



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Joseph R. Biden, Jr.
President of the United States Senate
Washington, DC 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 from the Pantex Plant in Amarillo, Texas, 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 July 17, 2013. The Board considered the petition, and on August 28, 2013, submitted its recommendation concerning this petition. The Secretary of Health and Human Services (HHS) considered the deliberations, findings, and recommendations of the Board, Director of NIOSH, and the Director of CDC and determined that the following employees do not meet the statutory criteria for addition to the SEC, as authorized under EEOICPA, 42 U.S.C. § 7384q.

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, during the period from January 1, 1951, through December 31, 1957.

Subsequently, the petitioner requested an administrative review of the final decision pursuant to 42 C.F.R. § 83.18. A panel of three HHS personnel (the Panel), independent of NIOSH, was appointed by the Secretary to conduct an administrative review and provide recommendations concerning the merits of the challenge and the resolution of issues contested by the petitioner in the challenge. Based on its evaluation, the Panel recommended a revision of the final decision not to add a class of workers from the Pantex Plant, and NIOSH agreed to provide a new designation comporting with the Panel's recommendations. I have considered the information and recommendations provided by the Panel, the Director of NIOSH, and the Board and decided to designate the following class of workers for addition to the SEC:

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The criteria and findings upon which this designation is based are provided in the enclosed report. In addition, for more details regarding the basis of my decision, please see the Panel's final report and addendum, and NIOSH's response posted at <http://www.cdc.gov/niosh/ocas/pantex.html#pet68>

If you have additional questions, please contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627.

Sincerely,

[Signature on File]

Sylvia M. Burwell

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

Dear Senator McConnell:

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Charles Schumer
Minority Leader
United States Senate
Washington, DC 20510

Dear Senator Schumer:

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Ted Cruz
United States Senate
Washington, DC 20510

Dear Senator Cruz:

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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 July 17, 2013. The Board considered the petition, and on August 28, 2013, submitted its recommendation concerning this petition. The Secretary of Health and Human Services (HHS) considered the deliberations, findings, and recommendations of the Board, Director of NIOSH, and the Director of CDC and determined that the following employees do not meet the statutory criteria for addition to the SEC, as authorized under EEOICPA, 42 U.S.C. § 7384q.

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Sylvia M. Burwell

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
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JAN - 4 2017

The Honorable Paul Ryan
Speaker of the U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable John Cornyn
United States Senate
Washington, DC 20510

Dear Senator Cornyn:

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Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pelosi:

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Sylvia M. Burwell

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN - 4 2017

The Honorable Mac Thornberry
U.S. House of Representatives
Washington, DC 20515

Dear Representative Thornberry:

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Sylvia M. Burwell

Enclosure

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

Pantex Plant

Amarillo, Texas



I. Designation

I, Sylvia M. Burwell, Secretary of the 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.

JAN - 4 2017

Date

Signature on File

Sylvia M. Burwell

II. Employee Class Definition

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, during the period from January 1, 1951, through December 31, 1957, 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 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 received SEC petition 00068 representing certain workers at the Pantex Plant (Pantex) in Amarillo, Texas, for the period from January 1, 1951, through December 31, 1991. Based on its evaluation, NIOSH initially concluded that it could complete dose reconstructions with sufficient accuracy for Pantex workers during the entire time period. However, after extensive reviews by and discussions with the Advisory Board on Radiation and Worker Health (the Board), the Board recommended, and the NIOSH Director concurred, that SEC classes should be added for workers who were employed at Pantex during the time period from January 1, 1958, through December 31, 1991. The Board and NIOSH further concluded that dose reconstruction was feasible for workers during the years 1951 through 1957.

Following recommendations from the Board and NIOSH, the Secretary designated two SEC classes covering the time periods from January 1, 1958, through December 31, 1991, and denied adding an SEC class for the time period from January 1, 1951, through December 31, 1957. The petitioner was notified of the Secretary's final decision and filed a request for an HHS administrative review of this denial. Subsequently, a panel of three HHS personnel (Panel), independent of NIOSH, was appointed to conduct an administrative review. The Office of the Assistant Secretary for Health (OASH) administered this Panel on behalf of the Secretary.

Based on its review, the Panel concluded that with respect to internal exposures to uranium, certain data and facts regarding the history of early operations at Pantex do not exist, or substantially conflicting in the administrative record. Accordingly, this insufficiency in the record did not permit the Panel to confirm the factual accuracy of the information supporting the final decision or the principal findings and recommendations of NIOSH and those of the Board. Thus, the Panel recommended that the Secretary revise the previous determination to deny SEC status to this class of Pantex employees. In a memorandum to OASH dated October 24, 2016, the Director of NIOSH agreed to provide a new designation to the Secretary that comports with the Panel's recommendation as set out in their final report.

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.

- NIOSH determined that members of this class may have received internal and external radiation exposure to alpha particles and gamma and beta radiation associated with uranium.
- In light of the Panel's review, NIOSH does not have sufficient information, which includes specific biological monitoring data, air monitoring information, and process and radiological source information to estimate the total internal dose from exposures to uranium for all radiological workers who worked at Pantex for the period from January 1, 1951, through December 31, 1957. Therefore, it is not feasible to reconstruct *internal* doses with sufficient accuracy.
- NIOSH, however, concluded that it has access to sufficient personnel and workplace monitoring data to reconstruct *external* doses, including medical x-ray dose, with sufficient accuracy for Pantex workers for the period January 1, 1951, through December 31, 1957. The Panel also agreed that external dose reconstruction is feasible for the evaluated time period.
- Although it is not possible to reconstruct internal radiation dose for the proposed class, NIOSH intends to use any 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 Pantex from January 1, 1951, through December 31, 1957, but who do not qualify for inclusion in the SEC, may be performed using these data as appropriate.
- Based on the foregoing, 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.

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 has determined, and OASH concurs, 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 has 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 established for one or more other classes of employees in the Cohort.”
- (2) NIOSH has determined, and OASH concurs, that members of the class were not 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 health of the class may have been endangered and the class is defined in accordance with 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), 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.