

December 7, 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 Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, 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 September 18, 2012. The Board considered the petition, and on November 7, 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 the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at the Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, from June 17, 1943, through July 31, 1955, 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



December 7, 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 Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, to be added to the Special Exposure Cohort (SEC).

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December 7, 2012

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

Dear Senator McConnell:

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Sincerely,

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Kathleen Sebelius



December 7, 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 Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, to be added to the Special Exposure Cohort (SEC).

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Sincerely,

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Kathleen Sebelius



December 7, 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 Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, to be added to the Special Exposure Cohort (SEC).

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Sincerely,

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Kathleen Sebelius

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

Oak Ridge National Laboratory (X-10)

Oak Ridge, Tennessee



I. Designation

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

December 7, 2012 Date [Signature on File] Kathleen Sebelius

II. Employee Class Definition

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at the Oak Ridge National Laboratory (X-10) in Oak Ridge, Tennessee, from June 17, 1943, through July 31, 1955, 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.

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 November 7, 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.

- NIOSH determined that principal sources of internal radiation for members of the Oak Ridge National Laboratory (X-10) proposed class included plutonium, uranium, thorium, mixed fission products, and various cyclotron-related radionuclides.
- Based on NIOSH's evaluation of available data, NIOSH concluded that it is not feasible for NIOSH to reconstruct with sufficient accuracy the internal doses at the Oak Ridge National Laboratory (X-10) from: uranium exposures during the period June 17, 1943, through December 31, 1948; thorium exposures during the period from January 1, 1948, through July 31, 1955; and mixed fission product exposures during the period from November 4, 1943, through December 31, 1949. Combining these periods of infeasibility yields a collective time period for dose reconstruction infeasibilities of June 17, 1943, through July 31, 1955.
- NIOSH has access to Oak Ridge National Laboratory (X-10) urine bioassay and air sampling data and believes that for various periods of time between June 17, 1943, and July 31, 1955, it may be feasible to reconstruct doses for some of the other principal sources of internal radiation dose. However, during the period between June 17, 1943, and July 31, 1955 internal doses cannot be reconstructed for all principal sources of internal radiation dose. NIOSH will continue to evaluate additional urine bioassay data if it becomes available.
- NIOSH has determined that cyclotron-related radionuclides produced at the nearby Y-12 Facility were processed at the Oak Ridge National Laboratory (X-10) during the period under evaluation. NIOSH has reserved the evaluation of Oak Ridge National Laboratory (X-10) exposures to various radionuclides produced as a result of Y-12 cyclotron operations to allow cyclotron-related operations and exposures at the two sites to be collectively evaluated.
- NIOSH determined that the principal source of external radiation doses for members of the Oak Ridge National Laboratory (X-10) proposed class was a combination of direct exposure from various fission products, production nuclides from the reactors. Photon and beta exposure at the Oak Ridge National Laboratory (X-10) resulted from the mixed fission and activation products from the reactors and from isotopes produced at Y-12. Direct photon exposure resulted from work in the proximity of the test and the research nuclear reactors.
- NIOSH has sufficient data that includes name of the employee, badge number, sample date, year, "Gamma_Exposure," and "Beta_Exposure" (the field labeled "Gamma_Exposure" includes all site-assigned neutron exposure results). NIOSH has evaluated the available information and believes that external dose reconstruction is feasible.

- Prior to October 3, 1947, occupational medical X-rays were performed at Oak Ridge Hospital (an EEOICPA-covered site located on what was then the Clinton Engineering Works site). Starting October 3, 1947, occupational medical X-rays were performed on the Oak Ridge National Laboratory (X-10) site. NIOSH has determined that adequate reconstruction of medical dose is feasible by using claimant-favorable assumptions and the technical information bulletin Dose Reconstruction from Occupational Medical X-Ray Procedures (ORAUT-OTIB-0006).). Therefore, NIOSH concluded that reconstruction of external doses, including occupational medical doses, is likely feasible for the period from June 17, 1943, and July 31, 1955.
- NIOSH determined that it 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 all workers who worked at the Oak Ridge National Laboratory (X-10) during the period from June 17, 1943, through July 31, 1955. Based on the available information, NIOSH believes external dose reconstruction is feasible for the evaluated time period.
- 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). Therefore, dose reconstructions for individuals employed at Oak Ridge National Laboratory (X-10) facility during the period from June 17, 1943, through July 31, 1955, 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 Board concurred with the NIOSH evaluation 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.