



# Biohazard Containment Facilities

*Planning & Design Considerations*

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health education + research associates  
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# Laboratory Types with Bio-Containment Facilities

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- **Pharmaceutical**
- **College & University**
- **Biochemical R&D**
- **Forensic**
- **Genomics / Proteomics**
- **Food & Beverages**
- **Environmental**
- **Nanotechnology**
- **Medical Examiner or Coroner**
- **Department of Health**
- **Clinical**
- **Biotechnology**
- **Consumer Products**
- **Agricultural**

# Regulations

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## Federal

### **Public Law 107- 56:**

Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (U.S.A. Patriot Act of 2001)

Prohibits restricted persons from shipping, possessing or receiving select agents

### **Public Law 107- 188:**

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Requires institutions to notify DHHS or USDA of possession of specific pathogens or toxins

**42 CFR Part 73 / Part 1003:** (Department of Health and Human Services)  
Possession, Use and Transfer of Select Agents and Toxins

Select Agent Act of 2002

# Regulations



## CDC List of Select Agents

### Viruses

- Crimean-Congo Haemorrhagic Fever
- Eastern Equine Encephalitis
- Ebola
- Equine Morbillivirus
- Lassa Fever
- Marburg
- Rift Valley Fever
- So. American Haemorrhagic Fevers
- Tick-borne Encephalitis
- Variola Major
- Venezuelan Equine Encephalitis
- Hantavirus
- Yellow Fever

### Bacteria

- Bacillus Anthracis
- Burkholderia Abortus
- Burkholderia Mallei
- Burkholderia Pseudomallei
- Clostridium Botulinum
- Francisella Tularensis
- Yersinia Pestis

### Fungi & Rickettsiae

- Coccidioides Immitis
- Coxiella Burnetii
- Rickettsia Prowazekii
- Rickettsia Rickettsii

### Toxins

- Abrin
- Aflatoxins
- Botulinum
- Clostridium Perfringens Epsilon
- Conotoxin
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Sigatoxin
- Staphylococcal Enterotoxin
- Tetrodotoxin
- T-2 Toxin

# Standards and Guidelines

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## **Biological Safety**

**Centers for Disease Control with National Institutes of Health**  
*Biosafety in Microbiological and Biomedical Laboratories*

**U.S. Department of Agriculture**

**Agricultural Research Service (ARS)**  
*Facility Design Standards*

**Animal & Plant Health Inspection Service (APHIS)**

*Quarantine Facility Guidelines for Microorganisms*

*Quarantine Facility Guidelines for Weeds*

*Quarantine Facility Guidelines for the Receipt and Containment*

*Non-indigenous Arthropod Herbivores, Parasitoids, Predators*

**American Committee of Medical Entomology**

*Arthropod Containment Guidelines*

# Standards and Guidelines

## Biological Safety

### Guidelines for Containment at Biosafety Level 3

	CDC Select Agent	NCI Oncogenic Viruses	Human Pathogens	Prions	rDNA	USDA Restricted	Animal Pathogens	Zoonotic Pathogens	Small Animal Studies	Large Animal Studies	Plant rDNA & Pathogen	Arthropod-Borne	Large Scale	Insectary	Greenhouse
ARS Facility Design Standards		X		X	X	X	X	X	X	X	X	X			
CDC with NIH - BMBL	X		X	X				X	X			X			
NIH RAC rDNA Guidelines					X		X				X		X		X
APHIS Quarantine Facility Guide											X	X		X	X
ASM Arbovirus Lab Safety												X		X	
American Mosquito Control Assoc														X	
NCI Guide for Oncogenic Viruses		X													

# Standards and Guidelines

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## Biological Safety

### National Institutes of Health

*Guidelines for Recombinant DNA Research*

*Laboratory Safety Supplement to the Guidelines*

### Occupational Safety and Health Administration

*Bloodborne Pathogens*

*Tuberculosis Standard*

### National Cancer Institute with NIH

*Guidelines for Oncogenic Viruses*

### World Health Organization

*Laboratory Safety Guidelines*

# Standards and Guidelines

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## Biological Safety within overall guidelines

**AAALAC – Guide for Care and Use of Laboratory Animals**

**Local Building Code**

**National Building Code**

**NFPA Standards**

**Fire Protection Code**

**Mechanical Code**

**Plumbing Code**

**Electrical Code**

**Energy Code**

**Nuclear Regulatory Commission**

**OSHA**

**Americans with Disabilities Act of 1990**



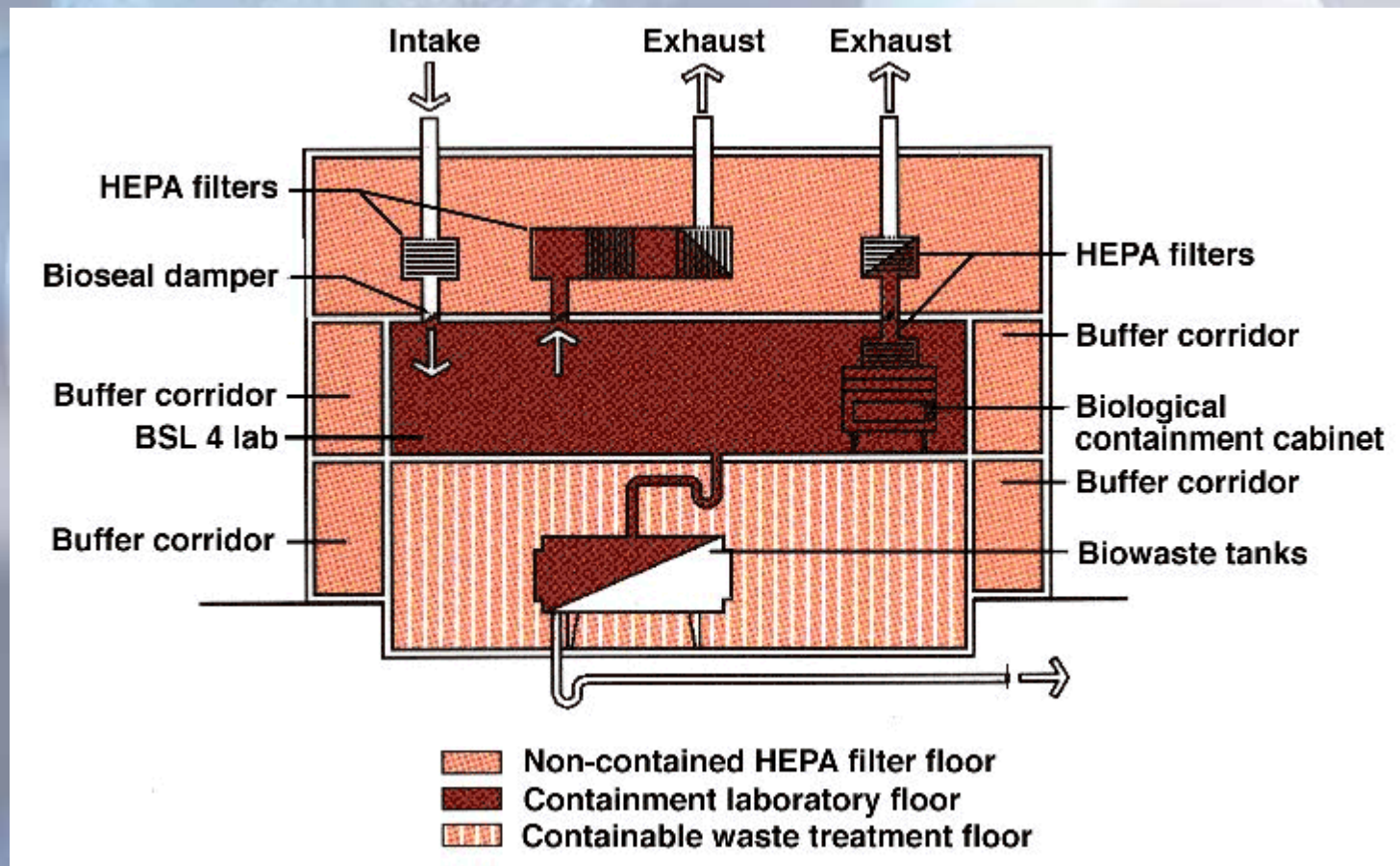
# Cost Premium for Facilities

	BSL-2 Standard	BSL-3 Standard	BSL-3 Enhanced	BSL-4 Cabinet	BSL-4 Suit
Gross Area	1,538	2,000	2,800	3,778	6,857
Net to Gross Ratio	65%	55%	50%	45%	35%
Net Usable Area	1,000	1,100	1,400	1,700	2,400
Cost per Sq. Foot	\$310	\$450	\$520	\$880	\$1,200
Estimated Construction Cost	\$476,923	\$900,000	\$1,456,000	\$3,324,444	\$8,228,571

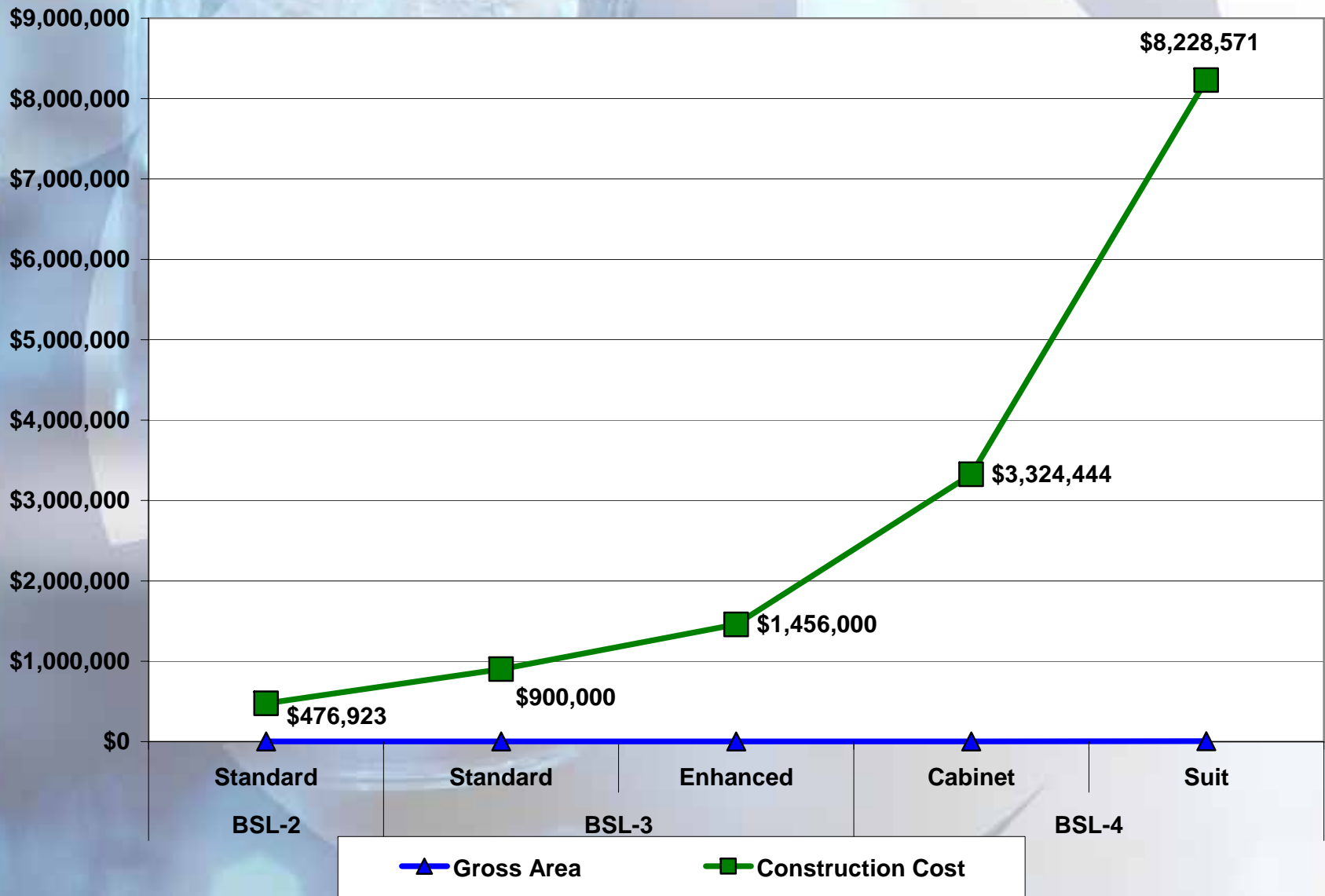


# Cost Premium for Facilities

## Diagram of Containment Concept



# Cost Premium for Facilities



# Biosafety Planning Issues

## Primary/Secondary Barriers

Biosafety Cabinets

Gas Tight Room  
Tested/Certified

Air Locks with air  
pressure doors

Electrical  
Outlets

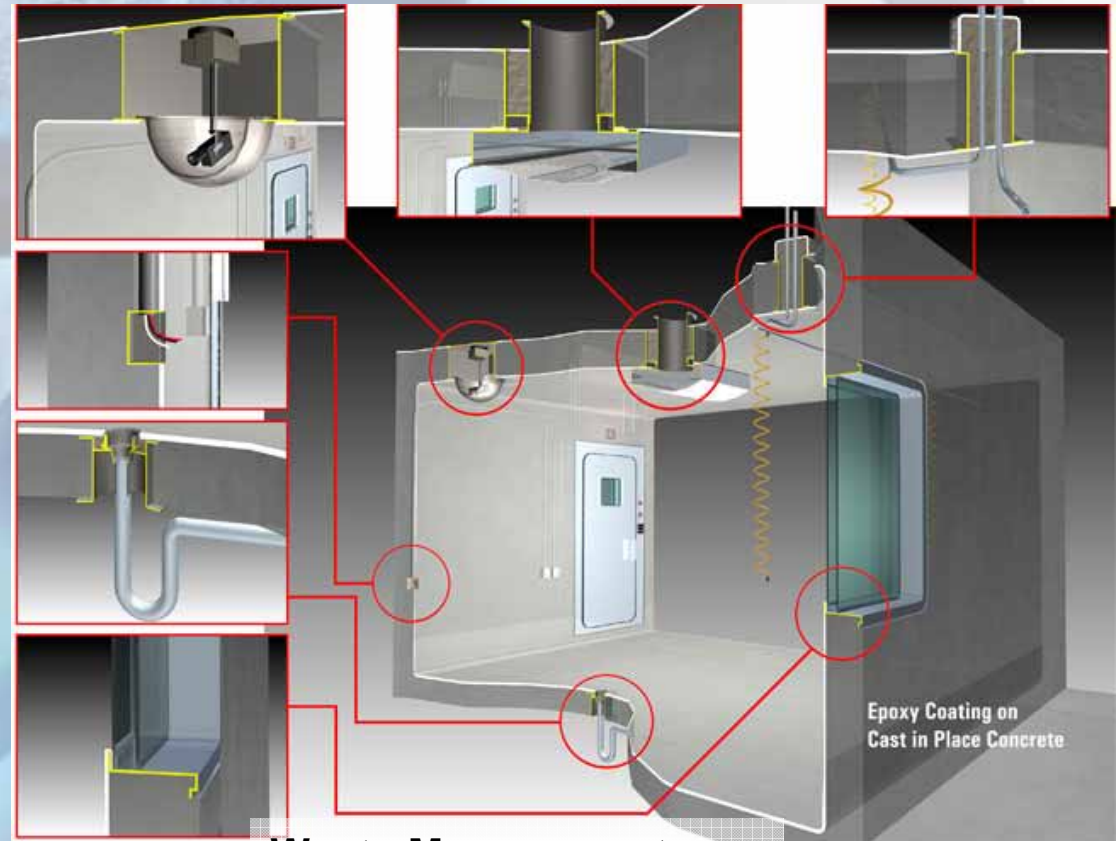
Floor/Sink  
Drains

Window  
Frame

Camera  
Bubble

Air  
Supply  
Diffuser

Breathing  
Air



**Waste Management**  
All waste rendered  
harmless

- autoclave waste from lab
- decontaminate effluent waste
- HEPA filter air

# Biosafety Planning Issues

- Design of containment barriers
- Quality research = containment
- Ventilation requirements

Sealed pipe penetrations



BSL-3 lab in Canada



# Biosafety Planning Issues

## Containment Barriers

- **Primary barrier**
  - Biological safety cabinet
  - Personal protective gear
- **Secondary barrier**
  - Room enclosure
  - Engineering systems
- **Tertiary barrier**
  - Containment around systems



BSL-3 lab in Canada

# BSL-2 Planning Issues

Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
<p>Suitable for work involving agents of moderate potential hazard to personnel and the environment</p>	<p><b>BSL-1 plus:</b></p> <ul style="list-style-type: none"> <li>• Controlled access</li> <li>• Hand washing</li> <li>• Keep lab clothing within lab, do not wear outside lab</li> <li>• Baseline serum levels of staff</li> <li>• Needles / sharps precautions</li> </ul>	<ul style="list-style-type: none"> <li>• Class II BSC's or other physical containment devices used for all open manipulations of agents</li> <li>• PPE: protective gear as needed</li> <li>• Eyewash available</li> <li>• Sink for hand wash</li> <li>• Autoclave available</li> </ul>	<p><b>BSL-1 plus:</b></p> <ul style="list-style-type: none"> <li>• Physical separation, &amp; locked, self-closing doors from access corridors</li> <li>• Sturdy, easily cleaned furniture and work surfaces</li> <li>• Exhausted air not recirculated</li> <li>• Negative airflow into laboratory</li> <li>• Insect screens on windows</li> </ul>

# BSL-3 Planning Issues

Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
<p><b>Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences</b></p>	<p><b>BSL-2 plus:</b></p> <ul style="list-style-type: none"> <li>• <b>Controlled access</b></li> <li>• <b>Work in certified BSC</b></li> <li>• <b>Decontamination of all waste</b></li> <li>• <b>Decontaminate lab clothing before laundering</b></li> <li>• <b>Baseline serum levels of staff</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Class II or III BSC's or other physical containment devices used for all open manipulations of agents</b></li> <li>• <b>PPE: protective lab clothing, gloves, respiratory protection as needed</b></li> <li>• <b>Autoclave in lab suite</b></li> <li>• <b>HEPA filter vacuum lines</b></li> </ul>	<p><b>BSL-2 plus:</b></p> <ul style="list-style-type: none"> <li>• <b>Physical separation from access corridors</b></li> <li>• <b>Locked self-closing, double-door access</b></li> <li>• <b>Exhausted air not recirculated</b></li> <li>• <b>Negative airflow into laboratory</b></li> <li>• <b>Room penetrations are sealed</b></li> <li>• <b>Room surfaces are water resistant for cleaning</b></li> </ul>



# Goals of a BSL-3 Facility

- **Protect personnel** in the laboratory
- **Provide productive scientific environment**
  - Protect research, samples, and products
- **Protect staff** who operate and maintain systems
- **Protect environment**
  - Surrounding personnel and functions
  - Outside environment, adjacent communities



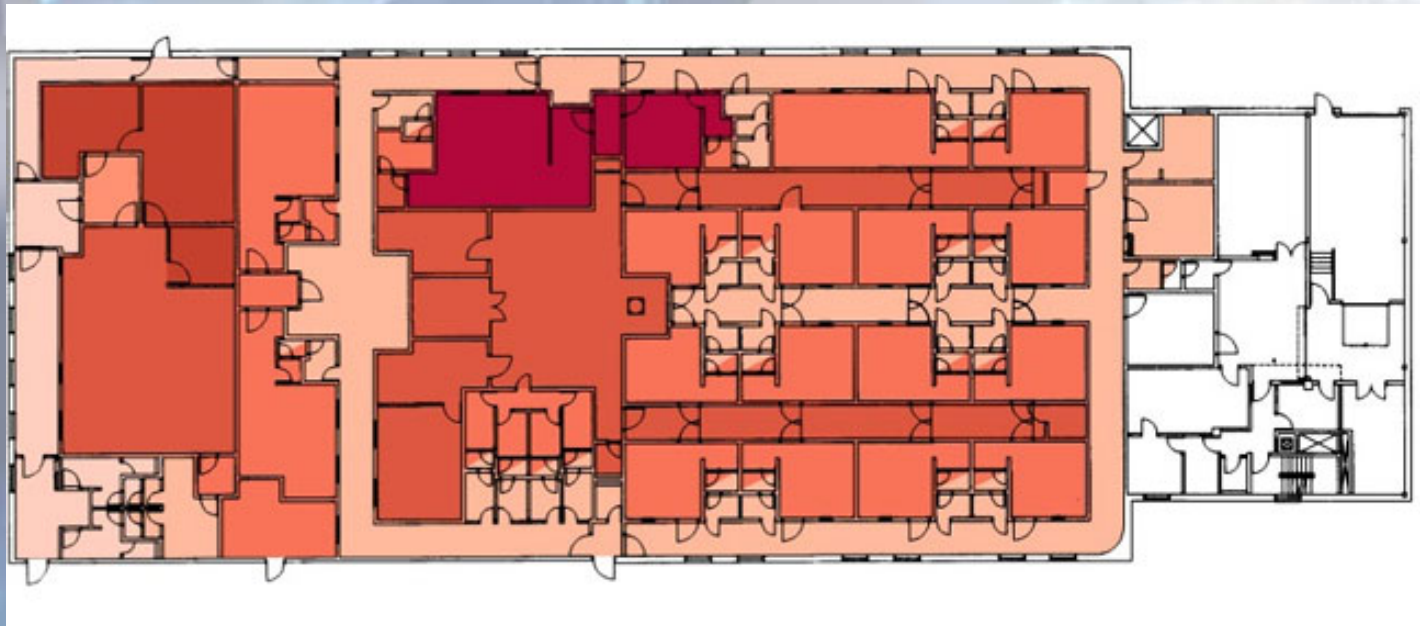
# Definition of a BSL-3 Facility

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**Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route**

- **Exposure potential to pathogens spread by aerosol**
- **Infection serious, possibly lethal**

M. Tuberculosis, St. Louis Encephalitis, Coxiella Burneti



# BSL-3 Facility Planning Issues

## Concentrate and Minimize

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- Limit number of individuals and processes that must work under BSL-3 conditions
- Provide appropriate service support outside
- Provide appropriate functional support inside
- Estimate capital and life cycle costs for operating facility: (BSL-4 estimates are \$750 million per year!)

*Capital cost* includes design, construction, commissioning, and equipment fit-out of the laboratory

*Life cycle cost* includes utility expense for ventilation and electric power, filter testing/replacement, inspections, insurance/liability

# BSL-3 Facility Planning Issues Plan for Future Expansion

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- **Connection and redundancy**
- **Advantage of immediate adjacency**
- **Cons of immediate adjacency**
- **Economies of redundancy**

# BSL-3 Facility Planning Issues Plan for Flexibility

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- Regulatory and research changes
- New pathogens
- New equipment