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# **Biosecurity in a Biosafety Environment: A Survey of the Bioscience Community**

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Reynolds M. Salerno**

**BTR 2005: Unified Science & Technology for Reducing Biological  
Threats & Countering Terrorism**

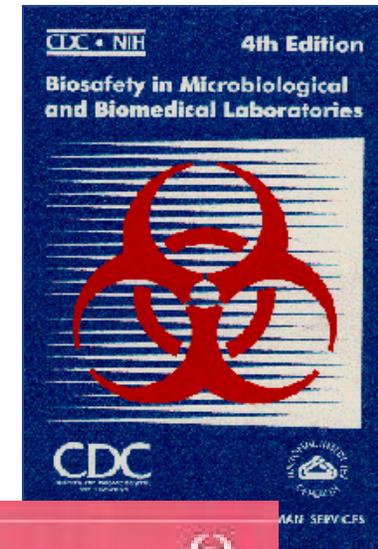
**March 18, 2005**

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
for the United States Department of Energy's National Nuclear Security Administration  
under contract DE-AC04-94AL85000.



# Goals and Objectives

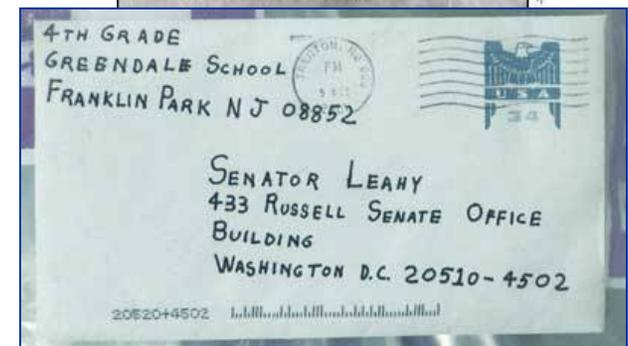
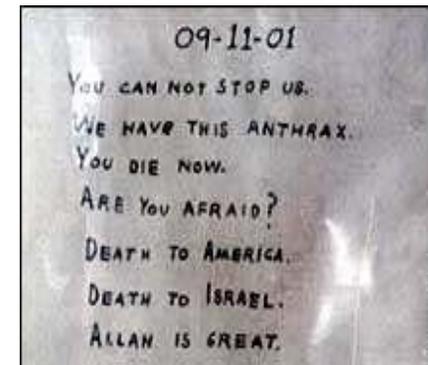
- **Laboratory biosafety and biosecurity share a similar goal**
  - **Keeping dangerous pathogens safely and securely inside the areas where they are stored and used**
- **Laboratory biosafety and biosecurity have different objectives**
  - **Laboratory biosafety: Reduce or eliminate accidental exposure to or release of potentially hazardous agents**
  - **Laboratory biosecurity: Protect biological agents against theft and sabotage**





# US Policy Response to the Bioterrorist Threat

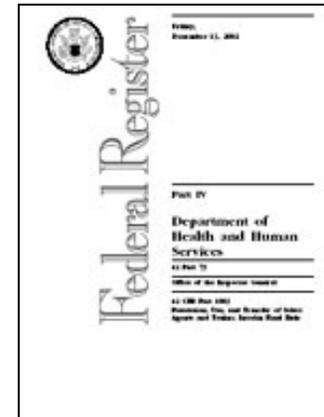
- **Emerging US security regime has two sets of objectives**
  - Enhance ability to respond to public and agricultural health emergencies
  - Reduce the risk that bioscience and biotechnology could be used maliciously
- **Realization that bioscience facilities are potential sources of biological weapons material (viable and virulent pathogens)**
  - US Select Agent Rule, 2003
- **New US regulatory “biosecurity” environment has broad international repercussions that the international community cannot ignore**





# New US Regulatory Environment for Biosecurity

- **USA PATRIOT Act of 2001 – US Public Law 107-55**
  - Restricted Persons
- **Bioterrorism Preparedness Act of 2002 – US Public Law 107-188**
  - 42 CFR 73 (Human and Overlap)
  - 9 CFR 121 (Animal and Overlap)
  - 7 CFR 331 (Plant)
- **The CFR require specific measures**
  - Registration of a facility if they possess one of the 82 Select Agents
  - Background checks for individuals with access to Select Agents
  - Facility must designate a Responsible Official
  - Security, safety, and emergency response plans
  - Safety and security training
  - Regulation of transfers of Select Agents
  - Recordkeeping
  - Safety and security inspections





# Biosafety and Biosecurity Issues

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## Areas of Overlap

- Risk assessment and risk management
- Personnel management
- Material transport protocols
- Physical security elements
- Training
- Emergency planning
- Program management

## Possible Conflicts

- Access controls
  - Allow for emergency ingress and egress but still ensure security of materials
- Badges
  - In some situations, badges can be a safety hazard but proper identification signifying authorization is crucial for both biosafety and biosecurity
- Signage
  - Necessary to alert staff and visitors of hazards but may identify materials, locations, and people



# Survey of Bioscience Community: Methodology

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- **Reed Research Group**
  - **Assisted in refining survey**
  - **Email blasts directed respondents to a secure web server – Reed collected the first 222 responses**
  - **Preliminary results were presented at two national meetings**
  
- **SNL continues to collect data at a secure website**
  - **From October 2004 – February 2005, 138 additional responses were solicited through a link at the ABSA website, announcements at meetings, and word-of-mouth**
  - **Survey is still open**



# Demographics of Respondents: Roles and Institutions

- Total number of respondents – 360

<b>Role</b>	<b>%</b>
<b>Biosafety Officers</b>	<b>22</b>
<b>Responsible Official</b>	<b>8</b>
<b>Principal Investigator</b>	<b>16</b>
<b>Laboratory support staff (technician)</b>	<b>12</b>
<b>Director/manager</b>	<b>27</b>
<b>Other</b>	<b>15</b>

<b>Institution</b>	<b>%</b>
<b>University</b>	<b>43</b>
<b>Clinical Lab</b>	<b>12</b>
<b>Diagnostic Lab</b>	<b>4</b>
<b>Industry</b>	<b>18</b>
<b>Government</b>	<b>15</b>
<b>Other</b>	<b>8</b>

**Select Agent Respondents – 181**

**Non Select Agent Respondents – 171**



# Access Controls

- **Select Agent Facilities**

<b>Campus</b>	<b>24%</b>
<b>Building</b>	<b>70%</b>
<b>Laboratory</b>	<b>85%</b>
<b>Freezers</b>	<b>75%</b>



- **Non Select Agent Facilities indicated that access controls were not heavily used**



- **68% of all respondents suggest that people and property are just as important to protect as dangerous pathogens and toxins**





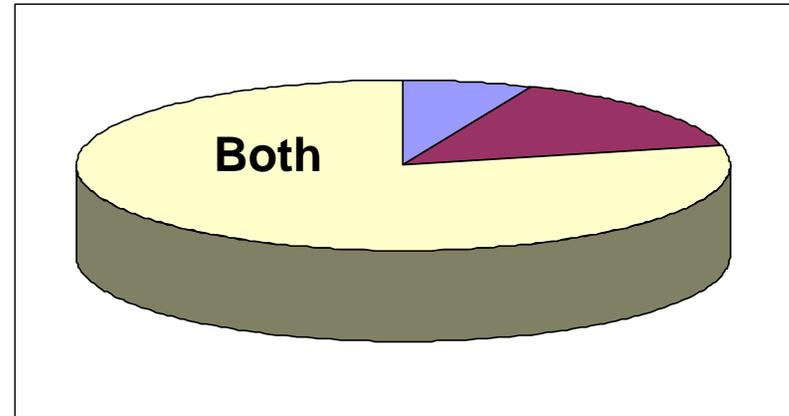
# Access Controls

Type of access control	Facility (% SA)	Facility (% non SA)	SA Freezer (% SA)	Non SA Freezer (% SA)	Non SA Freezer (% non SA)
Electronic	75	45	18	6	2
Guard	39	23	6	4	1
Mechanical	45	48	66	33	32
Retinal	2	1	3	1	0
Finger	9	3	3	2	0



# Visitor Escorting is a Safety and Security Issue

- **Select Agent Facilities**
  - **Require escort:**
    - 80% Yes
  - **Reason: 60% Both**

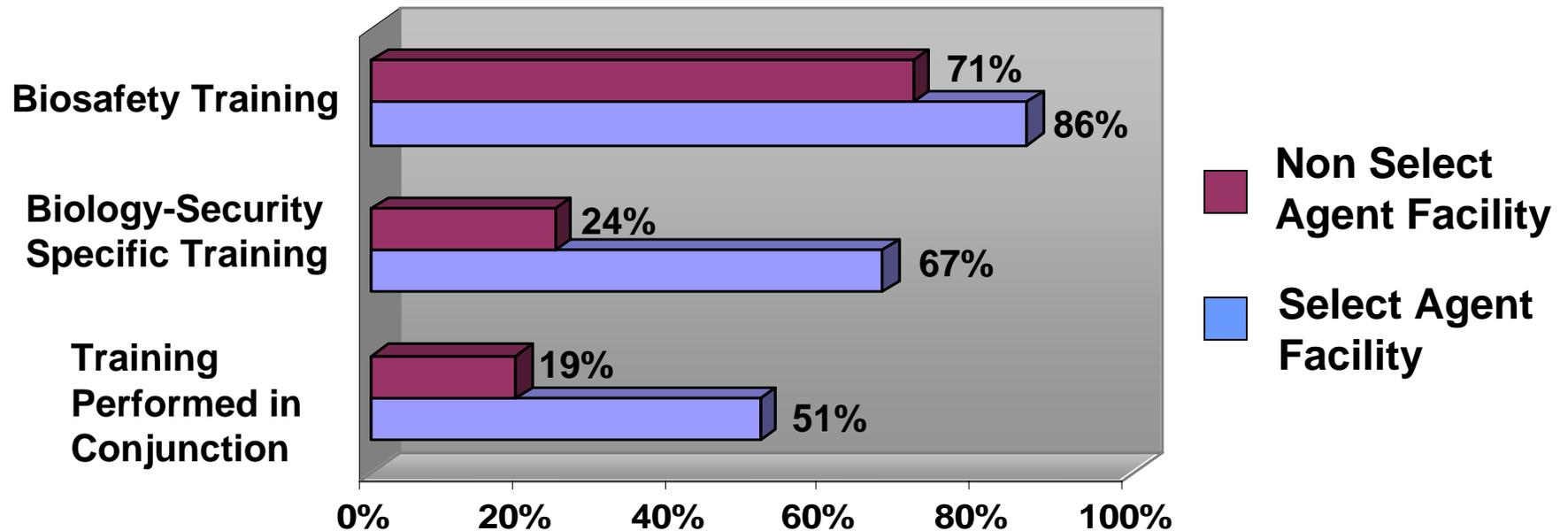


■ **Biosecurity**  
■ **Biosafety**

- **Non Select Agent Facilities**
  - **Require escort:**
    - 11% Yes, most said the reason was both



# Biosafety and Biosecurity Training



- Of those facilities that provide biosecurity training, most do so in conjunction with their biosafety training.



# Views on Security of Biological Materials: All Respondents

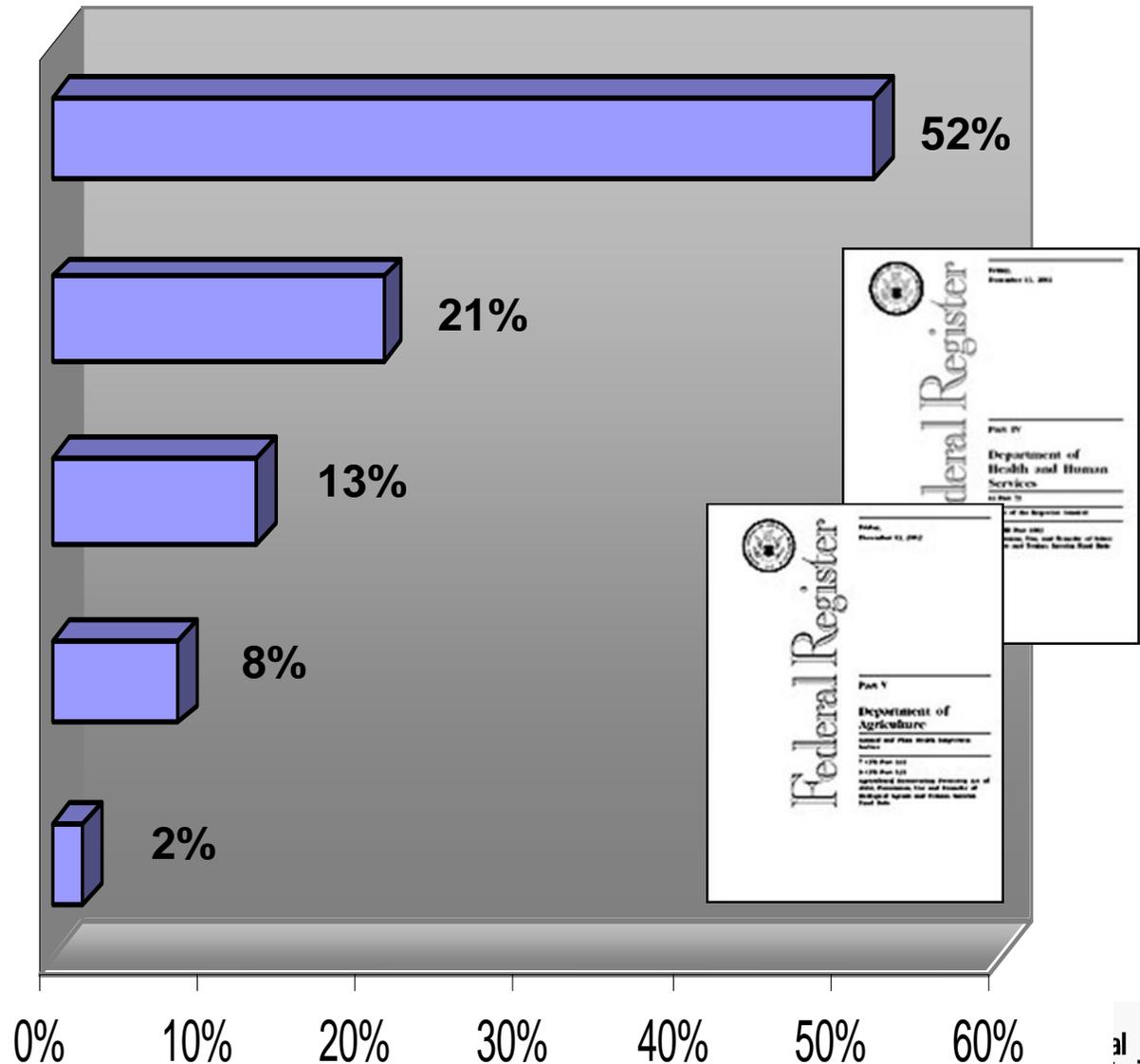
The CFR are on the right track but need to be revised to provide clarity

The CFR impose prudent security measures

The CFR are a good first step but don't go far enough

Some security of some pathogens and toxins is warranted but the CFR are not the right approach

Security of pathogens and toxins is unnecessary





# Perceived Impacts of CFR Security Requirements: Select Agent Respondents

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- **Positive Impacts**

- Increased awareness of risks posed by some pathogens and toxins – 72%
- Increased funding for biosafety and biosecurity staff – 28%
- Increased funding from the institution for needed security – 26%
- Increased research funding – 25%
- Increased number of researchers – 9%
- No positive impacts – 8%

- **Negative Impacts**

- Time required to comply with regulations – 48%
- Inconvenience of increased security – 28%
- Required to use research funding for required security upgrades – 28%
- Decrease in research funding – 7%
- Decrease in number of qualified research personnel – 12%
- No negative impacts – 4%



# Potential Conflicts between Biosafety and Biosecurity: Select Agent Respondents

- Signage
  - OSHA requires biohazard warning signs to be posted outside the laboratory for BSL2 organisms and higher
  - Must list precautions according to the latest information from NIH, CDC and USDA – often reveals the Select Agent in use
- 72% of **Select Agent** Respondents post signs outside the laboratory
  - 77% - international biohazard sign
  - 50% - sign reveals agent in use
  - 33% - sign that reveals agent posted **inside** the laboratory door





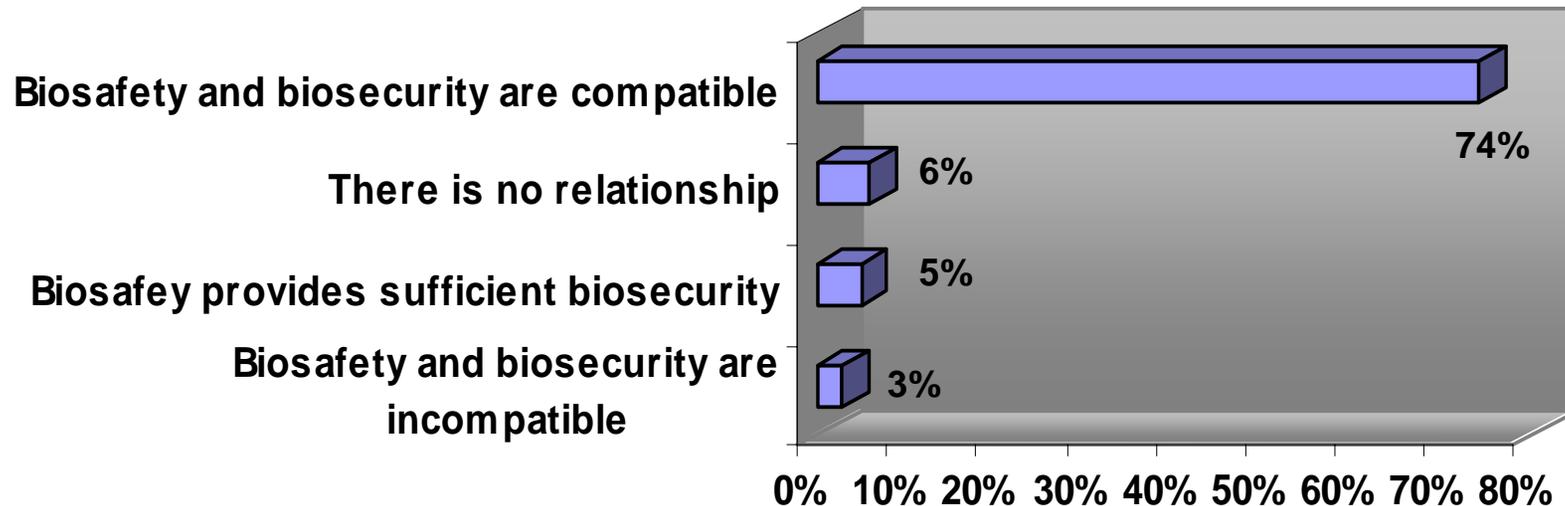
# Potential Conflicts between Biosafety and Biosecurity: Select Agent Respondents

- Identification badges
  - 69% of **Select Agent** Respondents require badges at all times
  - Of those, 7% indicated that biosafety considerations overrode the badge requirement
  
- Access controls and emergency response – **Select Agent responders**
  - Can emergency responders enter the laboratory by overriding access controls?
    - Yes, with escort, 25%
    - Yes, without escort, 8%
    - No, 25%
    - No response, 42%





# Relationship of Biosafety and Biosecurity: All Respondents



**“A program should be designed to incorporate both activities [biosafety and biosecurity] into a daily regime that allows for productive work as well as safety and security.”**



# Summary

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- **98% of respondents feel that biosecurity is warranted for some pathogens and toxins**
- **52% of respondents think the CFR should be revised to provide clarity**
- **74% of the community feels that biosafety and biosecurity are compatible. Only 3% think they are incompatible**
- **Goals:**
  - **Continue to collect data via our website – to date 360 total respondents**
  - **Continue to analyze data and publish results**
  - **Look for international parallels**



# Contact Information

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