# 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

Oak Ridge Institute of Nuclear Studies (ORINS) Cancer Research Hospital Oak Ridge, Tennessee



#### I. Designation

I, Michael O. Leavitt, 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.

NOV - 9 2006

Date

Michael O. Leavitt

#### II. Employee Class Definition

Employees of the Department of Energy predecessor agencies and their contractors or subcontractors who were monitored or should have been monitored while working at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital from May 15, 1950, through December 31, 1963, and who were employed for a number of work days aggregating at least 250 work days or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

#### 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 October 12, 2006.

## 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 upon the findings summarized below.

- (1) The ORINS facility conducted research on the use of various radioactive isotopes for the treatment of cancer, and workers were exposed to radioactive materials through a number of work activities. Those activities included administering medicines containing radioactive material (radioisotopes) to patients, and treating patients with radiation-generating devices that emitted photon (gamma) radiation. Although the potential existed for substantial internal exposures arising from preparing, administering, and disposing of radioisotopes and radioactive waste, NIOSH found no evidence of personal or workplace monitoring that could be used to bound internal radiation exposures.
- (2) NIOSH cannot establish a maximum internal exposure scenario that addresses all of the internal exposure potential for members of the class, and therefore cannot estimate internal doses for this class with sufficient accuracy.
- (3) Pursuant to 42 C.F.R. § 83.13(c)(1), NIOSH determined that there is insufficient information either 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, or to estimate the radiation doses of members of the class more precisely than a maximum dose estimate.
- (4) NIOSH determined that it is possible to reconstruct or bound both external doses and occupational medical doses.

#### Health Endangerment

The Secretary established the health endangerment determination for the class of employees covered by this report 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 the finding of NIOSH 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 designation of one additional class to the SEC for review by Congress, pursuant to 42 U.S.C. §§ 7384l(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. § 7384l(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.