



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

AUG 25 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, three petitions were filed on behalf of workers employed at the Y-12 facility in Oak Ridge, Tennessee, who worked in uranium enrichment operations or other radiological activities from March 1943 through December 1947. The petition requested inclusion as a Special Exposure Cohort (SEC). Under 42 C.F.R. §§ 83.7 – 83.9, the petitions qualified for evaluation by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH).

NIOSH evaluated the petitions using the procedures set forth in 42 C.F.R. § 83.13. At the July 5, 2005, meeting of the Advisory Board on Radiation and Worker Health (the Board), NIOSH presented its finding to the petitioners and the Board. Based on the meeting, in a letter dated July 26, 2005, the Board recommended granting SEC status to this petition; and in a subsequent letter dated July 29, 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:

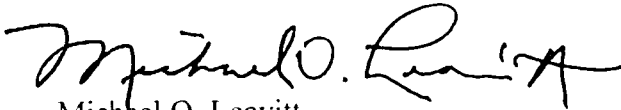
Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked in uranium enrichment operations or other radiological activities at the Y-12 facility in Oak Ridge, Tennessee from March 1943 through December 1947 and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

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

Page 2 – The Honorable Richard Cheney

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 25 2005

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

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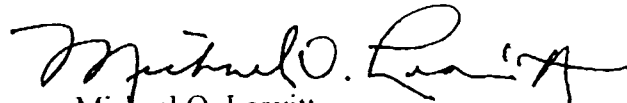
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Page 2 – The Honorable J. Dennis Hastert

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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

Y-12 Plant
Oak Ridge, Tennessee

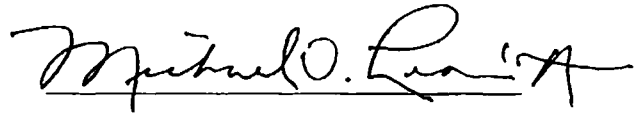


HHS Special Exposure Cohort Designation:
Y-12 Plant, Oak Ridge, Tennessee

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 25 2005



Michael O. Leavitt

II. Employee Class Definitions

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked in uranium enrichment operations or other radiological activities at the Y-12 facility in Oak Ridge, Tennessee from March 1943 through December 1947 and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days 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 employees involved in the calutron uranium enrichment process were exposed to levels of airborne uranium products that cannot be determined because of the absence of bioassay data for the time period and the lack of air sampling sufficient to develop maximum exposure scenarios.
- (3) NIOSH is unable to estimate such doses based on source term and process information for lack of documentation on the varying levels of enrichment of the source materials and on the production rate of the operations, and because the manual recycling and cleaning activities are unique and not comparable to any operations for which NIOSH has access to adequate monitoring data.
- (4) There is not sufficient information for individual dose reconstruction on other radiological activities during this time period, including the development of beneficial radiological isotopes, development and testing of a neutron monitor, maintenance and use of a large Radium 226 sealed source, and thorium extraction. However, NIOSH has determined that it is possible to estimate the exposure that resulted from occupational medical x-rays, but lacking other information, NIOSH can not rely on the x-ray doses alone to complete sufficiently accurate dose reconstructions for this class.

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 found that the primary radiation exposure hazard to employees resulted from episodic inhalations of radionuclides that cumulatively resulted in chronic exposures. The NIOSH evaluation report documents substantial exposures from this hazard. Additionally, employees in the class involved in other radiological activities, separate from the calutron enrichment process, may have incurred substantial external, as well as internal, radiation exposures.

(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
Occupational 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 _____
ES _____
CDC *[Signature]* JLG.

FROM: Director
National Institute for Occupational Safety and Health (NIOSH)

SUBJECT: Designating Certain Employees of the Y-12 Plant in Oak Ridge,
Tennessee ("Y-12") 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 Y-12 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

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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 three SEC petitions representing certain employees who worked at Y-12 from 1943 through 1957 (Tab D). NIOSH evaluated most of the petitions and, meeting the statutory conditions for adding a class to the SEC, determined that it is not feasible to estimate the radiation doses of employees who worked in uranium enrichment operations or other radiological activities at Y-12 from March 1943 through December 1947 with sufficient accuracy and that the health of these employees may have been endangered by such doses (Tab E). NIOSH has not completed the evaluation of the portion of one petition which concerns the period 1948 to 1957.

NIOSH presented the findings of the evaluation regarding March 1943 – December 1947 at the Board meeting on July 5, 2005. NIOSH reported that there is insufficient air sampling and bioassay data to estimate maximum radiation dose for employees involved in the calutron uranium enrichment process during that period. NIOSH was also unable to obtain sufficient area monitoring data, source term, or process information for other radiological activities such as the development of beneficial radiological isotopes, development and testing of a neutron monitor, maintenance and use of a large Radium 226 sealed source, and thorium extraction. However, NIOSH determined that it is possible to estimate the exposure that resulted from occupational medical x-rays. As a result of all of the findings, NIOSH concluded that there is insufficient 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.

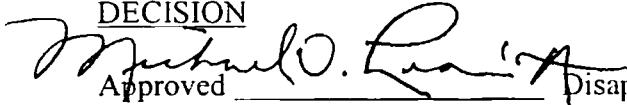
Subsequently, the Board considered the information presented by the petitioners and NIOSH. After deliberations, the Board concurred with NIOSH, recommending the addition to the SEC of the class of employees who worked in uranium enrichment or other radiological activities from March 1943 through December 1947 (Tab F). The July 5, 2005 vote was 8-0, with one abstention, one recusal, and 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 in uranium enrichment operations or other radiological activities at Y-12 during the period from March 1943 through December 1947.

DECISION


Approved _____

Disapproved _____

Date AUG 25 2005


John Howard, M.D.

Seven Attachments:

- Tab A – Designation of a Class of Employees from Y-12
- Tab B – Executive Order #13179
- Tab C – 42 CFR Pt. 83
- Tab D – Y-12 SEC Petitions 00018, 00026, 00028
- Tab E – NIOSH SEC Petition Evaluation Report, *Petition SEC-00018*
- Tab F – Board Recommendation Letter to Secretary Leavitt, July 26, 2005
- Tab G – Transcript of the July 5, 2005 Board Meeting