



Commissioning and Certification of A Large High Containment Facility

Jeff Potts, MPH
Suzanne Krall

Division of Occupational Health & Safety, NIH

Department of Health and Human
Services

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Overview

- Commissioning versus Certification.
- Problems Identified during construction and activation phases.
- Continuity of program and documented history of project.


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Project Timeline

- Ground Breaking – October 1, 2003
- Substantial Completion – 12/9/05 (Excluding 3rd Floor BSL 3)
- Endurance Period on High Containment and Vivarium – 1/24/06 thru 2/24/06
- Endurance Period for 3rd Floor BSL-3 – 4/24/06 thru 5/24/06
- Various revision including bubble dampers, load banks, and room changes – 5/24/06 thru 12/11/06
- Final Functional Testing 12/13/06 – 1/18/07
- Certification Process – Feb '07
- CDC/USDA Inspections – May '07





Commissioning (Cx) Overview

- Ensure a high standard of care is used in the installation and “start up” of the systems. It requires extensive documentation of the processes and activities performed throughout Cx and much scrutiny of those activities.
- Ensure the design intent, systems, and operational procedures are thoroughly documented.
- Ensure that training for Building Maintenance personnel is thoroughly documented.
- Ensure systems are optimally tuned and functionally tested.
- The Cx team should perform extensive functional testing.

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Comprehensive Testing

- HVAC Systems
- Plumbing Systems
- Electrical Systems
- Fire Protection Systems
- Endurance Testing
- Big Kaboom!

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Certification Overview

- Initial certification should verify the appropriateness and effectiveness of administrative and engineering controls for compliance to the intent of the BMBL.
- Annual certification should do the same as above to meet government regulations and industry standards. Also to identify any potential failures through observed deviation from documented baseline data, maintenance records and observed component deficiencies.

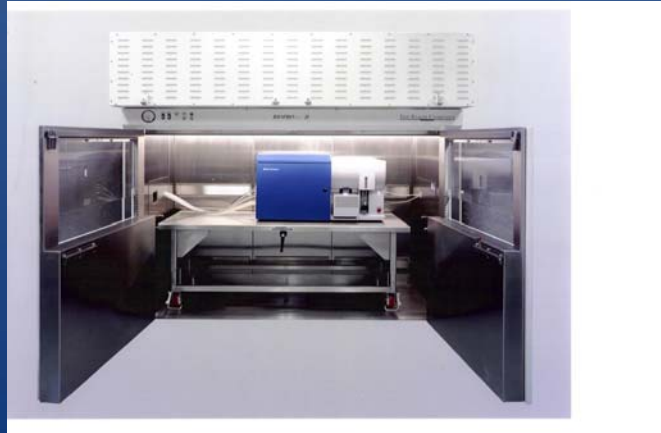
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Bumps in the Road



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“We may need to sort non-fixed, infectious samples using a FACS.”



Balancing an HVAC system is a complex task. When you add the complication of BSL-3 laboratories, autoclaves and hard ducted biological safety cabinets, challenges abound.



Building Infrastructure

- BSC placement in BSL-2 laboratories
- Vivarium ceiling
- Hands-free devices?
- Autoclave bioseal design specifications.
- Autoclave canopy connections in BSL-3
- Autoclave locations in BSL-3 labs
- Location of showers in BSL-3 entrance air locks

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Procedural Issues

- Transport of infectious materials and animals
- Select Agent security and personnel issues
- Building security
- Immunizations

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Continuity of a Project

- Dedicated personnel with the appropriate training and knowledge.
- Detailed recorded history of the project.