Dated: June 16, 2008.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E8–14826 Filed 6–30–08; 8:45 am]

BILLING CODE 4160–17–P

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.*

Dated: June 16, 2008.

John Howard,

Director, National Institute for Occupational Safety and Health.

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BILLING CODE 4160–17–P

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

46.107]. Thus, to fulfill their regulatory responsibilities, IRB members must be informed about human subjects protection requirements.

Investigators involved in the conduct of human subjects research that is conducted or supported by HHS play a crucial role in protecting the rights and welfare of human subjects. Investigators have specific responsibilities under the human subjects protection requirements related to the conduct of IRB-approved research. For example, no investigator may involve a human being in research that is conducted or supported by HHS or covered by the institution's assurance unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative in accordance with, and to the extent required by, HHS regulations at 45 CFR 46.116. Moreover, investigators are responsible for providing required information to the IRB [45 CFR 46.103(b)(5), 46.111]. Investigators are responsible for obtaining prior approval from the IRB for any modifications of the previously approved research, except those necessary to eliminate apparent immediate hazards to subjects, and investigators are responsible for ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved FWA [45 CFR 46.103(b)(4), 45 CFR 46.109(e), 45 CFR 46.115(a)(1)]. Thus, investigators need to be informed about human subjects protection requirements. The HHS Office of Inspector General (OIG), in its 1998 Report, ''Institutional Review Boards: A Time for Reform,'' called for strong Federal action concerning education of investigators conducting, and IRB members reviewing, human subjects research (*http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf*). In that report, the OIG recommended enactment of Federal requirements that help ensure that investigators and IRB members are adequately educated about, and sensitized to, human subjects protections.

In October 2000, the National Institutes of Health (NIH) instituted a policy that requires education on the protection of human research participants for all key personnel as a condition of funding grant applications or contract proposals involving human subjects research (*http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-010061.html*). Key personnel include all individuals who are responsible for the design and conduct of research studies involving human subjects.

In its 2001 report, ''Ethical and Policy Issues in Research Involving Human Participants,'' the National Bioethics Advisory Committee (NBAC) recommended that all institutions and sponsors engaged in research involving human participants should provide educational programs in research ethics to appropriate institutional officials, investigators, IRB members, and IRB staff (*http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.pdf*). NBAC also recommended that the Federal Government, in partnership with academic and professional societies, should enhance research ethics education related to protecting human research subjects, as well as stimulate development of innovative educational programs.

In its 2002 report commissioned by HHS, ''Responsible Research: A Systems Approach to Protecting Research Participants,'' the Institute of Medicine (IOM) recommended that research organizations should ensure that investigators, IRB members, and other individuals substantively involved in research with humans are adequately educated to perform their respective duties (*http://www.nap.edu/books/0309084881/html/*).

On March 29, 2007, SACHRP recommended that OHRP require that institutions ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials, including the official that signed the institution's FWA.

Over the past several years, OHRP has identified serious, systemic noncompliance with the requirements of HHS regulations for the protection of human subjects at a significant number of major institutions engaged in human subjects research conducted or supported by HHS. In OHRP's experience, inadequate training and education of individuals involved in the conduct or review of human subjects research has been a major root cause of such noncompliance.

OHRP developed the FWA as a new type of assurance in December 2000. Initially, OHRP proposed that the FWA include requirements for training and education regarding human subjects protection regulations for institutional officials, IRB members, IRB staff, investigators and other institutional personnel. Following public comment on the proposed FWA, OHRP issued a revised version of the FWA on March 20, 2002 that strongly recommended, rather than required, such training and education. This decision was based, in part, on a determination that rulemaking would be a more appropriate mechanism for requiring such training and education.

In the current FWA terms of assurance, OHRP strongly recommends that the institutional official, human protections administrator, and IRB chairperson(s) designated under the assurance complete the OHRP Assurance Training Modules available on the OHRP Web site at *http://137.187.172.153/CBTs/Assurance/login.asp.* Furthermore, OHRP recommends that the institution and the designated IRB(s) establish educational training and oversight mechanisms appropriate to the nature of the institution's research portfolio to ensure that research investigators, IRB members, IRB staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. OHRP also recommends that IRB members and staff complete relevant educational training before reviewing human subjects research; and that research investigators complete appropriate institutional educational training before conducting human subjects research.

II. Request for Information and Comments

Based on the recommendations of the OIG, NBAC, IOM, and SACHRP, as well as OHRP's own experience in compliance activities, which has revealed that many individuals involved in the conduct or review of HHS-supported or conducted research at numerous institutions had a significant gap in knowledge about human subject protections, OHRP is seeking comment 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 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. 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 FWAs understand and meet their regulatory responsibilities for protecting human subjects.

OHRP specifically seeks comment on the following questions. Comments should also include a reference to the specific numbered question being addressed:

(1) For the past 5 years OHRP has strongly recommended through the Terms of the FWA that:

- Institutional signatory officials, human protections administrators, and the IRB chairpersons personally complete the relevant OHRP Assurance Training Modules (see *http://137.187.172.153/CBTs/Assurance/login.asp*), or comparable training that includes the content of these modules;
- Institutions and their designated IRBs establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: Relevant ethical principles; relevant federal regulations; written IRB procedures; OHRP guidance; other applicable guidance, state and local laws; and institutional policies for the protection of human subjects;
- IRB members and staff complete relevant educational training before reviewing human subjects research; and
- Research investigators complete appropriate institutional educational training before conducting human subjects research.

(1a) Have institutions holding OHRP-approved FWAs routinely implemented OHRP's recommendations?

(1b) What, if any, are the reasons for institutions not implementing OHRP's recommendations?

(1c) Has any failure of institutions to implement OHRP's recommendations been a significant contributing factor to noncompliance with the requirements of 45 CFR part 46 and inadequate protection of the rights and welfare of human subjects? If so, please provide examples.

(1d) If failure of institutions to implement OHRP's recommendations has been a significant contributing factor to noncompliance with the requirements of 45 CFR part 46 and inadequate protection of the rights and welfare of human subjects, would promulgation of a regulation requiring institutions to implement training and education programs for certain individuals involved in the conduct, review or oversight of human subjects research be the best mechanism to address this problem, or should different mechanisms be used (for example, would it be better if OHRP instead issued additional guidance regarding training and education programs)?

(1e) Even if there are no data suggesting that failure of institutions to implement OHRP's recommendations regarding education and training has been a contributing factor in non-compliance with the requirements of 45 CFR part 46, are there other sound reasons for developing further guidance or a regulation regarding education and training, and if so, what are they?

(2) If HHS decided to propose further guidance recommending, or a regulation requiring, that institutions implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research, which of the following categories of individuals should receive training and education and why: IRB chairpersons; other IRB members; IRB staff; principal investigators; others involved in the conduct of human subjects research (e.g., co-investigators, study coordinators); FWA signatory officials; human protection administrators; or any other category of individuals (please specify)?

(3a) Should further guidance or a regulation include provisions stipulating specific content for the training and education programs? If so, what should the specific content include and why (for example, should a regulation require inclusion of any or all of the following in the content of the training and education programs: The commitments and responsibilities of the institution under the FWA; relevant ethical principles cited in the institution's FWA; relevant Federal regulations for human subjects protection; OHRP guidance; other applicable guidance; relevant state and local laws; institutional policies for the protection of human subjects; or other content (please specify))?

(3b) Should the training and education recommendations or requirements differ depending upon the nature of the individual's involvement in research? If so, in what manner?

(3c) Notwithstanding whether training should be tailored according to an individual's role in the clinical research process, is there a minimum level of knowledge and skill that should be expected of anyone working in some aspect of the research enterprise?

(3d) How often should the content of the materials used for this training be updated?

(4) Should further guidance or a regulation include provisions stipulating that proficiency in human subjects protection requirements be demonstrated in some way (please specify)?

(5) Should further guidance or a regulation include recommendations or requirements for individuals to complete some minimum amount of training and education prior to any involvement in the conduct, review, or oversight of human subjects research?

(6) Should further guidance or a regulation include recommendations or requirements for periodic continuing training and education? If so, should the guidance or regulation stipulate a specific time interval for such periodic training and education (for example, should the regulation require individuals to complete continuing training and education activities every 1, 2, or 3 years)?

(7) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written procedures for ensuring implementation of the training and education requirements?

(8) Should further guidance or a regulation include recommendations or requirements for institutions to prepare and maintain written documentation that individuals covered by the regulation have completed the required training and education activities?

(9) If HHS decided to propose a regulation, what would the estimated costs of the regulation be to institutions in terms of infrastructure and man-hour costs? OHRP is interested in receiving specific information on such estimated costs from all types and sizes of institutions that hold OHRP-approved FWAs. OHRP recognizes that the HHS human subjects protection regulations extend to a wide-range of institutions, from very small organizations and businesses that employ no more than a total of 5–10 individuals, to major academic research and health centers that may have literally thousands of individuals affected by any new training and education regulation. When providing comments regarding cost estimates, please include a description of assumptions that were made for calculating cost estimated (for example, assumptions made regarding the number and types of individuals who would be required to undergo training and education, the modalities that would be used for delivering the training and education, the time it would take for covered individuals to complete initial and continuing training and education, and how often continuing training and education would need to occur).

Dated: June 19, 2008.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections.

[FR Doc. E8–14917 Filed 6–30–08; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension of Certification on Maintenance of Effort for the Title III and Certification of Long-Term Care Ombudsman Program Expenditures

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 31, 2008.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.6974 to the OMB Desk Officer for AoA, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Rodd Clay, e-mail: *rodd.clay@aoa.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, AoA has submitted the following proposed collection of information to OMB for review and clearance. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Certification on Maintenance of Effort for the Title III and Certification of Long-Term Care Ombudsman Program Expenditures provides statutorily required information regarding state's contribution to programs funded under the Older Americans Act and conformance with legislative requirements, pertinent Federal regulations and other applicable instructions and guidelines issued by Administration on Aging (AoA). This information will be used for Federal oversight of Title III Programs and Title VII Ombudsman Program.

AoA estimates the burden of this collection of information as follows: 56 State Agencies on Aging respond annually which should be an average burden of one half (½) hour per State agency per year or a total of twenty-eight hours for all state agencies annually. In the **Federal Register** of March 19, 2008 (Vol. 73, No. 54 Page 14821), the agency requested comments on the proposed collection of information. No comments on the content of the collection were received.

Dated: June 26, 2008.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. E8–14898 Filed 6–30–08; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register** , Vol. 73, No. 46, pp. 12451–12452, dated Friday, March 7, 2008) is amended to reflect a change in the name and updates to the functions for the Center for Beneficiary Choices.

Part F. is described below:

• Section F. 20. (Functions) reads as follows:

Center for Drug and Health Plan Choice (FAE)

• Responsible for all national policies and operations necessary for the purchasing of Medicare Prescription Drug (Part D) and Medicare Advantage (Part C) health plan benefits. Designs, implements, and manages the procurement of prescription drug plans (PDPs) and Medicare Advantage plans (MA and MA–PD plans), including the solicitation and approval of applications, review of benefits and negotiation of competitive bids, the implementation of quality improvement and performance measures, review of fiscal solvency and contractor management activities.

• Develops and improves all bidding and payment policies related to the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) program.

• Validates payments to the Part D prescription drug and MA plans, including routine annual risk adjustment data validation based on medical record review.

• Coordinates the development and management of business requirements for the national systems for enrollment, payment, and contractor management for the Prescription Drug Benefit and the Medicare Advantage (MA) programs.

• Develops and implements the national policy and oversees operational implementation for all issues related to the Retiree Drug Subsidy Program.

• Develops national policy for eligibility, enrollment and entitlement for Medicare Parts A, B, C, and D, including oversight of activities related to Part D auto-enrollment, low income subsidy, and creditable coverage.

• Develops national policy and oversees operational activities related to Medicare Part A, B, C, and D claims-related hearings, appeals, grievances and other beneficiary-centered dispute resolution processes.

• Serves as the focal point for issues related to a variety of Federal standards affecting private health insurance coverage, including those pertaining to its administration of the Medigap program, Title I of the Health Insurance Portability and Accountability Act and the Consolidated Omnibus Budget Reconciliation Act.

• Works closely with the regional Consortium for Medicare Health Plans Operations (CMHPO) on all operational aspects of the Part C and Part D programs.

• Develops and implements Part C and Part D contractor performance monitoring programs and Part C and Part D compliance and oversight programs and carries out these programs collaboratively with CMHPO.

• Develops surveys to measure consumer experiences with their health plans and health care providers; manages the Consumer Assessment of Health Care Provider and Systems (CAHPS) survey; develops and prepares performance measures for Part C sponsors; analyzes and reports Health Plan Employers Data and Information Set data for Part C performance measures and consumer reports; and