

Health and Safety Regulations and Guidelines

Public Health Security and Bioterrorism Preparedness and Response Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by CDC at [42 CFR 73](#), Select Agents and Toxins. Those regulations supersede the requirements at 42 CFR 76.2 (Interstate Shipment of Etiological Agents), which established certain shipping and handling requirements on laboratory facilities that send or receive select agents. Copies of these regulations are available from the Import Permit Program and Select Agent Program, respectively, CDC, 1600 Clifton Road, MS E-79, Atlanta, GA 30333; telephone: 404-498-2255. These regulations also are available at <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>.

Research involving select agents and recombinant DNA molecules also is subject to the *NIH Guidelines for Research Involving DNA Molecules* (NIH Guidelines) (see "[NIH Guidelines for Research Involving DNA Molecules and Human Gene Transfer Research](#)" in this subsection for applicability of these guidelines). The NIH Guidelines apply to (1) research projects involving recombinant DNA that are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research (for research performed abroad, the NIH Guidelines apply if the research is supported by NIH funds) and (2) research projects involving testing in humans of materials containing recombinant DNA developed with NIH funds, if the organization that developed the materials sponsors or participates in those projects. The NIH Guidelines are available at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.

USA PATRIOT Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see "[Public Health Security and Bioterrorism Preparedness and Response Act](#)" in this subsection).

Additional Health and Safety Regulations and Guidelines

Grantees are responsible for meeting Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910. These regulations are available at <http://www.osha.gov/comp-links.html>.
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at <http://bmbi.od.nih.gov/index.htm>.
- Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication can be obtained by telephoning 800-624-8373. It also is available at <http://www.nap.edu/catalog/4911.html>.

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.