

# ANTI-BIOTERRORISM RESEARCH POST-9/11 LEGISLATION: THE USA PATRIOT ACT AND BEYOND

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## I. INTRODUCTION

Legislation addressing the risks of bioterrorism has been with us for fifteen years. The Biological Weapons Anti-Terrorism Act made bioterrorism a crime in 1989<sup>1</sup> and the 1996 Antiterrorism and Effective Death Penalty Act<sup>2</sup> established controls over transfers of any of a set of especially dangerous biologically active materials called “select agents.” These controls and their implementing regulations covered university biological research activities that involved obtaining and sharing select agents.<sup>3</sup> Throughout the late 1990s and into the new century, follow-on legislation was considered by Congress. After the September 11, 2001, terrorist attacks and the anthrax letters that immediately followed, those bills were remolded and quickly adopted. First, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of

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1. Pub. L. No. 101- 298, 104 Stat. 201 (1990) (codified as amended at 18 U.S.C.A. §§ 175–178 (2000 & West Supp. 2003)).

2. Pub. L. 104-132, 110 Stat. 1284 (1996) (codified as amended in scattered sections of 18 U.S.C.A.).

3. Stories abound, at least anecdotally, of these regulations being honored in the breach by university faculty. Many university biological researchers seem to be able to tell at least one story of a colleague carrying a deadly biological agent on an airplane in a test-tube vial. Certainly this was the case at least before the enactment of these statutes. An Office of Inspector General inspection of USDA-funded research laboratories during the summer of 2002 found widespread security gaps of a most serious nature, including dangerous pathogens kept in unsecured and undersecured freezers. OFFICE OF INSPECTOR GEN., S.E. REGION, U.S. DEP’T OF AGRIC., AUDIT REPORT: CONTROLS OVER BIOLOGICAL, CHEMICAL, AND RADIOACTIVE MATERIALS AT INSTITUTIONS FUNDED BY THE U.S. DEPARTMENT OF AGRICULTURE (Sept. 2003), *available at* <http://www.usda.gov/oig/webdocs/50099-14-At.pdf>. Dr. Donald A. Henderson, who headed the World Health Organization’s smallpox eradication program in the 1970s and founded the Center for Civilian Biodefense Strategies, has been quoted as saying that scientists had safely carried biohazardous materials such as smallpox in double-sealed containers in briefcases, and that the current regulatory regime clashes with long-standing scientific practices. *Charges Against Scientist Widened*, BALT. SUN, Sept. 4, 2003, at 3A.

2001 (the "USA PATRIOT Act")<sup>4</sup> built on the two previously enacted statutes, and then in June 2002, the Bioterrorism Preparedness and Response Act (the "BPARA")<sup>5</sup> mandated a comprehensive set of regulations specifically governing research with select agents. Together, these two enactments make it easier to prosecute use of biological materials as a weapon, exclude certain individuals from conducting research on select agents, promote enforcement by creating a national database of select agents and the facilities and people that handle them, reduce the risks of theft and diversion, and, ultimately, better protect U.S. residents and our food and water supplies.<sup>6</sup>

The two statutes significantly changed the way that an institution can conduct research with select agents. More specifically, these changes include:

- Registration of facilities and select agents with the federal government;
- Mandatory safety and security plans;
- Background checks on and registration of all researchers and other individuals with access to select agents, and exclusion of "restricted persons" from such access;
- Federal prior approvals on both the overarching safety, security, containment and emergency response procedures as well as certain specific select agent activities:
  - transfers of select agents between facilities,
  - selection of employees working with select agents,
  - research protocols being employed; and
- Mandatory training of all individuals who enter select agent facilities.<sup>7</sup>

Needless to say, the changes constitute an unprecedented insertion of federal oversight into university research activities, covering even unfunded faculty-initiated research.

The purpose of this article is to survey the new legislation, its implementing regulations and agency guidance and pronouncements, and address its impact on academic biological research laboratories. The article also identifies areas of statutory and regulatory ambiguities, and contrasts agency decision-making with the statutory and regulatory requirements. The article provides some practice pointers throughout and concludes with an informal list of "do's and don'ts" for laboratories preparing for governmental compliance inspection.

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4. Pub. L. No. 107-56, 115 Stat. 272 (2001) (to be codified in scattered sections of 5, 8, 12, 15, 18, 20, 21, 22, 28, 31, 42, 47, 49, 50 U.S.C.) [hereinafter USA PATRIOT Act].

5. Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002) (to be codified in scattered sections of 7, 18, 21, 29, 38, 42, 47 U.S.C.) [hereinafter BPARA]. Subtitle A of Title II covers risks to human health under the jurisdiction of the Department of Health and Human Services (to be primarily codified at 42 U.S.C. § 262a). Subtitle B of Title II covers risks to animal and plant health and products, and is referred to as the Agricultural Bioterrorism Act of 2002 (to be primarily codified at 7 U.S.C. § 8401).

6. See *infra* Parts III, IV.

7. See *infra* Parts III, IV.

II. BRIEF OVERVIEW OF PRIOR LAWS<sup>8</sup>A. Biological Weapons Anti-Terrorism Act of 1989<sup>9</sup>

This first anti-bioterrorism act imposed maximum life terms for instances of bioterrorism.<sup>10</sup> The Act criminalized the use, development, or possession of biological agents, toxins, and delivery systems for use as a weapon.<sup>11</sup> The Act explicitly excluded prophylactic, protective, and other peaceful purposes.<sup>12</sup> The 1996 amendments added attempts, threats, and conspiracies to the prohibition.<sup>13</sup>

The Act did not explicitly reach research activities, nor did it clearly exempt research. One might hope that all university research would be viewed as prophylactic, protective, or peaceful, but this is not a foregone conclusion. Much university research aims to develop knowledge and understanding, and is not easily categorized as “offensive” or “defensive.” Some research seeks to improve our defensive capabilities by developing our understanding of offensive methods. Only by understanding how infectious particles are aerosolized, for example, can we know how to design counter measures to protect buildings. Would research into aerosolization be prophylactic under the statute?

Conversely, even research into, for example, protective clothing, would have significant offensive bioweapons potential. After all, such protective clothing might be a prerequisite for those using bioweapons offensively. Fortunately, the author is not aware of any prosecutions under the Act against research facilities, and the ambiguity was, as will be shown, resolved in 2001. No prosecutions under the Act have reached the level of a reported appellate court decision.

B. 1996 Antiterrorism and Effective Death Penalty Act<sup>14</sup>

This law first required the U.S. Department of Health and Human Services (“HHS”) to identify “select agents”—biologically active materials that pose a threat to human safety and have a potential for terrorist use.<sup>15</sup> The Act required

8. University bioresearch laboratories must comply with numerous other federal laws and regulations that directly and indirectly impact research. A nonexclusive listing of such requirements is contained in Appendix A to this article. For Appendix A, Other Regulations and Statutes Affecting University Research on Dangerous Biological Materials, visit The Journal of College and University Law, Symposium Webpage, at [http://www.nd.edu/~jcul/USA\\_PATRIOT\\_Act/Bienstock\\_Appendix\\_A.pdf](http://www.nd.edu/~jcul/USA_PATRIOT_Act/Bienstock_Appendix_A.pdf) (last visited Apr. 22, 2004).

9. Pub. L. 101-298, 104 Stat. 201 (1990) (codified as amended at 18 U.S.C.A. §§ 175–178 (2000 & West Supp. 2003)).

10. *Id.* § 3(a), 104 Stat. at 202 (codified as amended at 18 U.S.C.A. § 175(a)).

11. *Id.*

12. *Id.* § 3(b), 104 Stat. at 202 (codified as amended at 18 U.S.C.A. § 175(b)).

13. Antiterrorism and Effective Death Penalty Act of 1996 § 511(b)(1), Pub.L. 104-132, 110 Stat. 1214, 1284 (1996) (codified as amended at 18 U.S.C.A. § 175(a)).

14. Pub. L. 104-132, 110 Stat. 1214 (1996) (codified as amended in scattered sections of 8, 15, 18, 19, 21, 22, 28, 42, 49, 50 U.S.C.A.).

15. *Id.* § 511(a)(1), 110 Stat. at 1284 (not codified, but published as 42 U.S.C.A. § 262 note (2003)) (led to addition of 42 C.F.R. §§ 72.6, 72.7 app. A).

HHS to create a list of "select agents" and promulgate regulations governing the use of these select agents.<sup>16</sup> The regulations set up a regulatory and registration regime governing the transfer of select agents between institutions.<sup>17</sup> Many institutions of higher education conducting anti-bioterrorism research registered with the Centers for Disease Control and Prevention ("CDC") under these regulations, but these registration requirements have been superseded by the BPARA.<sup>18</sup> The related transportation safety requirements for etiological agents remain in effect.<sup>19</sup> Note further that the Department of Transportation, the Food and Drug Administration, and other agencies may have their own transportation requirements.<sup>20</sup>

### III. USA PATRIOT ACT<sup>21</sup>

Section 817 of the USA PATRIOT Act made two significant changes to the Biological Weapons Anti-Terrorism Act. First, the Act added "bona fide research" to the list of exempt uses, clarifying that ambiguity.<sup>22</sup> Second, the Act added a variant on the original offense. Rather than requiring "use as a weapon" as an element of the offense, with affirmative exceptions for certain valued uses, the Act criminalized any possession that is not justified by one of those uses.<sup>23</sup> This presumably lightens the prosecutor's burden: instead of the prosecutor having to prove use as a weapon, the prosecutor need only prove that the facts do not demonstrate one of the valued uses. The Act also added a new set of restrictions on the handling of select agents, creating a category called "restricted persons" and making it a crime for such persons to transport or possess select agents.<sup>24</sup>

Section 817 was widely perceived as flawed, however, in that its prohibition was directed only to the restricted person, and not to the facility employing the restricted person. Because many university facilities felt uncomfortable employing a person who, merely by performing his or her job duties, was committing a crime, facilities began implementing mechanisms to screen employees to identify restricted persons and then remove them from select agent responsibilities. Most facilities, however, held back in part because of the cost, in part because it was unclear what level of background screening would suffice, and in part because of the discomfort with the intrusion into university employment practices.

Moreover, less than one year after the USA PATRIOT Act amended the biological weapons statutes to criminalize restricted person access to select agents, the

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16. *Id.* § 511(a)(3).

17. *See* 42 C.F.R. §§ 72.1–72.7 (2003).

18. *Id.* § 73.0(b)(4).

19. *Id.* §§ 72.1–72.5.

20. *See* Appendix A, *supra* note 8.

21. Pub. L. No. 107-56, 115 Stat. 272 (2001) (to be codified in scattered sections of 8, 12, 18, 21, 22, 28, 31, 47, 50 U.S.C.)

22. *Id.* § 817(1), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175 (2000 & West Supp. 2003)).

23. *Id.* § 817(1)(C), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)).

24. *Id.* § 817(2), 115 Stat. at 386 (codified at 18 U.S.C.A. § 175b) (the definition of restricted persons is set forth *infra* in Section IV.C.3).

BPARA expanded the criminal prohibitions in the following ways:<sup>25</sup>

- Transfer or possession is criminalized whenever the person is not registered and approved under the BPARA, even if the person is not a restricted person; and
- For these new crimes, biological agents under the Agricultural Bioterrorism Protection Act are covered, in addition to select agents.

The new crimes are punishable by a maximum sentence of five years, in comparison to the ten years for possession or transfer of select agents by restricted persons.<sup>26</sup>

#### IV. BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

The BPARA was enacted on June 12, 2002. It primarily impacts research laboratories working with biohazardous materials through the imposition of federal prior approvals for most aspects of select agent research, and a set of comprehensive regulations governing laboratory safety and security. These regulations extended the oversight of select agents from the domain of inter-laboratory transfer, which had been regulated by the Antiterrorism and Effective Death Penalty Act of 1996,<sup>27</sup> into the broader domain of laboratory infrastructure, procedures, and employees. The BPARA regulations are discussed in detail in Section V of this article.

Two broader aspects of the BPARA are worth addressing here. First, the BPARA addressed the questions left unresolved by the USA PATRIOT Act's creation of the restricted person category, and its criminalization of restricted person access to select agents.<sup>28</sup> In doing so, the BPARA struck a balance between national security and civil liberties that merits attention. Second, and perhaps relatedly, the BPARA provided for the collection of massive amounts of data pertaining to biosecurity and created the Freedom of Information Act ("FOIA") exemptions for much of that data.<sup>29</sup>

##### A. RESTRICTED PERSONS; TENSIONS BETWEEN CIVIL LIBERTIES AND NATIONAL SECURITY

Much of the tension between civil liberties and national security is played out in the BPARA's regulation of researchers' access to select agents. The BPARA built on the "restricted persons" category in the USA PATRIOT Act, and addressed its major unresolved issues.

The BPARA clearly allocated responsibility for identifying restricted persons, and responsibility for restricting them. It placed responsibility for identifying re-

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25. BPARA § 231, 116 Stat. 594, 660–62 (codified at 18 U.S.C.A. § 175b).

26. *Id.*

27. Pub. L. 104-132, 110 Stat. 1284 (1996) (codified as amended in scattered sections of 18 U.S.C.A.).

28. *See infra* Part IV.A.

29. *See infra* Part IV.B.

stricted persons on the federal government through the U.S. Attorney General,<sup>30</sup> thereby lifting a significant burden from research facilities. Indeed, the BPARA minimized the potential burden on the Attorney General as well, limiting that office's role to searching existing databases (criminal, immigration, national security, and others) to determine whether an individual is in one of the restricted person categories.<sup>31</sup> The BPARA then squarely placed responsibility on the research facility to deny access to select agents to any person identified by the Attorney General as a restricted person.<sup>32</sup>

While preserving the categories of restricted persons defined in the USA PATRIOT Act, the BPARA extended the ability of the federal government to restrict access to select agents to another class of individuals—those “reasonably suspected of” terrorism-related ties.<sup>33</sup> Late drafts of the legislation had cast a much wider net, allowing restriction of individuals who were merely named in a warrant or under investigation for certain activities, or who were suspected of spying; it was only in conference that the scope of these provisions was narrowed to reasonable suspicion.<sup>34</sup> This narrowing did not, however, limit the scope to persons suspected of actually committing crimes; the provisions include those reasonably suspected of “knowing involvement with an organization” engaged in “terrorism . . . or . . . intentional crimes of violence.”<sup>35</sup>

The drafters were cognizant of the discretion and power given to the Attorney General, and created what they presumably hoped would be a check and balance. Whereas persons the Attorney General identified as restricted persons were automatically restricted from access to select agents, persons reasonably suspected of terrorism-related ties could be restricted only by order of the Secretary of Health and Human Services, or the Secretary of Agriculture, who must consult with, but need not defer to, the Attorney General.<sup>36</sup>

The scope of the Attorney General's investigatory powers to determine whether researchers needing access to select agents are responsible persons was a matter of some dispute during the debate in enacting the BPARA. The legislation provides that “the Attorney General shall, for the sole purpose of identifying whether the

30. BPARA § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(e)(2)(C) (2003)); § 212(e)(2)–(3), 116 Stat. at 649–50 (codified at 7 U.S.C.A. § 8401(e)(2)–(3) (West Supp. 2003)).

31. *Id.* § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(e)(3)); § 212(e)(3), 116 Stat. at 649–50 (codified at 7 U.S.C.A. § 8401(e)(3)).

32. *Id.* § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(e)(2)(C)); § 212(e)(2)(C), 116 Stat. at 649 (codified at 7 U.S.C.A. § 8401(e)(2)(C)).

33. *Id.* § 201(a), 116 Stat. at 639–40 (codified at 42 U.S.C.A. § 262a(e)(3)(B)(ii)); § 212(e)(3)(B)(ii), 116 Stat. at 650 (codified at 7 U.S.C.A. § 8401(e)(3)(B)(ii)).

34. H.R. CONF. REP. NO. 107-481, at 118 (2002), *reprinted in* 2002 U.S.C.C.A.N. 464, 475.

35. BPARA § 201(a), 116 Stat. at 640 (codified at 42 U.S.C.A. § 262a(e)(3)(B)(ii)(II)); § 212(e)(3)(B)(ii)(II), 116 Stat. at 650 (codified at 7 U.S.C.A. § 8401(e)(3)(B)(ii)(II)). BPARA includes the following terrorism-related ties in 42 U.S.C.A. § 262a(e)(3)(B)(ii); 7 U.S.C.A. § 8401(e)(3)(B)(ii)(2): committing a Federal crime of terrorism (as defined in 18 U.S.C.A. § 2332b(g)(5) (2000 & West Supp. 2003)); knowing involvement with an organization engaged in terrorism (as defined in 18 U.S.C.A. § 2331 (2000 & West Supp. 2003)) or crimes of violence; or being an agent of a foreign power (as defined in 50 U.S.C.A. § 1801 (2003)).

36. *Id.* § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(e)(2)(D)); § 212(e)(2)(C), 116 Stat. at 649 (codified at 7 U.S.C.A. § 8401(e)(2)(C)).

individuals involved are [restricted persons], promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.”<sup>37</sup> The Conference Report makes clear the limitations of this language. The Conference Report emphasizes the “sole purpose” language, and while it states that nonelectronic databases and files may be used “to clarify or confirm information obtained during the electronic database search,” it confirms that the initial inquiry is to be limited to identifying names in electronic databases.<sup>38</sup>

Congressman John D. Dingell, a co-sponsor of the BPARA, responded to the Conference Report’s explanation by stating his view that:

[T]he screening process is not expected to encompass the complex investigation that would occur prior to issuance of a security clearance, but to be similar to the check for prospective gun owners in its use of electronic databases. It will be carried out by the Department of Justice and limited to using appropriate electronic databases available to the government for this purpose to determine if the persons or individuals being screened are listed in those databases . . . It is not the purpose of this provision to permit the Attorney General to do extensive individual investigations or use non-credible, unsubstantiated information that may be contained in those other “files” to deny persons or individuals access to select agents.<sup>39</sup>

One area in which the BPARA favored national security concerns rather than civil liberties was through provisions allowing for administrative or judicial review of decisions to deny access to select agents. In both arenas, the statute authorizes *ex parte* review in some circumstances.<sup>40</sup> The standard is an easy one for the government to meet—*ex parte* review is authorized “to the extent that disclosure of the information *could* compromise national security or an investigation by any law enforcement agency.”<sup>41</sup>

#### B. Information: Database Creation and FOIA Exemptions

The BPARA mandates HHS and the U.S. Department of Agriculture (“USDA”) to create a national database including the names and locations of people registered and authorized to use select agents, and, most significantly in light of the anthrax

37. *Id.* § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(e)(3)(A)); § 212(e)(3)(A), 116 Stat. at 649–50 (codified at 7 U.S.C.A. § 8401(e)(3)(A)).

38. H.R. CONF. REP. NO. 107–481, at 120 (2002), *reprinted in* 2002 U.S.C.C.A.N. 464, 477.

39. 148 CONG. REC. E919, at E919–20 (daily ed. May 24, 2002) (statement of Rep. Dingell).

40. BPARA § 201(a), 116 Stat. at 640 (codified at 42 U.S.C.A. § 262a(e)(7)(A)(ii)); § 212(e)(7)(A)(ii), 116 Stat. at 651 (codified at 7 U.S.C.A. § 8401(e)(7)(A)(ii) (administrative review)).

41. *Id.* § 201(a), 116 Stat. at 640 (codified at 42 U.S.C.A. § 262a(e)(7)(A)(ii)); § 212(e)(7)(A)(ii), 116 Stat. at 651 (codified at 7 U.S.C.A. § 8401(e)(7)(A)(ii) (administrative review) (emphasis added)). *Accord id.* § 201(a), 116 Stat. at 640 (codified at 42 U.S.C.A. § 262a(e)(7)(B)(i)); § 212(e)(7)(B)(i), 116 Stat. at 651 (codified at 7 U.S.C.A. § 8401(e)(7)(B)(i) (judicial proceedings)).

attacks of 2001, sufficient information about the select agents themselves to facilitate the identification and source of any select agent.<sup>42</sup>

In order to ensure that this information is not used by bioterrorists, the BPARA exempts both the database itself and much of the information that the BPARA requires laboratories to report to the federal government from the Freedom of Information Act's ("FOIA")<sup>43</sup> public access provisions.

In particular, it affirmatively prohibits disclosure under FOIA of:<sup>44</sup>

- the database;
- registration or transfer information that identifies a specific registered person or ties someone to a specific listed biohazardous agent;
- inspection records containing such information, when in the interests of public health or safety;
- site-specific or transfer-specific safety or security measures; and
- notifications of release, loss, or theft of biological agents.

Note, however, that individual facilities themselves are not prohibited from releasing information about their select agents; the statute only restricts federal government release.

## V. BPARA REGULATIONS

The BPARA required that implementing regulations issue in the form of an Interim Final Rule within 180 days of its enactment.<sup>45</sup> HHS, through the CDC, and the USDA, through the Animal and Plant Health Inspection Service ("APHIS"), issued the Interim Final Rule on December 13, 2002, with an effective date of February 7, 2003.<sup>46</sup> Its provisions became applicable at various times over the course of 2003, with all provisions in effect by November 12, 2003.<sup>47</sup> CDC and APHIS accepted comments on the Interim Final Rule, but the Interim Final Rule went into effect without consideration of the comments.<sup>48</sup>

### A. What biological agents are covered?

#### 1. Select Agents

The regulations govern the use, handling, and transfer of specified biologically hazardous bacteria, fungi, viruses, toxins, and nucleic acids as follows. The bio-

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42. *Id.* § 201(a), 116 Stat. at 639 (codified at 42 U.S.C.A. § 262a(d)(2)); § 212(d)(2), 116 Stat. at 648–49 (codified at 7 U.S.C.A. § 8401(d)(2)).

43. 5 U.S.C. § 552 (2000).

44. BPARA § 201(a), 116 Stat. at 643 (codified at 42 U.S.C.A. § 262a(h)(1)); § 212(h)(1), 116 Stat. at 654–55 (codified at 7 U.S.C.A. § 8401(h)(1)).

45. *Id.* § 202(b), 116 Stat. at 646 (not codified, but published as 42 § U.S.C.A. § 262a note); § 213(c), 116 Stat. at 657 (not codified, but published as 7 U.S.C.A. § 8401 note).

46. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886 (Dec. 13, 2002) (codified at 42 C.F.R. pt. 73).

47. *Id.*

48. The comments will be taken into account for the Final Rule, to be issued in 2004.



logical agents and toxins that are threatening to humans, and that are therefore under the jurisdiction of the CDC, are formally referred to as “select agents and toxins” in the BPARA regulations.<sup>49</sup> The BPARA also covers other categories of dangerous biological agents and toxins and places them under the jurisdiction of the USDA.<sup>50</sup> These categories consist of agents and toxins that pose a severe threat to animal health and animal products, “high consequence livestock pathogens and toxins,” regulated at 9 C.F.R. pt. 121; and agents and toxins that pose a severe threat to plant health and plant products, “plant pathogens,” regulated at 7 C.F.R. pt. 331.

CDC and APHIS have published lists of agents that fit within each of these categories.<sup>51</sup> Substances that are identified on both the CDC list and the APHIS animal list (i.e., those that cover both human and animal health and products) are referred to as “overlap agents.” For convenience, this article often refers to all substances covered by the Act generically as “select agents.”

The regulations also cover genetic elements of viruses, including nucleic acids that can encode the select agent viruses or toxins. The regulations originally were to be limited to full-length nucleic acids, but were modified to include fragments if the nucleic acids could encode infectious or replication-competent viruses.<sup>52</sup> Nucleic acids that encode the toxins are covered broadly.<sup>53</sup> Coverage under the regulations cannot be avoided by altering the genetic makeup of a select agent such that its name no longer applies; the regulation captures genetically modified forms of the listed agents.<sup>54</sup>

The BPARA sets the criteria CDC and APHIS must use for determining select agent status: effect on health, contagiousness, methods of contagion, availability and effectiveness of treatment, and availability and effectiveness of immunization.<sup>55</sup> For animal and plant pathogens, the BPARA adds one additional crite-

49. See 42 C.F.R. §§ 73.1, 73.4 (2003).

50. BPARA § 212(a)(1), 116 Stat. at 647–48 (codified at 7 U.S.C.A. § 8401(a)(1)(West Supp. 2003)).

51. “Select agents and toxins” are listed at 42 C.F.R. § 73.4. “Overlap select agents and toxins”—those that are hazardous both to humans and to animals—are listed at 42 C.F.R. § 73.5 and 9 C.F.R. § 121.3(b) (2004). “Animal agents and toxins” are listed at 9 C.F.R. § 121.3(d). “Plant agents and toxins” are listed at 7 C.F.R. § 331.3 (2004). See also CDC, Office of the Director, Select Agent List, *available at* <http://www.cdc.gov/od/sap/docs/salist.pdf> (last visited Mar. 8, 2004).

52. Compare Interstate Shipment of Etiological Agents; Select Agents, 67 Fed. Reg. 54,605, 54,607 col. 3 (Aug. 23, 2002), with Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76,886, 76,888 col. 1 (Dec. 13, 2002).

53. 42 C.F.R. §§ 73.4(e), 73.5(e); 9 C.F.R. § 121.3(c)(1). Nonoverlap animal and plant genetic elements are not covered directly. Instead, the nonoverlap animal and plant agents and toxins are listed by name, and then “genetic elements” are excluded provided they are “not capable of causing disease.” 9 C.F.R. § 121.3(f)(2); 7 C.F.R. § 331.3(c)(2). This implicitly includes genetic elements that are capable of causing disease, but the definition is not as well developed as for the human and overlap animal agents.

54. 42 C.F.R. §§ 73.4(e)(3), 73.5(e)(3); 9 C.F.R. § 121.3(c)(3). There is no comparable provision for nonoverlap animal agents or for plant agents.

55. BPARA § 201(a), 116 Stat. at 637–38 (codified at 42 U.S.C.A. § 262a(a)(1)(B)(i)); § 212(a)(1)(B)(i), 116 Stat. at 648 (codified at 7 U.S.C.A. § 8401(a)(1)(B)(i)).

tion—effect on production and marketability of animal or plant products.<sup>56</sup>

The BPARA contains a provision authorizing differential laboratory protocols for the various select agents. The provision states that the regulations “shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin *commensurate with the risk such agent or toxin poses to public health and safety* (including the risk of use in domestic or international terrorism).”<sup>57</sup> The CDC regulations, however, ignore this mandate. The regulations do nothing to encourage selective safety or security provisions, and arguably, by their silence, disfavor such agent-specific plans. The silence of the regulations is somewhat surprising, given that a CDC task force in 2000 developed criteria for prioritizing select agents based upon their risk to national security, and then grouped the criteria into a three-tier categorization.<sup>58</sup> The APHIS regulations, in contrast, require the plan to “be commensurate with the risk of the agent or toxin, given its intended use.”<sup>59</sup>

## 2. Exemptions

There are several categories of exemptions from the BPARA requirements. The first category of exemptions are exclusions from the definition of “select agent,”<sup>60</sup> the most significant of which are:

- a select agent in its naturally occurring environment, provided it has not been intentionally extracted from its natural source;<sup>61</sup>
- nonviable organisms (i.e., organisms unable to replicate<sup>62</sup>) and non-functional toxins;<sup>63</sup>
- small amounts of toxins (measured by the amount held by each princi-

56. *Id.* § 212(a)(1)(B)(i)(I), 116 Stat. at 647–48 (codified at 7 U.S.C.A. § 8401(a)(1)(B)(i)(I)).

57. *Id.* § 201(a), 116 Stat. at 638 (codified at 42 U.S.C.A. § 262a(e)(1) (emphasis added)). See also *id.* § 212(e)(1), 116 Stat. at 649 (codified at 7 U.S.C.A. § 8401(e)(1)). The House and Senate Conference Managers referenced the differential levels already in place for biosafety as a model for this provision. H.R. CONF. REP. NO. 107-481, at 118 (2002), *reprinted in* 2002 U.S.C.C.A.N. 464, 475.

58. CDC, Recommendations of the CDC Strategic Planning Workgroup, *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response*, MORBIDITY AND MORTALITY WEEKLY REPORT, Apr. 21, 2000, at Box 3 (Critical biological agents), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4904a1.htm> (last visited Mar. 8, 2004).

59. 9 C.F.R. § 121.12(a); 7 C.F.R. § 331.11(a).

60. 42 C.F.R. §§ 73.4(f), 73.5(f). See generally 9 C.F.R. § 121.3; 7 C.F.R. § 331.3.

61. 42 C.F.R. §§ 73.4(f)(1), 73.5(f)(1); 9 C.F.R. § 121.3(e); 7 C.F.R. § 331.3(b). This includes, for example, naturally infected human and animal specimens. CDC/APHIS Briefing Meeting, Washington, D.C. (Dec. 16, 2002). In contrast, one university was told by the CDC that deliberately inoculated animals are not exempt. Deliberately inoculated animals must therefore be kept in select agent areas, and their handlers are subject to security requirements, etc.

62. See CDC, Select Agent Program: FAQ for New Select Agent Regulation [hereinafter CDC FAQ], Questions Regarding the New Select Agent Regulation (42 C.F.R. § 73) for Facilities Not Currently Registered under 42 C.F.R. § 72.6 and Not Currently Possessing Select Agents, Additional Clarification following Question No. 2, at <http://www.cdc.gov/od/sap/faq.htm#> (last updated Oct. 3, 2003).

63. 42 C.F.R. §§ 73.4(f)(2), 73.5(f)(2); 9 C.F.R. § 121.3(f)(1); 7 C.F.R. § 331.3(c)(1).

pal investigator);<sup>64</sup> and

- particular attenuated strains of select agents excluded by HHS after written submission of an application by the user.<sup>65</sup>

Second, diagnostic or clinical laboratories are exempt from many of the requirements if they have select agents only because they are contained in specimens (or were isolated from specimens) used for diagnosis, verification, or proficiency testing.<sup>66</sup> These labs are, however, subject to certain regulatory requirements upon identification of a select agent, including:<sup>67</sup>

- prompt notification to HHS and other authorities;<sup>68</sup>
- prompt destruction of the specimen/isolate, or transfer to authorized facility;
- certain recordkeeping requirements; and
- the general transfer requirements applicable to other facilities.

Note that this means that an unregistered lab may not retain a select agent as a control or reference sample.<sup>69</sup>

Third, products containing select agents that have been approved by other specified laws are exempt from the BPARA regulations.<sup>70</sup> These other laws include, for

64. 42 C.F.R. §§ 73.4(f)(4), 73.5(f)(4) specify the threshold for each of several toxins. The APHIS regulations do not add additional exclusions for non-overlap toxins. See 9 C.F.R. § 121.3(f)(3). Because viruses and bacteria can replicate, there is no corresponding exemption for small amounts of them. But note that organisms that produce select agent toxins, but that are not themselves select agents, are not covered. CDC FAQ, *supra* note 62, Questions Regarding the new Select Agent Regulation (42 C.F.R. § 73) for Facilities Not Currently Registered under 42 C.F.R. § 72.6 and Not Currently Possessing Select Agents, Question No. 3. Ironically, genetic material from those same organisms may itself be covered. See *id.*, Questions Regarding the New Select Agent Regulation (42 C.F.R. § 73) for Facilities Not Currently Registered under 42 C.F.R. § 72.6 and Not Currently Possessing Select Agents, Question No. 4.

As a practice pointer, institutions should consider tracking the amounts of the covered toxins held by each principal investigator, even if the amount is below the exemption limit. Otherwise, the institution runs the risk that additional receipt of a sub-threshold amount of that toxin by an investigator will result in a net amount in excess of the threshold, thereby triggering coverage under the Act.

65. 42 C.F.R. § 73.4(f)(5); 9 C.F.R. § 121.3(g); 7 C.F.R. § 331.3(c). The current list of excluded HHS and overlap strains is available at CDC, Office of the Director, Select Agent Program, Notification of Exclusion, at <http://www.cdc.gov/od/sap/exclusion.htm> (last visited Mar. 8, 2004). The list of excluded USDA strains is available at APHIS, Notification of Exclusion of Attenuated Strains, at [http://www.aphis.usda.gov/vs/ncie/pdf/exclusion\\_10-15-03.pdf](http://www.aphis.usda.gov/vs/ncie/pdf/exclusion_10-15-03.pdf) (last visited Mar. 8, 2004).

66. 42 C.F.R. § 73.6(a)(1); 9 C.F.R. §§ 121.4(a)–(b), 121.5(a)–(b); 7 C.F.R. § 331.4(a). But for overlap agents, and for plant and animal agents generally, immediate reporting is required. 9 C.F.R. §§ 121.4(a)(1), 121.4(b)(1), 121.5(a)(1), 121.5(b)(1); 7 C.F.R. § 331.4(a)(1).

67. 42 C.F.R. § 73.6(a)(2)–(7); 9 C.F.R. §§ 121.4(a)(1)–(2), 121.4(b)(1)–(2), 121.5(a)(1)–(2), 121.5(b)(1)–(2); 7 C.F.R. § 331.4(a)(1)–(2).

68. The timing of the notification depends on the select agent involved, but may in no event be longer than seven days. Cf. 42 C.F.R. § 73.6(a)(2) with 42 C.F.R. § 73.6(a)(7); 9 C.F.R. § 121.4(a)(2); 7 C.F.R. § 331.4(a)(2).

69. CDC FAQ, *supra* note 62, General Questions Regarding the New Select Agent Regulation, Question No. 6.

70. 42 C.F.R. § 73.6(b); 9 C.F.R. §§ 121.4(c), 121.5(d). There is no comparable exemption for plant agents.

example, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")<sup>71</sup> and the Federal Food, Drug, and Cosmetic Act.<sup>72</sup>

Finally, HHS and USDA may issue exemptions for investigational products<sup>73</sup> to facilitate response to an emergency.<sup>74</sup>

#### B. Who and What Must Register Under the Act?

The Act requires registration of facilities that possess or use select agents as well as individuals who have access to them. A facility that possesses or uses select agents must apply for and receive a certificate of registration from HHS and/or USDA. The facility must name a Responsible Official with both the authority and the responsibility for compliance with the Act and its regulations. The Responsible Official should be either the biosafety officer or a senior management official. It should not be someone who actually works with select agents. The Responsible Official may name one or more Alternate Responsible Officials, who themselves must meet the qualifications of the Responsible Official, including registration and passing the background checks.<sup>75</sup>

The registration application is the key compliance document—it requires information about the basic compliance elements, and a certification that the information is accurate.<sup>76</sup> The required information includes:

- an inventory of the select agents held, including source, quantities, and location;<sup>77</sup>
- a description of the research to be conducted with the select agents;<sup>78</sup>
- a list of individuals with access;<sup>79</sup> and
- information about the required safety, security, and emergency response plans.<sup>80</sup>

71. 7 U.S.C. §§ 136–136y (2000).

72. 21 U.S.C. §§ 301–399 (2000).

73. 42 C.F.R. § 73.6(c); 9 C.F.R. § 121.4(d). *See also* 7 C.F.R. § 331.4(b) (general authority for APHIS to grant an exemption for good cause).

74. 42 C.F.R. § 73.6(d), (e); 9 C.F.R. § 121.4(e), (f). *See also* 7 C.F.R. § 331.4(b) (general authority for APHIS to grant an exemption for good cause).

75. 42 C.F.R. § 73.9; 9 C.F.R. § 121.6(b), (c); 7 C.F.R. § 331.5(b), (c).

76. HHS/USDA, APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT BIOLOGICAL AGENTS AND TOXINS, *available at* <http://www.cdc.gov/od/sap/downloads2.htm> (last updated Feb. 14, 2003) [hereinafter APPLICATION].

77. *Id.* *See also* 42 C.F.R. §§ 73.15(b), (c) for additional inventory requirements, including documentation of destruction, internal transfers, and moves from storage to laboratory. The inventory requirements for plant and animal agents are less detailed. *See* 9 C.F.R. § 121.15; 7 C.F.R. § 331.14. Enough information should be provided to enable government officials to identify the source of an agent in the event of a terrorist attack, such as strain, sequence, and genebank accession numbers. CDC/APHIS Briefing Meeting, Washington, D.C. (Dec. 16, 2002).

78. APPLICATION, *supra* note 76. Question 18 on the application form asks: "Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), including a description of the methodologies or laboratory procedures that will be used." *Id.*

79. *Id.*

80. *Id.*

A registration may cover a set of locations in one general area, and can include a complex of buildings as long as there is only one mailing address.<sup>81</sup>

Certificates of registration are valid for three years, unless terminated earlier.<sup>82</sup> The registration certificate is valid only for the information submitted in the application.<sup>83</sup> A facility that acquires additional select agents, for example, must submit a revised application. Facilities must notify CDC or APHIS of even relatively minor changes.<sup>84</sup> Any addition or removal of individuals from the list of those with access requires notification.<sup>85</sup> Even training events including select agents require separate listings in (or modifications to) the registration form.<sup>86</sup> Similarly, the regulations provide that facilities must notify HHS of any changes in the objectives of studies or even research protocols.<sup>87</sup> This latter requirement seems counterintuitive. Neither the regulation nor the application itself requires the actual research protocols to be disclosed in the first place;<sup>88</sup> the regulation is silent, and the application asks only for a one-paragraph overview.<sup>89</sup> Perhaps the drafters of the regulations did not understand that in academia, the phrase “research protocol” implies a fairly detailed description.

If a facility wants to destroy or inactivate a select agent in order to discontinue activities with it, or if a facility consumes a select agent that has been transferred to it, it must notify CDC and/or APHIS at least five days in advance.<sup>90</sup>

### C. What are the Background Check Requirements under the Act and Regulations?

Both the facility itself, and a significant subset of the employees working there, must submit to background checks (“security risk assessments,” in the language of the regulations) in order to be approved to work with select agents. The background checks are conducted by the Department of Justice through the Federal Bureau of Investigation (“FBI”) Criminal Justice Information Services Division. The FBI will report the results to HHS and the Department of Agriculture, as appropriate, which will make the official decision on approval, using the criteria discussed below. Approvals are valid for five years.<sup>91</sup> The background checks are obtained

81. 42 C.F.R. § 73.7(f). The animal and plant agent regulations do not address this point.

As a practice pointer, most institutions are treating the mailing address requirement as being met if all the covered facilities are on the same campus and covered by the same Responsible Official, even if the multiple buildings indeed have separate mailing addresses. It remains to be seen whether the CDC and APHIS will accept this approach.

82. 42 C.F.R. § 73.7(g); 9 C.F.R. § 121.7(g); 7 C.F.R. § 331.6(f).

83. 42 C.F.R. § 73.7(d); 9 C.F.R. § 121.7(d); 7 C.F.R. § 331.6(c).

84. 42 C.F.R. § 73.7(d); 9 C.F.R. § 121.7(e); 7 C.F.R. § 331.6(d).

85. 42 C.F.R. § 73.7(d). *Cf.* 9 C.F.R. § 121.7(e); 7 C.F.R. § 331.6(d).

86. CDC FAQ, *supra* note 62, General Questions Regarding the New Select Agent Regulation (42 C.F.R. § 73), Question No. 33.

87. 42 C.F.R. § 73.7(d). *Cf.* 9 C.F.R. § 121.7(e); 7 C.F.R. § 351.6(d).

88. 42 C.F.R. § 73.7(b)(2). *See supra* text accompanying note 77.

89. APPLICATION, *supra* note 76

90. 42 C.F.R. §§ 73.7(h), 73.14(h); 9 C.F.R. § 121.7(f); 7 C.F.R. § 331.6(e).

91. 42 C.F.R. § 73.8(f); 9 C.F.R. § 121.11(k); 7 C.F.R. § 331.10(j). It is not clear how the

by filling out FBI Form FD-961.<sup>92</sup> Fingerprints are also required.<sup>93</sup>

### 1. Facility and owner background checks

The facility must obtain background checks and approvals for itself and certain key individuals: its Responsible Official, any Alternate Responsible Officials, and “any individual who owns or controls the entity.”<sup>94</sup> This latter requirement has been considerably watered down in implementation.

The regulations exempt “Federal, State, or local government agencies” from the provisions for approval of the facility itself.<sup>95</sup> Although the word “agencies” in the exemption is not unambiguous,<sup>96</sup> the FBI appears to interpret it as including state institutions of higher education.<sup>97</sup>

The requirement for approval for individuals who own or control the entity has, in contrast, been the subject of much confusion. The CDC website document “Security Risk Assessment” notes rather obviously that “if the entity is a local, state, or federal institution, then the owners do not require a security risk assessment . . . .”<sup>98</sup> Therefore, both public entities and their “owners” are exempt from background checks, although their responsible officials, alternates, and employees using select agents must go through them.

The situation for private academic institutions is a bit more ambiguous. The CDC’s Security Risk Assessment provides the following guidance, which is inconsistent in its use of the terms “own” and “control”:

How is the owner of an entity defined? FBI/CJIS has determined that for the assessment under the Bioterrorism Act, an individual who owns or controls an entity is defined as:

“Except for an accredited academic institution, a person shall be deemed to own or control an entity if that person is a partner, officer, director, holder, or owner of 50 percent or more of its voting stock and is in a managerial or executive capacity with regard to select agent [sic]

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five-year approvals will mesh with the three-year duration of certificates of registration. See text accompanying *supra* note 81.

92. FBI, FEDERAL BUREAU OF INVESTIGATION BIOTERRORISM PREPAREDNESS ACT: ENTITY/INDIVIDUAL INFORMATION, available at <http://www.fbi.gov/terrorinfo/fd-961.pdf> (last visited Mar. 8, 2004) [hereinafter FBI’S ENTITY/INDIVIDUAL INFORMATION].

93. See FBI, BIOTERRORISM PREPAREDNESS AND RESPONSE ACT, FBI INFORMATION FORM (FORM FD-961), available at <http://www.fbi.gov/terrorinfo/bioterrorfd961.htm> (last visited Mar. 8, 2004) [hereinafter FD-961].

94. 42 C.F.R. § 73.7(b)(1); 9 C.F.R. § 121.2(b). Cf. 7 C.F.R. § 331.5(b), (c) (note that the plant agent regulations do not include the requirement for an individual who owns or controls the entity).

95. 42 C.F.R. § 73.8(a); 9 C.F.R. § 121.7(b)(1) n.7; 7 C.F.R. § 331.6(b)(1) n.4.

96. Under some states’ laws, the word “agency” does not include state institutions of higher education.

97. Posting of Tony DeCrappeo, Associate Director, Council on Governmental Relations, [tdecrappeo@cogr.edu](mailto:tdecrappeo@cogr.edu), to COGR listserv, [cogr-list@usc.edu](mailto:cogr-list@usc.edu) (Apr. 1, 2003) (on file with author).

98. CDC, Security Risk Assessment, available at [www.cdc.gov/od/sap/securisk.htm](http://www.cdc.gov/od/sap/securisk.htm) (last visited Mar. 8, 2004).

possessed, used, or transferred by the entity. For an accredited academic institution, a person shall be deemed to control an entity if that person is a responsible official with regard to the select agent possessed, used, or transferred by the entity.”<sup>99</sup>

The document goes on to state that “owners of accredited academic institutions, do not require security risk assessments.”<sup>100</sup>

This generous guidance seems inconsistent with the provisions in the regulation requiring as a condition of registration that the entity must apply for approval for “any individual who owns or controls the entity,” as noted above. The regulation contains no authority for an exemption for accredited academic institutions. Beyond this, the statement also seems to exclude individuals with passive ownership interests. Only those owners who are in a managerial or executive capacity are required to obtain security assessments.

In lieu of formal security assessments, the FBI is requiring submission of basic information for certain individuals. The instructions for Form FD-961 state as a “clarification” that “private academic entities” must complete the section calling for disclosure of corporate officers, entity leadership, the board of directors, and principal stockholders.<sup>101</sup> While “private academic entities” is not defined, the FBI form, by including “principal stockholders” in the required entity information, implies that nonprofit institutions might not be covered by the phrase “private academic entities.”<sup>102</sup> In a letter to the Council on Government Relations in April 2003,<sup>103</sup> the FBI wrote: “We are interested in principal members or, where the laboratory has a separate board overseeing its activities, that specific board.” In a communication to one institution, the FBI stated that “Submission of the Chair and Vice Chairs will satisfy our legal requirements.”<sup>104</sup> Note that the form does not require the officer or director to submit to a background check, nor to submit fingerprints. The only information required for such individuals is name, date of birth, and social security number.<sup>105</sup>

We are thus left with some inconsistencies, but some clarifications for academic

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99. *Id.* The CDC reports that:

An accredited academic institution is defined by the FBI/CJIS as:

“Postsecondary, language and vocational schools must be accredited by an accrediting agency recognized by the United States Department of Education. Proof that a school has been determined to be eligible under Title IV of the Higher Education Act of 1965 is sufficient to establish that a school is properly accredited, since such accreditation is a prerequisite for recognition under Title IV of the latter Act. The specific requirements for Title IV eligibility are specified at 34 C.F.R. part 600.”

*Id.*

100. *Id.*

101. FD-961, *supra* note 93.

102. *See id.*

103. Letter from David Hardy, Chief of the Record/Information Dissemination Section, Records Management Division, Federal Bureau of Investigation, to Tony DeCrappeo, Associate Director, Council on Governmental Relations (Apr. 4, 2003) (on file with author).

104. Letter from Tony DeCrappeo, Associate Director, Council on Governmental Relations, to David Hardy, Chief of the Record/Information Dissemination Section, Records Management Division, Federal Bureau of Investigation (Apr. 4, 2003) (on file with author).

105. FD-961, *supra* note 93.

institutions, as follows:

- For accredited state educational institutions, entity security risk assessments are not required at all, and only responsible officials and those with access to select agents require security assessments.
- For non-profit accredited educational institutions, entity approval is required. Form FD-961 also appears to require disclosure of the names, dates of birth, and social security numbers of governing officials (corporate officers, entity leadership, and the board of directors). The COGR letter referenced above provides some limits on the individuals who must be disclosed in the form.
- For-profit accredited educational institutions are subject to the same requirements. Additionally, while ownership is not defined, Form FD-961 also requires disclosure of principal stockholders, defined as "individuals holding greater than 50% of share holdings."<sup>106</sup> Any such individual is not, however, subject to a security risk assessment.
- For unaccredited institutions, security risk assessments are required for certain individuals who exercise management authority.

## 2. Researcher background checks

Individuals with "access" to select agents must obtain background checks and approvals.<sup>107</sup> HHS guidance has clarified that not all individuals who work in the facility's designated select agent areas must obtain the required security clearance.<sup>108</sup> The requirement pertains only to those individuals who have authorized access without direct oversight. Unapproved individuals must, however, be monitored.<sup>109</sup>

## 3. Security criteria for approval

When conducting background checks, the FBI screens individuals by using its informational databases. The following are criteria for disqualification from access to select agents:<sup>110</sup>

- being a "restricted person;"<sup>111</sup>
- having committed certain crimes specified in 18 U.S.C.A. §

106. FBI'S ENTITY/INDIVIDUAL INFORMATION, *supra* note 92, Question 7.

107. 42 C.F.R. § 73.8(b) (2003); 9 C.F.R. § 121.11 (2004); 7 C.F.R. § 331.10 (2004).

108. *See infra* text at note 147.

109. 42 C.F.R. § 73.11(d)(2); 9 C.F.R. § 121.12(a)(2)(iv)(B); 7 C.F.R. § 331.11(a)(2)(iv)(B).

110. 42 C.F.R. § 73.8(d)-(e); 9 C.F.R. § 121.8(a)(1)-(2); 7 C.F.R. § 331.7(a)(1)-(2).

111. The concept of "restricted person" was created by the USA PATRIOT Act's revisions to the Biological Weapons Anti-Terrorism Act. It is defined to mean an individual who has been convicted or is under indictment for a crime punishable by imprisonment for a term exceeding one year, is a fugitive from justice, is an unlawful user of any controlled substance, is an illegal alien, has been adjudicated mentally defective or committed to any mental institution, is an alien (not lawfully admitted for permanent residence) of a country supporting terrorism, as determined by the Secretary of State (currently Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria), and has been dishonorably discharged from the military. 18 U.S.C.A. § 175b(d)(2) (West Supp. 2003).



2332b(g)(5);

- being involved with an organization engaged in terrorism;
- being involved with an organization engaged in violence; and
- being an agent of a foreign power.

Restricted persons are prohibited from accessing select agents under the jurisdiction of the CDC.<sup>112</sup> For non-overlap plant and animal agents, the prohibition is discretionary with APHIS.<sup>113</sup> This distinction derives from the fact that the Biological Weapons Anti-Terrorism Act, as amended, criminalizes possession by restricted persons of “select agents,”<sup>114</sup> but does not address the other categories of biohazardous materials regulated by the BPARA.

For individuals who are not restricted persons, but meet the other exclusion criteria above, as determined by the Department of Justice, HHS and the Department of Agriculture have authority to authorize access in the interests of public health and safety or national security.<sup>115</sup>

Note that the means used to identify restricted persons—screening names and identifying information through existing databases—seem ill-suited to one of its definitional elements: unlawful use of a controlled substance. Nor are those means likely to identify fugitives from justice, except perhaps for those fugitives who continue to use their given names. Nevertheless, facilities are under no affirmative obligation to undertake affirmative measures to screen researchers who pass the FBI security assessments. Presumably, however, an institution that does independently learn that a select agent researcher is a restricted person has an obligation to exclude that person from access.

#### D. What Are the Safety, Security and Emergency Response Plans Required?

The regulations impose requirements on facilities to promote safety and security, both under normal operating procedures and in the event of an emergency. It is important to understand the distinction between safety and security. Safety requirements had been in place for years prior to the passage of the BPARA. They seek to protect the people working in and around a facility where biohazardous materials are used. Security requirements, on the other hand, seek to make it more difficult for unauthorized people to get access to biohazardous materials for terrorist or other dangerous purposes. There were few security requirements prior to the BPARA.

The Act and its regulations require select agent facilities to adopt three plans: a safety plan, an emergency response plan, and a security plan. Most such facilities already had at least safety and emergency plans in place based upon prior legal requirements.

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112. 42 C.F.R. § 73.8(e).

113. 9 C.F.R. § 121.8(a); 7 C.F.R. § 331.7(a).

114. 18 U.S.C.A. § 175b(a)(1).

115. 42 C.F.R. § 73.8(e); 9 C.F.R. § 121.8(a); 7 C.F.R. § 331.7(a).

### 1. Safety

The Act and its regulations do not impose new safety requirements on facilities so much as they incorporate into its enforcement scheme other safety guidelines. The regulations provide that facilities “should consider” the following guidelines in developing safety plans:<sup>116</sup>

- The *Biosafety in Microbiological and Biomedical Laboratories* (“BMBL”),<sup>117</sup> a CDC and NIH publication contractually incorporated into many federal grants, but not otherwise binding;
- If applicable, the Occupational Safety & Health Administration (“OSHA”) requirements for handling toxins found in 29 C.F.R. §§ 1910.1450 and 1910.1200; and
- If applicable, requirements for handling recombinant genetic elements contained in the NIH Recombinant DNA Guidelines,<sup>118</sup> which is also incorporated into federal grants.

### 2. Emergency response

As with the safety requirements, the regulations incorporate existing emergency response guidelines<sup>119</sup>—the OSHA emergency response standards for hazardous waste operations.<sup>120</sup> The BPARA regulation has been criticized for its choice of OSHA regulation. The OSHA regulation addresses large scale hazardous materials spills. It would seem more appropriate to have incorporated the OSHA regulations governing laboratory-scale spills and releases.<sup>121</sup>

BMBL also provides guidance on emergency response, and recommends conducting a site-specific risk assessment and threat analysis.<sup>122</sup>

Additionally, the emergency response plans must meet a matrix of requirements set forth in the BPARA regulations. The regulations specify a suggested range of emergency events to cover: bomb threats, hurricanes, floods, earthquakes, power outages, etc.<sup>123</sup> The CDC regulation then articulates a range of issues that must be addressed, including, but not limited to:

- risks of spreading biohazardous materials during emergency response;

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116. 42 C.F.R. § 73.10; 9 C.F.R. § 121.12; 7 C.F.R. § 331.11.

117. CDC, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (4th ed. 1999), available at <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> (last visited Mar. 8, 2004) [hereinafter BIOSAFETY IN LABORATORIES].

118. NIH, GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Apr. 2002), available at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> [hereinafter NIH GUIDELINES].

119. 42 C.F.R. § 73.12; 7 C.F.R. § 121.12(a)(3); 9 C.F.R. § 331.11(a)(3).

120. 29 C.F.R. § 1910.120 (2003).

121. Howard Hughes Medical Institute, Office of Laboratory Safety, Comments on 42 C.F.R. pt. 73, Interim Final Rule; Possession, Use, and Transfer of Select Agents and Toxins (Jan. 21, 2003), available at [http://www.hhmi.org/research/labsafe/rule/recommendations\\_cfr.html](http://www.hhmi.org/research/labsafe/rule/recommendations_cfr.html). The regulations are addressed in 29 C.F.R. § 1910.38 and 29 C.F.R. § 1910.1450.

122. BIOSAFETY IN LABORATORIES, *supra* note 117, app. F.

123. 42 C.F.R. § 73.12(b); 9 C.F.R. § 121.12(a)(3); 7 C.F.R. § 331.11(a)(3).

- coordination with outside emergency responders;
- evacuation;
- decontamination; and
- site security during an emergency.<sup>124</sup>

The CDC regulation requires notification of HHS and local public health agencies of any “release outside of the primary containment barriers.”<sup>125</sup> This is peculiar language, and goes beyond the mandate of the BPARA itself, which requires notification only if the release has occurred “outside of the biocontainment area.”<sup>126</sup> A biocontainment area will generally contain both primary and secondary (or even tertiary) barriers, so that the regulations require notification even when secondary barriers have prevented release outside of the biocontainment area. The APHIS regulations track the statutory language,<sup>127</sup> and avoid the problem.<sup>128</sup>

### 3. Security

Perhaps the most significant of the new requirements imposed by the Act and its regulations pertain to the required security plan.<sup>129</sup> The CDC regulation sets forth a laundry list of new security requirements, most of which are also reflected in the APHIS regulations. Many of the requirements demand significant restructuring of previous methods of operating.

The following pages discuss the requirements imposed by the CDC and those contained in both the CDC and the APHIS regulations. The APHIS regulations require, in addition, specific biocontainment and incident response procedures.<sup>130</sup> They also make explicit that the security systems and procedures must be based upon a site-specific risk assessment.<sup>131</sup> The APHIS regulations also add the friendly offer of a telephonic help line.<sup>132</sup> The BMBL also includes detailed security recommendations, some of which are set forth below.<sup>133</sup>

124. 42 C.F.R. § 73.12(c). The APHIS regulations are not prescriptive in this regard.

125. 42 C.F.R. § 73.17(d).

126. BPARA § 201(a), 116 Stat. 594, 638 (codified at 42 U.S.C.A. § 262a(j) (2003)); § 212(j), 116 Stat. at 656 (codified at 7 U.S.C.A. § 8401(j) (West Supp. 2003)).

127. 9 C.F.R. § 121.17(b); 7 C.F.R. § 331.16(b). The APHIS regulations also remove the requirement of notifying local public health agencies, providing instead that APHIS itself will make any necessary notifications “upon . . . a finding that the release poses a threat . . .” 9 C.F.R. § 121.17(b); 7 C.F.R. § 331.16(b).

128. As a practice pointer, identify key regional safety officials (police and fire captains and emergency medical coordinators, for example), and make sure that they are fully trained to enter select agent areas. Reach prior arrangements such that in the event of an emergency, those specific individuals will personally coordinate any necessary emergency responses for their departments. Consider getting FBI risk assessments for those individuals.

129. 42 C.F.R. § 73.11; 7 C.F.R. § 331.11; 9 C.F.R. § 121.12.

130. 9 C.F.R. § 121.12(a); 7 C.F.R. § 331.11(a).

131. 9 C.F.R. § 121.12(a)(2); 7 C.F.R. § 331.11(a)(2).

132. 9 C.F.R. § 121.12(a) n.11; 7 C.F.R. § 331.11(a) n.8.

133. BIOSAFETY IN LABORATORIES, *supra* note 117.

*a. Access only as needed*

Facilities must predetermine not only which individuals will have access to select agents, but also the reasons for each individual's access. The only individuals allowed access are those performing "specifically authorized functions" as part of a "defined job."<sup>134</sup> Additionally, for each such employee or category of employee, the facility must specify education, experience, and training requirements.<sup>135</sup>

*b. Defined select agent areas*

Select agents may be stored and used only in predefined areas, as set forth on building floor plans.<sup>136</sup> Access to these areas must be controlled.<sup>137</sup> Facilities may not transfer select agents between their own storage areas without a defined protocol that ensures monitoring by an approved person.<sup>138</sup>

*c. Unapproved persons must be supervised*

The regulations provide that an individual may not have "access" to a select agent without "approval,"<sup>139</sup> and that when an "approved person" is not present, the select agent "area" must be secured.<sup>140</sup> Within the select agent areas, only approved individuals may have unescorted access.<sup>141</sup> Unapproved individuals may conduct routine non-laboratory functions such as cleaning and maintenance only when escorted and continually monitored by approved persons.<sup>142</sup> The references to "approved individuals" refer to those persons who received clearances from DHHS or USDA based upon the Department of Justice ("DOJ") background check reports.

The facility must have clear written procedures to ensure that unapproved persons will not have unsupervised access. The procedures should specify, for example, that an unapproved employee remain under constant visual surveillance. CDC operatives have stressed to the author that if an unapproved employee has access to the select agent area, under the supervision of an approved employee, the facility's security plan must articulate the details of that supervision including, for example, how the unapproved employee will be monitored when the cleared employee uses the rest room.

Several features of these provisions have caused consternation. The first is that there are limitations on the provisions that allow some flexibility in deciding which

134. 42 C.F.R. § 73.11(d)(1); 9 C.F.R. § 121.12(a)(2)(iv)(A); 7 C.F.R. § 331.11(a)(2)(iv)(A).

135. 42 C.F.R. § 73.11(b)(1). *Cf.* 9 C.F.R. § 121.12(a)(2)(iii); 7 C.F.R. § 331.11(a)(2)(iii) ("The plan must describe . . . personnel suitability for those individuals with access . . .").

136. 42 C.F.R. §§ 73.7(b)(2)(iii), 73.11(e). The APHIS regulations do not contain a comparable provision.

137. 42 C.F.R. § 73.11(b)(2), (b)(8), (d)(6); 9 C.F.R. § 121.12(a)(2)(iii), (iv)(G)(1); 7 C.F.R. § 331.11(a)(2)(iii), (iv)(G)(1).

138. 42 C.F.R. § 73.11(d)(5); 9 C.F.R. § 121.12(a)(2)(iv)(E); 7 C.F.R. § 331.11(a)(2)(iv)(E).

139. 42 C.F.R. §§ 73.8(b), 73.9(c)(2); 9 C.F.R. § 121.11(a), (b); 7 C.F.R. §§ 331.10(a), (b).

140. 42 C.F.R. § 73.11(b)(8); 9 C.F.R. § 121.12(a)(2)(iv)(C); 7 C.F.R. § 331.11(a)(2)(iv)(C).

141. 42 C.F.R. § 73.11(d)(1); 9 C.F.R. § 121.12(a)(2)(iv)(A); 7 C.F.R. § 331.11(a)(2)(iv)(A).

142. 42 C.F.R. § 73.11(d)(2); 9 C.F.R. § 121.12(a)(2)(iv)(B); 7 C.F.R. § 331.11(a)(2)(iv)(B).

employees will get background checks. As noted, the facility may allow unapproved individuals to have work-related access to select agent areas, provided the individuals stay under constant supervision. But the regulations refer in this regard only to individuals who “conduct routine cleaning, maintenance, repairs, and other non-laboratory functions.”<sup>143</sup> This implies that employees who perform laboratory functions, in contrast, must be subject to background checks and approvals; monitoring appears not to be an alternative for such laboratory employees. The CDC’s contractor for advising facilities,<sup>144</sup> however, has told the author that such laboratory research employees can also go “unapproved” if an institution’s policies are very clear regarding their access (or lack thereof).<sup>145</sup> When the author’s institution received its CDC audit, in contrast, the auditors stated that all individuals who work regularly in the select agent area must receive DOJ clearance, regardless of whether they actually work with select agents.<sup>146</sup> Neither position has been documented in written CDC guidance.

Second, it is unclear what is meant by the requirement that unapproved persons may not have “unescorted access” to “areas” containing select agents. Some university research facilities are used by a wide variety of researchers, conducting a range of research. If one researcher stores a select agent securely in a laboratory, even if the select agent is used rarely, the entire facility would arguably be an “area containing select agents,” triggering background check requirements for the other researchers in the facility (or at least requiring their monitoring and supervision). Facilities are required to separate areas containing select agents from public areas,<sup>147</sup> but the requirement to limit access by unapproved persons might effectively require separating such areas from even other nonpublic research areas.

On the other hand, the CDC provides a more liberal interpretation. The CDC FAQ notes that “access” means “the freedom or ability to obtain or make use of,” and limits the approval requirement to people “who have the freedom or ability to obtain or make use of a select agent.”<sup>148</sup> The FAQ goes on to state that access can be limited by security containers or escorts. This clarification suggests that if the select agent is adequately secured, and is utilized in the research facility only under the direct supervision and constant visual surveillance of an approved person, then others present in the facility do not have “unescorted access,” and are therefore not required to be subject to background checks, approvals, and/or monitoring.

#### *d. Documentation*

The regulation of access includes documentation of each act of ingress or egress

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143. 42 C.F.R. § 73.11(d)(2); 9 C.F.R. § 121.12(a)(2)(iv)(B); 7 C.F.R. § 331.11(a)(2)(iv)(B).

144. The CDC has published a “help line” e-mail staffed by its contractor, Analytical Sciences, to answer questions about the regulations, at [lrsat@cdc.gov](mailto:lrsat@cdc.gov).

145. Telephone interview with Lori Bane, Biocontainment Laboratory Certification Specialist, Analytical Sciences (Feb. 24, 2003).

146. CDC inspection exit interview with Dr. Paul Mehta and Mr. Brian Satterfield, Laboratory Certified Specialists, Select Agent Program, Analytical Sciences (Mar. 13, 2003).

147. 42 C.F.R. § 73.11(e). The APHIS regulations do not contain a comparable provision.

148. CDC FAQ, *supra* note 62, General Questions Regarding the New Select Agent Regulation (42 C.F.R. § 73), Question No. 21.

to or from the designated select agent area, as well as documentation of each access of select agents from long-term storage.<sup>149</sup> For unapproved individuals, the ingress and egress documentation must include the identity of the accompanying approved person.<sup>150</sup>

*e. Packages*

All packages entering or leaving the designated select agent area must be inspected.<sup>151</sup> While the regulations do not define “packages,” the CDC explains that “package” means “a wrapped or boxed object, parcel, or container in which something is packed.”<sup>152</sup> This appears to exclude employees’ personal items, such as backpacks, purses, and briefcases. Despite the regulations’ unambiguous applicability to “all packages,” the FAQ goes on effectively to limit the regulation to “unexpected or suspicious packages,” although it notes that this is “a minimum standard.”<sup>153</sup> The FAQ gives as examples of unexpected or suspicious packages those with unusual weight or size, and makes references to the U.S. Postal Service guidelines for recognizing suspicious parcels. Those guidelines include: unusual amount of tape, strange odors or stains, an unexpected or unfamiliar source, peculiar markings, etc.<sup>154</sup> Presumably, the concern underlying the regulations as to incoming packages is safety (i.e., to guard against bombs, incendiary devices, and the like) and, as to outgoing packages, security (i.e., to guard against theft).

*f. Select agent containers*

The regulations contain several provisions requiring secure storage of select agents, both long term and short term. The security plan must specifically address such access control.<sup>155</sup> The control plan must include careful documentation of every instance of access to select agents, including dates and times, individuals involved, and, for toxins, amounts removed and returned (for biologically active agents, amounts are not recorded, because the supplies will increase or decrease spontaneously due to biological activity).<sup>156</sup>

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149. 42 C.F.R. § 73.15(c). *See also* 9 C.F.R. § 121.15(a)(6) (2004); 7 C.F.R. § 331.14(a)(b) (2004).

150. 42 C.F.R. § 73.15(c)(2)(iv). The APHIS regulations do not contain a comparable provision.

151. 42 C.F.R. § 73.11(d)(4); 9 C.F.R. § 121.12(a)(2)(iv)(D); 7 C.F.R. § 331.11(a)(2)(iv)(D).

152. CDC FAQ, *supra* note 62, General Questions Regarding the New Select Agent Regulation (42 C.F.R. § 73), Question No. 37.

153. *Id.*

154. U.S. Postal Service, USPS Message to Customers: We Are Taking Every Possible Measure To Assure The Safety Of Customers And The Mail (Oct. 17, 2001), at [http://www.usps.com/news/2001/press/pr01\\_1010tips.htm](http://www.usps.com/news/2001/press/pr01_1010tips.htm).

155. 42 C.F.R. §§ 73.11(b)(5), (d)(3); 9 C.F.R. §§ 121.12(a)(2)(iii), (iv)(C); 7 C.F.R. §§ 331.11(a)(2)(iii), (iv)(c).

156. 42 C.F.R. § 73.15(c)(1). The APHIS regulations do not contain a comparable provision.

*g. Physical security*

The plan must provide for lockup of select agents when no approved person is present. Containers must be locked when not in direct view of an approved person.<sup>157</sup> The plan must provide for changing locks or access codes when there are staff changes.<sup>158</sup> The plan must address events such as loss of keys and accidental release of access codes.<sup>159</sup>

*h. Other security plan elements*

The regulations also require the following elements for security plans:

- provisions for reporting suspicious persons, and for removing unauthorized persons;<sup>160</sup>
- provisions for reporting suspicious events, loss, theft, or release of select agents;<sup>161</sup>
- cybersecurity;<sup>162</sup> and
- provisions for providing cleaning, maintenance, and repairs without jeopardizing security.<sup>163</sup>

BMBL Appendix F also recommends:

- conducting periodic performance tests to check keys, locks, and alarms;
- ensuring that administrators be familiar with all employees;
- requiring that all employees and guests wear visible photo ID badges showing access rights;
- changing access codes regularly;
- limiting routine maintenance to hours when authorized employees are present;
- establishing central receiving areas for incoming select agents; and
- opening packages in an appropriate biocontainment device.<sup>164</sup>

E. What Training Is Required?

The regulations require training on safety and security for all persons entering select agent areas.<sup>165</sup> These new requirements are significant, but uncontroversial. Perhaps most significantly, they apply not only to employees, but also to guests and visitors. This application to guests and visitors creates a compliance challenge,

157. 42 C.F.R. § 73.11(d)(3); 9 C.F.R. § 121.12(a)(2)(iv)(C); 7 C.F.R. § 331.11(a)(2)(iv)(C).

158. 42 C.F.R. § 73.11(b)(8); 9 C.F.R. § 121.12(a)(2)(iii); 7 C.F.R. § 331.11(a)(2)(iii).

159. 42 C.F.R. § 73.11(d)(7)(i); 9 C.F.R. § 121.12(a)(2)(iv)(G)(1); 7 C.F.R. § 331.11(a)(2)(iv)(G)(1).

160. 42 C.F.R. § 73.11(b)(4); 9 C.F.R. § 121.12(a)(2)(iii); 7 C.F.R. § 331.11(a)(2)(iii).

161. 42 C.F.R. § 73.17; 9 C.F.R. § 121.17; 7 C.F.R. § 331.16.

162. 42 C.F.R. § 73.11(b)(1); 9 C.F.R. § 121.12(a)(2)(iii); 7 C.F.R. § 331.11(a)(2)(iii).

163. 42 C.F.R. § 73.11(b)(2); 9 C.F.R. § 121.12(a)(2)(iii); 7 C.F.R. § 331.11(a)(2)(iii).

164. BIOSAFETY IN LABORATORIES, *supra* note 117, app. F.

165. 42 C.F.R. § 73.13; 9 C.F.R. § 121.13; 7 C.F.R. § 331.12.

as even brief visits trigger the training requirement.

For employees, the training must cover safety, containment, and security.<sup>166</sup> The training applies both to employees authorized for unmonitored access, and to unapproved employees who require monitoring.<sup>167</sup> The training must be job-appropriate; changes in job duties require reassessment of the training provided to date, and, if appropriate, supplemental training.<sup>168</sup> All employees must receive annual refresher training.<sup>169</sup> For guests and visitors, the training must ensure that the person understands the hazards presented by the select agents.<sup>170</sup> For both employees and visitors, the training must include a post-test procedure to ensure that the person understood the training received.<sup>171</sup> Both the training and the post-test must be documented.<sup>172</sup>

#### F. What Approvals and Documentation are Required for Transfers to and from Other Institutions?

The regulations update the previous rules for inter-institutional transfer of select agents. The new procedures are as follows:

- The recipient must obtain CDC and/or APHIS approval in advance, using CDC form EA-101 (APHIS form 2041).<sup>173</sup> The approval is to be based upon a straightforward and ministerial review, solely for the purpose of ensuring that the recipient's certificate covers the incoming select agents.<sup>174</sup>
- The recipient must notify CDC/APHIS:
  - within two days of receipt of the select agent, via a hard copy of EA-101/2041;
  - if the select agent is not received on time; and
  - if the package has been damaged.<sup>175</sup>

#### G. What Inspections Are Mandated or Authorized by the Act?

The Responsible Official must conduct annual inspections of the facility for

166. 42 C.F.R. § 73.13(c); 9 C.F.R. § 121.13(a); 7 C.F.R. § 331.12(a).

167. 42 C.F.R. § 73.13(a). *See* 9 C.F.R. § 121.13; 7 C.F.R. § 331.12.

168. *See* 42 C.F.R. § 73.13(b); 9 C.F.R. § 121.13; 7 C.F.R. § 331.12.

169. 42 C.F.R. § 73.13(b); 9 C.F.R. § 121.13(b); 7 C.F.R. § 331.12(b).

170. 42 C.F.R. § 73.13(a). The APHIS regulations do not contain a comparable provision.

171. 42 C.F.R. § 73.13(e). The APHIS regulations do not contain a comparable provision.

172. *See id.*; 42 C.F.R. § 73.15(g); 9 C.F.R. § 121.15(a)(3); 7 C.F.R. § 331.14(a)(3).

173. 42 C.F.R. § 73.14; 9 C.F.R. § 121.14; 7 C.F.R. § 331.13.

174. CDC/APHIS Briefing Meeting, Washington, D.C. (Dec. 16, 2002).

175. 42 C.F.R. § 73.14; 9 C.F.R. § 121.14; 7 C.F.R. § 331.13.

As a practice pointer, remember that the Bioterrorism Preparedness and Response Act and its regulations are not the only, or even the primary, sources of law regarding the transfer of select agents. Other laws and regulations govern the transportation and packaging of biohazardous materials, including 42 C.F.R. § 72, 49 C.F.R. §§ 100–180, 9 C.F.R. § 121, 7 C.F.R. § 331 and international regulations (i.e., those promulgated by the International Air Transportation Association ("IATA")). *See* Appendix A, *supra* note 8.



compliance with the safety plan.<sup>176</sup> The inspections must be documented and deficiencies must be corrected.<sup>177</sup> Additionally, HHS and APHIS may conduct inspections without notification.<sup>178</sup> Facilities must make records available and provide access to the entire premises.<sup>179</sup>

#### H. What Records Must Be Kept?

While this is discussed in context throughout this article, the major new record-keeping requirements are also summarized here:

- individuals authorized to have access to select agent areas;
- individuals who have actually accessed select agents;
- inventory data;
- documentation of all intra-institutional transfers and removals from long term storage;
- documentation of all inter-institutional transfers;
- recordation of entry to and exit from select agent areas for all individuals, including guests;
- for guests in the select agent area, the name of the accompanying monitors; and
- training records for all employees and visitors, including records of the means used to ensure understanding.<sup>180</sup>

#### I. What Experiments Are Specifically Restricted?

Certain categories of experiment with recombinant DNA are specially restricted under the Bioterrorism Preparedness and Response Act, requiring approval of the Secretary of HHS or the Administrator of APHIS. These restrictions apply to human and animal agents, but not to plant agents.

##### 1. Experiments to deliberately transfer drug resistant traits to certain biological agents

The APHIS regulations make this restriction more comprehensive for animal agents than the corresponding CDC regulation for human and overlap agents. While the CDC regulation restricts only recombinant DNA (“rDNA”) experiments involving transferring drug resistance to select agents,<sup>181</sup> the APHIS regulation also restricts transfer of any pathogenic trait to any biological agent.<sup>182</sup> It thus appears that experiments to deliberately transfer pathogenic traits other than drug resistance to overlap agents would be exempt from the requirement of approval by the Secre-

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176. 42 C.F.R. § 73.10(b). The APHIS regulations do not contain a comparable provision.

177. *Id.*

178. 42 C.F.R. § 73.16; 9 C.F.R. § 121.16; 7 C.F.R. § 331.15.

179. 42 C.F.R. § 73.16; 9 C.F.R. § 121.16; 7 C.F.R. § 331.15.

180. 42 C.F.R. § 73.15. The APHIS regulations are somewhat less detailed. *See* 9 C.F.R. § 121.15; 7 C.F.R. § 331.14.

181. 42 C.F.R. § 73.10(c)(1).

182. 9 C.F.R. § 121.10(c)(1).

tary of HHS, but would fall under the requirement of approval by the APHIS Administrator.

2. Experiments to form recombinant DNA to synthesize certain toxins<sup>183</sup>

This restriction is also more comprehensive for animal agents in that it covers toxins that are not select agents.<sup>184</sup> The breadth of the APHIS regulations is puzzling, in that it creates a tension with the NIH Guidelines for Research Involving Recombinant DNA Molecules.<sup>185</sup> The Guidelines, which cover most of the same experiments, mandate prior NIH approval.<sup>186</sup> The APHIS regulations now appear to require APHIS approval for the same experiments. Because there does not appear to be statutory authority in the BPARA for APHIS regulations to reach beyond select agent research, the APHIS regulations may be vulnerable to challenge to the extent they restrict non-select agent research.

#### VI. CONSEQUENCES OF NONCOMPLIANCE

The BPARA provides for criminal sentences of up to five years, and civil penalties with fines up to \$250,000 for individuals and \$500,000 for entities.<sup>187</sup>

#### VII. CDC/APHIS INSPECTIONS

As noted above, CDC and APHIS have authority to conduct inspections of select agent facilities.<sup>188</sup> The author's institution was the beneficiary of a CDC inspection in March 2003, the day after the BPARA registrations were due. Prior to the inspection, he and colleagues at his institution polled other institutions that had experienced audits under prior regulatory regimes, and developed guidance. Other measures were developed internally. Additionally, some of his institution's employees had experienced similar inspections at former jobs and applied those lessons.

The results were quite favorable. The inspectors announced at the exit interview that the institution's compliance more than met the regulatory requirements, stated that the facility was the best one they had seen during the inspections, and used words such as "excellent" and "impeccable."

The following "do's and don'ts" derive from the above experience:

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183. The CDC and APHIS regulations differ slightly on these prohibitions. *Cf.* 42 C.F.R. § 73.10(c) (CDC) *with* 9 C.F.R. § 121.10(c) (APHIS).

184. *Cf.* 42 C.F.R. § 73.10(c)(2) *with* 9 C.F.R. § 121.10(c)(2).

185. NIH GUIDELINES, *supra* note 118.

186. *Id.* §§ III-A-1-a, III-B-1.

187. BPARA § 231, 116 Stat. 594, 660–62 (codified at scattered sections of 18 U.S.C.A. (2000 & West Supp. 2003)).

188. *Id.* § 201(a), 116 Stat. at 638 (codified at 42 U.S.C.A. § 262a(f) (2003)); § 212(f), 116 Stat. at 652 (codified at 7 U.S.C.A. § 8401(f) (West Supp. 2003)).

## A. “Do’s”

1. Conduct mock inspections at least one week prior to the actual inspection. The mock inspections should include both a lab walk-through and a paper inspection. Assign knowledgeable institutional officials to play the role of the inspectors. The officials need to be tough, and to stay in role! At the end, the mock inspectors should critique the results and work with the compliance team to identify areas for correction and improvement.

2. Make sure that each inspector has a staff person accompanying him/her at all times; don’t allow the inspectors to roam alone, if possible. You want to make sure that any concerns they have can be addressed immediately.

3. Include high level institutional officials at the entrance meeting, and make sure they are articulate about the need for compliance and their support for it institutionally. Inclusion of these officials at the entrance meeting will signal your institution’s support for compliance. If your officials are unwilling, this may be a sign that you in fact need to reprioritize compliance.

4. Bring out mid-level institutional officials for the exit interview to ensure appropriate attention to follow-up compliance.

5. Plan presentations at all levels—your large-scale antibioterrorism research goals; your organizational structure; your security, safety, and emergency infrastructure; etc. Cover every area you think the inspectors will care about. Don’t plan on dominating the process, but if you can give the inspectors the information they need through an organized presentation, you will be able to convey more information.

6. Copy and organize all relevant paperwork so that anything sought by the inspectors can be produced immediately.<sup>189</sup> Make sure you have full documentation from the past several years on all select agent transactions.

7. Have all knowledgeable staff on standby and available to answer all anticipated question areas. Be ready to cover everything from air-flow engineering to medical surveillance.

8. Clean and tidy up the facilities before the inspection.

9. Conduct a signage audit. Make sure you have signs and posters covering safety procedures, containment procedures, warnings, appropriate lab attire, decontamination instructions, etc.

## B. “Don’ts”

1. Don’t have attorneys present during the entire inspection. That signals both an adversarial context, as well as perhaps the notion that the facility must not be in compliance, or otherwise lawyers would not be necessary. On the other hand, lawyers should be present during the exit interview in order to help ensure that any guidance received at that time is translated into improvements (and to signal to the inspectors that the institution’s goal is in fact to maximize compliance). Also, if the exit interview is negative, lawyers can listen and perhaps ask probing questions

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189. This author’s institution organized documents by section numbers of the CFR regulations.

so as to begin to gather ammunition for any necessary defense.

2. Don't be defensive when the inspectors point out compliance weaknesses. Be appreciative of the guidance.

3. Don't underestimate the work involved in getting ready. Be blunt about the risks of noncompliance and the need for faculty and staff at all levels to reprioritize to get ready.

4. Don't ignore adjacent non-select agent areas. Assume that any part of the facility that will be seen by the inspectors is under inspection and must be up to code. Guard against food in laboratories, improper waste disposal, inadequate signage, etc., in the entire building.

5. Don't allow the inspectors to get special treatment in terms of access to facilities. Make sure you run them through all the requirements that any guest would have to undergo before gaining access—safety and security training with post-tests, medical interviews, respirator training, etc.

6. Don't leave compliance until the time inspectors come knocking on the door. A successful inspection requires a strong underlying compliance regime. The best inspection planning and management can't overcome serious long-term compliance gaps.