

Development of a Training Program for the Biomedical Research Laboratory at George Mason University

ChABSA Conference

June 13, 2012



Where Innovation Is Tradition

Objectives

- Development of Training Program
- Assessment after 12 months
- Challenges Moving Forward



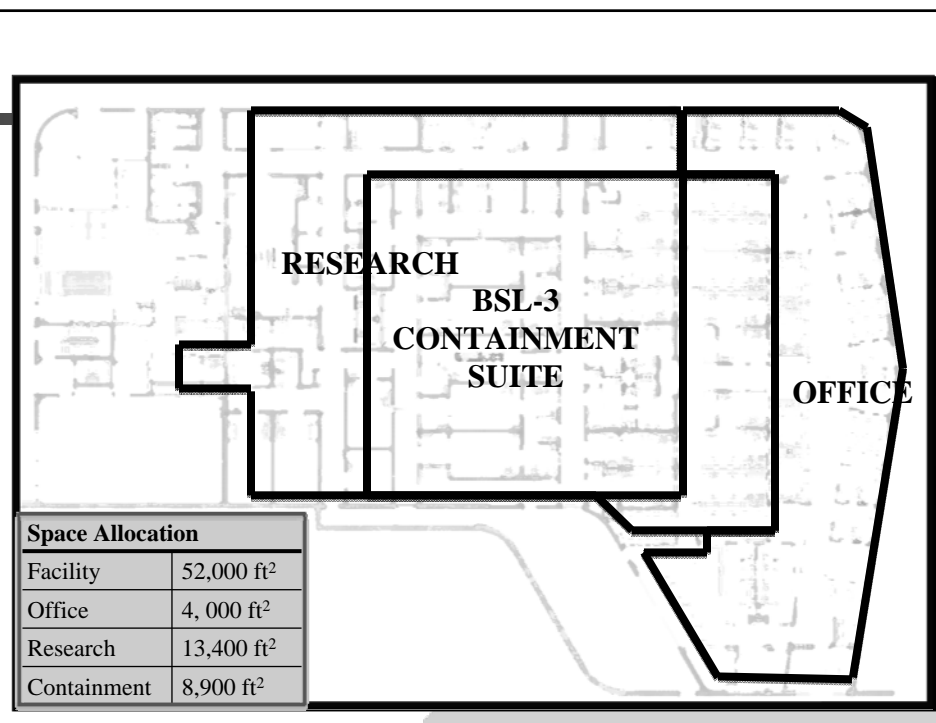
Where Innovation Is Tradition

GMU Biomedical Research Lab

- One of 13 NBL/RBL's funded by NIAID
- Doors opened May 2010
- CDC approval for SAT Feb, 2012
- Operated by GMU's National Center for Biodefense and Infectious Disease (NCBID)



Where Innovation Is Tradition



Space Allocation	
Facility	52,000 ft ²
Office	4, 000 ft ²
Research	13,400 ft ²
Containment	8,900 ft ²

Work at the BRL



- Testing and evaluating new vaccines and therapeutics for prevention and treatment of highly infectious pathogens
- Creating pre-symptomatic diagnostic technologies for diseases that are potential bioterror threats and emerging infectious disease
- Developing technologies to detect and identify biological threat agents in environmental samples.



Where Innovation Is Tradition

Evaluating Training Needs

- Select Agent Regulations (42 CFR 73.15, 9 CFR 121.15, 7 CFR 331.15)
- *Biosafety in Microbiological and Biomedical Laboratories, 5th Ed.*
- Occupational Safety and Health Administration training requirements
- Industry Standards



Where Innovation Is Tradition

Evaluating Training Needs

- BRL is the first and only BSL-3/ABSL-3 lab at GMU
- Newly registered to work with select agents and toxins
- Personnel with varying degrees of experience working at BSL-3/ABSL-3

Only 10% of SRA approved personnel have previous work experience at BSL-3/ABSL-3.



Where Innovation Is Tradition

Preparation

BSL-3 Science and Safety, Emory University



Hands-on incident response exercises
Entry and Exit Procedures
Pre-assessments

BSL-3 Theory and Practicum, UTMB



Detailed decon exercises (bsc, incubators)
LAI case studies



Where Innovation Is Tradition

Planning

Biosafety Staff	Principal Investigators
<ul style="list-style-type: none"> ➤ Training on Individual Responsibilities ➤ Cover Written Plans ➤ Module concept for flexibility ➤ Hands-on interactive training ➤ Must demonstrate proficiency ➤ Documented mentorship process ➤ Topical refresher training 	<ul style="list-style-type: none"> ➤ Training relevant to their work ➤ Ability to take modules in any order ➤ Hands-on interactive training ➤ Pre-assessments ➤ Clear mentorship requirements



Where Innovation Is Tradition

Training Levels

Level	Description
1	Visitor: Visitor or contractor who will enter the containment suite with an escort to perform work
2	Support Staff: BRL administrative staff, security staff, ITU personnel, University public relations, BRL BSL-2 and ABSL-2 workers, various GMU personnel who support the BRL but will not enter the containment suite
3	SRA Approved Facilities and Operations Staff: SRA approved facilities personnel, IT personnel, operations personnel and security personnel who may enter the containment suite to perform work
4	Laboratory Worker/Animal Care Staff: SRA approved PI's and laboratory personnel who will work in BSL-3 labs in the containment suite



dition

Training Modules

Twelve Training Modules	
Module 1 Visitor Training 1 hr, Annual Requirement	Module 7 IR: Manmade Threats and Medical Emergencies 3 hr, One Time Requirement
Module 2 BRL Orientation 1.5 hr, One Time Requirement	Module 8 IR: Spill Response 3 hr, One time Requirement
Module 3 Entry and Exit Procedures 3 hr, One Time Requirement	Module 9: Select Agent Program Overview 1 hr, One time Requirement
Module 4 Medical Surveillance 2 Hr, One time Requirement	Module 10: Mentorship Minimum 40 hr
Module 5 Biosafety Training 6 hr, One time Requirement	Module 11: Vivarium Training 1 hr, One time requirement
Module 6 IR: Emergency Evacuation & Facility Emergencies 3 hr, One Time Requirement	Module 12: Refresher Training As required by RO (at least annually, probably quarterly)

Training Requirements

Level	Training Requirements
1	Module 1
2*	Module 2
3**	Modules 2, 3, 4, 6, 7, 9, 11, 12
4**	Modules 2, 3, 4, <u>5</u> , 6, 7, <u>8</u> , 9, 10, 11,12
*	University Police attend Modules 6 and 7. Security Managers attend modules 6, 7, and 9
**	Bloodborne pathogen, First Aid , CPR , Fire Extinguisher Training, & Respirator Training



Where Innovation Is Tradition

Training Commitment

Level	Initial Training (Hours)	Mentorship (Hours)	Annual Refresher (Hours)	Number of Trainees
1	1	0	1	4
2	2	0	1	60
3	15	40	Variable	19
4	24	40	Variable	16
Total				99



Where Innovation Is Tradition



Review of First Year



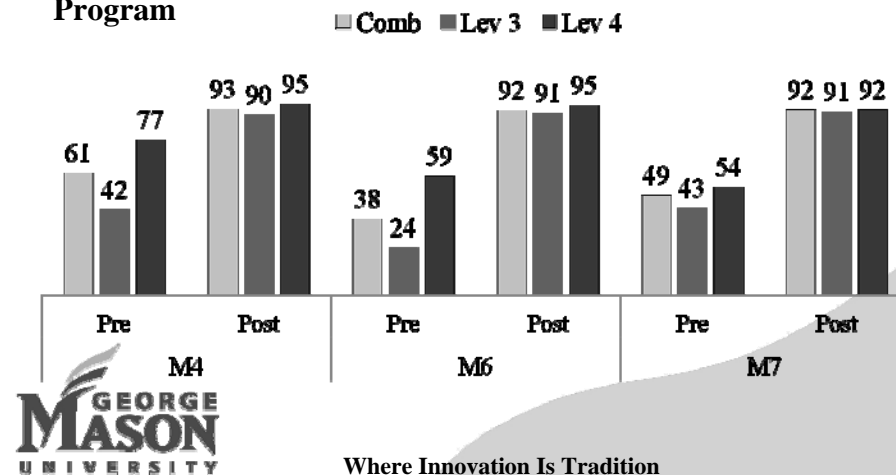
Module	Sessions	Hours	Attendees
1	2	2	4
2	12	18	114
3	6	18	28
4	4	8	29
5A	4	12	15
5B	4	12	16
6	7	21	44
7	7	21	43
8	5	15	18
9	4	4	27
11	2	1	16
Total	57	132	



Where Innovation Is Tradition

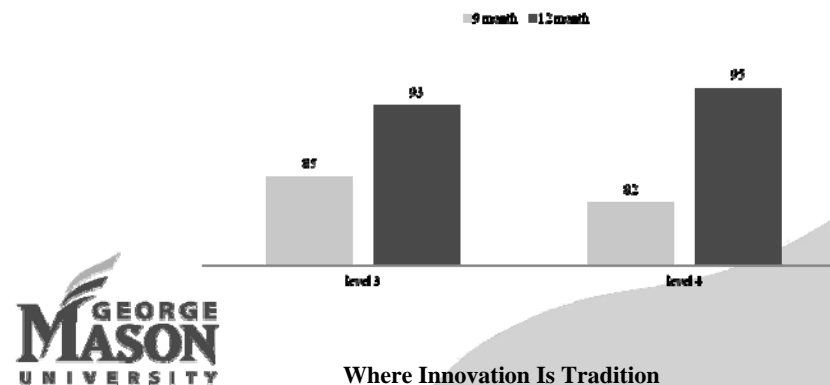
Documenting Proficiency

Comparison of the Overall Average Score on Pre- and Post-Assessments for Personnel Enrolled in the Select Agent Program



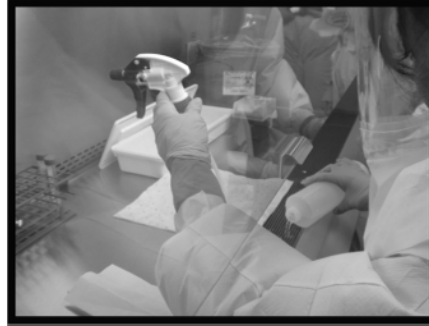
Retention

Average Score on Comprehensive Assessment



Mentorships

- All Personnel must complete a minimum of 40 hours of hands-on supervised work in the containment suite
- Practice the work they will perform in containment
- Proficiency must be documented and signed off by mentor
- Proficiency Assessment by Biosafety Manager



**Based on individual needs.
Minimum of 40 hours.**



Where Innovation Is Tradition

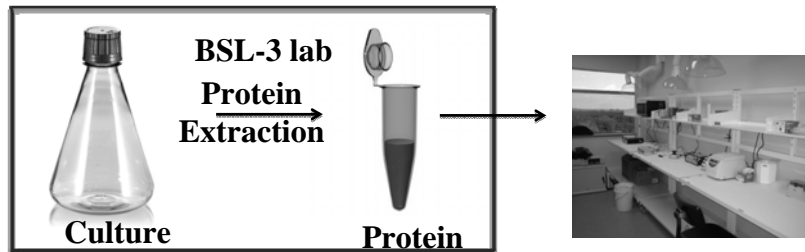
Assessment After the First Year

- What Worked?
 - Hands on Activities
 - Interactive exercises
 - Attending Modules in any order



Where Innovation Is Tradition

Let's Conduct A Risk Assessment



A researcher wants to extract protein from an agent and bring the protein out of the containment suite for analysis.

What are the risks? Can this be done Safely?

The Procedure must be tested and validated to prove that the agent is completely inactivated BEFORE any sample can be brought out of the Containment Suite.

Assessment After the First Year

➤ What Didn't Work?

- Large Class Sizes for hands-on activities
- Spreading classes over weeks (1/per week)
- Modules 4 and 9



	Level 3 (% Fail)	Level 4 (% Fail)
Module 3	7.6	6.7
Module 4	15	0
Module 6	0	0
Module 7	0	0
Module 9	54	0

Challenges –Cost/Time

	Level 3	Level 4	Total to Date
PPE	\$60	\$102	\$2772
Handouts			
Supplies			



Where Innovation Is Tradition

Challenges

- Relocating exercises now that the lab is active
- Refresher Training



Where Innovation Is Tradition

Acknowledgements

BRL Faculty and Staff

- Charles Bailey
- Calvin Carpenter
- Kylene Kehn-Hall
- Monique van Hoek
- Ramin Hakami
- Myung Chung
- Svetlana Senina
- Aarthi Narayanan

EHS Personnel

- Cara Leitch
- Louann O'Reilly
- Julie Zobel

Fellow Biosafety Professionals

- NBL/RBL Network Group
- UTMB Trainers
- Emory Trainers



Where Innovation Is Tradition