

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

General Atomics

La Jolla, California



I. Designation

I, Sylvia M. Burwell, Secretary of the U.S. Department 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.

September 25, 2014
Date

[Signature on File]
Sylvia M. Burwell

II. Employee Class Definition

All Atomic Weapons Employees who worked for General Atomics at its facility in La Jolla, California, during the period from January 1, 1960, through December 31, 1969, 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 the National Institute for Occupational Safety and Health (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 dose of individual members of the class 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, 2014.

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.

- Principal sources of internal radiation for members of the proposed class included exposures to uranium isotopes (depleted, natural, enriched, and recycled), plutonium, thorium, tritium, and other fission and activation products associated with radiological research and production activities, including reactor and accelerator operations.
- NIOSH has determined that it is necessary to remove the area-specific and monitoring criteria from the class description associated with NIOSH's 2006 evaluation of SEC-00064 exposures for the period from January 1, 1960, through December 31, 1969, because of the potential for difficulties in implementing the class definition. Additionally, due to the issues identified during ongoing dose reconstruction and methodology reviews conducted by NIOSH and the Board after implementation of SEC-00064, NIOSH has determined that infeasibilities associated with sufficiently accurate reconstruction of internal exposures during that period extend beyond the assessment of thorium exposures as was presented in NIOSH's 2006 evaluation of General Atomics.
- NIOSH lacks sufficient information that would allow it to estimate with sufficient accuracy the potential unmonitored internal exposures, including unmonitored uranium, thorium, tritium, and fission and activation products, to which the proposed class may have been subjected during the period from January 1, 1960, through December 31, 1969.
- Principal sources of external radiation for members of the proposed class included exposures to radiation fields associated with reactor, accelerator, and fuel production operations and experiments. NIOSH will determine through discussion with the Board to what extent external radiation doses from operations can be reconstructed.
- NIOSH considers that sufficiently accurate reconstruction of medical dose for General Atomics workers is feasible by using claimant-favorable assumptions, as well as applicable protocols specified in the complex-wide *ORAUT-OTIB-0006, Technical Information Bulletin: Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*.
- NIOSH lacks sufficient information, which includes biological monitoring data, sufficient air monitoring information, or sufficient process and radiological source information, that would allow it to estimate with sufficient accuracy the potential unmonitored internal exposures, including unmonitored uranium, thorium, plutonium, tritium, and fission and activation products, to which the proposed class may have been subjected during the period from January 1, 1960, through December 31, 1969.
- Although NIOSH found that it is not possible to completely reconstruct radiation doses for the proposed class, 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). Depending on the outcome of its discussion with the Board, NIOSH intends to either completely reconstruct external exposures, or to use any external monitoring data

that may become available for an individual claim (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures).

- 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 NIOSH's recommendation to add the proposed class of workers 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. §§ 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.