Overview of Federal Regulations, Guidelines and Policies Governing Biosafety and Biocontainment in High Containment Laboratories

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Presentation to the Biocontainment Work Group
Department of Health and Mental Hygiene
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15 November 2012

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AAAS
ADVANCING SCIENCE, SERVING SOCIETY

Outline

- The history of the issue with the Federal government
  - Government Accountability Office
  - Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (2009)*
- What the Trans-Federal Task Force determined
  - Framework for existing Federal oversight
  - Role of state and local oversight
  - Recommendation1.2: Develop a Federal Registry
- Existing Federal oversight
  - Statutes, Regulations, Guidelines and Policies
- Industry Best Practices and an International Model

Sen. Joseph Lieberman (D-CT)
Sen. Barbara Collins (R-ME)

How many BSL-3 and BSL-4 labs are in the US?

Do they have sufficient Federal biosafety oversight?

Are they secure?

Senate Committee on Homeland Security & Governmental Affairs

Government Accountability Office

2007 GAO report:

"no single Federal agency has the mission and, therefore, is accountable for tracking the number of all BSL-3 and BSL-4 labs within the United States…."

"no Federal agency is responsible for determining the risk associated with expanding the number of high and maximum containment laboratories."

2008 Commission on Weapons of Mass Destruction report:

"…consider centralizing the regulatory functions for biosafety and biosecurity by developing a new oversight mechanism for high-containment laboratories…."

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

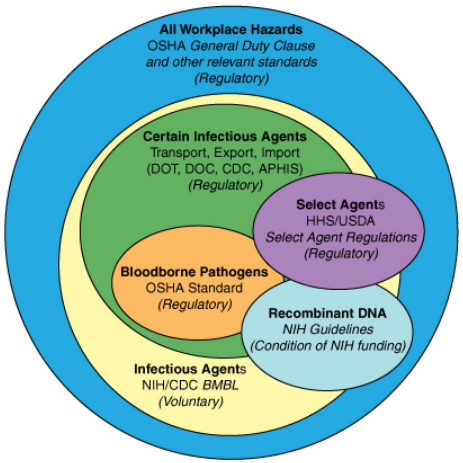
2007: Chaired by HHS and USDA

Charge: evaluate existing Federal oversight of high (HCL) and maximum (MCL) containment laboratories, and make recommendations for enhancing Federal oversight *without hindering research*.

2009: Identified16 recommendations to enhance Federal oversight, including a recommendation to establish a Federal registry of all U.S. HCLs (2.2)

The Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (July 2009)
http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx.

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight



Existing HCL Oversight

"Multiple, complementary, and sometimes overlapping biosafety and biocontainment oversight requirements exist at [these] levels":

- ✓ Federal
- ✓ State
- ✓ Municipal
- ✓ Institutional

Layered and deliberately redundant approach to lower risk from working with hazardous biological agents

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Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

"Develop a registry of all high and maximum containment research facilities in the United States"

Recommendation 1.2:

Issue: no USG mechanism to identify and track all HCLs in the U.S.

- ✓ Identification/tracking/accounting
- ✓ Capacity assessments
- ✓ Oversight quality assurance
- ✓ Information sharing

Short and long term steps to explore mechanisms to address this gap in biosafety and biocontainment oversight.

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HCL or High Containment Lab
Biosafety Level 3 Laboratory (Minimal)

Definitions

Engineering controls:
- ✓ Secure access via anteroom
- ✓ Two interlocking doors
- ✓ Sealed penetrations
- ✓ Hands free sink at lab exit
- ✓ Ducted, negative airflow into lab
- ✓ Specialized exhaust (e.g. HEPA)

Administrative controls:
- ✓ Occ Health program
- ✓ Initial and, thereafter, annual certification/validation
- ✓ Personnel training/proficiency

Work Practices controls:
- ✓ Enhanced PPE
- ✓ Open manipulations in BSC or other 1° containment
- ✓ Decon on site

Image taken from the WHO Biosafety Manual, 3rd Ed. 2004
CDC/NIH. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. 2007

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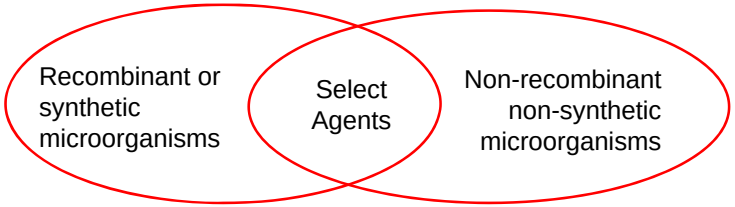
Definitions

Some Infectious Microorganisms That May Be Manipulated Using BSL3 principles, practices and facilities*

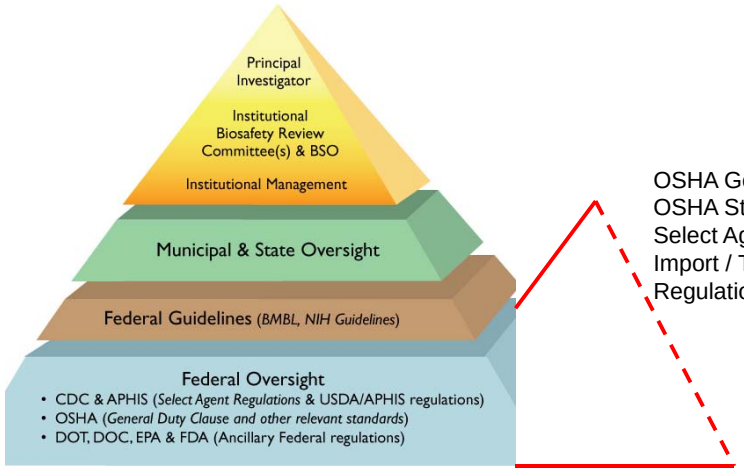


Select Agents:
Risk Group 2: *Clostridium botulinum*, *Bacillus anthracis*
Risk Group 3: *Burkholderia mallei, pseudo*, Monkeypox Virus, SARS-CoV, HPAI aH5N1

Non Select Agents:
Risk Group 2: *Chlamydophila psittaci, C. trachomatis*
Risk Group 3: *Mycobacterium tuberculosis*; 1957 non/com hH2N2, JEV, HIV, WNV
Risk Group 4: Herpes B virus (simian)

* Determination of biosafety levels are based on biological risk assessments. Refer to *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (CDC/NIH, 2007) for a discussion of the biological risk assessment process.
Risk Groups: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. March 2013

Federal Regulations



OSHA General Duty
OSHA Standards
Select Agent Regulations
Import / Transportation Regulations

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http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx.

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
Laboratory Safety Standards

Exposure Control Plan:

- ✓ Exposure determination
- ✓ Procedures for evaluating incidents
- ✓ Implementation of standard and risk mitigation SOPs

Personnel Training:

- ✓ All occupational settings that are covered by OSH Act.
- ✓ All employees for whom the standard is relevant
- ✓ Includes all U.S. HCLs

Record Keeping:

- ✓ Hazard Communications
- ✓ Training records
- ✓ Incident records
- ✓ OSHA 300 Log

29CFR1910

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
General Duty Clause

"furnish to each of [its] employees employment and a place of employment which are **free from recognized hazards** that are causing or likely to cause death or serious physical harm to [its] employees."

Purpose:

- ✓ This provision allows OSHA to enforce workplace safety even when specific hazards are not covered in an existing standard.

Scope:

- ✓ All occupational settings that are covered by OSH Act.
- ✓ Includes all U.S. HCLs.

Responsibilities:

- ✓ Identify and mitigate serious hazards based on national consensus standards and industry best practices (CDC, NIH NIOSH, ANSI).
- ✓ For HCLs: administrative, work practice, and engineering controls.

29 U.S.C. 654(a)(1), Section 5(a)(1)

STATUTE
OSH Act, 1970
NSP Act, 2001

Occupational Safety and Health Administration
Bloodborne Pathogens Standard

eliminate or minimize employee exposure to human blood or other potentially infectious materials.

Purpose:

- ✓ Protects workers from pathogenic microorganisms that are present in human blood and can cause disease in humans, including HBV and HIV.

Scope:

- ✓ All employees with "reasonably anticipated" exposure to human blood and body fluids
- ✓ Includes all U.S. HCLs in which applicable work is performed

Responsibilities:

- ✓ Identify and mitigate hazards, including needlestick hazards
- ✓ Write/implement ECP
- ✓ Train employees
- ✓ Offer HBV vaccine
- ✓ Keep records

29CFR1910.1030

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
Personal Protective Equipment Standards

"protective equipment, including personal protective equipment for **eyes**, **face**, **head**, and **extremities**, **protective clothing**, **respiratory devices**, and **protective shields and barriers**, shall be provided, used, … wherever it is necessary by reason of hazards … capable of causing injury or impairment..."

Respiratory Protection:

- ✓ Full or partial face respiratory protection to prevent transmission of aerosols through filter media.
- ✓ Medical evaluation
- ✓ Annual fit test
- ✓ N-95 respirators, PAPRs

Eye and Face Protection:

- ✓ Eye or face shields to prevent injury from hazards: liquid chemicals, acids or caustic liquids, gases or vapors
- ✓ Mucous membranes
- ✓ Safety glasses, goggles, face shields

Hand Protection:

- ✓ Measures to prevent absorption of harmful substances; … punctures; chemical burns; thermal burns
- ✓ Handwashing facilities
- ✓ Soap / paper towels
- ✓ Gloves

29CFR1910.132-134/138

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
Additional Relevant Standards

Provisions in the following standards also help eliminate or minimize exposure to biological agents and toxins:

Occupational Exposure to Hazardous Chemicals in Laboratories (Laboratory Standard)
29 CFR 1910.1450

Hazardous Waste Operations and Emergency Response (HAZWOPER)
29 CFR 1910.120

Sanitation 29 CFR 1910.141

Medical Services and First Aid 29 CFR 1910.151

Access to Employee Exposure and Medical Records 29 CFR 1910.1020

Hazard Communication 29 CFR 1910.1200

Retention of DOT Markings, Placards and Labels 29 CFR 1910.1201

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
Proposed Standard: Reducing Occupational Exposure to LAIs

Rule Making Process → OSHA must demonstrate that the standard:

1. substantially reduces a significant risk of material impairment or harm
2. employs the most cost-effective means of achieving its protective goal

Purpose:

- ✓ If enacted, would cover contact transmissions not covered by the BBP Standard (e.g. MRSA)

Scope:

- ✓ Patient support
- ✓ Infectious agent transport
- ✓ Work in laboratories
- ✓ May include HCLs

Responsibilities:

- ✓ Worker infection control plan
- ✓ Occ Health Program
- ✓ Hazard Communications
- ✓ Record Keeping

http://www.regulations.gov/#!documentDetail;D=OSHA-2010-0003-0236

STATUTE
OSH Act, 1970

Occupational Safety and Health Administration
General Duty Clause and Lab Safety Standards

Infectious Agent	Clinical / Diagnostic	Federal Intramural	Academic/Private Research/R&D NIH Funded	Private R&D no NIH $
Mycobacterium Tuberculosis w/GFP Reporter	✓	✓	✓	✓
Bacillus Anthracis w/GFP reporter	✓	✓	✓	✓
Synthetically derived hH2N2 n/contemporary wildtype	✓	✓	✓	✓

29 U.S.C. 654(a)(1), Section 5(a)(1) and 29 CFR 1910

Occupational Safety and Health Administration
HCL Performance Record

Standard Industrial Classification:

- ✓ HCLs and MCLs are either classified under the broad **SIC 8731** category for "commercial physical and biological research" or **SIC 8733** for non-commercial organizations (e.g. academic institutions).

Inspections:

- ✓ OSHA conducts facility inspections, either as an unplanned activity or in the context of the National Emphasis Program (NEP). HCLS are not specifically targeted in the NEP.

Record Keeping Regulations:

- ✓ HCLs are partially exempt from OSHA record keeping regulations. Outside of a fatality or catastrophe, HCLs are not required to report injuries and illnesses unless specifically requested by OSHA or BLS.

Sample Survey Results
Scientific Research and Development Injury and Illness Data
US Department of Labor, Bureau of Labor Statistics (2006)

Number and Rate of Occupational Injuries and Illnesses for All Private Industry and Private Scientific R&D Facilities, 2006

Characteristics	All Private Industry		Scientific Research and Development Facilities*	
	Number (in thousands)	Rate	Number (in thousands)	Rate
Injuries and Illnesses				
Total cases	4085.40	4.4	8.1	1.4

- ✓ Overall injury and illness rates for **NAICS Code 5417** is well below the national average
- ✓ DART rate: 2.3 is the national average and 0.6 is the **NAICS Code 5417** average

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http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx.

A Review of Biocontainment Lapses and Laboratory-acquired Infections: Intramural NIAID Incidents from 1982-2003

Table B.3-1 — Personnel Hours Worked and Outcomes of Accidental Exposures to Infectious Agents: Intramural NIAID 1982–2003

Hours at Risk			
	Bench	Animal	Total
BSL-3	553,000	81,500	634,500
BSL-2/3 P[a]	2,235,500	360,200	2,555,200
Total	2,788,500	441,700	3,189,700

Outcomes of Accidental Exposures			
	Clinical Infections	Silent Infections	Other Exposures, No Infections
BSL-3	1	2	9
BSL-2/3 P[a]	0	2	15
Total	1	4	24

- ✓ one clinical infection without secondary consequences
- ✓ four silent infections in more than 3 million hours
- ✓ Includes continuous exposure of personnel to HIV+ HBB fluids. One case required prophylaxis; no infection occurred.

DHS Environmental Impact Statement Process for the National Bio and Agro-Defense Facility, Appendix B. 2009.
http://www.dhs.gov/xlibrary/assets/nbaf_feis_appendix_b.pdf

STATUTE
Bioterrorism Act, 2002

HHS and USDA/APHIS
Select Agent Regulations

Outline the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed … have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

Adherence to technical guidance is mandated for informing the Biosafety Plan:

- ✓ BMBL
- ✓ OSHA Standards
- ✓ NIH Guidelines

Scope:

- ✓ All occupational settings of entities that are registered with the National Select Agent Program.
- ✓ Includes all HCLs located in SAP registered entities.

Registered entity:

- ✓ Can be institution (assigns an RO) or person (is the RO)
- ✓ Security Risk Assessment / Personnel Reliability
- ✓ Biosafety, Security, and Incident Response Plans

42 CFR 73, 7 CFR 331, 9 CFR 121
Public Health Security and Bioterrorism Preparedness and Response Act, 2002

STATUTE
Bioterrorism Act, 2002

HHS and USDA/APHIS
Select Agent Regulations

Outline the "requirements for **possession**, **use**, and **transfer** of select agents and toxins. The biological agents and toxins (BSAT) listed … have the potential to pose a severe threat to public health and safety, to animal health, or to animal products".

Consideration of technical guidance is mandated for informing the Biosafety Plan:

- ✓ BMBL
- ✓ OSHA Standards
- ✓ NIH Guidelines

Scope:

- ✓ All occupational settings of entities that are registered with the National Select Agent Program.
- ✓ Includes all HCLs located in SAP registered entities.

Registered entity:

- ✓ Training
- ✓ Transfers
- ✓ Theft, Loss, and Release
- ✓ Restricted Experiments
  - ✓ AM resistance
  - ✓ Toxins (LD_{50} <100ng/kg)

42 CFR 73, 7 CFR 331, 9 CFR 121
Public Health Security and Bioterrorism Preparedness and Response Act, 2002

STATUTE
Bioterrorism
Act, 2002

HHS and USDA/APHIS
Select Agent Regulations
What's New

Tier 1 Agents:

- ✓ BSAT that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence

Ebola virus, Marburg virus, Variola major virus, Variola minor virus, *Francisella tularensis*, *Yersinia pestis*, Botulinum neurotoxin and botox producing *Clostridia*, *Bacillus anthracis*, *Burkholderia mallei*, *Burkholderia pseudomallei*

Registered entity:

- ✓ Ongoing personnel reliability program for those with access to Tier 1 Agents
- ✓ New physical security requirements (Tier 1)

New Additions to BSAT List:
- ✓ SARS-associated CoV (BSL3)
- ✓ Chapare Virus
- ✓ Lujo Virus

42 CFR 73, 7 CFR 331, 9 CFR 121
Public Health Security and Bioterrorism Preparedness and Response Act, 2002

STATUTE
Bioterrorism
Act, 2002

HHS and USDA/APHIS
Select Agent Regulations

Infectious Agent	Clinical / Diagnostic	Federal Intramural	Academic/Private Research/R&D NIH Funded	Private R&D no NIH $
Mycobacterium Tuberculosis w/GFP Reporter				
Bacillus Anthracis w/GFP reporter	✓	✓	✓	✓
Synthetically derived hH2N2 n/contemporary wildtype				

42 CFR 73, 7 CFR 331, 9 CFR 121

STATUTE

US Government
Import, Transfer, and Export Regulations

These regulations cover transportation of infectious microorganisms within and to the United States (Department of Transportation and USDA/APHIS), and importation from other countries (HHS/CDC and USDA/APHIS).

CDC Foreign Quarantine Regulations

Import Regulations for Infectious Biological Agents, Infectious Material, and Vectors

- ✓ Prevent introduction of exotic communicable diseases into the US
- ✓ Through the **Etiologic Agent Import Permit Program,** any importation of etiological agents of human disease must be accompanied by a permit from CDC.

42 CFR 71.51

STATUTE

HHS and USDA/APHIS
CDC Foreign Quarantine Regulations

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USDA/APHIS Plant and Animal Health Protection Acts:

Plant Protection Act
- ✓ control importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed
- ✓ "Organism and Soil" / "Plants and Plant Products" permits granted through the **Plant Protection and Quarantine (PPQ) Service**

Animal Health Protection Act
- ✓ control importation or movement in interstate commerce of any animal … to prevent the introduction or dissemination of any pest or disease in the US
- ✓ Permits are granted through **Veterinary Services (VS)** Centers

7 CFR 330, 340 9 CFR 122

STATUTE

USDA/APHIS
Plant and Health Protection Acts

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DOT Transportation of Etiologic Agents:

Infectious substances and materials known or suspected to contain them are regulated as Division 6.2 (infectious) hazardous materials under the Pipeline and Hazardous Materials Administration (PHMSA) Hazardous Materials Regulations (HMR; 49 CFR 171-180)

- ✓ Each institution must package and ship infectious agents using approved shipping packaging and labeling
- ✓ Each shipper mush be trained in the Safe Transport of Division 6.2 Infectious Substances, Biological Specimens, Dry Ice and Related Materials
- ✓ the shipping courier must have a security plan to prevent unauthorized access
- ✓ Civil or criminal penalties

49 CFR 171-180 and 49 CFR 802

STATUTE

US Government
Department of Transportation Regulations

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STATUTE
FIFRA 1947

Environmental Protection Agency
Federal Insecticide, Fungicide, and Rodenticide Act

"provide federal control of pesticide distribution, sale, and use. **All pesticides used in the United States must be registered** (licensed) by EPA, properly labeled, will not cause unreasonable harm to the environment. **Use of each registered pesticide must be consistent with use directions contained on the label or labeling**."

Purpose:

- ✓ This provision allows EPA to enforce standards regarding the use of disinfectants, sterilants and antimicrobial pesticides.

Scope:

- ✓ All antimicrobial pesticides (sanitizers, disinfectants, sterilants)
- ✓ Applicable to all U.S. HCLs.

Responsibilities:

- ✓ Product cannot cause adverse health effects
- ✓ Demonstrate efficacy when properly use, in agreement with efficacy data and labeling
- ✓ User must use as indicated

7 U.S.C. 136-136y and 40 CFR 150-189

STATUTE
FIFRA 1947

Environmental Protection Agency
Federal Insecticide, Fungicide, and Rodenticide Act

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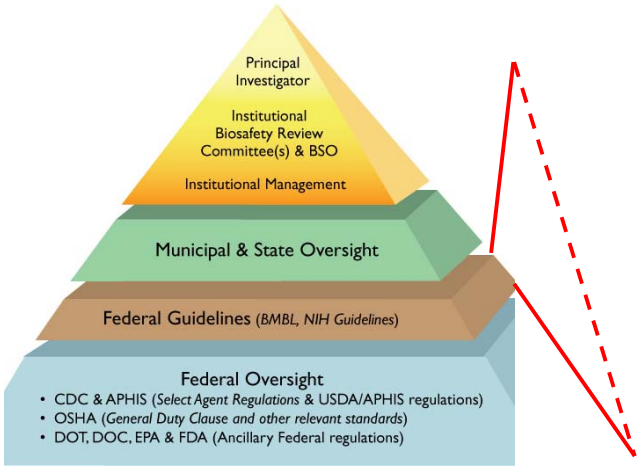
Federal Guidelines



Biosafety in Microbiological and Biomedical Laboratories

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

NIH Design Requirements Manual

The Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (July 2009)
http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Pages/default.aspx.

GUIDELINE
Voluntary*
Best Practice

CDC/NIH
Biosafety in Microbiological and Biomedical Laboratories

"the code of practice for biosafety – the discipline of addressing the safe handling and containment of infectious microorganisms and hazardous biological materials"

Purpose:

- ✓ Introduced in 1984
- ✓ 5th Edition (2007)
- ✓ Uses containment and risk assessment principles to prevent laboratory associated infections (LAIs)

Scope:

- ✓ Diagnostic, research, and large scale production activities
- ✓ Human and agricultural etiological agents

- ✓ Sets forth biocontainment principles based on:
  1. work practices
  2. safety equipment
  3. facility safeguards

Biological risk assessment:
Process to determine the biocontainment required to prevent LAIs

CDC/NIH. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. 2007
* Select Agent Regulations mandate that all registered entities should consider BMBL as part of compliance with the Select Agent Program.
* NIH Grants Policy Statement recommends BMBL for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities

GUIDELINE
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Biosafety in Microbiological and Biomedical Laboratories

"the code of practice for biosafety – the discipline of addressing the safe handling and containment of infectious microorganisms and hazardous biological materials"

Organization:

- ✓ Biorisk Assessment
- ✓ Biosafety Principles
- ✓ BSL, ABSL 1-4, and equivalent agricultural laboratory criteria
- ✓ Lab Biosecurity
- ✓ Occ Heath
- ✓ Agent Summary Statements

Biological Risk Assessment:

- ✓ Agent and procedure hazards
- ✓ Facility safeguards
- ✓ Personnel proficiency
- ✓ Special populations

Resources:

Evidence based literature

Appendices:
Applicable Federal regulations
Decontamination
1° Containment
Agricultural Biosafety
Arthropod and Primate

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GUIDELINE
T&C of NIH funding

NIH

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

"specify practices for constructing and handling **recombinant nucleic acid** molecules, **synthetic nucleic acid** molecules ... and **cells, organisms and viruses containing such molecules**"

Purpose:

- ✓ Provides oversight of rDNA and synthetic research activities at the local (IBC) and funding agency (NIH OD and RAC) levels.

Scope:

- ✓ All research conducted at institutions receiving any NIH funding for research, including research testing in humans

Responsibilities:

- ✓ Establish Institutional Biosafety Committee and Biosafety Officer (for BSL-3 or large scale activities) to review covered research and specify required biosafety levels and additional safety requirements to conduct the research.

NIH Grants Policy Statement
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. March 2013
* Select Agent Regulations mandate that all registered entities should consider NIH Guidelines as part of compliance with the Select Agent Program

GUIDELINE
T&C of NIH funding

NIH

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

"specify practices for constructing and handling **recombinant nucleic acid** molecules, **synthetic nucleic acid** molecules ... and **cells, organisms and viruses containing such molecules**"

Covered activities:

- ✓ Risk Group 1 – Risk Group 4 human etiologic agents
- ✓ Animal and plant biocontainment

Layered Oversight:

- ✓ Exempt (BSO determination?)
- ✓ IBC approval
- ✓ IBC/IRB approval
- ✓ IBC, NIH OBA approval
- ✓ IBC, RAC and NIH Director approval

Enforcement:

- ✓ NIH can suspend, limit or terminate $ for non-compliance with the NIH Guidelines
- ✓ Compliance is mandated in NIH Grants Policy Statement

NIH Grants Policy Statement
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. March 2013
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T&C of NIH funding*

NIH

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Infectious Agent	Clinical / Diagnostic	Federal Intramural Research	Academic/Private Research/R&D NIH Funded	Private R&D no NIH $
Mycobacterium Tuberculosis ~~w/GFP Reporter~~	N/A	?	?	
Bacillus* Anthracis w/GFP reporter	N/A	✓	✓	✓
~~Synthetically derived~~ hH2N2 n/contemporary wildtype	N/A	?	?	

NIH Grants Policy Manual
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. March 2013
* Select Agent Regulations mandate that all registered entities should consider NIH Guidelines as part of compliance with the Select Agent Program

REQUIREMENT
NIH Owned

NIH

Design Requirements Manual (DRM)

"NIH grant-supported construction or modernization"

The minimum design requirements for NIH grant-supported construction or modernization are set forth in 42 CFR 52b.12. The **NIH Design Requirements Manual** incorporates the regulatory standards for construction or modernization grants and those for major A&R projects.

Grantees are not subject to the NIH site specific requirements contained in the *NIH Design Requirements Manual* but should meet the intended design objectives in such cases.

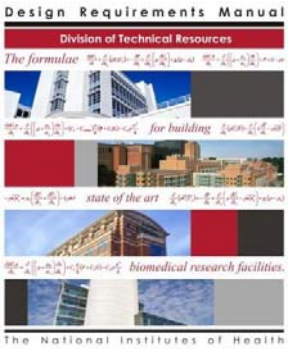
NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch10.htm)
NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM).2008.

REQUIREMENT
NIH Owned

NIH

Design Requirements Manual (DRM)

"promulgates **minimum performance design standards** for NIH owned and leased new buildings and renovated facilities, ensures that those facilities will be of the highest quality to support Biomedical research"



Purpose:

- ✓ Provides minimum performance design standards.

Scope:

- ✓ NIH owned and leased new buildings and renovated facilities

Covered activities:

- ✓ Lays out specific BSL3 and ABSL3 facility design requirements, including HVAC
- ✓ Outlines a set of criteria for the NIH BSL-3 certification and validation process.

NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch10.htm)
NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM).2008.

Industry Best Practices

GUIDELINE
Clinical Labs

Clinical Laboratory Standards Institute

Protection of Laboratory Workers from Occupationally Acquired Infections

"detailed recommendations for the protection of workers from disease agents transmitted from aerosols, droplets, blood and body substances." Focus on HIV, HBV, HCV.

Outlines:

Protection Techniques
Med Waste Management
Diagnostic Instrumentation and Equipment

Enforcement:
College of American Pathologists (CAP) Laboratory Accreditation Program

Clinical and Laboratory Standards Institute M29-A3, 3rd Ed.

Industry Best Practices

STANDARD

International Organization for Standardization (ISO)

Laboratory Quality Assurance and Medical Laboratory Safety Standards

ISO15189
"Medical laboratories — Particular requirements for quality and competence"
- quality management system

ISO15190
"Medical laboratories -- Requirements for safety"
-risk group classification
-designing for safety
-hazard identification
-incident reporting
- aerosols
- BSCs
- PPE
- Personnel training

http://www.iso.org

Industry Best Practices

WORKSHOP AGREEMENT

European Committee for Standardisation

CWA 15793:2011

Biorisk Management "Standard"

"The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this laboratory biorisk management standard."

Outlines management practices for:

Biological Hazard Identification	Risk Assessment and Management
Work Practices	Occupational Health
Training	Emergency Response
Laboratory Biosecurity	

Enforcement:
tied to international laboratory accreditation programs

CEN CWA 151793:2011 Biorisk Management Standard
Guidance document at: http://www.absa.org/pdf/CENprCWA_55_2011_Guidanceon_CWA15793.pdf

Canadian Human Pathogens and Toxins Act (2009)


CONSOLIDATION
CODIFICATION
Human Pathogens and Toxins Act
Loi sur les agents pathogènes humains et les toxines
S.C. 2009, c. 24
L.C. 2009, ch. 24

"to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins"

When enacted, will function as a National Registry:

✓ Requires that all institutions involved in a controlled activity with all Risk Group 2 – Risk Group 4 agents be licensed.

- ✓ Possession
- ✓ Producing / Storing
- ✓ Transfer / Import
- ✓ Abandoning
- ✓ Disposing

✓ Requires that a licensee:*
- ✓ Identify licensee location and name, and license period
- ✓ Facility description
- ✓ Inventory of all agents used

Criminal penalty for noncompliance

Canadian Human Pathogens and Toxins Act. 2009

Thank You