Trans-Federal Task Force on
Optimizing Biosafety and Biocontainment Oversight

Charge

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 pubic and private sectors, as well as in the Federal sector.*

Purpose: To propose options to improve oversight of biosafety and biocontainment research at high and maximum containment 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 scope of activities considered by the Task Force includes those that occur in all high and maximum containment research laboratories in all sectors (Federal, state, private, and commercial laboratories) utilizing potentially biohazardous agents. The activities covered include research with hazardous pathogens that can infect humans, zoonotic agents, toxins, and agricultural pathogens. Outside the scope of the Task Force are considerations of diagnostic and treatment (non-research) facilities such as hospitals, clinics, veterinary, and food diagnostic labs, as well as (non-research) licensed biomedical production facilities. The Task Force envisions effective, comprehensive local and Federal oversight that protects laboratory personnel, public health, agriculture, and the environment, while simultaneously fostering progress in life sciences research.

Background: New scientific tools and understanding have created unprecedented opportunity to unveil the molecular origins of pathogenicity and the mechanisms by which new infectious disease threats can emerge. Coincident with this era of opportunity is the potential for terrorists to use the same biological agents as weapons, thus prompting the need for rapid development of vaccines and other biodefense mechanisms. Research into these areas has become a national priority, with burgeoning Federal grants programs to promote scientific investigation in Federal, academic, and commercial settings.

Currently in place are a broad range of regulations, policies, and guidelines governing different facets of laboratory biosafety and biocontainment. When research involves an infectious agent or toxin on the Select Agent list, the *Select Agent Regulations* developed by the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) apply. Also in place are rules enforced by the

Department of Labor (DOL), Department of Transportation (DOT), Department of Commerce (DOC), HHS, and the USDA that also govern the possession, use, transfer, export, or import of these agents, as well as general workplace safety. When research involves recombinant nucleic acids and is conducted or sponsored by institutions receiving NIH support, the *NIH Guidelines for Research Involving Recombinant DNA Molecules* apply.

These regulations and guidelines notwithstanding, Federal agencies recognize that laboratory biosafety and biocontainment can be improved. Toward that end, the Federal Government has established a Trans-Federal Task Force to undertake an intensive analysis of the current framework of biosafety and biocontainment oversight of research in high and maximum containment laboratories. The Task Force has conducted an in-depth analysis of the existing biosafety and biocontainment oversight framework, and is exploring strategies that would best meet the biosafety and/or biocontainment needs of these expanding research programs.

Membership: The Task Force shall be co-chaired by HHS and USDA and comprised of representatives of a broad range of Federal agencies that have responsibility for, and oversight of, requirements related to the management of biosafety and biocontainment risks. In addition to HHS and USDA, membership includes:

- Department of Commerce
- Department of Defense
- Department of Energy
- Department of Homeland Security
- Department of Labor
- Department of Transportation
- Department of Veterans' Affairs
- Environmental Protection Agency
- National Science Foundation

Given the importance of laboratory biosafety and biocontainment to many private sector research activities, as well as to the protection of laboratory workers, public health, agriculture, and the environment, input from private entities and the public at large will be key.

Task: The Task Force shall develop an options paper that shall address:

- The current framework for local and Federal biosafety and biocontainment oversight of research at high and maximum containment laboratories
- Potential gaps in biosafety and biocontainment oversight of high and maximum containment laboratories conducting research involving infectious agents and other hazardous biologics
- Recommendations for addressing these gaps

Process: The process will be one that actively engages affected communities and the general public. If the Task Force requires advice from specific experts and stakeholder groups, this will be done in keeping with the Federal Advisory Committee Act and may

involve leveraging existing relevant Federal advisory committees, such as the NIH Recombinant DNA Advisory Committee.

Time frame: The options paper will be presented to the HHS and USDA Secretaries upon completion.