

Charge of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

Notes:

1. *All Federal agencies and departments with a role in the conduct or oversight of research with hazardous biological materials should participate in efforts to improve biosafety and biocontainment oversight.*
2. *The report of the Task Force should serve as the impetus for developing mechanisms to provide a seamless net of biosafety and biocontainment oversight encompassing research in high and maximum containment laboratories in the public, academic, and private sectors, as well as in the Federal sector.*

New scientific tools and understanding have created unprecedented opportunities for progress in life sciences research, including discoveries of the molecular mechanisms by which certain microbes cause disease, and the means by which new infectious disease threats can emerge. These opportunities can enable many important advances in medicine, public health, and agriculture. Coincident with this era of opportunity have been elevated concerns about bioterrorism as well as criminal acts involving the use of biological agents, giving rise to an urgent need for the rapid development of diagnostics, vaccines, and other biodefense-related medical countermeasures. Research into these areas has become a national priority, with increased Federal support for programs to promote scientific investigation in academic and commercial settings, as well as in Federal research facilities.

The importance of effective biosafety and biocontainment practices and oversight of activities involving work with potential biological hazards (infectious disease-causing organisms and biological toxins) at individual research institutions and Federal agencies cannot be overemphasized. Although the Federal Government is committed to ensuring the highest quality design and construction of high and maximum containment facilities, the rigorous training of personnel who work in them, and the safe conduct of research undertaken in them, there are areas of concern. Press reports, articles in scientific publications,¹ Government Accountability Office reports,^{2,3} and a report by the Commission on the Prevention of WMD Proliferation and Terrorism,⁴ as well as

¹ Kaiser J. Biosafety breaches: Accidents spur a closer look at risks at biodefense labs. *Science*. 2007. 317 (5846):1852-1854.

² U.S. Government Accountability Office. *HIGH-CONTAINMENT BIOSAFETY LABORATORIES, Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*. 2007. GA0-08-108T.

³ U.S. Government Accountability Office. *Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories*. 2008. GAO-08-1092. HHS/CDC has provided corrections to the GAO preliminary report but a revised, corrected version has not been published as of June 2009.

⁴ *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*. Released December 2, 2008. See <http://www.preventwmd.gov/report/>.

congressional concerns have focused attention on the issues of biosafety and biosecurity⁵ at high and maximum containment laboratories.

On October 4, 2007, the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, held a hearing entitled “Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States.” At the hearing, subcommittee members voiced concerns about what they viewed as the risks associated with the proliferation of high and maximum containment laboratories (biosafety level 3 [BSL-3] and biosafety level 4 [BSL-4] and their agricultural equivalents) in the United States. At issue was the status of Federal oversight of BSL-3, BSL-4, and equivalent containment facilities, including the number and locations of all BSL-3 facilities.

At the October 2007 hearing, agency representatives from the U.S. Department of Health and Human Services (HHS) announced the establishment of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (Task Force). The Task Force was established to undertake an intensive analysis of the current framework of biosafety and biocontainment oversight of high and maximum containment research on hazardous biological agents and toxins, with the goal of exploring strategies to address concerns voiced by Congress and the general public.

The Task Force is chaired by officials from HHS and the U.S. Department of Agriculture (USDA), and is comprised of representatives from a broad range of Federal departments and agencies that have responsibility for, and oversight of the management of biohazard risks. Included in the Task Force are members from HHS, USDA, and the Departments of Commerce, Defense, Energy, Homeland Security, Labor, State, Transportation, and Veterans’ Affairs, as well as the Environmental Protection Agency and the National Science Foundation (see Appendix A).

Task Force Charge and Vision

The purpose of the Task Force is to propose options and recommendations to improve biosafety and biocontainment oversight of research activities at high and maximum containment research laboratories in the United States through a comprehensive review of mechanisms by which individual research (local) institutions and the Federal Government can ensure safe working conditions. The Task Force envisions effective, comprehensive, local (institutional) and Federal oversight that protects laboratory workers, public health, agriculture, and the environment, without hindering the progress of science. The Task Force was charged to present this report to the USDA and HHS Secretaries for their consideration.

⁵ In addition, Executive Order 13486, entitled *Strengthening Laboratory Biosecurity in the United States*, signed on January 9, 2009, by former President George W. Bush, ordered the establishment of the Working Group on Strengthening the Biosecurity of the United States. The new working group is charged with preparing a report on laboratory biosecurity and personnel reliability, topics that are related to biosafety. Executive Order 13486 is available at <http://fas.org/irp/offdocs/eo/eo-13486.htm>.

Scope of Activity

The scope of research activities considered by the Task Force includes those that occur in all high and maximum containment laboratory research facilities in all sectors (Federal, State, academic, private, and commercial laboratories) utilizing potentially hazardous biological agents (pathogens and toxins).

Beyond the scope of the Task Force report are activities involving select agents that take place in diagnostic and treatment (non-research) facilities such as hospitals, clinics, veterinary, and food diagnostic laboratories. These include some laboratories associated with the National Animal Health Laboratory Network (NAHLN) and the Food Emergency Response Network (FERN). Most licensed biomedical production facilities and mobile field analytical laboratories also lie outside the scope of this report because they are not research facilities. The activities of these facilities vary markedly from those engaged in high and maximum containment research.

Although this report offers a brief discussion of the relationship between laboratory biosecurity and biosafety, laboratory biosecurity *per se* is not the focus of this report. The term “laboratory biosecurity” denotes the protection of hazardous biological agents, including toxins, from loss, theft, diversion, or intentional misuse. Good biosafety and biocontainment practices contribute to effective laboratory biosecurity, and the disciplines of biosafety and laboratory biosecurity are complementary in many aspects. However, the Task Force did not want to deviate substantially from its focus on biosafety and biocontainment oversight.

Approach

In developing the report, the working group of the Task Force focused on:

- Conducting a comprehensive assessment of the current biosafety/biocontainment oversight framework for high and maximum containment laboratory research activities and facilities in all sectors. Oversight is achieved at many levels, the most critical of which are individual research institutions (“local oversight”) and Federal entities such as HHS/CDC and USDA/APHIS (“Federal oversight”). The Task Force review encompassed the identification and assessment of pertinent laws, regulations, policies, standards, and guidelines in addition to examining current biosafety/biocontainment oversight mechanisms in use by local institutions as well as municipal, State, and Federal oversight entities.
- Developing specific objectives for improving the current biosafety/biocontainment oversight framework. The objectives are based on identifying issues and needs related to the current biosafety/biocontainment

oversight framework for high and maximum containment laboratories in which research on hazardous biological agents is conducted.

- Developing options and recommendations for achieving the objectives. In efforts to explore strategies that best meet the biosafety and biocontainment needs of Federal and non-Federal research involving biological hazards, Task Force members endeavored to strike a balance among solutions to optimize biosafety and biocontainment oversight and the potential impact of increased oversight. **The focus was on devising a framework that improves biosafety and biocontainment oversight, incident-reporting, and training without causing unintended negative consequences for progress in research.**

The working group's process of deliberation and consultation also included soliciting the perspectives and input from key stakeholders. A public consultation meeting was held December 8–9, 2008. Based on input from those who attended the meeting or submitted comments to the website established for that purpose, the Task Force further developed and revised this report.

Engaging the public as a key stakeholder is vital given the critical importance of biosafety and biocontainment oversight for protecting laboratory workers, public health, agriculture, and the environment. Public engagement also is critical to address the concerns of communities in which high and maximum containment facilities are located or planned, because of public perception that these facilities could adversely affect public health or the environment. The Task Force recognizes that extensive consultation with the researchers, biosafety professionals, and science administrators responsible for high and maximum containment research facilities also is crucial for implementing measures to enhance the existing framework for biosafety and biocontainment oversight, and for ensuring the measures are appropriate, practical, and acceptable.

Continued strengthening of biosafety/biocontainment oversight of research at high and maximum containment facilities in all sectors will require informed action on the part of the Federal Government; State and municipal authorities; experts in biosafety and biocontainment; scientists; professional organizations; and the public. It is the expectation of the Task Force that its recommendations will lead to the development and implementation of an optimized framework for biosafety and biocontainment ove