



BioCARS Facility Update

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Office of Science
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<http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>



Biosafety Levels

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink requireda
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers = Class I or II BCSs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or	BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs <u>in combination with</u> full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decon systems Other requirements outlined in the text



Source Documents

- **DOE Notice 450.7 The Safe Handling, Transfer, and Receipt of Biological Etiologic Agents at Dept. of Energy Facilities**
 - Defines requirement for an Institutional Biosafety Committee
 - Implement guidelines in BMBL (NIH/CDC), NIH Guidelines, and WHO
- **DOE Order 440.1A Worker Protection, Section 18, Industrial Hygiene and Section 19, Occupational Medicine**
- **DOE G 440.1-4, Contractor Occupational Medical Program Guide for Use with DOE Order 440.1**
- **ESH Manual Section 3.1, Occupational Medical Program (employees)**
- **ESH Manual Section 12.2, Respiratory Protection**

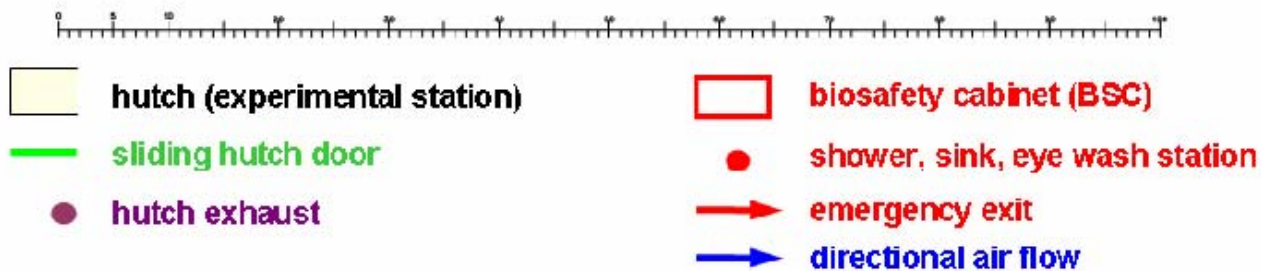
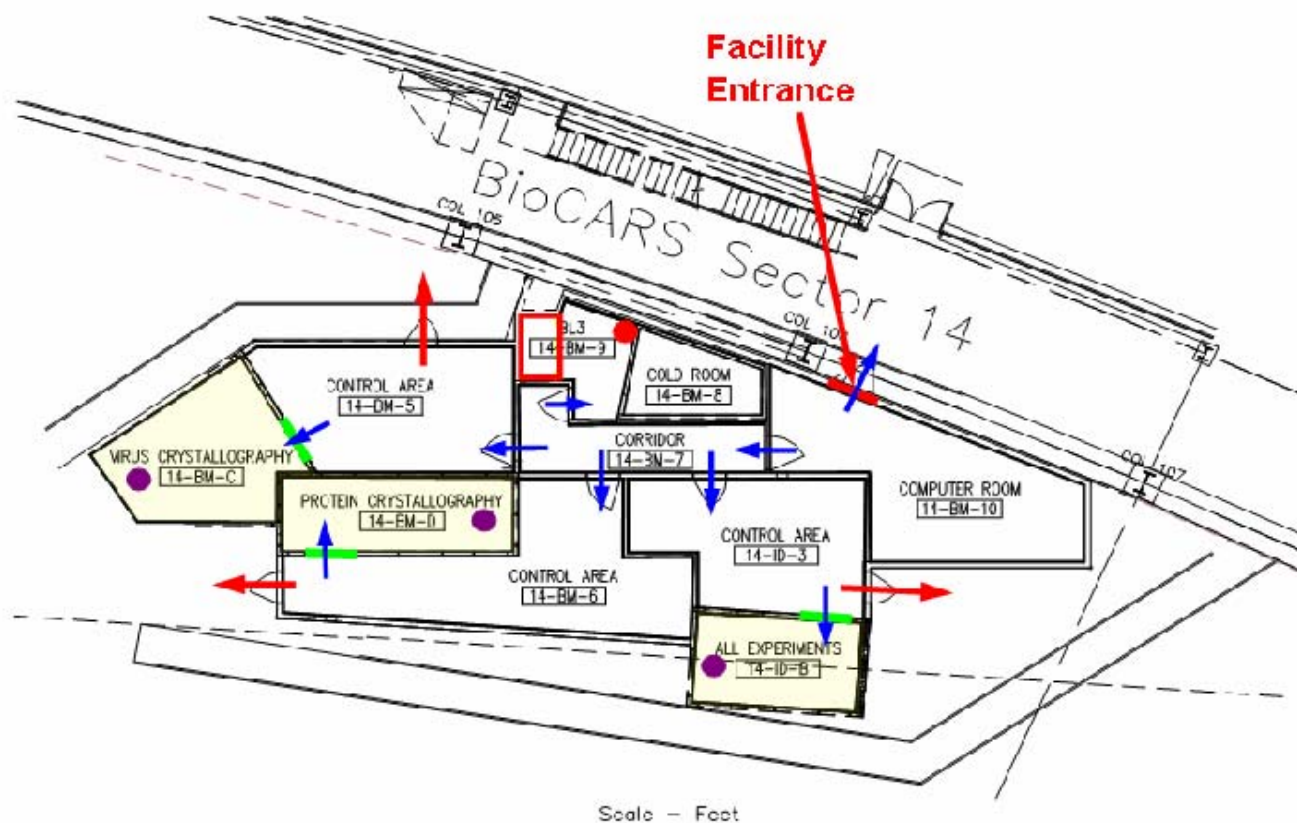


BioCARS Facility Overview

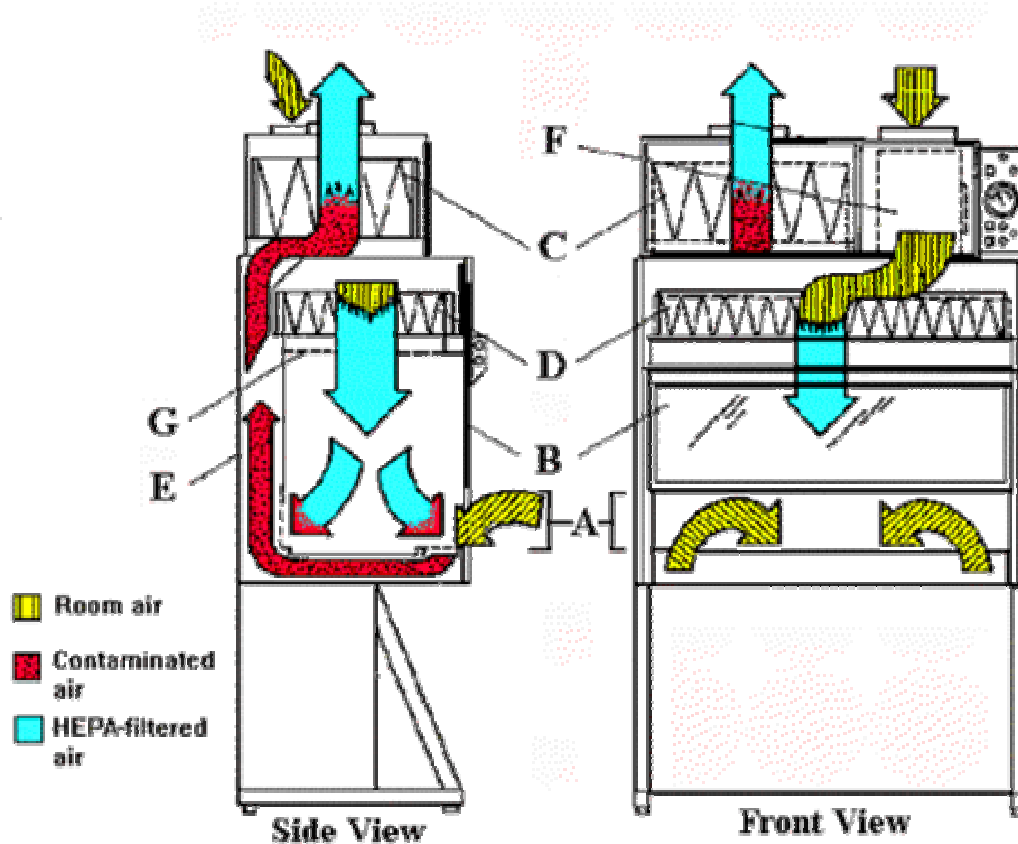
- Only a subset of experiments will require BSL-2 or BSL-3 practices
- Three stations upgraded to BSL-2/3 capability
- The facility is equipped with a Class II, Type B2 Biosafety Cabinet
- Only a single BSL-2/3 experiment can be conducted at any time (one station at a time)
- Cultures of BSL-2/3 microorganisms are prohibited at BioCARS
- No long term storage of BSL-2/3 materials at the facility
- Use of BSL-4 agents and Select Agents (as defined in CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121) is prohibited at BioCARS and ANL
- Only a single crystal of BSL-2/3 material will be in the station
- BSL-2/3 experiments require 24 hour attendance by two users and one BioCARS staff member



BioCARS Facility



BioCARS Class II, Type B2 Biosafety Cabinet



- A. front opening
- B. sash
- C. exhaust HEPA filter
- D. supply HEPA filter
- E. negative pressure exhaust plenum
- F. supply blower
- G. filter screen

Note: The cabinet exhaust is connected to the facility exhaust fan EF104.



BioCARS Facility – New Ventilation



HEPA Filters



New Ductwork



BioCARS Facility Access

- **The only entrance to and exit from the facility is through the computer room (14-BM-10, Column 106).**
- **This entrance is posted with the Biohazard Warning Sign.**
- **List of authorized personnel is posted at entrance.**
- **Only personnel that fulfill medical requirements will be authorized.**
- **Only trained personnel are allowed to work with the agents.**
- **Users working with BSL-2/3 agents must be qualified and trained by their home institution**



BioCARS SOPs

SOP 101: Responsibilities

SOP 102: Approval of BSL-2/3 Experiments

SOP 103: Shipping and Receiving of BSL- 2/3 Samples

SOP 104: User Training and Certification

SOP 105: Protective Clothing and Other Personal Protective Equipment

SOP 106: Preparation of the Facility for BSL- 2/3 Operation

SOP 107: BSL- 2/3 Practices and Procedures

SOP 108: Response to Incidental Overt or Potential Personnel Exposure to BSL- 2/3 Agent

SOP 109: Response to the Facility HVAC Failure

SOP 110: Medical and Facility Emergencies

SOP 111: BSL- 2/3 Waste Disposal

SOP 112: End of Experiment Procedures

SOP 113: Facility Decontamination

SOP 114: HVAC maintenance and testing



Application for Beamtime

- **Application via regular APS proposal submission route**
- **Classification of samples as BSL-2/3 must be stated**
- **Advanced notification to APS and BioCARS – 3 months preferred**
- **BioCARS Biosafety Coordinator collects experiment information**
- **Information forwarded to APS User Safety Officer, ANL Biosafety Officer, and ANL IBC Chair**



Approval of Experiment

- **BSL-2/3 questionnaire and medical certification forms sent to users. Medical and Respiratory protection certification necessary for granting access.**
- **Users provide:**
 - **MSDS and other relevant information regarding hazards**
 - **Appropriate disinfectant(s) and procedure**
 - **Home institution medical surveillance and respirator policy/training**
 - **Certificate of training for BSL-2/3 from home institution**
 - **Copy of possession and transportation permits (when required)**
 - **Shipping/transportation plans**
 - **Home institution BSL-3 SOP**
 - **Procedures and equipment to be used at BioCARS**
- **Additional information as required by ANL IBC.**



Approval of Experiment

- Experiment must be approved by the ANL IBC
- ANL IBC makes decisions regarding:
 - Approval of experiment
 - Authorized personnel
 - PPE for experiment
 - Post-experiment decontamination
- BioCARS and APS will give final approval after ANL IBC approval
- At time of experiment, BioCARS Biosafety Officer reviews SOPs and gives site-specific training to users.



Select Agents and High Consequence Agents Regulated by HHS and USDA

HHS Select Agents and Overlap Select Agents

- Crimean-Congo haemorrhagic fever virus
- Ebola Virus
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- South American Haemorrhagic Fever viruses (Jinni, Machupo, Sabia, Flexal, Guanarito)
- Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])
- Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)
- Eastern Equine Encephalitis virus
- Nipah and Hendra Complex viruses
- Rift Valley fever virus
- Venezuelan Equine Encephalitis virus

Possession, Use, and Transfer of Select Agents, Interim Final Rule, 42 CFR Part 73 (December 13, 2002). Department of Health and Human Services, Office of the Inspector General <http://www.cdc.gov/od/sap/docs/btarule.pdf>



Biological Agents and High Consequence Agents Regulated by HHS and USDA

USDA High Consequence Livestock or Plant Viruses

- **Akabane virus**
- **African swine fever virus**
- **African horse sickness virus**
- **Avian influenza virus (highly pathogenic)**
- **Blue tongue virus (Exotic)**
- **Camel pox virus**
- **Classical swine fever virus**
- **Foot and mouth disease virus**
- **Goat pox virus**
- **Lumpy skin disease virus**
- **Japanese encephalitis virus**
- **Malignant catarrhal fever virus (Exotic)**
- **Menangle virus**
- **Newcastle disease virus (VVND)**
- **Peste Des Petitis Ruminants virus**
- **Sheep pox virus**
- **Swine vesicular disease virus**
- **Vesicular stomatitis virus (Exotic)**
- **Plum Pox Potyvirus**
- **Rinderpest virus**

Possession, Use and Transfer of Biological Agents and Toxins, 7 CFR 331 and 9 CFR 121 (December 13, 2002).

Department of Agriculture, Animal and Plant Health Inspection Service (APHIS)

<http://www.aphis.usda.gov/vs/ncie/pdf/btarule.pdf>

