required changes to operational procedures and subsequent retraining
e) Assurance that corrective action(s) are monitored for effectiveness

3. Biosafety Program Review

Periodic review of biosafety programs shall be conducted by all entities seeking accreditation. This review shall consist of self-inspections and audits conducted at planned intervals, at least annually. The results of this program review [known as the annual self-evaluation] shall be submitted to the Accreditation Board.

E. Facility Design and Maintenance

Each laboratory must be designed, operated, and maintained to meet the principles of biocontainment as described in the applicable laboratory regulations, guidelines, and standards (Appendix B). Each entity must demonstrate that all necessary infrastructure safety and security requirements procedures are in place.

Each entity must demonstrate that all laboratories are designed to minimize release of biological materials.

Each entity must demonstrate a clear process for sustained maintenance. Each entity must have a designated person(s) responsible for maintenance of the facility that will serve as a point of contact during the site visit process for facility-related questions. Floor plans, commissioning documents, and periodic validation and verification documents shall be made available to facilitate site inspector understanding of the facility design and to verify the facility is operating according to design intent.

F. Equipment

Appropriate safety and laboratory equipment, as determined in the risk assessment, shall be made available to laboratory staff. A list of all safety equipment used must be provided as part of the application. Equipment maintenance records must be made available for review during the inspection.

G. Personal Protective Clothing and Equipment

Personal protective clothing and equipment (PPE) shall be selected by a risk assessment and used only as a complement to engineering controls. PPE includes but is not limited to: gowns, aprons, gloves, safety glasses, goggles, respiratory protection, and hearing protection. PPE must be available in a variety of sizes to fit all employees. The entity shall provide the rationale used for the selection of PPE. Appropriate training for use of all PPE must be provided and documented.

H. Occupational Health and Medical Surveillance

A documented medical surveillance program must be in place for laboratory personnel. This program shall include surveillance, vaccination, animal allergy prevention, and serum banking, as appropriate. The entity must provide occupational health care appropriate for the agents in use for all personnel working in or supporting the laboratories.

I. Incident Reporting

Each entity shall have a clearly defined process for internal reporting of all accidents, incidents, exposures, illnesses, and near misses involving hazardous microorganisms or their toxins. This process will be reviewed during the inspection.

J. Training

Personnel working in containment laboratories must be qualified and appropriately trained to work in these laboratories. Documentation of staff technical competency and training records must be available to site inspectors during the visit.

Each entity must have documentation of the training appropriate to the agents, laboratory equipment and facility. Training should include special microbiological practices the agents in use. A mechanism is in place to document the competency of individuals working in high containment laboratories.

K. Security

Documentation of laboratory biosecurity systems as appropriate based upon the risk assessment shall be in place, and available for review during the inspection. These systems include but are not limited to physical security of the site, building, and laboratory, and information systems security. Evidence of previously completed security, vulnerability, and threat assessments for the site and agents in use shall be available to inspectors when applicable.

L. Agent Handling

1. Inventory of Biological Agents: Each entity shall have a functional system in place to account for the agents in use and in storage in their facilities. Documentation of the inventory must be available to inspectors.

2. Storage and Physical Security: Access to biological agents and toxins must be restricted to appropriately trained laboratory personnel and support staff. Effective physical security measures must be implemented based on risk.

3. Agent Transport: Biological agents or toxins being transported by air, land, or sea must be packaged and labeled according to all applicable dangerous goods regulations. All personnel involved in packaging, labeling and shipping such materials must be properly trained. Transport of materials within an entity's property must also be appropriately packaged and transported to ensure that there is no exposure to personnel or release of materials.

M. Disinfection, Decontamination, Sterilization, and Inactivation

1. The entity shall establish and maintain procedures to ensure that appropriate methods for disinfection, sterilization, and decontamination are chosen, validated, and implemented effectively. Efficacy of disinfection, decontamination, and sterilization for a particular agent or group of agents should be evaluated by data obtained from scientific literature. If no such data exist, efficacy must be determined prior to use. Autoclaving must be validated using biological indicators on a regular basis as appropriate. Frequency is often specified by state or local regulations. Area decontamination using gases or vapors must be validated using appropriate biological or chemical indicators. The entity must have procedures for validation of autoclaving or area decontamination.

2. Agent inactivation for use at lower containment level when transferring an agent from high containment to a lower containment level, the entity must demonstrate inactivation of the agent leaving the containment laboratory. Means of inactivation include physical or chemical methods. Inactivation must be confirmed before transferring to a lower containment level.

N. Emergency Response and Disaster Preparedness

Entities shall have a documented emergency response plan and evidence that the plan has been tested on a regular basis. Testing can include table-top exercises, live drill exercises, or actual emergency responses.

Appendices

Appendix A Glossary

Accreditation: Accreditation is confirmation that the entity has established, documented, implemented and maintained a risk management system that oversees the operation of a high containment laboratory, [hereafter known as containment laboratory (ies)] and that the design, maintenance and operation standards have been met.

Animal Biological (Biosafety) Safety Level (BSL): There are four animal biosafety levels and each consists of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. In addition, there is an additional level called Biosafety Level Three agriculture for uncontained "loosely housed" animals. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents and the laboratory function or activity. The animal biosafety level classification results from a combination of engineering controls, management policies, work practices and procedures, and, occasionally, medical interventions. Risk groups (RG, see description below) relate to but do not "equate" to the animal biosafety level (BSL) of entities designed to work with organisms in each RG**.**

Biocontainment: A term used differently in facilities for the study of human pathogens versus those used for the study of agricultural pathogens.
1. In agricultural facilities, the definition for "biocontainment" resembles that for "biosafety," i.e., the safety practices and procedures used to prevent unintended infection of plants or animals or the release of high-consequence pathogenic agents into the environment. For all high and maximum containment facilities, environment refers to air, soil, or water. *2.* "Biocontainment" also refers to the physical containment barriers in a facility such as contained dressing and shower rooms, sealed service penetrations, specialized doors, entry and exit avenues to prevent cross-contamination, specialized air handling systems for contamination control, personal protective equipment, biosafety cabinets, etc.

Biohazard: a contraction of the words "biological" and "hazard." A biohazard is an infectious agent or hazardous biological agent or part thereof regardless of origin (naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance) that presents a real or potential risk to humans, animals, or plants, either directly through infection, or indirectly through the disruption of the environment. Biohazards include certain types of recombinant DNA; organisms and viruses that cause infectious in humans, animals, or plants (*e.g.*, parasites, viruses, bacteria, fungi, prions, rickettsia); and other biologically active agents (*e.g.*, toxins, allergens, venoms) that may cause disease in living organisms, or adversely affect the environment, community, commerce, or trade agreements.

Biological agent: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. [from the CDC Select Agents and Toxins Final Rule. 72 CFR § 73.1 Definitions]

Biological safety or biosafety: The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated. The objective of containment is to confine biohazards and to reduce the potential exposure of the laboratory worker, persons outside of the laboratory, and the

environment to potentially infectious agents. It can be accomplished through the following means:

Primary Containment: Protection of personnel and the immediate laboratory environment through good microbiological technique (laboratory practice) and the use of appropriate safety equipment.

Secondary Containment: Protection of the environment external to the laboratory from exposure to infectious materials through a combination of facility design and operational practices. Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment.

Biological (Biosafety) Safety Level (BSL): There are four biosafety levels and each consists of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. The biosafety level classification results from a combination of engineering controls, management policies, work practices and procedures, and, occasionally, medical interventions. Risk groups (RG, see description below) relate to but do not "equate" to the biosafety level (BSL) of laboratories designed to work with organisms in each RG**.**

Dangerous Goods: Articles or substances which are capable of posing a risk to health, safety, property or the environment, and which are shown or classified in the IATA Dangerous Goods regulations.

Decontamination: Disinfection or sterilization of infected articles to make them suitable for use.

Disinfection: Selective elimination of certain undesirable microorganisms in order to prevent their transmission.

Engineering Controls: Engineering controls eliminate or reduce exposure to a biological, chemical or physical hazard through the use or substitution of engineered machinery or equipment. Examples include self-capping syringe needles, exhaust systems, ventilation systems such as a biosafety cabinet, sound-dampening material to reduce noise levels, safety interlocks, and radiation shielding.

Entity: Institutions that own/operate high containment laboratories that are seeking accreditation.

High Containment Laboratory: All facilities that meet or exceed the criteria for BSL-3 according to descriptions in the BMBL.

Laboratory Biosecurity: Laboratory Biosecurity is the system to prevent unauthorized entry to laboratory areas and access to dangerous pathogens. Laboratory Biosecurity is similar to biosafety but the focus is on preventing the unauthorized removal of biological agents from the laboratory. This prevention includes layers of barriers to the physical location of the agents, methods to indicate and document access or egress of people entering the area, and tracking

the location of the agents. Personnel aspects include training and evaluation of employees, restriction and documentation of access to entities, and restriction of non-laboratory staff to the laboratory areas.

Laboratory Enhancements: Situations may arise for which enhancements to laboratory practices and equipment are required. An example would be when a BSL-3 laboratory performs diagnostic testing on specimens from patients with hemorrhagic fevers thought to be due to dengue or yellow fever viruses. When the origin of these specimens is Africa, the Middle East, or South America, such specimens might contain etiologic agents, such as arenaviruses, filoviruses, or other viruses that are usually manipulated in a BSL-4 laboratory. Examples of enhancements to BSL-3 laboratories might include 1) enhanced respiratory protection of personnel against aerosols, 2) HEPA filtration of dedicated exhaust air from the laboratory, and 3) a personal body shower upon exit from the laboratory. Each enhancement must be described when using the term "enhanced."

Maximum Containment Laboratory: All facilities that meet or exceed the criteria for BSL-4 according to descriptions in the BMBL.
Research: Activities that occur in high containment facilities and may include studies of hazardous microorganisms (that infect humans and/or animals), toxins, and agricultural pathogens including foreign and emerging agricultural agents that can infect livestock and crops.

Risk assessment: An action or a series of actions taken to recognize or identify hazards and to measure the risk or probability that something will happen because of that hazard. In evaluating risk, the severity of the consequences is also taken into account. The information identified through risk assessment is used to guide the selection of appropriate microbiological practices, safety equipment, and facility safeguards that, when used properly, can prevent worker exposures and releases of agent to the outside environment. , Limiting worker exposure reduces the incidence of LAIs and reducing the possibility for a release outside of biocontainment protects public and animal health, agriculture and the environment

Risk Group: The Risk Group classification system was developed to provide a means to select appropriate safety measures before beginning any work with an agent(s) (natural or recombinant). Risk groups (RG) relate to but do not "equate" to the biosafety level (BSL) of laboratories designed to work with organisms in each RG**.** Risk groups basically partition an organism based on its ability to cause disease. It is emphasized that the Risk Group classification of an agent is not absolute. For human disease, the Risk Group classification is based on the following criteria:

- Ability of the agent to cause disease in healthy humans
- General severity of the disease
- Ability of the agent to cause an epidemic
- Availability of effective antidotes and suitable preventive measures (prophylaxis)

Other criteria should be considered for classification of an agent into a Risk Group such as:

- Route of infection
- Infectivity
- Dose necessary to initiate an infection (infectious dose)
- Ability of an agent to survive

On a case-by-case situation based on a risk assessment, the following should be considered:

- Immune status of those working with the agent
- Immune status of the population not working with the agent

Self-Evaluation: An audit that is completed by an entity, using inspection checklists, to review the management system and biosafety program elements.

Sterilization: 1) Complete destruction of living microorganisms; 2) A carefully monitored process that will assure the probability of an item being contaminated by a microbe to be equal to or less than one in a million

Zoonotic agent: An agent that can infect both humans and animals.

Zoonotic diseases: Diseases caused by infectious agents that can be transmitted between (or are shared by) animals and humans.

Appendix B: References for High Containment Entities

- Title 7 Code of Federal Regulations (CFR) Part 171 and Title 9 C.F.R. part 131 APHIS Final Rule on Select Agents
- 15 C.F.R. parts 738, 742, 745, and 774 (2006) Implementation of Unilateral Chemical/Biological Controls on Certain Biological Agents and Toxins
- 29 C.F.R part 1910.1200 Hazard Communication Standard
- 29 C.F.R. part 1910.1201 Retention of DOT Markings, Placards and Labels
- 29 C.F.R. part 1910.1030 Occupational Exposure to Bloodborne Pathogens
- 29 C.F.R. part 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories
- 42 C.F.R. part 72 Interstate Shipment of Etiologic Agents
- 42 CFR parts 72 and 73 Possession, Use, and Transfer of Select
- Agents and Toxins; Final Rule
- 49 C.F.R. parts 171-178 (2006) Transportation of Hazardous Materials
- Title 21 CFR Part 58, *Good Laboratory Practice for Nonclinical Laboratory Studies*. 2008.
- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH guidelines), March 2013. Available at: http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.html*Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition. 2007. Available at: http://www.cdc.gov/biosafety/publications/bmbl5/
- *Guide for the Care and Use of Laboratory Animals. 1996.* Institute of Laboratory Animal Resources Commission on Life Sciences, National Research Council, National Academy Press Washington, D.C. Available at: http://www.nap.edu/openbook.php?record_id=5140
- *Laboratory Biosafety Guidelines Available at: http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index-eng.php*
- *International Air Transport Association Dangerous Goods Regulations (most current edition)*

- *Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents*. 2002. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5119a1.htm
- *NIH Grants Policy Statement*. 2003. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD. Available at http://grants1.nih.gov/grants/policy/nihgps_2003/nihgps_2003.pdf
- *Laboratory Biosafety Manual*. 2004. Third edition, World Health Organization, Geneva. Available at: CEN (European Committee for Standardization) Workshop Agreement (CWA) 15793 - *Laboratory biorisk management standard*. 2008. Available at: ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf.