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

Y-12 Plant
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.

AUG 15 2008

Date

Michael O. Leavitt

II. Employee Class Definition

All employees of the Department of Energy (DOE), its predecessor agencies, and DOE contractors or subcontractors who worked at the Y-12 Plant in Oak Ridge, Tennessee from March 1, 1943 through December 31, 1947 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.

NIOSH previously evaluated (in evaluation report SEC-00018) the feasibility of performing dose reconstruction for workers at Y-12 who were employed from

March 1943 through December 1947. In that report, NIOSH concluded that it was not feasible to estimate radiation doses with sufficient accuracy for workers who worked in uranium enrichment operations and other radiological activities at the Y-12 site. The Board and the Secretary concurred with NIOSH's determination; the recommended class was added to the SEC on September 24, 2005. During its initial phase of administering the class, the Department of Labor (DOL) experienced difficulties in administering the class because of potential ambiguities in the class definition. To resolve those ambiguities, NIOSH developed a new evaluation report (SEC-00098) which clarifies that the class definition includes all workers at the Y-12 site from March 1943 through December 1947. NIOSH determined that the potential for radiation exposure existed for all Y-12 employees who were present at the site, due to operations related to uranium enrichment and other radiological activities. In effect, the class defined in the latest evaluation report subsumes the class that was added to the SEC on September 24, 2005, and therefore the SEC-00098 class should be the class used by DOL to process and re-evaluate all claims during this period at Y-12. NIOSH believes that all employees who meet the three requirements of the class: (1) employment at Y-12 from March 1943 through December 1947; (2) 250 work days at the Y-12 facility or in combination with work days in another SEC class; and (3) a specified cancer, should be covered by this class.

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 July 17, 2008.

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.

(1) NIOSH does not have access to sufficient uranium urinalysis records to estimate internal exposures, nor does NIOSH have records relating to other *in vitro* (fecal, nasal, sputum, etc.) or *in vivo* (whole-body, lung or other organ count) analyses.

(2) Available air sampling data are not suitable for an accurate estimate of intake scenarios. The sampling strategy and frequencies are unknown and it is not possible to determine whether the data represent high, low, or average concentrations to which a worker could have been exposed. The absence of breathing zone data makes it impossible for NIOSH to establish maximum exposure scenarios based on process data or source term data.

(3) The calutron operations and related support activities, such as the recycling and cleaning processes, are not comparable to any other operations for which NIOSH has access to adequate monitoring data.

(4) NIOSH has no air monitoring data, source term, or process information associated with the other radiological activities at Y-12. Consequently, NIOSH is unable to estimate internal exposures based on the data available.

(5) NIOSH lacks external dosimetry or source term information regarding the external exposures resulting from other radiological activities at the facility during this time period.

(6) Although the main mission of the Y-12 site during the period evaluated in this report was the electromagnetic enrichment of uranium in the calutrons, it also included a range of other smaller-scale radiological operations. Since exposure potential at the site may not have been limited to only specific buildings or groups of workers, NIOSH recommends that the class definition include all employees who worked at the site during the specified time period.

(7) 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.

(8) The Board concurred with the NIOSH evaluation and recommended the proposed class for addition to the SEC.

(9) Although NIOSH found that it is not possible to completely reconstruct radiation doses for these employees, NIOSH intends to use any available internal monitoring data that may be available for an individual claim (and can be interpreted using existing NIOSH dose reconstruction processes or procedures). Further, NIOSH has determined that calutron-related external exposures for workers directly associated with the calutron enrichment processes, and the occupational medical dose for all workers, can be reconstructed. Therefore, dose reconstructions for individuals with non-presumptive cancers or fewer than 250 days employment in the class period may be performed using these data as appropriate.

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-workday 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.