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

Feed Materials Production Center (FMPC) 1951-1983

Fernald, Ohio



I. Designation

I, Kathleen Sebelius, Secretary of the Department of Health and Human Services (HHS), 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.

[Signature on File]	September 30, 2013
Kathleen Sebelius	Date

II. Employee Class Definition

All employees of the Feed Materials Production Center (FMPC) in Fernald, Ohio, who were not employed by National Lead of Ohio, NLO, or the Department of Energy or its predecessor agencies, who worked at FMPC from January 1, 1951, through December 31, 1983, 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.

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.

NIOSH determined that there is insufficient information to estimate the radiation doses that the class received with sufficient accuracy under the two abovementioned situations. 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 September 3, 2013.

IV. Designation Findings

Infeasibility of Estimating Radiation Doses with Sufficient Accuracy

The Secretary designates 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.
- NIOSH has access to an electronic data set that contains the results of the uranium urinalysis bioassay program for all the years of FMPC operations, and the overwhelming majority of employees of the prime contractor (National Lead of Ohio, later named NLO Inc.) have results in the bioassay data set. However, the data set does not contain bioassay results for employees of companies other than the prime contractor (i.e., non-prime contractor employees).
- NIOSH has obtained a limited number of bioassay samples from non-prime contractor employees
 through data captures, but cannot be certain that all non-prime contractor employees' bioassay
 data were retained by the site or captured by data capture efforts. Additionally, there are some
 reasons to conclude that the prime contractor did not consistently evaluate whether non-prime
 contractor employees should be monitored for radiation exposure because of the transitory nature
 of their work.
- Therefore, NIOSH lacks sufficient information, which includes specific biological monitoring
 data, air monitoring information, process and radiological source information, and surrogate data
 from similar operations at other sites that would allow it to estimate the total internal dose from
 exposures to all the principal sources of internal radiation for workers who worked at FMPC from
 January 1, 1951, through December 31, 1983 who were not employed by National Lead Co. of
 Ohio, NLO, Inc., or the DOE or its predecessor agencies.
- 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.
- NIOSH has access to routine monitoring program data for measuring employees' external
 radiation exposures to gamma and beta radiation and concluded it is feasible, using methods
 available in existing NIOSH procedures, to reconstruct external radiation doses for all FMPC
 workers for the period from January 1, 1951, through December 31, 1983.
- 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,
 ORAUT-TKBS-0017-3, Section 3.2.
- NIOSH concluded it is feasible, using methods available in existing NIOSH procedures, to reconstruct external radiation doses for all FMPC workers for the period from January 1, 1951, through December 31, 1983.
- Although NIOSH now finds that it is not possible to completely reconstruct internal radiation doses for the period from January 1, 1951, through December 31, 1983, NIOSH intends to use

any internal monitoring data that may become available for an individual claim (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures). Dose reconstructions for individuals employed at FMPC during the period from January 1, 1951, through December 31, 1983, but who do not qualify for inclusion in the SEC, may be performed using these data as appropriate.

 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*l*(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*l*(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.