



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

July 22, 2013

Dear

Thank you for your letter on behalf of petitioner requesting an administrative review of my determination not to add a class of employees from Hangar 481, Kirtland Air Force Base in Albuquerque, New Mexico, to the Special Exposure Cohort (SEC).

Pursuant to 42 CFR § 83.18(b), and because you filed a challenge to this determination, I appointed a panel of three Department personnel, independent of the National Institute for Occupational Safety and Health (NIOSH), to conduct an administrative review. The panel completed its review of the challenge.

After reviewing the administrative record in this case, the panel concluded that: (1) The Department complied with the regulatory procedures set out in 42 CFR part 83; (2) my decision contained no evidence of factual error and was supported by factually accurate information; and (3) there were no errors of fact or in the methods of evaluation, or omission in the principal findings and recommendations of NIOSH and the Advisory Board on Radiation and Worker Health. In summary, the panel concluded that the challenge to my decision is without merit, and they have not recommended any change to my decision to deny adding a class of Hangar 481 employees to the SEC.

After review of the administrative review panel's thorough report, I have decided not to revise my May 11, 2012, final decision. I am enclosing a copy of the administrative review panel's final report to me. I hope you find this information helpful.

Sincerely,

Kathleen Sebelius

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

June 26, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Hangar 481, Kirtland Air Force Base Special Exposure Cohort Administrative Review Panel

Dear Madam Secretary:

The undersigned Administrative Review Panel unanimously concurs with your decision of May 11, 2012, as authorized under the Energy Employees Occupational Illness Compensation Act of 2000 (EEOICPA), 42 U.S.C. § 7384q(b), in which you determined that the following class of employees does not meet the statutory criteria for addition to the Special Exposure Cohort (SEC):

All employees who worked at Hangar 481, Kirtland Air Force Base (AFB), from March 1, 1989 through February 29, 1996.

Pursuant to 42 U.S.C. § 7384q, a class may be designated for addition to the SEC if the Secretary determines, 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 reasonable likelihood that such radiation dose may have endangered the health of members of the class. The basis for your decision in this case was the determination that it is feasible to estimate with sufficient accuracy the radiation doses encountered by employees at Hangar 481, Kirtland Air Force Base (hereinafter "Hangar 481"), located in Albuquerque, New Mexico; thus, a determination of health endangerment was not required.

In a letter dated June 14, 2012, attorney _____ on behalf of petitioner _____ a surviving spouse of a former employee of Ross Aviation, which was a Department of Energy (DOE) contractor that performed services at Hangar 481, filed a

challenge to your May 11, 2012, determination. A copy of petitioner's appeal letter is attached. EEOICPA implementing regulations at 42 CFR § 83.18(a) provide that, in order to contest a final decision by the Secretary to deny adding a class to the Cohort, a challenge "must include evidence that the final decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures" set out in 42 CFR part 83.

The petitioner's appeal letter states: "Petitioner contends and maintains that the Secretary's final determination relies on (1) a record of substantial factual errors, and/or (2) a record of substantial errors in the implementation of the procedures enumerated in 42 C.F.R. pt. 83." Further, the petitioner's letter includes several specific allegations, including: (1) that "the information provided to NIOSH representatives was to a certain degree unreliable and unverifiable;" (2) petitioner takes exception to the Determination Findings set out in the Secretary's May 11, 2012, "Determination Concerning a Petitioner for Employees from Hangar 481, Kirtland Air Force Base, Albuquerque, New Mexico;" and (3) that the information presented in the attachments to his appeal letter were "not adequately addressed in the evaluation process of SEC00139."

Because of this challenge and pursuant to 42 CFR § 83.18(b), you appointed a panel of three Department of Health and Human Services (HHS) personnel, independent of the National Institute for Occupational Safety and Health (NIOSH), to conduct an administrative review and provide recommendations concerning the merits of the challenge and the resolution of the issues contested by the challenge. The undersigned, Michael A. Noska, M.S., Steven L. Simon, Ph.D., and Pataje G. Prasanna, Ph.D., comprise this panel. Our collective expertise includes radiation biology, health physics, radiation exposure, dose assessment and dose reconstruction, and radiation risk analysis. We were charged with conducting an administrative review of your determination not to add a class of Hangar 481 employees to the SEC, which included reviewing the data and information that formed the basis of your decision. Pursuant to 42 CFR § 83.18(b), we considered whether HHS substantially complied with the regulatory procedures set out in 42 CFR part 83 and whether the Secretary's final decision was supported by accurate factual information, and we also reviewed the principal findings and recommendations of NIOSH and the Board. As explained below, we concluded that petitioner's challenge to your decision is without merit, and we do not recommend any change to your decision to deny adding a class of Hangar 481 employees to the SEC.

In conducting our review, pursuant to 42 CFR § 83.18(b), we examined the views and information submitted by the petitioner in the challenge, the NIOSH evaluation reports, the report containing the recommendations of the Board, the recommendations of the Director of NIOSH to the Secretary, information presented or submitted to the Board, and the deliberations of the Board prior to the issuance of its recommendations. Since 42 CFR § 83.18(a) prohibits petitioners from introducing any new information or documentation, our review was based entirely on the administrative record in this case, as described above.

A memorandum to you, dated April 11, 2012, from the Director of NIOSH, which was initialed by the Director of the CDC and which you approved and signed, states that, based on its full research of the class under evaluation, NIOSH determined that the available monitoring records, process descriptions and source term data are sufficient to complete dose reconstructions for the evaluated class of employees. This conclusion was reflected in the NIOSH Evaluation

Reports (including the initial report, dated December 11, 2009, the revised report dated September 23, 2010, and the addendum to the report, dated August 2, 2011), which evaluated the feasibility for completing dose reconstructions for all employees who worked at Hangar 481, Kirtland Air Force Base (AFB), from March 1, 1989 through February 29, 1996. Specifically, this April 11, 2012 memorandum states as follows:

NIOSH determined that:

1. No unsealed radioactive materials were handled nor were radioactive materials stored at the Hangar 481 facility. Radioactive materials handled by workers at Hangar 481 were in sealed DOT-compliant containers and monitored in accordance with DOT regulations to verify radiation and contamination levels on package exteriors.
2. Based on the available information on the radiological program and potential for internal exposure sources, NIOSH concluded that internal radiological exposures to Ross Aviation employees resulting from services rendered for the DOE at Hangar 481 are unlikely to have occurred.
3. Sandia National Laboratories, being an adjacent facility, was used to provide a bounding estimate of the dose from ambient environmental internal dose during the covered period.
4. External dose records exist for many Ross Aviation personnel and the Radiation Exposure Information and Reporting System (REIRS) reported data have been verified using Eberline dosimetry data from 1990-1994. The individual results of these records or use of the highest dose received by monitored personnel, adequately bounds external dose for unmonitored workers.
5. Responses to questions and interviews with former Hangar 481 workers indicate that annual occupational X-ray examinations were not performed at Hangar 481. Based on this information, medical X-ray dose for Hangar 481 personnel is not a covered exposure to be included in the dose reconstruction. Therefore, medical X-ray dose is not a consideration for workers at Hangar 481.
6. After reviewing the additional information and data obtained subsequent to the original evaluation, NIOSH has concluded that the original feasibility determination is confirmed. Specifically, given the availability of TLD data for the covered years of employment, it is feasible to bound the evaluated worker class external dose (reconstruct external doses with sufficient accuracy). The TLD data available from 1989 through 1995 is believed to adequately assess the radiological exposures at Hangar 481, Kirtland AFB during this timeframe and is, therefore, adequate for performing dose reconstructions. Using the methods described in ORAUT-OTIB-0008, dose for 1996 can be overestimated by using the highest individual dosimetry data for all previous covered years (1989 through 1995).

In sum, in that memorandum, NIOSH determined that it has access to sufficient site-specific information to either (1) estimate the maximum external and internal radiation dose for every type of cancer that could have been incurred under plausible circumstances by any member of the evaluated class; or (2) estimate the external and internal radiation doses to

members of the evaluated class more precisely than a maximum dose estimate. The memorandum also indicates that the Board concurred with this NIOSH determination.

With respect to the six points above as enumerated by NIOSH and the conclusions which they supported, we provide the following responses from our administrative review:

1. With regard to the first point, this panel concurs with the finding that no unsealed radioactive materials were handled or stored at the Hangar 481 facility. Further, any materials handled by Hangar 481 workers were in sealed Department of Transportation (DOT)-compliant containers showing no sign of leakage based on routine radiological surveys of aircraft and swipe monitoring of package surfaces, which would identify removable contamination. This panel did not find any evidence indicating violation of established DOT regulations with respect to handling of radioactive materials. For example, NIOSH submitted a questionnaire to the DOE Office of Secure Transport (OST) for evaluation and input, and conducted a site visit at the Hangar 481 building and adjacent areas at Kirtland AFB, which was attended by NIOSH staff, the petitioner and the petitioner's representative. In response to the questionnaire, and in response to questions raised by NIOSH and the petitioner/petitioner's representative at a meeting conducted in conjunction with this site visit, DOE OST confirmed that radioactive materials were only handled at Hot Pads 2 and 5 (which were at least three kilometers from Hangar 481) by monitored personnel in a secure area (See SEC Petition Evaluation Report SEC-00139, Rev #1 - Addendum, August 2, 2011, pages 7-8). In the absence of any evidence of security or safety violations, there is no basis for an exposure pathway at Hangar 481.
2. With regard to the second point, this panel concluded, based on the evidence, that internal radiological exposures to Ross Aviation employees resulting from services rendered for the DOE at Hangar 481 were unlikely to have occurred. For example, in 1997, the Transportation Safeguards Division of DOE's Albuquerque Operations Office issued a "Technical Basis for Radioactive Material Intake Potential" regarding activities performed by Ross Aviation at Hangar 481, which states that Ross Employees at Hangar 481 did not have any contact with package contents; examination of the operational history, including "confirmatory surveys," showed no evidence of signs of leakage and; the program used DOT-compliant packages and procedures. The report concluded that there was not a credible pathway for an intake of radioactive materials (See SEC Petition Evaluation Report SEC-00139, Rev #0, December 11, 2009, page 17; SRDB Ref. ID 71009).
3. With respect to the third point above, this panel concurs with the approach by NIOSH to utilize ambient environmental monitoring data from Sandia National Laboratories (SNL) to bound an estimate of internal dose for workers at Hangar 481 during the covered period (See SEC Petition Evaluation Report SEC-00139, Rev #0, December 11, 2009, page 19; ORAUT-TKBS-0037). We believe this approach is valid. Even though Hangar 481 workers were not directly exposed to radioactive materials from the handling of containers, it is conceivable that they might have received low-level exposures from effluent releases at SNL, though it is unlikely. Because of the significant distance from

SNL to Hangar 481 and the resulting dilution in the atmosphere that would inevitably occur, ambient measurements at the boundary between SNL and Kirtland Air Force Base would represent the upper bound of potential exposures to Hangar 481 workers.

4. NIOSH states that external records exist for many Ross Aviation personnel. These records were verified by individual dose records for the period of 1990-1994, which NIOSH obtained from Eberline. This panel concurs that these monitoring results, including the use of the highest doses received by monitored workers, effectively bound the external dose for unmonitored workers in the proposed class.
5. With respect to the fifth point, this panel notes that there does not appear to be any dispute that annual occupational X-ray examinations were not conducted for Hangar 481 workers. Hence, there is agreement that medical X-ray dose for Hangar 481 workers is not an issue for consideration. We acknowledge the petitioner's statement regarding X-ray testing of aviation equipment at Hangar 481 ("non-destructive testing" or NDT). Records indicate that this testing was only performed during the evenings by trained radiation workers. One incident of an exposed dosimeter appeared to be related to a pilot leaving his dosimeter in his locker during an evening when NDT was conducted. (See SEC Petition Evaluation Report SEC-00139 Rev #1 - Addendum, August 2, 2011, page 22.) However, this is not indicative of exposures to other (unmonitored) workers.
6. Regarding the sixth point above, this panel agrees with NIOSH that the existence of individual TLD data for the covered period makes it feasible to bound the external dose of covered workers with sufficient accuracy. TLD data from a DOE-accredited laboratory are among the most reliable sources of exposure information for occupational workers. Further, the methods described in ORAUT-OTIB-0008 appropriately allow for the over-estimation of dose (giving claimants the benefit of the doubt) in 1996, the only year for which dosimetry results were not collected, since radiological operations had ceased by that time.

In regard to the petitioner's allegation that the information provided to NIOSH was "to a certain degree unreliable and unverifiable," we note that Ross Aviation's occupational safety program utilized well-established methods for assessing radiological hazards, including surveys and personnel monitoring by an accredited dosimetry provider. Further, NIOSH verified dosimetry records by confirming entries in the REIRS database and obtaining historical dosimetry records from the provider.

In reference to the petitioner's allegation that information attached to his appeal letter was not adequately addressed in the evaluation process of SEC00139, after reviewing the record in this appeal, we concluded that NIOSH and the Board sufficiently addressed this information during the evaluation process. We believe that NIOSH and the Board considered all the relevant information when evaluating SEC00139. In addition, NIOSH has indicated in the record that "all available documents (including additional documents acquired through recent data capture efforts) have been evaluated and incorporated into this review" (See SEC Petition Evaluation Report SEC-00139, Rev #1 - Addendum, August 2, 2011, page 21).

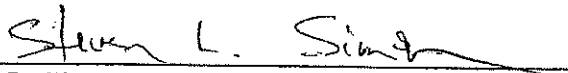
As a result of our administrative review of this case, we have concluded:

1. HHS complied with the regulatory procedures set out in 42 CFR part 83.
2. Your decision contained no evidence of factual error and was supported by factually accurate information.
3. There were no errors of fact or in the methods of evaluation, or omission in the principal findings and recommendations of NIOSH and the Advisory Board.

In summary: Based upon our review of the administrative record in this case, this panel believes that the regulatory procedures have been complied with in making your decision, that credible sources of information have been used as allowed for under EEOICPA implementing regulations, 42 CFR parts 82 and 83, and that you, NIOSH, and the Advisory Board came to reasonable and appropriate conclusions. In short, we have concluded that petitioner's challenge to your decision is without merit, and we see no reason to recommend any change to your decision to deny adding a class of Hangar 481 employees to the SEC.



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Attachments:

Petitioner's Appeal Letter, dated June 14, 2012

Phone:

June 14, 2012

Jennifer M. Cannistra
Executive Secretary to the Department of
Health and Human Services
Room 603-H
200 Independence Avenue, S.W.
Washington, DC 20201

Re: ADMINISTRATIVE REVIEW REQUEST
Petitioner:
SEC Tracking No: SEC00139
Our File No.:

Dear Ms. Cannistra:

This letter is submitted in compliance with the provisions set forth in the letter, dated May 16, 2012, of Mr. Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH).

On behalf of Petitioner we hereby request an Administrative Review of the Secretary's final determination to deny adding this class of employees (SEC000139) to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

Under SEC000139 Petitioner sought SEC status for "All employees who worked at Hangar 481, Kirtland Air Force Base, from March 1, 1989 through February 29, 1996."

Petitioner contends and maintains that the Secretary's final determination relies on (1) a record of substantial factual errors, and/or (2) a record of substantial errors in the implementation of the procedures enumerated in 42 C.F.R. pt. 83.

By submission this request Petitioner does not wish to cast aspersion on the well intentioned efforts of personnel of NIOSH who made investigations and recommendations concerning this matter. Rather Petitioner maintains that the information provided to NIOSH representatives was to a certain degree unreliable and unverifiable. Moreover in certain cases documentation to substantiate oral statements was nonexistent due to the passage of time and other factors.

Petitioner maintains that in regard to the parameters of this SEC class (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.

Jennifer M. Cannistra
Executive Secretary to the Department of
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Petitioner takes exception to the Determination Findings as to the feasibility of estimating radiation doses with sufficient accuracy and other findings set forth in the Determination Concerning a Petition for Employees from Hangar 481, Kirtland Air Force Base, Albuquerque, New Mexico dated May 11, 2012. The exceptions include the following matters:

1. Petitioner disputes the NIOSH determination that no unsealed radioactive materials were handled at Hangar 481 and that radioactive materials were, in all cases, in sealed DOT-compliant containers.
2. Petitioner disputes the NIOSH finding that available information on the radiological program and potential for internal exposure sources support its conclusion that internal radiological exposures to Ross Aviation employees resulting from services rendered for the DOE at Hangar 481 are unlikely to have occurred.
3. Petitioner disputes the NIOSH assessment that Sandia National Laboratories may properly be used to provide a bounding estimate of the dose from ambient environmental internal dose during the covered SEC period.
4. Petitioner disputes the assertion that external dose records that may exist for "many" Ross Aviation personnel and the Radiation Exposure Information and Reporting System (REIRS) reported data or the use of the highest dose received by monitored personnel adequately bounds external dose for all unmonitored workers.
5. Petitioner is informed that x-ray testing of equipment was performed at Hangar 481 during certain time periods but Petitioner does not dispute NIOSH position that annual occupational x-ray examinations were not performed at Hangar 481.
6. Petitioner disputes the NIOSH contention that the existence of TLD data for the covered years of employment may be utilized to bound the evaluated worker class external dose with sufficient accuracy.
7. Petitioner takes exception to NIOSH position that it has access to sufficient Hangar 481, Kirtland Air Force Base information to either (1) estimate the maximum internal and 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 evaluated class; or (2) estimate the internal and external radiation doses to members of the evaluated class more precisely than a maximum dose estimate.

Petitioner offers the following documents as the source of evidence for the statements set forth above. Petitioner maintains that the information presented in the attached documents was not adequately addressed in the evaluation process of SEC00139 and that administrative review is therefore appropriate. These documents are each believed to be in the Administrative Record concerning this matter:

Jennifer M. Cannistra
Executive Secretary to the Department of
Health and Human Services
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1. Affidavit of _____ dated November 9, 2010, with attachments.
2. Letter from Petitioner's counsel to James M. Melius, M.D., Dr. Ph., dated February 22, 2012, with attachments.

To the extent that it may be determined, on the basis of the documentation presented in support of this request for administrative review, that it is not feasible to estimate with sufficient accuracy the radiation doses encountered by all employees who worked at Hangar 481, Kirtland Air Force Base, from March 1, 1989 through February 29, 1996, a determination of health endangerment should be required.

In accordance with the Provisions of 42 C.F.R. § 83.18, Petitioner respectfully requests that the Secretary direct that this matter be submitted for an administrative review, that the Determination made concerning this matter on May 11, 2012 be set aside, and that this SEC Petition be ultimately recognized and recommended to Congress for approval.

Respectfully Submitted,

Enclosures: Affidavit of _____ dated November 9, 2010, with attachments.
Letter from Petitioner's counsel to James M. Melius, M.D., Dr. Ph., dated February 22, 2012, with attachments.

cc: _____ (w/o encls.)