

# **Laboratory Biosecurity: A Survey of the U.S. Bioscience Community**

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In 2004 and 2005, Sandia National Laboratories conducted a survey of the US bioscience community to assess the extent that laboratory biosecurity is implemented in laboratories and how it relates to laboratory biosafety and good laboratory practice in regulated select agent laboratories and non-select agent laboratories. This paper describes the results of this survey. SNL worked with Reed Research Group (Reed Business Information, Newton, MA) to write and conduct a survey of the US bioscience community. Reed used email lists to solicit potential respondents who were then directed to a web-based survey. Reed assisted SNL with refining the survey and collecting the first 222 responses. The SNL Biosecurity Team collected additional data through a web-based version of the survey on its secure server. An additional 129 responses were received through the SNL website. Responses to the survey on the SNL website have been solicited through the posting of a link on the American Biosafety Association (ABSA) website and an announcement on the ABSA email listserv. This report summarizes all of the responses received prior to March 2005 so it only covers the three interim Codes of Federal Regulations (CFRs) that specified security measures for approximately 80 pathogens and toxins—now known as select agents—that are deemed to pose a threat to human (47 CFR 73), animal (9 CFR 121), or plant (7 CFR 331) populations. Note: The given response percentages are based on the responses received to the specific questions. For some questions, respondents could select more than one response, so responses for some questions may not necessarily sum to 100%.

Disclaimer: The views expressed in this survey are those of the individual respondents and do not reflect the views of Sandia National Laboratories.

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## Survey Questions (in black) and Responses (in blue)

Biosafety and biosecurity are related, but not identical, concepts. Respondents used the following definitions in completing this survey.

Biosafety aims to reduce or eliminate exposure of individuals and the environment to potentially hazardous agents used in biological research, while the objective of biosecurity is to protect dangerous pathogens and toxins, along with critical security-related information, from theft and sabotage by those who intend to pursue bioterrorism or biological weapons proliferation.

### **All respondents answered the following questions:**

1. Does your institution or laboratory work with or handle pathogens or toxins?  
Only respondents who answered yes to this question were allowed to complete the survey – total of 351
2. What category best describes your institution?

University:	43.3%
Clinical lab:	12.5%
Diagnostic lab:	3.7%
Industry:	18.5%
Government:	15.1%
Other:	6.8%
3. Which of the following best describes your role?

Biosafety officer:	23.6%
Responsible official:	9.4%
Principal investigator:	16%
Laboratory support staff (technician):	12.3%
Director/manager:	27.6%
Other:	8.3%
4. How would you describe the principal activities of your lab? (check all that apply)

Clinical:	17%
Diagnostic:	26.5%
Basic research:	48.4%
Applied research:	39%
5. Which statement best describes your view regarding security of biological materials? CFR are the Select Agent Rules: 42 CFR 73, 7 CFR 331, 9 CFR 121 that require certain security measures for facilities using the pathogens and toxins on the list.

The CFR are a good first step but don't go far enough:	8.8%
The CFR impose prudent security measures:	25%
The CFR are on the right track but need to be revised to provide clarity:	45.3%
Some security of some pathogens and toxins is warranted but the CFR are not the right approach:	14.5%
Security of pathogens and toxins is unnecessary:	2.3%
- 5B Do you have any additional comments regarding the Select Agent Rules?

No graded approach for the size of the program. In some instances the security requirements are much too restrictive

ABSA or other renown party should help generate a basic plan.

Need revision to include stakeholders best practices

Implementation by the two regulating agents has been somewhat haphazard in that neither agency was well prepared or had well trained staff to oversee

## Survey Questions (in black) and Responses (in blue)

implementation and enforcement of the new regulations. Both agencies need better trained staff at this point.

Most of the select agents are available from the environment. If a terrorist could use the agent from a lab, he/she would also have the skills to isolate from the environment. Thus, applying a high level of security to the lab is of relatively minor improvement in security.

Gross overkill

I think the CFR require more security measures than are necessary for some of the select agents.

The CFR is not clear and there is no real place to go for quick answers. It seems that the federal agencies that review questions have to run their responses by teams of lawyers and other layers of bureaucracy.

It is unconscionable that diagnostic labs are excluded - they have the expertise and access to unregistered pathogens

Agencies involved desperately need to communicate better

It had a very poor start from a Fed. Admin standpoint, but worked out eventually. We were visited a great deal by Fed

The inventory issues for organisms are a nightmare, very difficult to deal with.

Necessary security requirements tend to hinder rather than promote research activities.

They need to be extensively revised to reflect different risk assessment based security levels for different select biological agents in different situations. They also are clearly written to apply to government type labs, where most or all of the individual laboratories are in one building (often referred to as "the lab") or small campus with a single main entrance. Many of the security requirements in the CFRs (especially in the USDA CFRs) make no sense when applied to a situation such as we have on campus, where our select biological agent lab consists of two room within a large building of non-select agent labs. An example is the name tag requirement. Less than ten people working in two rooms do not need name tags to know who should and who should not be there. Wearing name tags also marks them as the "select agent people" when they go out of the lab rooms to their offices or to do non-select agent work in shared lab space.

Many of the "select agents" are nothing new and can be easily obtained from the environment

They are confusing with much room for interpretation. Little guidance is provided even after contacting SA administrators

They need to be rewritten to have more clarity and harmonization

Not very specific in regards to biosecurity

Clarify lead agency; CDC, USDA, Dept. of Ag.? one responsible!

Many rules do not fit the applications involved in research.

The rules must be changed to allow for consideration of risks by the regulated entity.

They punish the "good guys" and have led to the destruction of valuable culture collections, without providing TRUE SECURITY.

Specifically define rules for genomic material and have them apply within the CDC and USDA.

Need more layman language and uniform guidance

Biosecurity guidelines are not realistic in a University setting.

The provisions are by design "political" and not science driven. More effort to balance scientific understanding of risk with political hot buttons would be helpful

Over time the CDC has taken a progressively more narrow interpretation of the regulations and as a consequence have had a negative impact on research.

There needs to be a realistic approach rather than universal decree

## Survey Questions (in black) and Responses (in blue)

The increased in funding and personnel for the Select Agent program is long overdue.

An increase in security was needed.

My experience with the USDA has been painful, CDC better

Needs much more clarification depending on the actual agent, quantities, etc...

Different federal agencies interpret them differently ( i.e., CDC, OIG, USDA)

Compliance monitoring by CDC is extremely dynamic and subjective. The use of contractors who have little background in research (particularly recomb. DNA) has made it difficult to reach agreement on diverse issues relating to the CFR.

More scientists and less politicians should have been involved

Compliance guidance and support is awful

CDC and USDA must work together to make it one regulation

Very time consuming paper-work and reporting. Not all reporting requirements are necessary to prevent biosecurity breaches. Paperwork reporting takes at least one full time employee. Antiterrorism benefit from this added expense is probably minimal.

They are a good framework to tailor to fit each institution

It seems like the people running the program have little knowledge of how an academic institution functions-they should come out to these sites more frequently because many of the rules seem like they are written in a cloistered vacuum. Also, compliance wise they should change the registration approval so that ROs DO NOT have to work with separate people at CDC/USDA and the FBI. There should be ONE contact person at the government for each institution.

Some agents do not belong on the SA list, but most do.

The section concerning packages in and out needs to be clarified.

Create an extra burden to research with very unclear benefit to improve security for really dangerous agents and toxins

Harmonization between CDC & USDA is absolutely necessary

They are idiotic.

The "bad" guys will not comply and you have no idea what they are doing, nor does the government.

6. Which statement below best describes the relationship of biosafety and biosecurity?

There is no relationship: 7.2%

Biosafety provides sufficient biosecurity: 5.8%

Biosafety and biosecurity are compatible: 83.4%

Biosafety and biosecurity are incompatible: 3.6%

6B. Do you have any additional comments on the relationship between biosafety and biosecurity?

Biosafety officers need to be prudent in biosecurity today.

There are some dichotomies but they can be overcome.

The investigators that work with regulated infectious agents and toxins should be involved in the regulatory process

Biosecurity should be like biosafety, somewhat different depending on risk level

I feel they are two separate issues, yet overlapping each other. One depends on the other.

The compatibility of biosafety and biosecurity lies in the expertise and experience that an Institutional Biosafety Committee can provide to both issues.

Actually they dovetail, in that biosecurity complements Biosafety and can be built into protocols and SOPs to ensure compliance.

Biosecurity protects biosafety

The two are incompatible only in the sense that a Biosafety Officer needs to be trusted by employees to look out for their support when facing unsafe work practices. It is difficult to trust a Biosafety Officer that is also required to report

## Survey Questions (in black) and Responses (in blue)

to DOJ on security concerns or suspicions that involve the same group of employees.

There can be conflicts between biosafety and biosecurity, but a flexible approach to compliance and establishment of biosecurity practices can make them compatible.

Security and safety are two separate challenges

I believe that the only correlation is in the term bio, when we look at security I am more concerned about external events like threats and when I look at safety I apply principles to the everyday work we do and the necessary precautions taken to protect our staff from the agents they are working with

Security and safety speak 2 different languages and we need to work on a common dialogue.

Even though they are completely different they go hand in hand

Currently in our lab they are handled primarily separately. Primarily because the biosafety systems were already in place.

While compatible, biosecurity adds different constraints

Not black and white...there are lots of difficult scenarios

Depend what you want secured (field, animal, lab, etc.)

Most biosafety professionals are not trained in biosecurity.

Biosecurity issues impose and defeat ability to communicate electronically

Most labs need more of both :-)

When it comes to listing agents on doors it is an issue

Their needs to be some knowledge of Biosafety to appropriately address all aspects of biosecurity. I do not believe a biosafety professional should be expected to become a biosecurity expert overnight.

I think that biosafety and biosecurity measures generally overlap a bit and are compatible. However, some security measures go against biosafety principals (for example, not putting the name of the agent being used on the door sign, and using coding instead of actual names on stored vials decreases biosafety by decreasing the hazard communication to personnel and increasing the chance of potential personnel exposure if vial coding gets confused). Many security measures are in conflict with life safety issues as well (exit/entry issues) . We need to be very careful in applying security so that we do not compromise personnel safety in the process. This is an area where the graded security levels come in. Personnel safety should override physical security when the risk of theft or release is not great. However, when the risk of theft is very great, security measures may need to take some priority over personnel safety. Each case really needs to be evaluated individually, and not lumped into one group and one set of security measures applied.

Both should be compatible but often not due to poor communication between responsible entities.

They are two different areas that sometimes overlap, each requires a different mindset because they attempt to achieve different goals.

Biosafety and security can go hand and hand but attempting to use the chemical surety approach is somewhat impractical. Also requiring to people with an SRA to access select agent yet once an infectious substance package is given to Fed ex handler are not required to have a two person rule and an SRA. Often time the truck sits unlocked as the driver stops to make additional deliveries.

Use the judgment of trained Biosafety Professionals

We were shocked to learn how lax some of the biosafety and biosecurity measures were at smaller institutions (and some large ones). As an IBC member, we were also shocked to learn how shoddy the IBC management was found to be at many

Survey Questions (in black) and Responses (in blue)

other institutions. No wonder the foot is now coming down. This is the few affecting the many (same old story)

Biosafety and biosecurity are separate but compatible concepts.

Your definition of biosecurity is questionable. An older definition of biosecurity adopted by the Australians and Europeans had more of a biocontainment bent (ensuring that the agent in the lab is contained) which included physical security of the agents, staff reliability and biosafety. I do not believe [Institution name] should attempt to change long standing definitions especially since you are relative new comers to the biosafety arena.

Biosecurity is not as mature as biosafety and takes too much emphasis from physical security professionals rather than develop own principles

Need to separate the two disciplines

7. Does your facility conduct biosafety training?  
Yes 89.5%  
No 10.5%
8. Does your facility have biology-specific security training?  
Yes 53%  
No (skip to q. 10) 47%
9. Is the security training done in conjunction with biosafety training?  
Yes 73.5%  
No 26.5%
10. Does your institution work with select agents (regulated by 42 CFR 73, 9 CFR 121 and/or 7 CFR 331)?  
Yes (Go to Q. 11-36) 51.3% "Select agent respondents"  
No (Go to Q. 37) 48.7% "Non-select agent respondents"

**Select agent respondents:**

11. Which of the following do you consider to be positive impacts resulting from the CFR security requirements? Please check all that apply.

Increased awareness of risks posed by some pathogens and toxins	78.9%
Increase funding from the institution for needed security	31%
Increased funding for biosafety and biosecurity staff	26.7%
Increased research funding	25%
Increased number of researchers	10%
No positive impacts have resulted from the CFR security requirements	8.3%

Other:

Enhances institutional oversight and communication  
Import from USA more difficult, but this is not necessarily "bad"  
Increased funding, but not adequate to cover mandated costs.  
More willingness for security department to work with research areas

## Survey Questions (in black) and Responses (in blue)

12. Which of the following do you consider to be negative impacts resulting from the CFR security requirements? Please check all that apply.

Decrease in number of qualified research personnel	14.4%
Decrease in research funding	10%
Required to use research funding for required security upgrades	37.8%
Inconvenience of increased security	45%
Time required from staff to comply with regulations	63.3%
No negative impacts have resulted from the CFR security requirements	9%
Other:	

13. What affect have the CFR had on your ability to do the following? Please rate on a scale of 1 to 5 where 5 is greatly affected and 1 not at all affected.

	5	4	3	2	1
Collaborate domestically	21%	18%	29%	16%	16%
Collaborate internationally	28%	13%	24%	16%	19%
Recruit qualified individuals	19%	18%	28%	20%	15%
Recruit foreign nationals	28%	16%	19%	14%	22%

14. Did increased funding for select agent research influence your decision to undertake this work?

Yes	23%
No	77%

15. Where is your select agent program registered?

Center for Disease Control Select Agent Program (CDC SAP)	59.2%
Animal Plant Health Inspection Service Select Agent Program (APHIS SAP)	10.6%
Both	30.2%

16. Is your institution subject to additional security requirements above and beyond those outlined in CFR (as outlined in 42 CFR 73.11, 9 CFR 121.12 and/or 7 CFR 331.11)?

Yes	20%
No	80%

17. Has your institution's select agent program been inspected?

Yes	75.6%
No (skip to Q.19)	24.4%

17B. If yes, by whom? (check all that apply)

CDC	72.8%
APHIS	22%
Department of Health and Human Services Inspector General Office	26.5%
United States Department of Agriculture Inspector General Office	15.4%

18. Please give your impressions of the inspection process.

Fair	79.5%
Inspection included elements beyond the scope of CFR requirements	19%
Unfair	1.5%

18b. If you have been inspected by both CDC and APHIS, please comment on any differences in the evaluations:

## Survey Questions (in black) and Responses (in blue)

CDC conducted document review and physical inspection, APHIS reviewed documentation and CDC findings  
APHIS inspectors more highly qualified, CDC inspectors more trained in the inspection process  
CDC - comprehensive, APHIS – superficial  
The APHIS checklist had many item on it not mandated by the CFR regulations. CDC inspectors seemed to be more professional and knowledgeable.  
CDC was very thorough, while APHIS inspection was for a specific USDA permit and was not as in-depth. The APHIS inspector was a veterinarian filling in the boxes.  
CDC is not as thorough as APHIS  
CDC knows what they are doing. I do not mind working with them. APHIS is a nightmare with their 20 or so page inspection sheet  
Each used a predetermined check-list. The inspectors did not have any special expertise or knowledge of the subject matter.  
CDC inspected based on a previous select agent registration; that project has been discontinued due to a retirement, and the registration has been withdrawn. We found the two CDC inspectors to be very knowledgeable, fair and helpful. The USDA OIG audited our entire biosafety program for a month. The USDA OIG inspectors were accountants who about 8 hours of training in biosafety/biosecurity issues, and they had absolutely no idea about what goes on in a laboratory or how to evaluate risks of microorganisms. They made evaluations and recommendations that were ridiculous (for example, they were astonished that a BSL-2 laboratory, which contained no select agents, was unlocked while occupied and had no security cameras).  
Prefer the CDC  
APHIS deferred mostly to the CDC regs  
DHHS-OIG had no idea what they were doing. Issued a completely bogus report. We countered it strongly. CDC (Constella) were seasoned pro  
CDC people were much better and knowledgeable than USDA  
The CDC inspection contractors were not as well trained as CDC staff. APHIS staff need significant amount of training and desperately need additional staffing for there program. They did go off to their expertise.  
An inspection sheet will be of great help.

19. Does your facility have a written biosecurity or security plan?

Yes	72%
No	28%

20. According to the CFR, “the security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.” Who conducted your risk assessment?

On site guard force	8.9%
Hired security contractor	9.9%
Local law enforcement	4.2%
Biosafety officer	48.4%
Other staff administrator	13.5%
Other	15.1%

21. Has anyone from your facility been denied approval to work with select agents?

Yes	10.8%
No	89.2%

22. Has your work been delayed due to the following? (check all that apply)

Obtaining FBI security risk assessment results	32%
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Survey Questions (in black) and Responses (in blue)

- |   |     |
|---|-----|
| Obtaining inspections/permission to operate | 31% |
| Obtaining research funding approval         | 18% |
| Having a security plan/system in place      | 13% |
23. Have you found it difficult to get an individual from another institution approved to work on a particular CFR-regulated pathogen/toxin at your facility, when they have been approved for such work at their home facility?
- |     |     |
|-----|-----|
| Yes | 23% |
| No  | 77% |
24. Describe your facility's security posture. (check all that apply)
- |  |     |
|--|-----|
| To protect people                            | 79% |
| To protect property (e.g. locked doors)      | 76% |
| To protect pathogens and toxins specifically | 74% |
- Other (please specify):
- Protection for patentable organisms and procedures
  - To protect patients in contiguous hospital
  - Top administrator stated he did not want to see our university become a police state and fears that academic freedom will be compromised by strict security rules.
  - Our security plan includes protection of all corporate assets including staff
  - Protect the community
  - Protect environment
  - To protect the environment
  - Protect information
  - Our risk assessment did not determine people were threatened (no GM food research)
  - To ensure that we can continue to work with select agents.
25. Please provide an estimate of your facility's overall cost of security upgrades as required by the CFR?
- |                           |             |             |
|---------------------------|-------------|-------------|
| \$10,000,000              | \$50,000    | \$100,000   |
| \$10,000                  | \$35,000    | \$5,000     |
| \$10,000                  | \$20,000    | \$10,000    |
| \$millions                | \$30,000    | \$50,000    |
| \$5,000                   | \$25,000    | \$20,000    |
| \$40,000                  | \$10,000    | \$10,000    |
| \$50,000 + personnel time | \$20,000    | \$50,000    |
| \$20,000                  | \$50,000    | \$50,000    |
| \$25,000                  | \$40,000    | \$20,000    |
| \$25,000                  | \$50,000    | \$400,000   |
| \$50,000                  | \$50,000    | \$95,000    |
| \$5,000                   | \$50,000    | \$350,000   |
| \$16,000                  | \$1,500,000 | \$8,000     |
| \$100,000                 | \$100,000   | \$1,000,000 |
| \$100,000                 | \$350,000   | \$10,000    |
| \$150,000                 | \$10,000    |             |
| \$60,000                  | \$100,000   |             |
26. Does your facility limit access to any of the following? (check all that apply)
- |   |       |
|---|-------|
| Campus (e.g. fence and gate)              | 27%   |
| Building (e.g. locks on exterior doors)   | 76.7% |
| Laboratory (e.g. locks on interior doors) | 92.8% |
| Freezers                                  | 80.6% |

## Survey Questions (in black) and Responses (in blue)

- 27A. What types of access controls are in use at your facility? (check all that apply)  
 27B. What type of access controls are located on freezers with select agents? (check all that apply)

	A. At facility	B. On freezers with select agents
Electronic badge swipe / proximity card/ PIN entry	81%	18.9%
Guard identification	41.6%	6.1%
Mechanical lock and key entry	52%	70%
Retinal / iris eye scanner	3.3%	2.8%
Fingerprint / hand geometry reader	11.1%	2.8%

28. Can emergency workers enter by overriding access controls?

Yes, with escort and/or permission 43.4%  
 Yes, by self 14.1%  
 No 42.5%

29. Do you require visitors to be escorted?

Yes 89.3%  
 No 10.7%

- 29B. If yes, is this requirement due to biosafety or biosecurity considerations?

Biosafety 9.1%  
 Biosecurity 16.9%  
 Both 74%

Additional comments:

JCAHO Requirements  
 Only select agent area  
 Must have brief biosafety training to enter  
 GLP  
 Also DOE facility security requirements  
 Safety in general  
 Confidential operations  
 Due to use of radiologics

30. At your institution, when are badges required to be worn in the lab?

Always 62.5%  
 Always, except for biosafety considerations 10.5%  
 Optional 10.5%  
 Our institution does not require badges 16.5%

31. OSHA biohazard warning signs require the international biohazard symbol for BSL2 rated organisms and higher in addition to listing precautions according to the latest information from the NIH, CDC and USDA. What information about a select agent do you think *should* be included on a sign (check all that apply)?

Name of agent 56.1%  
 Type of treatment/vaccination required 40.5%  
 Description of illness 22.2%  
 The international biohazard sign 85%

## Survey Questions (in black) and Responses (in blue)

32. Where does your lab post biosafety signs when a biohazard, including a select agent, is being handled?

Inside lab	37.2%
Outside lab	79.4%
Our lab does not post signs. (skip to q. 33)	3.3%

32B. Does the sign reveal the type of select agent(s) in use? For example, if *Bacillus anthracis* is in use, does the sign read something like “anthrax vaccination required.”

Yes	34.9%
No	65.1%

33. Do you inventory all pathogens and toxins?

Yes	80.6%
No (skip to q. 50)	19.4%

33B. Do you inventory select agents differently than non-select agents?

Yes	65.2%
No	34.8%

Additional Comments:

Select Agents have cradle to grave logs. Non-select but etiologic or regulated materials are inventoried as required by DOE order  
More frequently and thoroughly  
Select agents are inventoried on a running use log. We are workign on implementing a required campus wide inventory of human, animal and plant pathogens, but have not had the administrative support to require it and obtain compliance.  
Use Freezerworks  
SA inventory is only accessible by DOJ cleared (a few of ) employees and contains amounts and locations, on secured servers only.

34. What does the inventory track (check all that apply)?

Seed stocks	73%
Working stocks	77.3%
Vials	73%
Petri dishes	36.9%
Animals	25.5%

35. What type of inventory system do you have (check all that apply)?

Paper (e.g. logbook/lab notebook)	63.3%
Electronic spreadsheet style	33.3%
Electronic database	15.2%

36. Who has access to the inventory records (check all that apply)?

Biosafety officer	57.8%
Responsible official	58.3%
Principal investigator	62.8%
Other personnel that work with those materials	0%
Other personnel at the institution	0%
Anyone	0%

**Go to Q. 50**

Survey Questions (in black) and Responses (in blue)

**Non-select agent respondents:**

37. Has your institution ever worked with select agents?

Yes (Go to 38a and 38b) 24.1%

No (Go to 38c) 75.9%

38a. When did you cease such work?

Before CFR regulation (Feb 2003) 50%

After CFR regulation (Feb 2003) 50%

38b. Why did you cease work with select agents?

Organism we were using was declassified

PI left

That particular research was completed

Did not cease work, located outside United States

Researcher did not receive Cert of Registration in time-grant pulled

We were unable to upgrade the facilities in time to meet the requirements

The organisms were exempted

We do, but at exempt quantities

Research completed

Project relocated

The items used became "exempt" or were in "exempt" quantities

Because of the CFR Regulation

38c. Why not?

No interest in these agents at our facility 82.8%

To avoid CFR regulations 8.6%

Other: 8.6%

Will be using select agents in the future

Facilities still under construction

Pathogens is not our primary area of biosciences

Future Activities will include SA&Ts

No one area wants to pay for the upgrades of the BL2 facility

Only exempt amount toxins

Can use small quantities instead

Only working with exempt quantities of toxin

Work is with exempted quantities-work conducted off-site in government facilities

We deal with these agents at a EU subsidiary.

39. Does your institution conduct regular inspections (check all that apply)?

	Internal Self Assessment	External Inspection
Biosafety inspections	75.4%	36.8%
Biosecurity inspections	39.8%	11.1%
Other	4.7%	2.3%

40. Describe your facility's biosecurity posture. (check all that apply)

To protect people 14%

To protect property (e.g. locked doors) 14.6%

To protect pathogens and toxins specifically 9.9%

None (skip to q. 46) 9.4%

Other 5.3%

Survey Questions (in black) and Responses (in blue)

41. Does your facility have a written biosecurity or security plan?  
 Yes 39.8%  
 No 60.2%
42. Does your facility limit access to any of the following? (check all that apply)  
 Campus (e.g. fence and gate) 3.5%  
 Building (e.g. locks on exterior doors) 14%  
 Laboratory (e.g. locks on interior doors) 14.6%  
 Freezers 12.9%
43. What types of access controls are in use at your facility? (check all that apply)  
 43B. What type of access controls are located on freezers? (check all that apply)

	A. At facility	B. On freezers
Electronic badge swipe / proximity card/ PIN entry	6.5%	2.4%
Guard identification	27.6%	1.1%
Mechanical lock and key entry	55.3%	39.4%
Retinal / iris eye scanner	1.2%	0%
Fingerprint / hand geometry reader	3.5%	0%

44. Do you require visitors to be escorted?  
 Yes 80%  
 No 20%
- 44B. If yes, is this requirement due to biosafety or biosecurity considerations?  
 Biosafety 19%  
 Biosecurity 9.5%  
 Both 71.5%
45. At your institution, when are badges required to be worn in the lab?  
 Always 53.1%  
 Always, except for biosafety considerations 6.2%  
 Optional 6.2%  
 Our institution does not require badges 34.4%
46. Do you inventory all pathogens and toxins?  
 Yes 69%  
 No (skip to q. 50) 31%
47. What does the inventory track (check all that apply)?  
 Seed stocks 72.7%  
 Working stocks 63.6%  
 Vials 63.6%  
 Petri dishes 13.6%  
 Animals 31.8%
48. What type of inventory system do you have (check all that apply)?  
 Paper (e.g. logbook/lab notebook) 48%  
 Electronic spreadsheet style 19.3%  
 Electronic database 15.2%

## Survey Questions (in black) and Responses (in blue)

49. Who has access to the inventory records (check all that apply)?
- |                        |       |
|------------------------|-------|
| Biosafety officer      | 34.5% |
| Responsible official   | 31.6% |
| Principal investigator | 31.6% |

### (All respondents)

50. Please provide any additional comments regarding the integration of biosecurity into a biosafety environment:

As any new system promoting change was resisted at first but so far all personnel affected for it has adopted the process.

When we plan any work we do a safety review which includes security. That's for all work-- chemical, biological, etc

I do not see integration of physical security, biological safety and biocontainment to be a difficult process. To some degree we have always been performing these functions as responsible researchers and biosafety professionals.

This was not especially onerous, as we already had strict security on the laboratory. The largest burden was coordinating the information for the FBI background checks.

It is difficult but accepted

Security measures should commensurate with the level of hazard present.

Personnel safety is a much more real risk than theft or sabotage, and must take priority over security, unless a science/fact based risk assessment warrants otherwise.

Biosecurity and biosafety reside in the same office and often communicate. Lab access is only granted when biosafety (vaccine requirements) and biosecurity (CDC SRA approval) concur.

We treat select agents differently than regular agents (We have very few pathogens most are non-pathogenic strains)

To do this successfully requires more personnel and types of personnel other than biosafety and IHS.

It's important to involve safety, law enforcement, and researchers into the process of security plan development. Each group brings a unique perspective to the table, and the combination of all ideas can produce the most practical plan.

Difficult to protect research information regarding work with S.As.

It makes little sense to go to extremes of expense and protocol to secure laboratory stocks of pathogens which can readily be isolated from natural sources.

One has to determine the threat rather than the actuality.

I think some additional security measures are truly necessary, however, I believe what we are now having to do to comply with CDC Select Agents is complete overkill. THE administrative oversight and nit-picky details, in addition to requiring the use of forms that are not user-friendly (e.g., the tables 4B, 5A, 5B, certain sections of the application, inability to save (electronically) certain parts without saving the entire document, etc. ) has gobbled up valuable time that could have been better spent that produced real value for the program and the institution.

It is proving to be an uphill battle with many researchers; NIH study groups do not look at this issue routinely.

Biosecurity is not a concept we have dealt with a lot. I believe that access to records and inventories is the biggest issue for use to deal with.

Access requirements (keycard access which requires physical swiping, for example) can conflict with contamination control.

It has taken us a year to get money out of the university to just improve biosafety aspects of our select agent labs....will probably take another year to integrate all necessary biosecurity aspects

## Survey Questions (in black) and Responses (in blue)

We are struggling thru the new reg. It appears that the leading agencies (USDA & CDC) are expanding their list of questions and reporting requirements daily. I think the whole law (Patriot ACT) and subsequent regulation was rushed into implementation and some of the mechanisms offered for compliance (eg. on line form submission) do not work at all or are cumbersome to use.

Its been difficult eliciting the cooperation of administration and researchers

Should be done at our institution

Select Agents were removed so biosecurity is the same as all other security measures that effects lab operations

Compliment each other well EXCEPT for ID/name of toxin/organism on door or on shipping boxes

Although the biosafety officer should be involved, it is a group effort, and should not rest on BSO.

I feel that it is a very important area that needs to continue to be developed.

We have just begun looking at this issue, (other than locked lab doors in some areas)

It should be a natural extension of biosafety and general laboratory facility safety so that it is easy to maintain.

Some non-profit organizations are often at a disadvantage economically in introducing new security features

It needs to be totally integrated. Not just for SAs and toxins/pathogens, but on every level, even classroom and teaching laboratories. This way, the newcomers are exposed to it prior to working in a research environment where it is possible they have never heard of them let alone been exposed to them

Somewhat difficult to achieve on an "open" campus (academia) environment.

If you are using Select agents, then biosecurity and biosafety need to be integrated into the same program and training must be conducted.

### 51. Please provide any additional comments on biosecurity in general:

It needs to be results-oriented and involve common sense. Restricting access to pathogens readily available in the environment is ludicrous.

Needs to be better clarification on requirements vs. recommendations

Convenience of workers sometimes wins out over safety/security concerns

Biosecurity should be practical and related to the degree of real security risk present. Many infectious agents have a very limited biosafety risk.

Product/vector protection is also necessary to protect patents and research from commercial espionage

I think this will be a growing agenda item for Federal Officials. I believe it is important for Associations, Researchers and Biosafety professionals to be very involved in the development of guidelines that pertain to biosecurity.

There needs to be a standardization of terms and what is required by all agencies regulating the possession/use of SA&Ts

If biosafety becomes a security issue it will be addressed at that time

Concern at the top of the institution is arising - now they are looking for the money- some of us think it is progressing too slow for our comfort

Too much biosecurity = loss of academic freedom in many cases. It is very expensive to establish SA secure and non-secure BSL3 labs - thus many not working with SAs must comply with strict security regs. This adds to regulatory burden for all researchers. I believe that university wide biological inventories are a must - but DOJ clearance is too restrictive and I do not see the association with minor (yet technically correct) felony offences (such as pot smoking a long time ago) to be a sign of bioterrorism potential. The clearance process should only rely on foreign terrorism potential, immigration status and involvement with subversion groups.

## Survey Questions (in black) and Responses (in blue)

Uniform interpretation of the CFR, particularly by compliance auditors from CDC, would be extremely helpful. Right now we are at the mercy of the contractors hired by CDC who each have their own subjective take on what constitutes appropriate compliance measures. Need less "cop" and bureaucrat attitude, more scientifically-based, realistic approaches to biosecurity, particularly select agents.

Additional clarification on security requirements from the CDC/USDA would be helpful. It would help to evaluate our own program and be sure that we are up to standards. Since we are never going to be totally safe, we need to rethink the time, energy and money going to biosecurity.

In Canada, our security requirements are different than yours, as select agents per se are not regulated

I find most of the researchers can work with defective or vaccine strains.

The researchers do not comply with all security requirements such as escorting, issuing IDs. The security assessment was not completed following the guidelines. PI refused to implement some of recommendations. [Institution name] is wishy washy on topic.

The increased awareness about basic security in a laboratory working with hazardous materials has been a good result of the unfortunate incidences in 2001 and the subsequent resulting CFRs, but we must proceed with sense and rationality so that we don't forsake safety and public health in order to prevent the relatively low probability of bioterrorism occurring.

A double edged sword - what was not considered initially may be overdone now

Inspection by outside agencies is the only thing that wakes up faculty

Biosecurity is tacitly referenced in the BMBL under all 4 biosafety levels. The CFR merely required that we now place more emphasis on the actual mechanics of implementation.

The CDC and USDA are still not well coordinated regarding biosecurity.

I really dislike the term biosecurity....what we are talking about is physical security, protecting an asset that just happens to be a biological agent...coming up with new terminology is a bad idea and confusing to us old farts.

Need to shift mindset of biosecurity from "police" type approach to a collegial, professional footing working in concert with biosafety to facilitate research, not inhibit it.

As is [Institution name], we are a [Institution name] and have the advantage (if you want to call it that) of having security and foreign visitor procedures in place that we can point to in our biosecurity program. Also, we have the manager of our Safeguards and Security Division is on our IBC. However, the Security requirements in the Select Agent Regs are ludicrous. I don't know how the researchers get any work done.

More benchmarking needed between institutions.