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

Mound Plant Miamisburg, 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.

July 14, 2010	_[Signature on file]
Date	Kathleen Sebelius

II. Employee Class Definition

All employees of the Department of Energy (DOE), its predecessor agencies, and its contractors and subcontractors who had at least one tritium bioassay sample and worked at the Mound Plant in Miamisburg, Ohio from March 1, 1959 through March 5, 1980, 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, after receiving the Advisory Board on Radiation and Worker Health (Board)'s recommendation, the Secretary has determined, for the class defined in Section II of this report, 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 a class as an addition to the SEC in a letter received by the Secretary on June 16, 2010.

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 lacks sufficient information, which includes biological monitoring data, sufficient air monitoring information, or sufficient process and radiological source term information, to allow it to estimate with sufficient accuracy the potential internal exposures to radon isotopes associated with radium, actinium, and thorium to which the proposed class may have been subjected.
- NIOSH finds that it is likely feasible to reconstruct external doses, including occupational medical doses, for Mound Plant workers with sufficient accuracy.
- Principal sources of internal radiation for members of the proposed class include residual radioactive material from the radium-actinium-thorium process conducted in the SW Building. The residual material led to technologicallyenhanced emanation of radon-220, radon-222, and radon-219 into Room SW-19.
- NIOSH previously determined, in its evaluation of petition SEC-00090, that
 Mound workers could have received unmonitored intakes of radium-226,
 actinium-227, and thorium-228 during the period from October 1, 1949 through
 February 28, 1959. In 2008, the Department of Health and Human Services
 (DHHS) designated the following class for inclusion in the SEC:

Employees of the Department of Energy (DOE), its predecessor agencies, and DOE contractors or subcontractors who worked in any areas at the Mound Plant site from October 1, 1949, through February 28, 1959, 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 Special Exposure Cohort.

- NIOSH found through ongoing research associated with SEC-00090 that residual radioactive material from the radium-actinium-thorium process conducted in the SW Building led to technologically-enhanced emanation of radon-220, radon-222, and radon-219 into Room SW-19.
- NIOSH found no bioassay or workplace monitoring records relevant to these radon exposures prior to when air measurements were made in 1979 and 1980.
 NIOSH is unable to put an upper bound on the radon exposures in SW-19 until the point at which a ventilation system was installed in early 1980 (prior to March 5, 1980) to vent SW Building tunnel air.
- NIOSH finds it is not feasible to determine which of the workers in the R and SW buildings may have frequented Room SW-19; therefore NIOSH cannot reasonably limit the cohort of workers who could have been exposed to radon in

SW-19 more narrowly than the cohort of all workers in the R and SW buildings. Due to the extensive tritium operations occurring in these buildings, it was documented policy that everyone who worked in the R and SW buildings had to submit periodic urine samples to be analyzed for tritium. While it is possible that a worker could have occasionally visited the R and SW buildings without submitting a tritium urinalysis sample, it is not plausible that a worker could have spent 250 days in these buildings without providing a single tritium urine sample. Therefore, tritium urinalysis results will be taken as evidence of potential employment in the R and SW buildings. Conversely, absence of such urinalysis data will be taken as evidence that individuals did not have the potential to be employed in the R and SW buildings for 250 days.

- 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.
- 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 the Mound Plant during the period from March 1, 1959 through March 5, 1980, but who do not qualify for inclusion in the SEC, may be performed using these data as appropriate.
- In its previous evaluation of petition SEC-00090, NIOSH concluded that for the period from February 1949 to present, it has access to sufficient information to either: (1) estimate the maximum external 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 external radiation doses to members of the class more precisely than a maximum dose estimate. Consistent with its findings associated with SEC-00090, NIOSH has established that it has access to sufficient information to: (1) estimate the maximum external 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 external radiation doses to members of the class more precisely than a maximum dose estimate.
- Adequate reconstruction of medical dose is likely to be feasible by using bounding assumptions in the technical information bulletin, *Dose Reconstruction* from Occupationally Related Diagnostic X-Ray Procedures (ORAUT-OTIB-0006), and Mound technical basis documents, collectively referred to as ORAUT-TKBS-0016.
- The Board concurred with the NIOSH evaluation and recommended a 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.