



# Oversight of High-Containment Biological Laboratories: Issues for Congress

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## Summary

The federal government responded to the September 11, 2001, terrorist attacks and the subsequent anthrax attacks with increased focus on and funding for biodefense. A key consideration in this response was addressing shortages in diagnostic, clinical, and research laboratory capacity. Several departments and agencies have increased or are in the process of increasing their laboratory capacity. High-containment laboratories play a critical role in the biodefense effort, offering the hope of better responses to an attack and a better understanding of the threat posed by bioterrorism. However, they also could increase the risk of a biological attack by serving as a potential source of materials or training. Indeed, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism recommends tightening government oversight of high-containment laboratories.

Policymakers have become increasingly interested in the oversight of these facilities following reports of accidents, regulatory noncompliance, and community resistance. The increase in high-containment laboratory capacity has raised new policy questions and emphasized existing ones. How much laboratory capacity is enough? What is the necessary federal investment? Should laboratories be consolidated or dispersed? What plans exist to coordinate multiple agency efforts to expand high-containment laboratory capacity? Does increasing laboratory capacity increase the risk of accidents and the opportunity for purposeful misuse? What is an acceptable balance between the benefits these laboratories provide and the risks they pose?

Interested Members of Congress might take action to address some or all of these concerns. Alternatively, they might defer action until efforts currently under way assess and make recommendations regarding the existing regulatory structure. If Congress chooses to enhance oversight, it might require a survey of existing facilities and their use and a national needs assessment, perhaps barring further construction until these are complete. Stakeholders could focus on enhancing self-regulatory activities such as improving or standardizing laboratory worker training or building a mechanism for sharing lessons learned. Rather than relying on self-regulation, policymakers might enhance oversight through additional regulation of high-containment facilities, requiring laboratory or personnel certification, or by broadening the Select Agent Program. Which agencies should implement any new mandates remains an open question.

Biocontainment technologies are widely used by scientists around the world. Efforts to increase control of U.S. high-containment laboratories may put domestic industry at a competitive disadvantage and inhibit international academic collaboration. Absent international harmonization, the United States can only partially address the threat of a high-containment laboratory being the source of a bioterror weapon.

A key task for policymakers is to define their goals for enhancing oversight of high-containment laboratories. The focus of the oversight effort may affect which policy issues are addressed. For example, focusing on a registry of existing high-containment laboratory capacity may improve planning, coordination, and efficiency of use but provide relatively limited security benefits. Similarly, a rigorous oversight program including facility and personnel licensure, mandatory training, and restricted construction of new facilities may provide security benefits at the cost of regulatory burden, increased federal expenditures, and impeded scientific progress in countermeasure research, bioforensics, and public health. When weighing options to address these complex policy issues, policymakers may have to reconcile many competing and potentially conflicting national needs.

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## Introduction

The federal government responded to the September 11, 2001, terrorist attacks and the subsequent anthrax attacks with increased focus on and funding for biodefense. A key consideration in this response was addressing capacity shortages for diagnostic, clinical, and research laboratories. Since 2001, the Department of Defense (DOD), the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), and the Department of Agriculture (USDA) have increased or are in the process of increasing their laboratory capacity for the study of dangerous pathogens. Because stringent protocols and engineering are used to contain the most dangerous pathogens, these facilities are often referred to as high-containment laboratories. High-containment laboratories play a critical role in the biodefense effort, offering the hope of better responses to a biological attack and a better understanding of the bioterrorism threat. However, they could also increase the risk of a biological attack by being a source of materials or training.

In addition to increasing laboratory capacity, the federal government invested in research to develop countermeasures, diagnostics, and detectors for dangerous pathogens potentially usable in a terrorist attack. One group has calculated that congressionally appropriated funding for civilian biodefense increased from \$690 million in FY2001 to \$5.4 billion in FY2008.<sup>1</sup> Much of this funding supports academic and industrial researchers and laboratories that handle these dangerous pathogens. The influx of funds and researchers has exacerbated existing concerns about aging laboratory infrastructure and limited research and diagnostic laboratory capacity.

Non-federal entities have also expanded or constructed additional high-containment laboratories. In addition to the threat of bioterrorism, an increasing awareness of the threat posed by emerging and re-emerging diseases has led to the proliferation of high-containment laboratories internationally, as the technologies used are widely available.

The increase in high-containment laboratory capacity has raised new policy questions and increased focus on existing ones. How much laboratory capacity is enough? What is the necessary federal investment? Should laboratories be consolidated or dispersed? What is the optimal size and type of high-containment laboratory? With multiple agencies expanding high-containment laboratory capacity, is a plan coordinating these efforts necessary? Does increasing laboratory capacity and the number of trained scientists increase the risk of accidents and/or opportunities for purposeful misuse? What is an acceptable balance between the benefits these laboratories provide and the risks they pose?

Policymakers have become increasingly interested in the expansion of these facilities following reports of accidents, regulatory noncompliance, and recent examples of community resistance to the laboratories. The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism recommended tightening government oversight of high-containment

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<sup>1</sup> Crystal Franco, "Billions for Biodefense: Federal Agency Biodefense Funding, FY2001-FY2009," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 6, no. 2 (2008), pp. 131-146. Other groups use different definitions of what constitutes biodefense, but observe increases of similar magnitude. For example, see Alan Pearson, *Federal Funding for Biological Weapons Prevention and Defense, Fiscal Years 2001 to 2009*, The Center for Arms Control and Non-Proliferation, Washington, DC, May 27, 2008, [http://www.armscontrolcenter.org/policy/biochem/articles/fy09\\_biodefense\\_funding/](http://www.armscontrolcenter.org/policy/biochem/articles/fy09_biodefense_funding/).

laboratories.<sup>2</sup> These laboratories may also be regulated by state and local laws, regulations, and ordinances. This report focuses on the federal government's regulation of high containment laboratories. It explains the concepts of biosecurity and biosafety, including the mechanisms by which the federal government oversees their implementation; describes the proliferation of high-containment laboratories; discusses issues facing federal policymakers; and identifies policy options for congressional consideration.

## **Biosecurity and Biosafety**

Biosecurity and biosafety are closely related. Their definitions vary from source to source and sometimes overlap. In this report, biosecurity refers to steps taken to secure pathogens or biological materials from theft, unauthorized access, or illegal use, while biosafety refers to mechanisms or practices employed to lower the risk of unintentional infection in the laboratory or environmental release from the laboratory.<sup>3</sup> While biosecurity and biosafety are clearly related closely, their practices and oversight mechanisms have mainly developed independently.

## **Biosecurity and the Select Agent Program**

Although biosafety has been a concern of the general laboratory science community for many years, biosecurity has only recently come to the fore. The major federal regulatory program addressing biosecurity is the Select Agent Program.<sup>4</sup> The federal government created the Select Agent Program in order to regulate and oversee commerce in pathogens that might have severe consequences if released into the environment.

The Select Agent Program was first established by the Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132). This law required HHS to identify a list of organisms and toxins that could potentially be used for bioterrorist attacks and to regulate their transfer, though not their possession. These pathogens and toxins were to be known as select agents.

The 2001 anthrax mailings increased the federal government's interest in the threat of bioterrorism. Congress enacted the USA PATRIOT Act (P.L. 107-56) and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) which increased restrictions on the possession of pathogens and toxins that have been identified as possessing the greatest potential for malevolent use. Entities possessing select agents were required to develop explicit security and biosafety plans and procedures to be reviewed and certified by the federal government.<sup>5</sup> The Select Agent Program oversees regulation of select

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<sup>2</sup> Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *World at Risk*, December 2008.

<sup>3</sup> The terms can be used differently in other contexts. For example, in agricultural parlance, the term biosecurity may refer to practices to minimize the introduction of plant and animal pathogens to farms.

<sup>4</sup> For more information on the Select Agent Program, see online at <http://www.selectagents.gov/>.

<sup>5</sup> The Select Agent pathogen lists can be found at 7 C.F.R. 331 (plant pathogens), 9 C.F.R. 121 (animal pathogens), and 42 C.F.R. 73 (human pathogens). An entity is defined as any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. An entity is thus not limited to a single facility or to a single laboratory. An entity may possess one or multiple facilities, each facility containing one or multiple laboratories.

agents possession, transfer, and use. It focuses mainly on two areas: people who have access to select agents and facilities where select agents are used and stored.

Scientists who want access to select agents must register with the federal government. Applicants provide information to the Department of Justice (DOJ), which performs background checks to determine whether the applicant may be permitted to handle select agents. Such permits are nontransferable and are valid for five years.

Facilities that possess or use select agents must develop and implement a security plan to protect the select agents from theft or improper access. These plans are submitted either to HHS, through the Centers for Disease Control and Prevention (CDC), or to USDA, through the Animal and Plant Health Inspection Service (APHIS). These agencies review them for regulatory compliance and audit their security plan implementation. The CDC performs announced inspections of each regulated facility at least once every three years.<sup>6</sup>

Failure to comply with the regulations of the Select Agent Program is punishable by fines. Persons possessing select agents who have not successfully completed the DOJ security risk assessment process or are prohibited from possessing select agents under the USA PATRIOT Act may be in violation of 18 U.S.C. 175, which prohibits the possession of biological weapons.

## **Program Participation**

As of February 2009, approximately 390 entities had been issued certificates allowing work with select agents and 15,300 staff had active security risk assessment approvals to have access to select agents.<sup>7</sup> See **Table 1** for details. The largest group of certified entities are owned or operated by state or local governments. Many of these entities are state or local public health laboratories. As part of efforts to develop robust testing and response capabilities following a biological attack, the federal government has developed a Laboratory Response Network that links many of these state or local public health laboratories. One of the goals in establishing the Laboratory Response Network was to create a laboratory in each state capable of handling dangerous pathogens.<sup>8</sup>

Additionally, the large number of academic entities, and presumably researchers, has increased tensions over the Select Agent Program in academia. This community has a long tradition of openness and has, in some cases, viewed the select agent regulations as too onerous to continue performing research with these pathogens. Approximately 200 entities either transferred or destroyed their select agent inventories rather than registering under the select agent regulations.<sup>9</sup>

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<sup>6</sup> Dr. Richard Besser, Director of the Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

<sup>7</sup> Centers for Disease Control and Prevention, personal communication, February 9, 2009; and Department of Agriculture, personal communication, February 4, 2009.

<sup>8</sup> For more information on the Laboratory Response Network, see online at <http://www.bt.cdc.gov/lrn/>.

<sup>9</sup> Centers for Disease Control and Prevention, Office of Inspector General, Department of Health and Human Services, "Possession, Use, and Transfer of Select Agents and Toxins," 70 *Federal Register* 13294-13325, March 18, 2005.

**Table I. Entities That Work with Select Agents**

| Type of Entity         | CDC Regulated | USDA Regulated | Total |
|------------------------|---------------|----------------|-------|
| Academic               | 95            | 22             | 117   |
| Government—State/Local | 117           | 10             | 127   |
| Government—Federal     | 62            | 9              | 71    |
| Private                | 49            | 22             | 71    |
| Total                  | 323           | 63             | 386   |

**Source:** Centers for Disease Control and Prevention, personal communication, February 9, 2009; and Department of Agriculture, personal communication, February 4, 2009.

## Program Oversight

The performance of the Select Agent Program has been the topic of a number of investigations by agency Inspectors General (IG). These investigations have focused on agency internal controls on select agents,<sup>10</sup> the ability of lead agencies to process researcher and entity applications,<sup>11</sup> and the regulatory compliance of facilities receiving select agent certificates. The HHS IG found that 11 of 15 representative universities investigated did not fully comply with the select agent regulations.<sup>12</sup> It also found that none of the eight representative state, local, private, or commercial laboratories investigated were in full compliance. Three of these entities chose to withdraw their select agent licenses following the investigation.<sup>13</sup> The USDA IG found similarly that APHIS controls over registered entities and registered entities' compliance with select agent regulations were not complete.<sup>14</sup> In 2007, the CDC suspended a select agent entity certificate at Texas A&M University, reportedly because of failure to report occupational exposures in a timely fashion and because laboratory workers lacking a security risk assessment were allowed access to select agents.<sup>15</sup> Other companies, laboratories, and universities have also been cited and fined for

<sup>10</sup> Department of Energy, Office of Inspector General, *Coordination of Biological Select Agent Activities at Department of Energy Facilities*, DOE/IG-0695, July 2005.

<sup>11</sup> Department of Justice, Office of Inspector General, *Inspection of the FBI's Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins*, I-2005-003, March 2005.

<sup>12</sup> Department of Health and Human Services, Office of Inspector General, *Summary Report on Universities' Compliance with Select Agent Regulations*, A-04-05-02006, June 2006; and Department of Health and Human Services, Office of Inspector General, *Summary Report on Select Agent Security at Universities*, A-04-04-02000, March 2004.

<sup>13</sup> Department of Health and Human Services, Office of Inspector General, *Summary Report on State, Local, Private, and Commercial Laboratories' Compliance with Select Agent Regulations*, A-04-06-01033, January 2008.

<sup>14</sup> Department of Agriculture, Office of Inspector General, *Audit Report Controls Over Biological, Chemical, and Radioactive Materials at Institutions Funded by the U.S. Department of Agriculture—Government-wide Policies Are Needed to Establish Security Standards for Federally-Funded Research at Non-Federal Institutions*, Report No 50099-14-AT, September 2003; Department of Agriculture, Office of Inspector General, *Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations—Phase I*, Report No 33601-2-AT, June 2005; and Department of Agriculture, Office of Inspector General, *Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations—Phase II*, Report No. 33601-3-AT, January 2006.

<sup>15</sup> Emily Ramshaw, "A&M Lab Employee Lacked Clearance in Bioagent Case; Records Detail Security Breaches at University, Other State Schools," *The Dallas Morning News*, July 8, 2007; Emily Ramshaw, "A&M Admits Errors in Bioagent Case; Interim President Denies Wrongdoing, Questions CDC Timing," *The Dallas Morning News*, July 3, 2007; and Emily Ramshaw, "CDC Suspends A&M Research on Infectious Diseases; CDC Suspends Bioagent Work after Exposures Not Reported Promptly," *The Dallas Morning News*, July 2, 2007.



violations of the select agent regulations. The HHS OIG has levied a total of \$1,887,000 in fines on 12 organizations for failure to comply with the Select Agent regulations.<sup>16</sup>

## **Biosafety and Laboratory Best Practices**

Scientists studying dangerous pathogens generally acknowledge the risk of contracting the disease under study and the potential of accidentally releasing a pathogen into the environment. Over time, scientists have developed best practices to mitigate these risks. In the 1970s and 1980s, the U.S. government began collecting these practices and issuing them as formal guidelines. The most commonly referenced guidelines are disseminated by HHS in the publication *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*.<sup>17</sup>

### **Biosafety Levels**

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) have established four main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.<sup>18</sup> Each biosafety level is associated with specific physical and procedural protections. See **Table 2**. In general, the more dangerous the pathogen is to human health, the higher its recommended biosafety level. Each successive biosafety level consists of the protective measures of the lower biosafety levels, augmented with additional protective measures. Generally, the term “high-containment laboratory” refers to BSL-3 and BSL-4 laboratories.

The current BMBL guidelines grew out of earlier efforts by the DOD, HHS, and USDA. These best practices were developed to protect laboratory workers based on the various specific risks posed by different pathogens.<sup>19</sup> The guidelines present criteria to define the different biosafety levels, best practices for safe laboratory operation at these biosafety levels, and mechanisms for identifying the appropriate biosafety level for a given organism and procedure. Because the biosafety level may vary depending on the procedure, some experts recommend that biosafety levels be thought of as linked to a combination of pathogen and experiment, not as accompanying particular pathogens.<sup>20</sup>

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<sup>16</sup> Fines levied through August 16, 2008. See [http://oig.hhs.gov/fraud/enforcement/cmp/agents\\_toxins.asp](http://oig.hhs.gov/fraud/enforcement/cmp/agents_toxins.asp).

<sup>17</sup> Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Biomedical and Microbiological Laboratories (BMBL)*, 5<sup>th</sup> edition, 2007, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

<sup>18</sup> Other agencies have expanded on the BSL-1 to BSL-4 nomenclature through additional guidance. For example, USDA has developed a BSL-3Ag nomenclature and guideline to define BSL-3 containment applicable to large animal research. USDA, Agricultural Research Service, *ARS Facilities Design Standards*, 242.1-M ARS, July 24, 2002, <http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf>.

<sup>19</sup> *BMBL*, 5<sup>th</sup> edition, 2007, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

<sup>20</sup> Gigi Kwik Gronvall and Nidhi Bouri, “Biosafety Laboratories,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 6, 2008, pp. 299-307.

**Table 2. Biosafety Level Criteria**

| <b>BSL</b> | <b>Agents</b>  | <b>Practices</b>  | <b>Primary Barriers and Safety Equipment</b>  | <b>Facilities</b>  |
|------------|--|---|---|--|
| 1          | Not known to cause disease in healthy humans   | Standard microbiological practices  | None required   | Open bench and sink required   |
| 2          | Agents associated with human disease<br><br>Routes of transmission include percutaneous injury, ingestion, and mucous membrane exposure  | BSL-1 practice plus:<br><br>Limited access<br><br>Biohazard warning signs<br><br>Sharp objects precautions<br><br>Biosafety manual defining waste decontamination and medical surveillance policies | Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials<br><br>Laboratory coats and gloves required<br><br>Face protection as needed | BSL-1 plus:<br><br>Autoclave available   |
| 3          | Indigenous or exotic agents with potential for aerosol transmission<br><br>Disease may have serious or lethal consequences   | BSL-2 practice plus:<br><br>Controlled access<br><br>All waste decontaminated<br><br>Laboratory clothing decontaminated before laundering<br><br>Baseline worker health established                 | Class I or II BSCs or other physical containment devices used for all open manipulation of agents<br><br>Protective laboratory clothing and gloves required<br><br>Respiratory protection as needed   | BSL-2 plus:<br><br>Physical separation from access corridors<br><br>Self-closing, double-door access<br><br>Exhaust air not recirculated<br><br>Negative airflow into laboratory |
| 4          | Dangerous/exotic agents which pose high risk of life-threatening disease and for which aerosol-transmitted laboratory infections have occurred<br><br>Related agents with unknown risk of transmission | BSL-3 practices plus:<br><br>Clothing change before entering<br><br>Shower on exit<br><br>All material decontaminated on exit from facility   | All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit  | BSL-3 plus:<br><br>Separate building or isolated zone<br><br>Dedicated supply and exhaust, vacuum, and decontamination systems<br><br>Other requirements outlined in the BMBL    |

**Source:** BMBL, 5<sup>th</sup> edition, 2007.

The BMBL describes primary and secondary barriers to infection, as well as standard and special laboratory practices for each biosafety level. Unlike previous editions, the most recent edition of the BMBL also contains some security guidelines for the different biosafety levels.<sup>21</sup> According to federal grant policy and standard contract language, researchers and laboratory workers at institutions receiving federal funds are to be trained in the procedures described in the BMBL before they gain access to the laboratory.

<sup>21</sup> BMBL, 5<sup>th</sup> edition, 2007, Section VI, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

The correct biosafety level depends on the pathogen, its potential for transmission and treatment, and the research procedure or activity being conducted. Procedures deemed unlikely to produce disease in healthy humans should be conducted at BSL-1. Those that may cause disease in healthy humans, but for which immunization or antibiotic treatment is available, should be conducted at BSL-2. Procedures that may cause serious or potentially lethal diseases as a result of pathogen inhalation should be conducted at BSL-3. Procedures that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease should be conducted at BSL-4.<sup>22</sup>

Because the recommended biosafety level for a particular activity is determined by considering both the pathogen and procedure, it is possible to safely handle potentially deadly pathogens at lower biosafety levels when performing certain types of experiments or activities. Several pathogens thought to pose the greatest health threat, as defined by their inclusion on the select agent list, may be handled outside high-containment facilities. See **Table 3**. For example, the BMBL recommends the bacteria that causes the disease anthrax be handled at BSL-2 for “activities using clinical materials and diagnostic quantities of infectious cultures” and at BSL-3 for “work involving production quantities or high concentrations of cultures, screening environmental samples (especially powders) from anthrax-contaminated locations, and for activities with a high potential for aerosol production.”<sup>23</sup> Of the 73 human and animal select agents and toxins, 13 warrant BSL-4 containment for any procedure. However, 30 others may be studied at BSL-2 containment depending on the circumstances.<sup>24</sup>

**Table 3. Recommended Biosafety Levels for Some Select Agents**

| <b>Pathogen (Disease)</b>          | <b>Recommended BSL</b> |
|------------------------------------|------------------------|
| Bacillus anthracis (anthrax)       | 2 or 3                 |
| Ebola virus                        | 4                      |
| Marburg virus                      | 4                      |
| Francisella tularensis (tularemia) | 2 or 3                 |
| Variola major (smallpox)           | 4 <sup>a</sup>         |
| Yersinia pestis (plague)           | 2 or 3                 |
| Ricin toxin                        | 2 or 3                 |

**Source:** BMBL, 5<sup>th</sup> edition, 2007.

- a. An international agreement limits research with live smallpox virus to two specific laboratories, one in the United States and the other in Russia.

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<sup>22</sup> BMBL, 5<sup>th</sup> edition, 2007, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

<sup>23</sup> BMBL, 5<sup>th</sup> edition, 2007, Section VI, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

<sup>24</sup> CRS analysis of BMBL, 5<sup>th</sup> edition, 2007, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

Some of the work performed in BSL-4 facilities is on pathogens that are not select agents.<sup>25</sup> All of the BSL-4 facilities in the United States perform at least some work with select agents and therefore are regulated under the Select Agent Program. Only some of the work in BSL-3 facilities uses select agents, so many BSL-3 facilities are not subject to select agent regulations. A relatively small proportion of BSL-2 facilities fall under the Select Agent Program. See **Figure 1**.

### Guideline Enforcement

The BMBL guidelines are best practices. Compliance with these guidelines is typically voluntary, but it is widely adopted as facility policy. Some mandatory adoption and compliance requirements exist. For example, federal contracts and grants require compliance with the BMBL guidelines, and noncompliance can result in loss of current and potentially future federal funding. Some federal agencies have promulgated management directives requiring compliance with the BMBL in agency laboratories.

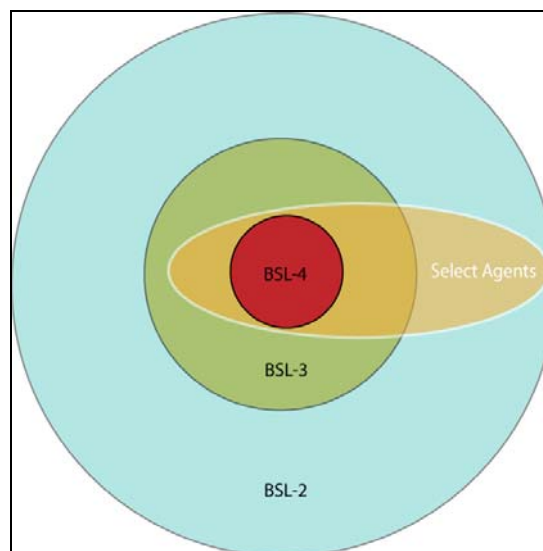
Industrial, academic, and non-profit laboratories generally establish health and safety officials or other responsible persons whose responsibilities include verifying the good operation of protective equipment installed in laboratories and thus continued compliance with the guidelines. Finally, laboratories regulated under the Select Agent Program are required to consider the BMBL guidelines when preparing the biosafety component of required security plans.

In addition to voluntary compliance, the BMBL guidelines are incorporated into building design standards, grant and contract requirements, other federal requirements related to DNA research, and the Select Agent Program.

### Building Design Standards

Federal facilities, and most other facilities built using federal funds, are built to design standards established by the agency that builds a facility or funds its construction. These design standards generally adhere to the guidelines promulgated in the BMBL. The design standards may contain or refer to other security requirements.

**Figure 1. Correlation of Regulation by the Select Agent Program with Biosafety Level**



**Source:** CRS analysis of BMBL and select agent list.

**Notes:** Areas are for illustrative purposes only and are not to scale. Although some BSL-4 work does not use Select Agents, all U.S. BSL-4 facilities work with some Select Agents. Thus, all U.S. BSL-4 facilities are regulated under the Select Agent Program.

<sup>25</sup> Certain experiments with pathogens not on the select agent list should be performed at BSL-4 containment. For example, newly discovered pathogens of unknown human infectiousness that are closely related to pathogens normally handled at BSL-4 should also be handled at BSL-4 until it is determined that they may be safely handled under lesser containment.

For example, the National Institutes of Health has design specifications for NIH buildings. These specifications provide requirements for systems such as ventilation, utilities, and access controls.<sup>26</sup> Security requirements are specified in a separate document.<sup>27</sup> For high-containment laboratories, NIH issues checklists to ensure that requirements are tested and determined to be satisfactory before the laboratory is occupied.<sup>28</sup> This testing process is often called certifying or commissioning a laboratory. The NIH has developed a guide to aid proper laboratory commissioning.<sup>29</sup> A similar process occurs in other agencies. The policies and directives established by other agencies generally require comportment with the biosafety guidelines established by HHS through the BMBL.<sup>30</sup>

Agencies generally contract out the process of commissioning a newly constructed or existing laboratory at a given biosafety level. Some agencies have guidelines for this process. For example, NIH suggests that commissioning or certifying occur via companies not involved in the design or construction of a facility. The NIH *Model Commissioning Guide* also states:

Individuals should be highly specialized in the types of facilities and systems being installed. Due to the degree of technical oversight which is expected, individuals should be licensed Professional Engineers (or as applicable for specialized systems/facilities) with extensive experience in the design, optimization, remediation, and acceptance testing of applicable systems as well as training and building manual preparation.<sup>31</sup>

### *Grant and Contract Language*

Laboratory facilities that receive federal funding, even if not owned or operated by the federal government, generally agree, as a funding condition, to adhere to the biosafety guidelines set forth in the BMBL. If these laboratories are found not to be in compliance with the guidelines, existing federal funding could be withdrawn and future federal funding withheld. For example, the NIH *Grants Policy Statement* states:

Grantee organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding office, grantees should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.<sup>32</sup>

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<sup>26</sup> Department of Health and Human Services, National Institutes of Health, Office of Research Facilities, *Design Policy and Guidelines*, 2003.

<sup>27</sup> Department of Health and Human Services, National Institutes of Health, Division of Public Safety, *NIH Security Design Policy and Guideline*.

<sup>28</sup> See, for example, Department of Health and Human Services, National Institutes of Health, *Biosafety Level 3-Laboratory Certification Requirements*.

<sup>29</sup> Department of Health and Human Services, *The NIH Model Commissioning Guide*, [http://des.od.nih.gov/eWeb/research/farhad2/Commissioning/nih\\_cx\\_guide/ComGuideTitle.htm](http://des.od.nih.gov/eWeb/research/farhad2/Commissioning/nih_cx_guide/ComGuideTitle.htm).

<sup>30</sup> See, for example, U.S. Department of Agriculture, Agricultural Research Service, *USDA Security Policies and Procedures for Biosafety Level-3 Facilities*, Department Manual 9610-001, August 30, 2002. See also Department of Homeland Security, "Listing of Applicable Directives for a National Biodefense Analysis and Countermeasures Center Operating Contract, a Federally Funded Research and Development Center," NBACC FFRDC RFP Attachment # 5, May 15, 2006.

<sup>31</sup> Department of Health and Human Services, *The NIH Model Commissioning Guide*, [http://des.od.nih.gov/eWeb/research/farhad2/Commissioning/nih\\_cx\\_guide/ComGuideTitle.htm](http://des.od.nih.gov/eWeb/research/farhad2/Commissioning/nih_cx_guide/ComGuideTitle.htm).

<sup>32</sup> Department of Health and Human Services, National Institutes of Health, *NIH Grants Policy Statement*, December 1, 2003, p. 49.

Similar language may be inserted into contracts and other award mechanisms.

### ***Institutional Biosafety Committees***

Federal research grants dealing with recombinant DNA research generally require that the grantee create an institutional biosafety committee (IBC) to oversee the grantee's compliance with federal guidelines addressing such research. One role of the IBC is to determine the appropriate biosafety level for novel recombinant DNA research. An IBC thus has the authority to require that recombinant DNA research activities be performed with specific biosafety precautions or not be performed at that institution. While this authority does not currently extend past recombinant DNA research, some have proposed using the IBCs as a mechanism to oversee other research with biosafety concerns.<sup>33</sup> The BMBL suggests that IBCs help scientists to determine the appropriate level of protection for specific proposed experiments.<sup>34</sup> Some non-governmental experts, however, have objected that the IBC mechanism does not provide sufficient oversight or rigorous review for such responsibilities.<sup>35</sup>

### ***Select Agent Program***

The Select Agent Program regulations incorporate the BMBL guidelines by reference.<sup>36</sup> This incorporation makes consideration of the BMBL a mandatory component of compliance with the Select Agent Program. Entities possessing select agents must develop the security plan discussed previously in "Biosecurity and the Select Agent Program" and a biosafety plan which takes into account the BMBL guidelines. Both of these plans may be reviewed by federal officials as part of the oversight process.

## **Proliferation of Laboratories**

The number of BSL-3 and BSL-4 laboratories is generally believed to have increased in recent years. While the number of BSL-3 laboratories is not known, the total amount of planned or existent BSL-4 space in the United States has increased by an estimated twelve-fold since 2004.<sup>37</sup> This expansion of high-containment laboratory space resulted from federal construction, increased federal funding of research and development activities requiring high-containment laboratories, and a greater focus on public health and diagnostic laboratory capacity.

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<sup>33</sup> For example, the National Science Advisory Board for Biosecurity (NSABB), an HHS federal advisory board, has recommended empowering the IBCs to review research that has implications for both defensive and offensive use. For more information on the NSABB, see CRS Report RL33342, *Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity*, by Dana A. Shea.

<sup>34</sup> *BMBL*, 5<sup>th</sup> edition, 2007, Section II, <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.

<sup>35</sup> The Sunshine Project, *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research*, October 2004.

<sup>36</sup> 42 C.F.R. 72.13.

<sup>37</sup> Edward Hammond, Director, The Sunshine Project, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

## Federal Laboratories

The federal government is constructing or funding the construction of numerous high-containment laboratories. This section provides examples of federal investment in biocontainment laboratories in the four departments principally sponsoring this expansion: the Departments of Defense, Homeland Security, Health and Human Services, and Agriculture. Some of the facilities are federally owned and operated, some are federally owned but privately operated, and some are privately owned and operated. Thus, the federal investment in high-containment laboratories is creating both government and private infrastructure.

### Department of Defense

The Department of Defense (DOD) has maintained a high-containment laboratory infrastructure for many years. These laboratories arose during World War II and have been modernized as research activities have evolved.<sup>38</sup> These laboratories performed both offensive and defensive research, i.e. they developed biological weapons and the means to protect troops against the use of biological weapons. In 1969, President Nixon discontinued the U.S. offensive biological weapons program.<sup>39</sup> All DOD biological laboratories perform solely defensive work, mainly focused on developing countermeasures to protect the warfighter or on preventive clinical research. The United States Army Medical Research Institute for Infectious Diseases (USAMRIID) in Frederick, MD, is the sole location of BSL-4 laboratory space in DOD, but BSL-3 laboratory space is found at other sites.<sup>40</sup>

The DOD is engaged in a \$683 million expansion of its facilities at USAMRIID that will increase its BSL-3 and BSL-4 laboratory space.<sup>41</sup> A number of other DOD laboratories have also either increased their BSL-3 capacity or increased their degree of containment since 2001.<sup>42</sup> The DOD maintains its BSL-3 and BSL-4 laboratories for a number of reasons, including basic and applied research into infectious disease, evaluation of vaccines and other biological countermeasures, and testing for naturally occurring disease outbreaks under the Global Emerging Infections Surveillance and Response System.<sup>43</sup>

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<sup>38</sup> For an overview of the establishment and development of Department of Defense laboratories, see David R. Franz, Cheryl D. Parrott, and Ernest T. Takafuji, "The U.S. Biological Warfare and Biological Defense Programs," in *Medical Aspects of Chemical and Biological Warfare*, (Washington, D.C: Office of The Surgeon General, United States Army, 1997).

<sup>39</sup> Executive Office of the President, National Security Decision Memorandum 35, November 25, 1969. The closely related offensive program using biologically derived toxins was ended three months later. Executive Office of the President, National Security Decision Memorandum 44, February 20, 1970.

<sup>40</sup> Department of Defense, *Chemical and Biological Defense Program Annual Report to Congress*, April 2007, p. 63.

<sup>41</sup> Department of Defense, *FY2009 Defense-Wide Military Construction Justification, Defense Medical Program, TRICARE Management Activity*, p. 29.

<sup>42</sup> Department of Defense, *Chemical and Biological Defense Program Annual Report to Congress*, April 2007.

<sup>43</sup> For overviews of these activities, see Department of Defense, *Chemical and Biological Defense Program Annual Report to Congress*, April 2007, and Department of Defense Global Emerging Infectious Surveillance and Response System at <http://www.geis.fhp.osd.mil/>.

## **Department of Homeland Security**

In the aftermath of the anthrax mailings, the federal government determined that it needed a specialized facility to analyze pathogens for specific characteristics that could help identify perpetrators of a biological attack. President Bush assigned this bioforensic responsibility in 2004 to the Department of Homeland Security (DHS).<sup>44</sup> To meet this responsibility, the DHS established the National Bioforensics Analysis Center as part of the National Biodefense Analysis and Countermeasures Center.<sup>45</sup> These laboratories are currently located in interim facilities at USAMRIID. Permanent facilities are under construction, also in Frederick, MD, including a BSL-4 laboratory and several BSL-3 laboratories to accommodate both bioforensic and biological threat assessment activities. These facilities are expected to become fully operational in 2010.<sup>46</sup>

The Homeland Security Act of 2002 (P.L. 107-296) transferred the Plum Island Animal Disease Center (PIADC), which contains BSL-3 facilities, from USDA to DHS. The DHS has determined that PIADC has reached the end of its usable lifespan. While maintaining the existing PIADC facility, the DHS is in the process of establishing the National Bio- and Agro-Defense Facility (NBAF), a BSL-4 laboratory, to replace PIADC.<sup>47</sup> This new high-containment facility will have the main goal of performing research on pathogens affecting animals and developing countermeasures against these pathogens. When complete, it will take over the research projects performed at PIADC and expand a currently limited research capability for animal pathogens requiring the highest level of biocontainment. The DHS announced its decision to site the NBAF in Kansas.<sup>48</sup>

## **Department of Health and Human Services**

The Department of Health and Human Services (HHS) currently maintains BSL-4 laboratories at the National Institutes of Health (NIH) in Bethesda, MD, and at the Centers for Disease Control and Prevention in Atlanta, GA.<sup>49</sup> Additionally it has invested in construction of two BSL-4 National Biocontainment Laboratories (NBLs) and thirteen BSL-3 Regional Biocontainment Laboratories (RBLs).

The NBLs and RBLs are to serve as a national resource for conducting clinical and laboratory research and testing on pathogens in support of the NIH National Institute of Allergy and Infectious Diseases' biodefense research agenda. Additionally, both are expected to be available

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<sup>44</sup> Executive Office of the President, The White House, *Biodefense for the 21<sup>st</sup> Century*, Homeland Security Presidential Directive-10, April 28, 2004.

<sup>45</sup> See CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

<sup>46</sup> J. Patrick Fitch, Laboratory Director, NBACC, and President, Battelle National Biodefense Institute, *Science-Based Biodefense Analysis in an Uncertain World*, Presentation at the Center for Strategic and International Studies, May 12, 2008, [http://www.csis.org/media/csis/events/080529\\_csis\\_fitch\\_presentation.pdf](http://www.csis.org/media/csis/events/080529_csis_fitch_presentation.pdf).

<sup>47</sup> See CRS Report RL34160, *The National Bio- and Agro-Defense Facility: Issues for Congress*, by Dana A. Shea, Jim Monke, and Frank Gottron.

<sup>48</sup> Department of Homeland Security, "Science and Technology Directorate; Record of Decision for the National Bio and Agro-Defense Facility Environmental Impact Statement," 74 *Federal Register* 3065-3080, January 16, 2009.

<sup>49</sup> Although built as a BSL-4 laboratory, the Bethesda laboratory operates at the BSL-3 level. See National Institute of Allergy and Infectious Diseases, *The Need for Biosafety Laboratory Facilities*, September 2007, [http://www.niaid.nih.gov/factsheets/facilityconstruct\\_06.htm](http://www.niaid.nih.gov/factsheets/facilityconstruct_06.htm).



to assist public health efforts during a bioterrorism or emerging infectious disease emergency.<sup>50</sup> The two NBLs are being built in Boston, MA, and Galveston, TX.<sup>51</sup> The RBLs are geographically dispersed throughout the United States.<sup>52</sup> The NBLs and RBLs are being constructed through a grant-making process and will be privately owned and operated.<sup>53</sup>

The HHS has also developed the Laboratory Response Network (LRN), a network of laboratories that engage in public health activities. The LRN is charged with maintaining an integrated network of laboratories that can respond to bioterrorism, chemical terrorism and other public health emergencies.<sup>54</sup> The LRN includes federal and state public health facilities, medical institutions, and others. These laboratories are primarily engaged in diagnostic and public health testing of samples, especially in an emergency situation where additional capacity for such testing is needed. Many of these laboratories possess BSL-3 capabilities.

## **Department of Agriculture**

The Department of Agriculture (USDA) will conduct research in the new NBAF being built by DHS. The USDA is also constructing new BSL-3 laboratories. These include laboratories in Ames, IA, consolidating animal health research, diagnosis, and product evaluation in a single facility, and at the National Wildlife Research Center in Fort Collins, CO.

## **University Laboratories**

Academic institutions are investing in high-containment laboratory facilities for a variety of reasons. As federal funding for biodefense research and development has increased, universities have responded by building more high-containment laboratory space. Such laboratory space is seen as increasing their faculty's ability to compete for federal funding and helping the university recruit new faculty. The University of Minnesota, Purdue University, and Ohio State University are examples that have constructed or plan to construct additional BSL-3 laboratory space.<sup>55</sup>

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<sup>50</sup> Department of Health and Human Services, *Broad Agency Announcement: Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL)*, BAA-NIH-NIAID-NCRR-DMID-03-36, February 10, 2003; and Department of Health and Human Services, *Request for Applications: Regional Biocontainment Laboratories (RBL) Construction Program*, RFA-AI-04-032, June 29, 2004.

<sup>51</sup> For more information about the NBL being built in Boston, MA, see online at <http://www.bu.edu/dbin/neidl/en/>. For more information about the NBL being built in Galveston, TX, see online at <http://www.utmb.edu/gnl/>.

<sup>52</sup> For an overview of the status and locations of the NBLs and the RBLs, see online at [http://www3.niaid.nih.gov/LabsAndResources/resources/dmid/NBL\\_RBL/site.htm](http://www3.niaid.nih.gov/LabsAndResources/resources/dmid/NBL_RBL/site.htm).

<sup>53</sup> For an overview of the original proposal for construction of the NBLs and RBLs, see online at <http://www.niaid.nih.gov/contract/archive/BAA0336-0.pdf>.

<sup>54</sup> For more information on the Laboratory Response Network, see online at <http://www.bt.cdc.gov/lrn/>.

<sup>55</sup> For information regarding the University of Minnesota's efforts, see online at <http://www1.umn.edu/groots/pdf/MBB.pdf>. For information regarding Purdue University's efforts, see online at [http://www2.itap.purdue.edu/bot/memberDocuments/StatedMeetingFiles/animal%20disease%20diagnostic%20laboratory%20\\_bsl-3\\_-desc-plan%20res%20\\_2\\_1a.pdf](http://www2.itap.purdue.edu/bot/memberDocuments/StatedMeetingFiles/animal%20disease%20diagnostic%20laboratory%20_bsl-3_-desc-plan%20res%20_2_1a.pdf). For information regarding the Ohio State University's efforts, see online at <http://researchnews.osu.edu/archive/bsl3%20lab.htm>, <http://researchnews.osu.edu/archive/new%20bsl3.htm>, <http://medicalcenter.osu.edu/research/researchtower/>, and <http://researchnews.osu.edu/archive/bsl3qanda.htm>.

## Industry and Non-Profit Laboratories

Private sector companies and non-profit institutions also maintain high-containment laboratory facilities. Pharmaceutical and other companies may need such facilities for medical testing and evaluation, animal efficacy studies, and other product development purposes. Some large companies have determined that the costs of an in-house high-containment laboratory are justified by their product development and manufacturing goals.<sup>56</sup> Others have chosen to contract with outside firms to obtain this capability. These contract firms include Lovelace Respiratory Research Institute, Battelle Memorial Institute, Southern Research Institute, and others.<sup>57</sup>

## Issues for Congress

The expansion of high-containment laboratories has raised several issues for policymakers. These include how to determine the appropriate capacity to meet national needs, whether oversight of facilities or personnel need to be increased, balancing the desire for additional laboratory capacity with its accompanying increase in risk, possible international ramifications, and local concerns.

### How Much Capacity Is Enough?

After the 2001 anthrax mailings, it became apparent to some policymakers that the existing high-containment laboratory infrastructure was insufficient to meet the needs of that crisis. Congress and the administration decided that additional high-containment laboratory space should be constructed. The high capital and maintenance costs of these facilities were deemed to require federal investment and support. At the same time, these high costs make it important to avoid over-building capacity and to fully utilize existing resources.

Decisions to build and support high-containment laboratories were made in multiple agencies and in multiple budget cycles. Agencies considered their individual requirements, without any robust national needs assessment or coherent, coordinated expansion or utilization plan.<sup>58</sup> As a consequence, policymakers have expressed concern that the new high-containment laboratory capacity may now exceed the national need or the amount that can be operated safely.<sup>59</sup>

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<sup>56</sup> See, for example, Dr. Bradley E. Kosiba, Senior Director, Wyeth Global Research Facilities, "Wyeth's New (2006) Containment Facility (BSL3-LS) for the Bio-manufacturing of Bacterial Vaccines," Presentation at the 2007 International Conference on Biocontainment Facilities, March 13, 2007.

<sup>57</sup> See <http://www.lrii.org/DPage.aspx?p=42>; [http://www.battelle.org/solutions/default.aspx?Nav\\_Area=Solution&Nav\\_SectionID=4&Nav\\_CatID=4\\_ThreatAssessmentCharacterization](http://www.battelle.org/solutions/default.aspx?Nav_Area=Solution&Nav_SectionID=4&Nav_CatID=4_ThreatAssessmentCharacterization); and <http://www.southernresearch.org/contract-services/emerging-pathogens-aerobiology-program.html>.

<sup>58</sup> See U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Hearing on Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., October 4, 2007, and U.S. Government Accountability Office, *High-containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T, October 4, 2007.

<sup>59</sup> See U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Hearing on Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., October 4, 2007.

A lack of information on existing federal and non-federal high-containment laboratory capacity is hindering more coordinated planning. The National Institute of Allergy and Infectious Diseases identified 277 domestic BSL-3 laboratories, but its survey suffered from a low response rate and other methodological shortcomings.<sup>60</sup> In compliance with the Project BioShield Act of 2004 (P.L. 108-276), DHS and HHS estimated that there are 630 BSL-3 and BSL-4 laboratories.<sup>61</sup> This estimate has also been criticized by nongovernmental experts.<sup>62</sup> The DHS and HHS estimate drew heavily on the number of facilities registered to work with select agents. However, a BSL-3 laboratory need not necessarily work with select agents and therefore may not be required to hold a registration certificate. Conversely, entities registered to work with select agents may or may not use high-containment laboratories (see **Table 3**). Other, nongovernmental estimates, though incomplete, have identified large increases in high-containment laboratory capability.<sup>63</sup> The Government Accountability Office was unable to definitively determine the number of BSL-3 laboratories, but did document an increase in laboratories.<sup>64</sup>

Determining whether ongoing and planned construction has surpassed future national needs likely requires a government-wide assessment with the participation of many federal agencies. Previous efforts by a single agency to determine the number of extant laboratories have failed.<sup>65</sup> Congress may consider whether such a survey should be performed at the agency level or through a higher or external coordinating body.

The continued construction of high-containment facilities raises questions about capacity utilization. Fully utilizing additional capacity will likely require increased funding for research, operations, and management. This increase in funding may be particularly difficult for those agencies that are undergoing a large increase in capacity. For example, an agency increasing its high containment laboratory capacity four-fold will have concomitant increases in operations and maintenance costs for the larger facility regardless of whether the agency fully uses the new capacity. Individual agencies may feel pressure to request larger research budgets to justify their increased operations and maintenance costs. Interagency federal planning efforts may help alleviate overcapacity costs, but would require agreement among agencies regarding prioritization and shared use of different agency facilities.

Planning efforts arising from individual agency initiatives may have difficulty influencing synergies or redundancies between agencies. For example, DHS, through the Under Secretary for Science and Technology, has attempted to coordinate homeland security research and development, but this activity was not prescriptive and did not address use of other agency

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<sup>60</sup> Constella Health Sciences, *Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States*, September 9, 2005. The GAO testified that this survey has methodological difficulties. See Sushil Sharma, GAO, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

<sup>61</sup> Department of Health and Human Services and the Department of Homeland Security, *Report to Congress Regarding Biocontainment Facilities*, January 2007.

<sup>62</sup> For example, see Alan M. Pearson, Center for Arms Control and Non-Proliferation, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

<sup>63</sup> Edward Hammond, Director of The Sunshine Project, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

<sup>64</sup> U.S. Government Accountability Office, *High-containment Biosafety Laboratories Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T, October 4, 2007.

<sup>65</sup> See “Survey of Facilities and Use” for further discussion of this point.

laboratory assets.<sup>66</sup> Conversely, higher-level, multi-agency strategies may not specify the utilization of existing or future facilities and laboratory space on an agency basis.<sup>67</sup> Congress may wish to consider whether multi-agency coordination of high-containment laboratory use is best performed through central coordination or at the agency level.

## **Sufficiency of Current Oversight and Enforcement**

The growth of BSL-3 and BSL-4 laboratories has raised concerns about the potential for pathogen release into local communities, as well as biological weapon proliferation, either through the transfer of pathogens or the transfer of technical knowledge through training and employment of foreign scientists in such venues.<sup>68</sup> Events, such as laboratory infections with select agents,<sup>69</sup> improper shipping of select agents,<sup>70</sup> and performance of research at inadequate biosafety levels<sup>71</sup> have led policymakers to reexamine the current oversight framework. Consensus has not been reached regarding the best approaches to overseeing these laboratories. The current, mainly self-regulatory approach is seen by some analysts as not stringent enough and in need of additional federal oversight. Some experts have suggested expanding regulations to require mandatory biosafety training or broadening biosecurity measures.<sup>72</sup> Others feel that the broad application of the results and processes of high-containment laboratory work may lend itself better to an enhanced self-regulatory approach, focused on greater worker engagement and responsibility. These experts suggest that training in best practices be increased and that scientists develop more robust self-policing.<sup>73</sup>

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<sup>66</sup> Department of Homeland Security, Science and Technology Directorate, *Coordination of Homeland Security Science and Technology*, December 2007 (Revised January 2008).

<sup>67</sup> See, for example, National Science and Technology Council, Committee on Homeland and National Security, Subcommittee on Foreign Animal Disease Threats, *Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012*, January 22, 2007.

<sup>68</sup> Such concerns have been reportedly identified and raised in the United Kingdom by British security services. Mark Townsend, "Terrorists Try to Infiltrate UK's Top Labs," *The Observer*, November 2, 2008, online at <http://www.guardian.co.uk/science/2008/nov/02/uk-security-weapons-technology>. For related concerns regarding proliferation of technical knowledge, see Eileen Choffnes, "Biological Weapons: New Labs, More Terror?" *Bulletin of the Atomic Scientists*, Vol. 58, No. 5 (September/October 2002), pp. 28-32. See also, CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

<sup>69</sup> Emily Ramshaw, "A&M Lab Employee Lacked Clearance in Bioagent Case; Records Detail Security Breaches at University, Other State Schools," *The Dallas Morning News*, July 8, 2007; Emily Ramshaw, "A&M Admits Errors in Bioagent Case; Interim President Denies Wrongdoing, Questions CDC Timing," *The Dallas Morning News*, July 3, 2007; and Emily Ramshaw, "CDC Suspends A&M Research on Infectious Diseases; CDC Suspends Bioagent Work after Exposures Not Reported Promptly," *The Dallas Morning News*, July 2, 2007.

<sup>70</sup> Martin Enserink and Jocelyn Kaiser, "Accidental Anthrax Shipment Spurs Debate Over Safety," *Science*, June 18, 2004, pp. 1726-1727.

<sup>71</sup> "Study of Ebola Virus in U.S. Lab Halted," *Associated Press*, September 20, 2007.

<sup>72</sup> American Society for Microbiology, "ASM Comments on Laboratory Biosafety," *Letter to Chairman Bart Stupak, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations*, October 3, 2007.

<sup>73</sup> Gigi Kwik Gronvall, Joe Fitzgerald, Allison Chamberlain, et al., "High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5, no. 1 (2007), pp. 75-85.

## **Threat Associated With Increased Number of Facilities**

Increased high-containment laboratory capacity is a two-edged sword. Expansion allows for a greater diversity of biodefense research, more efficient public health sample testing, and more research discoveries. However, the increase in laboratories also increases the potential for theft or accidental release of dangerous pathogens and transfer of technical knowledge to persons wishing to do harm.

Legislation passed by previous Congresses addressed concern about the theft of dangerous pathogens by augmenting the Select Agent Program to enhance the physical security of stored pathogens, as discussed in “Biosecurity and the Select Agent Program”. As the number of high-containment facilities has expanded, more facilities have registered to possess select agents. Investigations by GAO and agency inspectors general have revealed security weaknesses at several facilities participating in the Select Agent Program.<sup>74</sup> Additional regulatory focus on Select Agent Program compliance might minimize the likelihood of these events, though growing laboratory capacity may strain agency resources for these endeavors.

Whether public or private sector, high-containment laboratories are planned and designed to minimize the possibility of accidents from human error or mechanical failure. Despite such planning, accidents do occur and can overwhelm the safety controls and barriers designed to mitigate their consequences.<sup>75</sup> The GAO has testified that each high-containment facility has an inherent associated risk.<sup>76</sup> As additional facilities are constructed, the total risk increases.

The magnitude of this incremental risk is difficult to measure and may vary depending on each laboratory’s compliance with best practices and regulation. Factors that might contribute to the risk include the rate of accidental or other releases, the rate of subsequent illness from any releases, and the total number of laboratories. Because this information is not generally available, policymakers may perform an approximate cost/benefit analysis relying on estimates of the potential benefits provided by research in high-containment laboratories and the potential costs resulting from an infectious release from a high-containment laboratory. For example, breakthroughs in biodefense research, such as vaccines against pathogens requiring high-containment, might be considered as a benefit while the loss of infected animals or infection of laboratory workers might be used as an example of a cost. Subtle and institutional effects, which may be hard to measure, such as the development of a national sampling laboratory network and the proliferation of high-containment laboratory technique, may be overlooked by federal policymakers. As a result, policy may be driven by response to high profile incidents rather than by judging the actual risk, or the full costs and benefits, of the increased number of facilities.

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<sup>74</sup> Department of Health and Human Services, Office of Inspector General, *Summary Report on State, Local, Private, and Commercial Laboratories’ Compliance with Select Agent Regulations*, A-04-06-01033, January 2008; Department of Health and Human Services, Office of Inspector General, *Summary Report on Universities’ Compliance with Select Agent Regulations*, A-04-05-02006, June 2006; and Department of Health and Human Services, Office of Inspector General, *Summary Report on Select Agent Security at Universities*, A-04-04-02000, March 2004. See also U.S. Government Accountability Office, *Biosafety Laboratories: Perimeter Security Assessment of the Nation’s Five BSL-4 Laboratories*, GAO-08-1092, September 2008; and Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *World at Risk*, December 2008.

<sup>75</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, pp. 3-364, [http://www.dhs.gov/xres/labs/gc\\_1187734676776.shtm](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

<sup>76</sup> U.S. Government Accountability Office, *High-containment Biosafety Laboratories Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T, October 4, 2007.

Another concern is personnel surety or the “insider threat.” The expansion of high-containment laboratories requires additional trained technicians, scientists, and other employees to utilize this capacity. As more people receive training in high-containment technique, the risk that some of them have malicious intent increases. Some experts have asserted that such skills are not necessary to carry out a bioterrorist attack, but others believe that they are key.<sup>77</sup> The DOJ asserts that the perpetrator of the 2001 anthrax mailings was a government scientist expert in high-containment technique.<sup>78</sup>

## **International Issues**

The increase in high-containment capacity may have international ramifications. Other countries may perceive the increase in high-containment laboratory capacity as beyond that necessary for biodefense and health research. Such a perception might lead some governments to conclude that the United States is constructing this excess capacity for offensive biological weapons development.<sup>79</sup> Such a perception would likely damage U.S. efforts to persuade other countries to adhere to the Biological Weapons Convention.

Expansion of the U.S. infrastructure may also encourage construction of similar facilities in foreign countries in an effort to match U.S. efforts.<sup>80</sup> Such international laboratory proliferation may lead to greater international availability of high-containment technique and information and a greater risk that this training will be used for malevolent purposes.

Differences in biosafety regulation and oversight among countries may influence the business decisions of pharmaceutical and biotechnology companies. If multinational corporations consider the United States to have an unfavorable regulatory environment, they may tend to locate their research and production facilities in other countries. Apart from the possible economic effects of this decision, the location of pharmaceutical and biotechnology companies could also affect national capabilities to respond to bioterrorism or natural disease outbreaks. Countries that rely on foreign production of disease treatments might be at risk of reduced or restricted access to countermeasures during an international disease outbreak or bioterrorist attack. Governments may choose to hoard domestically produced countermeasures to treat their residents rather than allow the countermeasures to leave the country.<sup>81</sup>

Differences in biosecurity regulation between countries have led some U.S. scientists to curb their international collaborations.<sup>82</sup> Because many scientists believe that international collaborations

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<sup>77</sup> For a discussion of the diversity of opinion regarding the ease with which biological weapons can be made by non-state groups, see Milton Leitenberg, “An Assessment of the Biological Weapons Threat to the United States,” *The Journal of Homeland Security*, January, 2001.

<sup>78</sup> Department of Justice, *Transcript of Amerithrax Investigation Press Conference*, August 6, 2008, <http://www.justice.gov/opa/pr/2008/August/08-opa-697.html>. See also Scott Shane, “Portrait Emerges of Anthrax Suspect’s Troubled Life,” *The New York Times*, January 3, 2009.

<sup>79</sup> For a discussion of this issue, see Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat*, December 2005, <http://www.strategicstudiesinstitute.army.mil/pubs/display.cfm?pubID=639>.

<sup>80</sup> Jonathan Tucker, “Biological Threat Assessment: Is the Cure Worse than the Disease?,” *Arms Control Today*, Vol. 34, No. 8, October 2004, pp. 13-19.

<sup>81</sup> Michael Osterholm, “Preparing for the Next Pandemic,” *Foreign Affairs*, July/August 2005.

<sup>82</sup> Julie E. Fischer, *Stewardship or Censorship? Balancing Biosecurity, the Public’s Health, and the Benefits of Scientific Openness* (Washington, DC: The Henry L. Stimson Center, 2006), p. 33.

are a key component of the scientific process, this development may have a chilling effect. Perceived barriers to international collaboration between U.S. researchers and those in other countries may lead industry to locate or invest in research in countries where such barriers are perceived to be lower. The extent to which biosecurity regulations have hampered international collaboration, or research in general, remains ambiguous. Additionally, the presence of U.S. biosecurity standards may encourage international partners to develop similar or parallel policies harmonized with U.S. efforts.<sup>83</sup>

## Local Concerns

The construction of high-containment laboratories in the United States has been met with varying degrees of local resistance. Some groups have strongly supported the building of new laboratories in their communities, citing the importance of the mission and the likelihood of local economic benefits.<sup>84</sup> Proponents state that high-containment laboratories will generate high-paying jobs and require ancillary support from community businesses, providing a boost to the local economy.

Other groups have strongly opposed proposed new laboratories for public health and quality of life reasons, citing possible release of pathogens and increases in security and traffic.<sup>85</sup> These groups are dubious of economic benefit claims by proponents, questioning whether the high-paying jobs will be available to the existing local workforce rather than individuals recruited from elsewhere.

## Policy Options

In addressing these issues policymakers have several options. Interested congressional policymakers could deem current efforts sufficient and no further action is warranted. Several expert panels are examining these issues currently and Congress could defer additional action until their reports are complete and their recommendations heard. Alternatively, Congress could decide to step up current oversight of facilities, pathogens, or personnel, or to take other actions.

## Status Quo

Oversight efforts attempt to balance security controls with research productivity, weighing the potential for an adverse event against that of scientific progress. One scientist summarized the potential trade-offs between additional oversight and scientific progress: “While, in principle, the scientific community supports measures that would reduce the threat of terrorists acquiring deadly pathogens, there also is strong opposition to measures that make it more difficult to perform research.”<sup>86</sup> Policymakers may determine that current oversight efforts regarding high-

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<sup>83</sup> For an example of one effort to develop and harmonize international biosafety and biosecurity best practices, see the International Council for the Life Sciences, online at <http://www.iclscharter.org/>.

<sup>84</sup> For example see, Kansas NBAF Task Force, [http://www.nbafinkansas.org/task\\_force/](http://www.nbafinkansas.org/task_force/).

<sup>85</sup> Alternatives for Community & Environment, *What’s Wrong With a BSL4 Bioterrorism Laboratory at Boston Medical Center?*, March 10, 2004, <http://www.ace-ej.org/BiolabWeb/Biolabdocs/>.  
What’swrongwithaBSL4labatBMCMay04.pdf.

<sup>86</sup> Ronald Atlas, “Toward Global Harmonization for Control of Dual-use Biothreat Agents,” *Science and Public Policy*, vol. 35, no. 1 (February 2008), p. 26.

containment laboratories are sufficient and that additional measures may cause undue burdens on scientific progress. Some portion of the scientific community is likely to support relying on extant oversight mechanisms and taking no additional action.

Supporters of the status quo might argue that securing high-containment laboratories in the United States provides less increased security than focusing federal efforts on identifying potential bioterrorists and disrupting individual bioterrorist activities.<sup>87</sup> Additional resources dedicated to developing intelligence on potential bioterror groups, their organizational needs, and social aspects might allow for disruption of their activities at a lower total cost than the implementation of an overarching regulatory framework that affects, by and large, domestic scientists engaged in beneficial activities.

## **Await Recommendations**

Even if Congress concludes that current oversight efforts are insufficient, concerned policymakers may choose to defer action until they can obtain a fuller understanding of policy options and their impacts.<sup>88</sup> Since 2005, the Bush Administration created at least three expert groups to examine aspects of biosafety and biosecurity issues: the Working Group on Strengthening the Biosecurity of the United States, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and the National Science Advisory Board for Biosecurity. Additionally, GAO is continuing to investigate the proliferation of high-containment laboratories. Congress could choose to wait until some or all of these groups have completed their efforts and made their recommendations. To make its intent clear, Congress could explicitly endorse the groups' activities while awaiting their results. Additionally some policymakers may deem these efforts as insufficient and may require the performance of additional studies.

President Bush created the Working Group on Strengthening the Biosecurity of the United States on January 9, 2009, through Executive Order.<sup>89</sup> This working group, co-chaired by the Secretaries of Defense and Health and Human Services, consists of the Secretaries of State, Agriculture, Commerce, Transportation, Energy, and Homeland Security; the Attorney General; the Administrator of the Environmental Protection Agency; the Director of National Intelligence; and the Director of the National Science Foundation.<sup>90</sup> It is charged with reviewing and evaluating existing laws, regulations, guidances, and practices of physical, facility, and personnel security and assurance. Its recommendations to the President regarding existing and new biosafety and biosecurity laws, regulations, guidances, and practices are due in July 2009.

The HHS announced the formation of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight during congressional hearings in October 2007.<sup>91</sup> This group, established in December 2007,<sup>92</sup> is to develop an options paper that:

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<sup>87</sup> Kathleen Vogel, "Framing Biosecurity: an Alternative to the Biotech Revolution Model?," *Science and Public Policy*, vol. 35, no. 1 (February 2008), p. 45-54.

<sup>88</sup> The American Society for Microbiology has advocated this path. See Jocelyn Kaiser, "Senate Bill Would Alter Biosafety, Select Agent Rules," *Science*, June 20, 2008.

<sup>89</sup> Executive Office of the President, The White House, *Executive Order 13486: Strengthening Laboratory Biosecurity in the United States*, 74 Fed. Reg. 2289-2291, January 9, 2009.

<sup>90</sup> These individuals may appoint designees to represent them on the working group.

<sup>91</sup> Hugh Auchincloss, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, (continued...)



- addresses the current framework for local and federal biosafety and biocontainment oversight of research at high-containment laboratories,
- addresses potential gaps in biosafety and biocontainment oversight of high-containment laboratories, and
- provides recommendations for closing these gaps.<sup>93</sup>

Co-chaired by HHS and USDA, the task force includes staff from the Environmental Protection Agency, the National Science Foundation, and the Departments of Commerce, Defense, Energy, Homeland Security, Labor, Transportation, and Veterans Affairs. The task force's recommendations will be presented to HHS and USDA leadership.

The National Science Advisory Board for Biosecurity includes non-governmental voting members and non-voting members from 15 federal agencies and departments. The Board is developing policies relating to dual-use research (i.e., beneficial research that might be turned to malignant uses). Among other endeavors, the Board is trying to develop an effective framework for oversight of such research, a code of conduct for researchers, and effective biosafety training programs for researchers.<sup>94</sup> The Board has multiple working groups producing analysis and publishes recommendations on an ongoing basis.<sup>95</sup>

The GAO is expected to release a report in 2009 that addresses high-containment laboratory issues and builds on prior testimony.<sup>96</sup> This report may have additional recommendations for legislative branch and executive branch action.

By waiting for the recommendations of such studies, Congress may be able to use the results of these efforts rather than duplicating them and possibly undercutting them. Additionally, these efforts may generate new policy ideas or options not currently under consideration.

## **Enhance Oversight of Facilities**

Alternatively, Congress may decide that high-containment laboratories issues are too pressing to wait for the results of these groups and instead address this issue without waiting for executive branch or GAO reports. The following are several policy options that may facilitate this approach.

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<sup>92</sup> Steven Kappes, U.S. Department of Agriculture, "Welcome and Opening Remarks," U.S. Government Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight Public Consultation, Washington, DC, December 8, 2008.

<sup>93</sup> Department of Health and Human Services and U.S. Department of Agriculture, *Charge, Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*, <http://www.hhs.gov/aspr/omsph/biosafetytaskforce/taskforce-charge-081201.pdf>.

<sup>94</sup> Secretary of Health and Human Services, *Charter National Science Advisory Board for Biosecurity*, Department of Health and Human Services, Washington, DC, March 28, 2008.

<sup>95</sup> [http://oba.od.nih.gov/biosecurity/biosecurity\\_documents.html](http://oba.od.nih.gov/biosecurity/biosecurity_documents.html).

<sup>96</sup> U.S. Government Accountability Office, *High-containment Biosafety Laboratories Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T, October 4, 2007.

## Survey of Facilities and Use

Previous efforts to determine the number and capacity of such laboratories have failed to produce a robust and reliable determination of the number of high-containment laboratories. Multiple sources, including non-governmental organizations and congressionally established commissions, have called for a comprehensive inventory of existing capacity.<sup>97</sup>

While compiling such a comprehensive inventory may appear straightforward, it likely would not be an easy or simple task. Non-federal laboratories reside in a variety of locations performing a variety of work. Non-federal high-containment laboratories are located in academic research institutions, public health agencies, and industrial research and quality control facilities. A voluntary self-reporting mechanism may be insufficient to identify existing facilities and get information about their capacity. Also, a survey would be a snapshot of the actual high-containment capacity but would not necessarily capture future construction or expansion. Concerns about industrial competitiveness and reporting burden may act as substantial barriers for obtaining a complete inventory.<sup>98</sup> Efforts to incentivize self-reporting might increase participation depending on the incentive relative to the reporting barrier.

Alternatively, congressional policymakers could mandate that all high-containment laboratories, both public and private, register with the federal government. If laboratories face a sufficient penalty for not registering, this approach could produce a comprehensive list of high-containment laboratories. Such a registry could potentially provide the government with information regarding the total available laboratory capacity, its current use, its geographic distribution, and availability. Facility registration was a component of early implementation of the Select Agent Program, prior to amendments requiring certification of facilities and personnel. Registration might be required even if no further security measures were mandated.

Another option, given the difficulty of determining the full scope of high-containment laboratories, is to limit such a survey to federal facilities. Since federal facilities are within the scope of executive decree, all agencies could be required to report their high-containment facilities and capacity to Congress through the Executive Branch. If the existing federal capacity was well known by policymakers, the government might more efficiently plan for use and possible expansion of this capacity. A concomitant development of a government-wide needs assessment may also help the government to efficiently apportion resources. By comparing the needs assessment with existing and planned federal capacity, it may be possible for the government to determine if federal high-containment capacity is greater than the need. Overexpansion has both resource allocation costs and potentially increased security concerns.

In considering whether to attempt to survey the number of high-containment laboratories, Congress may wish to weigh the potential economic costs of doing so under both a self-reporting framework and a mandatory reporting framework, as well as the quality and utility of the

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<sup>97</sup> For example, see Edward Hammond, Director of The Sunshine Project, before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007; U.S. Government Accountability Office, *High-containment Biosafety Laboratories Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T, October 4, 2007; and The Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk* (New York: Vintage Books, 2008).

<sup>98</sup> The survey commissioned by HHS exemplifies this issue. The response rate to the survey was under 50%. Constella Health Sciences, *Final Report: Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States*, June 2, 2005.

information so acquired. Additionally, the benefits of such a survey may be maximized through comparison with a needs assessment, which is currently unavailable across federal agencies. Concerned Members of Congress might require the submission of a needs assessment from specific agencies or from multiple agencies in addition to capacity information.

## **Moratorium on Construction**

Some policymakers have called for a moratorium on new federally funded construction of high-containment laboratories and a decrease in the proposed final number of laboratories.<sup>99</sup> In weighing the effects of a moratorium, policymakers would likely have to address the benefit of constructing the right amount of laboratory capacity, rather than too much, versus the potential costs to research and other priorities posed by such a moratorium.

In the absence of a government-wide capacity needs assessment, building additional laboratories increases the probability that capacity will be over-built or redundant operations established among agencies. The establishment and operation of new high-containment laboratories is likely to reach a level of diminishing returns as the capacity approaches the level of need. Incremental increases in high-containment laboratory capacity may yield greater return than the construction of large amounts of new laboratory space, suggesting that existing laboratory space could be expanded rather than new laboratory space constructed. Some agencies have countered such criticism by stating that they have assessed interagency needs on a case by case basis and that existing infrastructure is dated and not a candidate for expansion. For example, DHS states it has performed such an assessment as part of its development for the National Bio- and Agro-Defense Facility.<sup>100</sup> However, in the absence of a government-wide assessment, it is possible that agency-specific needs assessments will not identify synergies or existing available infrastructure in other agencies.

Enacting a construction moratorium might have ramifications for the federal government's ability to meet previously established national goals. For example, delays in construction of laboratory facilities may result in delays in performing planned research activities that require those facilities. Previously identified national priorities, such as the establishment of a permanent bioforensics capability, might be delayed or hampered.<sup>101</sup> Additionally, advisory panels and other groups have made repeated calls for expansion of specific high-containment laboratory facilities.<sup>102</sup> A moratorium on construction might impede the development of capabilities deemed necessary by such panels.

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<sup>99</sup> Letter from Representative John Dingell, Chairman of House Committee on Energy and Commerce, and Representative Bart Stupak, Chairman of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, to President Bush, August 8, 2008.

<sup>100</sup> For additional information on this facility and a more thorough discussion of its needs assessment, see CRS Report RL34160, *The National Bio- and Agro-Defense Facility: Issues for Congress*, by Dana A. Shea, Jim Monke, and Frank Gottron.

<sup>101</sup> Such a capability was required through Executive Office of the President, The White House, *Biodefense for the 21<sup>st</sup> Century*, Homeland Security Presidential Directive (HSPD) 10, April 28, 2004. See also CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

<sup>102</sup> For example, advisory panels and groups have recommended the expansion of large animal high-containment facilities for several years. See, for example, USDA Strategic Planning Task Force on Research Facilities, *Report of the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations*, August 1999.

## **Require High-Containment Laboratory Certification**

Some analysts have suggested that the federal government license and certify all high-containment laboratories.<sup>103</sup> Currently, only laboratories that handle select agents are required to register with the federal government and receive certification that they comply with specified security regulations. Among the possible approaches are directly regulating high-containment laboratories and expanding the scope of the Select Agent Program. An analysis of these two options follows.

### *Directly Regulate High-Containment Laboratories*

One approach to licensing might be applying the Select Agent Program requirements to all high-containment laboratories, regardless of the pathogens used at the laboratory. Such an approach might provide a uniform set of expectations regarding the security level at all high-containment laboratories.

Alternatively, licensing could be another, separately administered program with its own requirements. Establishing a separately administered program might allow for flexibility in licensing requirements, differentiating, for example, between high-containment laboratories that possess select agents and those that do not.

Laboratory licensing and certification mandates might pose a series of challenges, both in implementation and in acceptance from the scientific community. Licensing and certifying high-containment laboratories may not address the full universe of laboratories of concern. For example, select agents may be handled outside of high-containment laboratories under certain circumstances, indicating that certain manipulation of these pathogens could occur outside of a unified regulatory framework that covers only high-containment facilities.

A more comprehensive approach would involve overseeing all laboratories capable of BSL-2 or higher containment. This approach would be certain to capture all locations of sufficient biosecurity for the use of any select agent but would have several disadvantages. Primary among them is the greatly increased number of facilities that would be overseen by this approach. Most facilities handling a human-infective pathogen would qualify under this approach, including and impacting public health, diagnostic, hospital, industrial, and academic laboratories.

### *Expand the Select Agent List*

A different approach, focusing on the pathogens of concern rather than the facilities capable of handling them, might involve expanding the select agent list. As the Select Agent Program uses a list of pathogens to identify regulated entities, some experts have argued that some dangerous pathogens are not captured by this program. Some potentially dangerous diseases not covered by the Select Agent regulations include severe acute respiratory syndrome (SARS), dengue fever, western equine encephalitis, and yellow fever. Some of the pathogens that cause these diseases have been considered as biological weapons.<sup>104</sup> Expanding the number of regulated pathogens

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<sup>103</sup> For example, see Jocelyn Kaiser, "Accidents Spur a Closer Look at Risks at Biodefense Labs," *Science*, vol. 317 (September 8, 2007), pp. 1852-1853.

<sup>104</sup> See CRS Report RL32391, *Small-scale Terrorist Attacks Using Chemical and Biological Agents: An Assessment Framework and Preliminary Comparisons*, by Dana A. Shea and Frank Gottron.

would mean that more high-containment facilities would become regulated through the Select Agent Program.

Some scientists have expressed concern about how the select agent list is constructed and may resist an expansion of the list. They argue that the current definition of a select agent, which relies on taxonomic definition of pathogens, may not be specific enough to accurately differentiate pathogens of concern from similar pathogens not of concern and thus may be unnecessarily hindering research.<sup>105</sup> The NIH has requested the National Academies to determine the scientific advances necessary to identify select agents based on other features and properties beyond taxonomy.<sup>106</sup>

By focusing on the Select Agent list, regulatory impacts would affect only those entities using pathogens of concern. Other high-containment facilities would not be affected. Such an approach would potentially limit disruption of scientific development and public health activities, as well as allow the government to focus its regulatory efforts on a subset of the high-containment laboratory universe deemed to pose the greatest risk.

## **Enhance Oversight of Laboratory Personnel**

Current Select Agent Program personnel background checks could be expanded to all personnel using BSL-3 and BSL-4 facilities. Select Agent Program personnel background checks have been identified by the DOJ Inspector General as sharing some of the requirements of other security regimes, such as the background investigation accompanying access to classified information or required for positions of public trust.<sup>107</sup>

Alternatively, a different level of background screening, perhaps less rigorous than used for possession of select agents, might be required for access to high-containment facilities that do not possess select agents. The scope of such background screening is likely to depend on policymakers' evaluation of the potential risks involved with gaining access to high-containment facilities.

Efforts to enhance personnel oversight at high-containment facilities may pose a series of implementation challenges. Primary may be the potential resistance to government documentation and certification of laboratory researchers. Some scientists may assert that they would prefer to exit research fields requiring high-containment laboratories rather than obtain the required government clearance. The extent of this possible resistance is unclear.<sup>108</sup>

Making such personnel screening effective may be difficult. The Department of Defense maintains personnel oversight programs more extensive than required for access to select

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<sup>105</sup> Jocelyn Kaiser, "Senate Bill Would Alter Biosafety, Select Agent Rules," *Science*, June 20, 2008.

<sup>106</sup> For more information on the National Academies committee, see online at <http://www8.nationalacademies.org/cp/projectview.aspx?key=49063>.

<sup>107</sup> Office of the Inspector General, *Inspection of the FBI's Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins*, Evaluation and Inspections Report I-2005-003, March 2005.

<sup>108</sup> See discussion in the section "Select Agent Program" regarding disposal of pathogens rather than registering under the Select Agent Program.

agents.<sup>109</sup> However, the DOJ has asserted that, despite this increased oversight, a DOD scientist perpetrated the 2001 anthrax mailings.<sup>110</sup>

## **Standardize Training**

The Select Agent Program requires worker training prior to gaining access to select agents as well as annual retraining. Rather than prescribing specific training requirements, the regulations state, “The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.”<sup>111</sup> While this allows for flexibility, it also risks allowing variation in quality. The development of training standards could help assure that each trainee receives certain core competencies.

Some experts have suggested that, although there are some exemplary biosafety training programs, these efforts are insufficient to meet current demand and should be expanded.<sup>112</sup> This type of training could be structured in many different ways, ranging from voluntary, local training to mandatory, federally centralized certification of competency. The effects of such training may be difficult to assess.

Expanded biosafety training may reduce the number of laboratory acquired infections, but the rate of these infections is reportedly lower than that for other injuries. Additionally, purely biosafety training may not address biosecurity weaknesses or vulnerabilities. Enhancement of training to include considerations related to the potential dual-use nature of pathogens handled in high-containment laboratories might address concerns related to biosecurity and provide a more uniform understanding of biosecurity concerns among the high-containment laboratory worker community.

## **Improve Reporting of Lessons Learned**

When accidents or other unexpected events occur in high-containment laboratories, lessons may be learned from the success or failure in addressing the particular incident. Reporting mechanisms, both voluntary and mandatory, have been suggested and implemented in other areas to help disseminate information about accidents or near accidents, to help the community learn from the experiences of others.<sup>113</sup> In the case of events involving select agents, the potential for criminal or other penalties to occur may pose a disincentive to reporting these events widely

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<sup>109</sup> For information on Department of Defense biological surety programs, see Kathleen Carr, Erik A. Henchal, Catherine Wilhelmsen, Bridget Carr et al., “Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 2, January 1, 2004, pp. 7-16; and Department of the Army, *Biological Surety*, Army Regulation 50-1, July 28, 2008.

<sup>110</sup> Department of Justice, *Transcript of Amerithrax Investigation Press Conference*, August 6, 2008, <http://www.justice.gov/opa/pr/2008/August/08-opa-697.html>. See also Scott Shane, “Portrait Emerges of Anthrax Suspect’s Troubled Life,” *The New York Times*, January 3, 2009.

<sup>111</sup> 42 C.F.R. § 73.15.

<sup>112</sup> Gigi Kwik Gronvall, Joe Fitzgerald, Allison Chamberlain, et al., “High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5, no. 1 (2007), pp. 75-85.

<sup>113</sup> For a discussion of some of these reporting mechanisms, see CRS Report RL31983, *Health Care Quality: Improving Patient Safety by Promoting Medical Errors Reporting*, by C. Stephen Redhead.

among the research community.<sup>114</sup> Researchers or research institutions might also not report because of perceived loss of stature, embarrassment, or other professional repercussions. This lack of sharing may inhibit the improvement of practices and procedures that might prevent such events from happening in the future.

Some experts have suggested enhancing the current reporting system to establish a database of accidents and corresponding remediation, such as changes in technology or practice. Such a database might provide warning to scientists involved in similar efforts, allowing future accidents to be avoided or minimized. The reporting required under the Select Agent Program could be coupled with such a database. Entries into such a database might be affiliated with the reporting entity or be anonymous after processing by HHS or USDA. Experts have recommended that penalties for reporting accidents to this database be minimized or eliminated so as to encourage such reports.<sup>115</sup> When considering such a mechanism, Congress may have to weigh the potential for negligence to go unpunished when reported and the interaction of such reporting with the existing criminal and other penalties present in the Select Agent Program.

## **Analysis**

When crafting the details of such programs, policymakers may have to assess the optimal balance between increasing oversight and the potential regulatory burden. Approaches that increase federal oversight would be likely met with at least some resistance from scientists and other affected stakeholders. The benefits of such increased oversight might be hard to quantify, expressing themselves mainly as reducing potential opportunities for ill-doers to use existing infrastructure in the pursuit of biological weapons.

Expansion of the Select Agent Program, either through expanding the Select Agent list or by applying the program requirements to more laboratories, may increase barriers to public health response and international collaboration. Critics of the Select Agent Program have stated that the public health response to emerging disease, such as SARS and avian influenza, relies on timely and efficient transfer of materials between high-containment laboratories both domestically and internationally.<sup>116</sup> Increasing the scope of the Select Agent Program, with its requirements for both laboratory and personnel certification, may increase the barriers to successful collaboration, leading to negative impacts on public health response. Similarly, international collaboration on regulated pathogens, both in the public health and the scientific research community, may be impeded because of a lack of comparable security regimes in foreign countries.

The impacts of a licensing and certification regime on the regulated entities might be significant. Scientists not involved in biodefense activities would be affected by the licensure requirement, potentially reducing scientific productivity in both the academic and industrial sectors. Also, public health laboratories and hospitals may accrue costs associated with these regulatory activities.

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<sup>114</sup> Accidents involving select agents are required to be reported to HHS or USDA under the Select Agent Program.

<sup>115</sup> Gigi Kwik Gronvall, Joe Fitzgerald, Allison Chamberlain, et al., "High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 5, no. 1 (2007), pp. 75-85.

<sup>116</sup> Center for Biosecurity, University of Pittsburgh Medical Center, *Preventing and Deterring Biological Attacks: Priorities that Should Emerge from the WMD Commission Report*, December 19, 2008.

Moreover, an increase in regulated facilities would require a concomitant increase in federal resources, both to process initial registration and to perform necessary inspections and certification oversight.

One overarching issue with any of these options is the identification of the most appropriate oversight agency. With regard to existing biosafety and biosecurity programs, policymakers determined that USDA and HHS had the necessary technical knowledge and relationship with the scientific community to make those agencies the appropriate regulators. Historically, many of these concerns were more focused on laboratory worker safety and minimizing the risk of pathogen accidental release. As homeland security concerns, such as pathogen theft and the possibility of training someone with malicious intent, have increased, policymakers may decide that another agency, such as DHS, would be more appropriate.

If policymakers augment existing authorities rather than creating new ones, oversight could be performed by the agency currently possessing statutory authority. If policymakers choose to develop new, additional authorities, then a mixture of oversight authority might occur, where one agency regulates for security under the Select Agent Program, and another under a new authority regulates high-containment laboratories. Harmonizing any new requirements with existing requirements, including deciding whether to consolidate all oversight into one agency, may be important to smooth implementation of new oversight responsibilities.

As biosafety is mainly based on voluntary adoption of best practices, limited federal resources have been expended in overseeing such adoption. If the scope of biosafety practices for high-containment laboratories is expanded, then the amount of federal resources necessary, even under a non-mandatory program, would likely increase. Additional funding or staffing may be necessary for those agencies to oversee and meet new mandates.

## **Legislation in the 111<sup>th</sup> Congress**

The 111<sup>th</sup> Congress has begun to consider some of these issues. Legislation addressing the Select Agent Program and the questions raised by the expansion of high-containment laboratory capacity have been introduced into both chambers. H.R. 1225 and S. 485 would extend the authorization of the Select Agent Program through 2013 or 2014 respectively and expand the criteria considered by CDC and USDA when determining if pathogens are select agents. The bills would require the National Academy of Sciences to review the Select Agent Program and recommend improvements. The HHS Secretary would be required to develop minimum biosafety and biosecurity training that would be mandatory to gain access to select agents. Additionally, the HHS Secretary would be required to issue guidance on improvements to the current select agent monitoring and inventory procedures.

These bills would also require the HHS Secretary, in consultation with the USDA Secretary, to report to Congress an evaluation of sufficiency of current and planned capacity; how laboratory capacity and lessons learned could be best shared across the biodefense and infectious disease communities; how to improve and streamline guidance on laboratory infrastructure, commissioning, and maintenance; and ways to improve personnel training. Finally, the HHS Secretary is directed, in coordination with the USDA Secretary, to establish the Biological Laboratory Incident Reporting System, through which laboratory personnel could voluntarily report biosafety or biosecurity incidents.



The Laboratory Surge Capacity Preparedness Act (H.R. 1150) would authorize DHS to award competitive grants to Regional Biocontainment Laboratories for their operation and maintenance costs. This bill would also require the DHS Secretary, in consultation with the HHS Secretary, to provide a report to Congress. This report would detail activities undertaken to integrate the RBL network and describe whether additional BSL-3 laboratory surge capacity is needed to effectively respond to a biodefense or emerging infectious disease emergency.

## **Looking Ahead**

Regardless of U.S. domestic efforts, biocontainment technologies are widely dispersed around the globe and used by many scientists in many countries. Absent international harmonization, the threat of a high-containment laboratory being the source of a bioterror weapon may be only partially addressed by solely domestic policy changes.

A key challenge for congressional policymakers is to define the goal of enhanced oversight of high-containment laboratories. The choice of goal may affect the relative importance of the issues of concern and thus the choice of policies to address them. For example, focusing on a registry of existing high-containment laboratory capacity may have benefits for planning, coordination, and efficiency of use but provide relatively limited security benefits. Similarly, a rigorous oversight program including facility and personnel licensure, mandatory training, and restricted construction of new facilities may provide security benefits at the cost of regulatory burden, increased federal expenditures, and impeded scientific progress in countermeasure research, bioforensics, and public health. When weighing potential policy options to address these complex policy issues, policymakers may have to reconcile many competing and potentially conflicting national needs.

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