

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

AUG 2 5 2005

The Honorable Richard Cheney President of the United States Senate Washington, D.C. 20510

Dear Mr. President:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) and 42 C.F.R. pt. 83, petitions were filed on behalf of certain workers employed as radiographers in support of Line 1 operations at the Iowa Army Ammunition Plant (IAAP). from May 1948 to March 1949, requesting inclusion as a Special Exposure Cohort (SEC). This petition was filed in conjunction with a request for SEC inclusion for Line 1 workers employed at IAAP from March 1949 through 1974.

After the petitions qualified for evaluation under 42 C.F.R. §§ 83.7 – 83.9, the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petitions using the procedures in 42 C.F.R. § 83.13. The Advisory Board on Radiation and Worker Health (the Board) and the Director of NIOSH both recommended the designation of an SEC class for the employees who worked at IAAP, Line 1, from March 1949 through 1974, which became effective on June 19, 2005. However, they deferred decision on the petition for radiographers until more information was obtained by NIOSH.

At the July 5, 2005. Board meeting, NIOSH presented the completed evaluation report of the petition for employees who worker as radiographers from May 1948 to March 1949 in support of Line 1 operations. Based on the meeting, in a letter dated July 26, 2005, the Board recommended granting the SEC status to this petition; and in a subsequent letter dated July 26, 2005, the Director of NIOSH concurred with the recommendation.

Based upon consideration of the findings, deliberations, and recommendations of the Board and concurrence by the Director of NIOSH and by the Director of CDC, I have designated the following class for addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked as radiographers from May 1948 to March 1949 in support of Line 1 operations at the Iowa Army Ammunition Plant and who were employed for a number of work days aggregating at least 250 work days. occurring under this employment in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

Page 2 - The Honorable Richard Cheney

The criteria and findings upon which this designation is based are provided in the enclosed report.

Please contact me if you have any further questions regarding this matter.

Sincerely.

Michael O. Leavitt

Enclosure



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

AUG 2 5 2005

The Honorable J. Dennis Hastert Speaker of the House of Representatives Washington, D.C. 20515

Dear Mr. Speaker:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) and 42 C.F.R. pt. 83, petitions were filed on behalf of certain workers employed as radiographers in support of Line 1 operations at the Iowa Army Ammunition Plant (IAAP), from May 1948 to March 1949, requesting inclusion as a Special Exposure Cohort (SEC). This petition was filed in conjunction with a request for SEC inclusion for Line 1 workers employed at IAAP from March 1949 through 1974.

After the petitions qualified for evaluation under 42 C.F.R. §§ 83.7 – 83.9, the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) evaluated the petitions using the procedures in 42 C.F.R. § 83.13. The Advisory Board on Radiation and Worker Health (the Board) and the Director of NIOSH both recommended the designation of an SEC class for the employees who worked at IAAP, Line 1, from March 1949 through 1974, which became effective on June 19, 2005. However, they deferred decision on the petition for radiographers until more information was obtained by NIOSH.

At the July 5, 2005, Board meeting, NIOSH presented the completed evaluation report of the petition for employees who worker as radiographers from May 1948 to March 1949 in support of Line 1 operations. Based on the meeting, in a letter dated July 26, 2005, the Board recommended granting the SEC status to this petition; and in a subsequent letter dated July 26, 2005, the Director of NIOSH concurred with the recommendation.

Based upon consideration of the findings, deliberations, and recommendations of the Board and concurrence by the Director of NIOSH and by the Director of CDC. I have designated the following class for addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked as radiographers from May 1948 to March 1949 in support of Line 1 operations at the Iowa Army Ammunition Plant and who were employed for a number of work days aggregating at least 250 work days. occurring under this employment in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

Page 2 - The Honorable J. Dennis Hastert

The criteria and findings upon which this designation is based are provided in the enclosed report.

Please contact me if you have any further questions regarding this matter.

Sincerely,

Michael O. Leavitt

Enclosure

HHS Designation of Additional Members of the Special Exposure Cohort

under the

Energy Employees Occupational Illness Compensation Program Act

Designating a Class of Employees from

Iowa Army Ammunition Plant (IAAP)
Burlington, Iowa



I. Designation

I, Michael O. Leavitt, Secretary of Health and Human Services ("the 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.

Date:

AUG 2 5 2005

Michael O. Leavitt

II. Employee Class Definitions

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked as radiographers from May 1948 to March 1949 in support of Line1 operations at the Iowa Army Ammunition Plant and who were employed for a number of work days aggregating at least 250 work days, occurring under this employment in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC

III. Designation Criteria and Recommendations

Pursuant to 42 U.S.C. § 7384q, the Secretary has determined for the class defined in Section II of this report, upon recommendation of the Advisory Board on Radiation and Worker Health ("the Board"), 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, 42 C.F.R. § 83.13(c)(1), states that it is feasible to estimate the radiation dose that the class received with sufficient accuracy under two situations. First, the rule states that radiation doses can 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 can 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. 42 C.F.R. § 83.3(c)(1)(i).

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 dated July 26, 2005 and received on July 29, 2005.

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) As governed by 42 C.F.R. § 83.13(c)(1), NIOSH determined that it lacks access to sufficient information to either 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 with sufficient accuracy.
- (2) NIOSH found that there is insufficient information to estimate either the maximum radiation dose incurred by the workers defined in the class or to estimate such radiation doses more precisely than a maximum dose estimate. Additional information is needed on the radiological sources, shielding, and the radiography process of radiographic operations during the period May 1948 March 1949 to reconstruct dose using surrogate data from later time periods. NIOSH concluded that it is not feasible to estimate with sufficient accuracy the external doses incurred by these radiographers at IAAP during the time period in question.

Health Endangerment

The Secretary established the health endangerment determination for the class of employees covered by this report upon the findings summarized below.

- (1) As governed by 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 finds that it is likely that radiation doses for this group of workers at the IAAP during this time period could have endangered the health of members of this class.

- (3) 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, such as a nuclear criticality incident, as defined under 42 C.F.R. § 83.13(c)(3)(i).
- (4) The Board concurred with the finding of NIOSH that the health of the class may have been endangered and further concurred with NIOSH in this respect by defining the class according to the 250 work day employment requirement specified under 42 C.F.R. § 83.13(c)(3)(ii).

V. Effect and Effective Date of Designations

The Secretary submits this report on designations 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. § 83.16(b). 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 criterion and findings on which the decision was based.



National Institute for
Occuptional Safety and Health
Centers for Disease Control
and Prevention (CDC)
200 Independence Avenue, SW
Washington, DC 20201

DATE:

July 29, 2005

TO:

The Secretary

Through: DS

COS

CDC Ju JIG

FROM:

Director

National Institute for Occupational Safety and Health (NIOSH)

SUBJECT:

Designating Certain Employees of the Iowa Army Ammunition Plant (IAAP)

as Members of the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000

(EEOICPA) -- ACTION

Action Required By: August 29, 2005

ISSUE

Attached for your approval and signature is a proposed designation to add certain employees from IAAP as members of the SEC under EEOICPA, 42 U.S.C. § 7384q (Tab A).

DISCUSSION

EEOICPA established an SEC, a designation applied to certain classes of employees who worked in United States nuclear weapons production facilities of the Department of Energy (DOE) or Atomic Weapons Employers (AWEs). EEOICPA confers to SEC designees a presumption of causation regarding the relation of their cancer to their employment at a DOE or AWE facility. This presumption allows them to obtain federal compensation under EEOICPA if they incur one of a list of "specified cancers" that, under EEOICPA, are presumptively linked with occupational exposures to radiation at DOE and AWE facilities. EEOICPA included four classes of employees in the SEC initially and further provided that the President could designate additional classes as members of the SEC if certain statutory conditions are met. This authority to designate additional members was delegated by the President to the Secretary of the Department of Health and Human Services (HHS) (Tab B), who promulgated procedures for doing so on May 28, 2004 (Tab C). Since promulgation of these procedures, Congress has amended EEOICPA, mandating that HHS report to Congress on designations and decisions to deny a designation within 30 days of receiving a recommendation by the Advisory Board on Radiation and Worker Health ("the Board") to

add the class to the SEC. Failure to report to Congress within this 30-day deadline would result in the automatic addition of the class to the SEC.

Under the HHS procedures to designate additional members to the SEC, NIOSH received SEC petitions representing certain employees at IAAP for the years 1947 through 1974 (Tab D). The Board and the NIOSH Director: recommended the designation of an SEC class for the employees who worked at IAAP, Line 1, from March 1949 through 1974 (the class became effective on June 19, 2005); determined that a class would not be added for the Line 1 employees who worked from June 1947 through May 1948; and deferred decision on the petition for employees who worked as radiographers from May 1948 to March 1949 in support of Line 1 operations until more information was obtained by NIOSH.

On July 5, 2005, NIOSH reported at the Board meeting the completed evaluation findings regarding radiographers who worked from May 1948 to March 1949 in support of Line 1 operations (Tab E). There is insufficient information to estimate either the maximum radiation dose incurred or to estimate such radiation doses more precisely than a maximum dose estimate. There is insufficient information on the radiographic operations during that time period to allow for monitoring data from a subsequent time to be used as surrogates; additional information on the radiological sources, shielding, and the radiography process would be needed. NIOSH concluded that it is not feasible to estimate with sufficient accuracy the external doses incurred by these radiographers at IAAP from March 1948 to March 1949.

Subsequently, the Board considered the information presented by the petitioners and NIOSH. After deliberations, the Board concurred with NIOSH, recommending the addition to the SEC of the class of employees who worked at IAAP as radiographers from May 1948 to March 1949 in support of Line 1 operations (Tab F). The July 5, 2005 vote was 10-0 with one absence (Tab G).

The petitioners will be given the opportunity to seek an administrative review of certain HHS decisions, either a class denial or a 250-day health endangerment requirement, as specified in the HHS SEC procedures (See § 83.16(b) in Tab C).

RECOMMENDATIONS

Based upon the foregoing, the Director of NIOSH and the Director of CDC recommend that the Secretary approve and sign the attached designation to add to the SEC certain employees who worked as radiographers from May 1948 to March 1949 in support of Line 1 operations at IAAP.

DECISION

Approved _______ Date AUG 2 5 2005

ohn Howard, M.D.

Page 3 – The Secretary

Seven Attachments:

Tab A - Designation of a Class of Employees from IAAP

Tab B – Executive Order #13179

Tab C – 42 CFR Pt. 83

Tab D – IAAP SEC Petition 00006 (combination of 00006, 00007, 00014, 00015)

Tab E - NIOSH SEC Petition Evaluation Report, Petition SEC-00006-2

Tab F - Board Recommendation Letter to Secretary Leavitt, July 26, 2005

Tab G - Transcript of the July 5, 2005 Board Meeting