



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 27, 2012

The Honorable Joseph R. Biden, Jr.
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), to be added to the Special Exposure Cohort (SEC).

The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petition and presented its findings to the Advisory Board on Radiation and Worker Health (Board) on April 26, 2012. The Board considered the petition, and on June 1, 2012, I received the Board's recommendation concerning this petition. I have also received the deliberations, findings, and recommendations of the Director of NIOSH and the Director of CDC. Based on this information, I have designated the following class for addition to the SEC:

All employees of DOE, its predecessor agencies, and their contractors, or subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1968, through December 31, 1978, 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 included in the Special Exposure Cohort.

The criteria and findings upon which this designation is based are provided in the enclosed report.

Please contact me if you have any further questions regarding this matter.

Sincerely,

[Signature on File]

Kathleen Sebelius
Secretary

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 27, 2012

The Honorable Harry Reid
Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Reid:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), to be added to the Special Exposure Cohort (SEC).

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Kathleen Sebelius
Secretary

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 27, 2012

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, D.C. 20510

Dear Senator McConnell:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), to be added to the Special Exposure Cohort (SEC).

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Kathleen Sebelius
Secretary

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 27, 2012

The Honorable Nancy Pelosi
Minority Leader
House of Representatives
Washington, D.C. 20515

Dear Representative Pelosi:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), to be added to the Special Exposure Cohort (SEC).

The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petition and presented its findings to the Advisory Board on Radiation and Worker Health (Board) on April 26, 2012. The Board considered the petition, and on June 1, 2012, I received the Board's recommendation concerning this petition. I have also received the deliberations, findings, and recommendations of the Director of NIOSH and the Director of CDC. Based on this information, I have designated the following class for addition to the SEC:

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Kathleen Sebelius
Secretary

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

June 27, 2012

The Honorable John A. Boehner
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 and 42 C.F.R. pt. 83, a petition was filed on behalf of workers who were employed at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), to be added to the Special Exposure Cohort (SEC).

The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petition and presented its findings to the Advisory Board on Radiation and Worker Health (Board) on April 26, 2012. The Board considered the petition, and on June 1, 2012, I received the Board's recommendation concerning this petition. I have also received the deliberations, findings, and recommendations of the Director of NIOSH and the Director of CDC. Based on this information, I have designated the following class for addition to the SEC:

All employees of DOE, its predecessor agencies, and their contractors, or subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1968, through December 31, 1978, 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 included in the Special Exposure Cohort.

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Kathleen Sebelius
Secretary

Enclosure

HHS Designation of Additional Members of the
Special Exposure Cohort
under the
Energy Employees Occupational Illness Compensation Program Act of 2000

Designating a Class of Employees from

Feed Materials Production Center (FMPC)

Fernald, Ohio



I. Designation

I, Kathleen Sebelius, Secretary of Health and Human Services, designate the class of employees defined in Section II of this report for addition to the Special Exposure Cohort (SEC), as authorized under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. § 7384q.

June 27, 2012
Date

[Signature on File]
Kathleen Sebelius

II. Employee Class Definition

All employees of DOE, DOE contractors, or subcontractors who worked at all locations at the Feed Materials Production Center (FMPC) in Fernald, Ohio, also known as the Fernald Environmental Management Project (FEMP), from January 1, 1968, through December 31, 1978, 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 classes of employees included in the Special Exposure Cohort.

III. Designation Criteria and Recommendations

Pursuant to 42 U.S.C. § 7384q, for the class defined in Section II of this report, the Secretary has determined, and the Advisory Board on Radiation and Worker Health (Board) has recommended, that

- (1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and
- (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.

The SEC final rule states in 42 C.F.R. § 83.13(c)(1) that it is feasible in two situations to estimate the radiation dose that the class received with sufficient accuracy. First, the rule states that radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of the class. Alternatively, radiation doses may be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than a maximum dose estimate.

The Board, pursuant to 42 U.S.C. § 7384q, advised the Secretary to designate the class as an addition to the SEC in a letter received by the Secretary on June 1, 2012.

IV. Designation Findings

Feasibility of Estimating Radiation Doses with Sufficient Accuracy

The Secretary established the feasibility determination for the class of employees covered by this report based upon the findings summarized below.

- The principal source of internal radiation doses for members of the proposed class was airborne uranium particulate material. This dust could be inhaled by workers and then deposited in the respiratory tract. In addition to uranium, which is the primary radionuclide contributing to internal dose at the Feed Materials Production Center (FMPC, also known as Fernald) exposure to various other radionuclides could have occurred. The other radionuclides of concern include thorium and the associated decay products, uranium decay products (including radium and the associated decay products), fission/activation products, and transuranics (recycled uranium contaminants). This Designation addresses only internal exposures to Thorium-232 (hereinafter referred to as thorium) and its decay products for the time period from January 1, 1968, through December 31, 1978.
- The FMPC processed thorium intermittently through the period from January 1, 1951, through December 31, 1989, using several different chemical and physical processes. Additionally, FMPC utilized different monitoring programs for different time periods. Specifically, from 1968 to 1988, FMPC used the Mobile In Vivo Radiation Monitoring Laboratory (MIVRML) technique to monitor workers' exposure to thorium. In its evaluation report, NIOSH proposes to use data from the MIVRML to perform dose reconstructions. To do so, NIOSH performed considerable research to determine the algorithm that the MIVRML utilized to convert gamma ray measurements to thorium milligrams for the years 1968-1978.
- Ultimately, the NIOSH Director and the Board determined that MIVRML results expressed as thorium milligrams could not be interpreted with confidence and consequently the reconstructed doses based on such an approach may not be done with sufficient accuracy. Therefore, the Board and the NIOSH Director concluded that it was not feasible to reconstruct with sufficient accuracy doses from internal thorium exposures for the years 1968-1978.
- The principal sources of external radiation doses for members of the proposed class include uranium, thorium and their associated decay products, and transuranics (recycled uranium contaminants) that give rise to gamma, beta, and some neutron exposures.
- The FMPC had a routine monitoring program for measuring employees' external radiation exposures to gamma and beta radiation, and the results of that monitoring program are available to NIOSH. In addition, the FMPC made measurements of the relative dose rates due to neutron and gamma radiation near materials that gave rise to neutrons. Based on this, NIOSH concluded that doses due to external radiation exposure could be reconstructed with sufficient accuracy.

- NIOSH concluded that the dose associated with medical X-ray exams, if required as a condition of employment and administered onsite, can be bound by using information in the Technical Basis Document of the Fernald Environmental Management Project – Occupational Medical Dose. Therefore, it is feasible to reconstruct occupational medical dose for workers at the FMPC during the period from January 1, 1968, through December 31, 1978, with sufficient accuracy
- The Board concluded, and the NIOSH Director concurred, that NIOSH lacks sufficient information, which includes specific biological monitoring data, sufficient air monitoring information, sufficient process and radiological source information, and surrogate data from similar operations at other sites that would allow it to estimate the potential internal radiological exposures to thorium and its decay products for all workers who worked at the FMPC during the period from January 1, 1968, through December 31, 1978.
- Although NIOSH found that it is not possible to completely reconstruct radiation doses for the proposed class, NIOSH intends to use any internal and external monitoring data that may become available for an individual claim (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures) to support a partial dose reconstruction for non-presumptive cancers and/or cases that have less than 250 work days of employment. Therefore, dose reconstructions for individuals employed at the FMPC during the period from January 1, 1968, through December 31, 1978, but who do not qualify for inclusion in the SEC, may be performed using these data as appropriate.
- Pursuant to 42 C.F.R. § 83.13(c)(1), NIOSH determined that there is insufficient information to either: (1) estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred under plausible circumstances by any member of the class; or (2) estimate the radiation doses of members of the class more precisely than a maximum dose estimate.
- The NIOSH Director concurred with the Board and recommended the proposed class for addition to the SEC.

Health Endangerment

The Secretary established the health endangerment determination for the class of employees covered by this report based upon the findings summarized below.

- (1) Pursuant to 42 C.F.R. § 83.13(c)(3), NIOSH established that there is a reasonable likelihood that such radiation doses may have endangered the health of members of the class. Pursuant to 42 C.F.R. § 83.13(c)(3)(ii), NIOSH specified a minimum duration of employment to satisfy this health endangerment criterion as “having been employed for a number of work days aggregating at least 250 work days within the parameters established for this class or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more other classes of employees in the Cohort.”

- (2) NIOSH did not identify any evidence from the petitioners or from other resources that would establish that the class was exposed to radiation during a discrete incident likely to have involved exceptionally high-level exposures, such as a nuclear criticality incident, as defined under 42 C.F.R. § 83.13(c)(3)(i).
- (3) The Board concurred with NIOSH's finding that the health of the class may have been endangered and defined the class according to the 250-work day requirement specified under 42 C.F.R. § 83.13(c)(3)(ii).

V. Effect and Effective Date of Designation

The Secretary submits this report on the designation of one additional class to the SEC for review by Congress, pursuant to 42 U.S.C. §§ 7384/(14)(C)(ii) and 7384q(c)(2)(A), as amended by the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375 (codified as amended in scattered sections of 42 U.S.C.). Pursuant to 42 U.S.C. § 7384/(14)(C)(ii), as amended by the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375 (codified as amended in scattered sections of 42 U.S.C.), the designation in this report will become effective 30 days after the date of this report's submission to Congress "unless Congress otherwise provides."

VI. Administrative Review of Designation

The health endangerment determination of the designation provided in this report may be subject to an administrative review within HHS, pursuant to 42 C.F.R. § 83.18(a). On the basis of such a review, if the Secretary decides to expand the class of employees covered by this designation, the Secretary would transmit a supplementary report to Congress providing the expanded employee class definition and the criteria and findings on which the decision was based.