

Dated: June 16, 2008.

John Howard,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Nuclear Materials and Equipment Corporation (NUMEC) facility, Parks Township, Pennsylvania, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 30, 2008, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employer (AWE) employees who worked at the Nuclear Materials and Equipment Corporation (NUMEC) facility in Parks Township, Pennsylvania, from June 1, 1960, through December 31, 1980, for a number of work days aggregating at least 250 work days occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on June 29, 2008, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science is seeking information and comments from affected entities and individuals about (a) Whether OHRP should issue additional guidance recommending that institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS) implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research, or (b) whether HHS should develop a regulation requiring the implementation of such training and education programs. This request for information and comment stems from the 1998 report from the HHS Office of Inspector General (OIG) recommending that Federal requirements be enacted to help ensure that investigators and institutional review board (IRB) members be adequately educated about, and sensitized to, human subjects protections. More recently, the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommended that OHRP require institutions to ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. The implementation of such training and education programs might help to ensure that individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federalwide Assurances (FWAs) understand and meet their regulatory responsibilities for protecting human subjects.

DATES: Submit written or electronic comments by September 29, 2008.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: humansubjectstraining@hhs.gov. Include "Human Subjects Protection Training and Education" in the subject line.

- Fax: 301-402-2071.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received within the public comment period, including any personal information, will be made available to the public upon request.

FOR FURTHER INFORMATION CONTACT:

Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail Michael.Carome@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the HHS regulations for the protection of human subjects, found at 45 CFR part 46, institutions or organizations that are engaged in human subjects research that is conducted or supported by HHS must file with OHRP an assurance of compliance with the human subjects protection regulations. The assurance must be executed by an individual authorized to act on behalf of the institution and authorized to assume, on behalf of the institution, the obligations imposed by the human subjects protection regulations [45 CFR 46.103(c)]. Thus, to fulfill his or her regulatory responsibilities, the institutional official must be knowledgeable about the requirements of the human subjects protection regulations.

The institution's assurance of compliance must also designate one or more IRBs to review research covered by the regulations, and the institution must ensure that each designated IRB has sufficient staff to support the IRB's activities [45 CFR 46.103(b)(2)]. IRB members must be sufficiently qualified through experience and expertise and diversity to promote respect for their advice and counsel in safeguarding the rights and welfare of human subjects. IRB members also must have the professional competence necessary to review human subjects research activities of the institution, including the ability to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice; therefore, members must be knowledgeable in those areas [45 CFR