



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

JAN - 4 2017

Dear 

Thank you for your request for an administrative review of the September 30, 2013, determination not to add a class of employees from the Pantex Plant, Amarillo, Texas, to the Special Exposure Cohort (SEC), established by the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).

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

In its final report and subsequent addendum, the panel concluded that HHS complied with the regulatory procedures set out in 42 CFR part 83. However, with respect to internal exposures to uranium, certain data and facts regarding the history of early operations at the Pantex Plant do not exist, or are 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 concluded that your challenge has merit, and they recommended that I revise the previous decision.

NIOSH agreed to provide a new designation comporting with the panel's recommendation. I have approved that designation, and it is being sent to Congress, as required by the EEOICPA regulations. You will be provided with additional information from NIOSH in due course.

I am enclosing a copy of the administrative review panel's final report and addendum, and the NIOSH response, which I hope you will find helpful.

Sincerely,

Signature on File

Sylvia M. Burwell

Enclosures

February 19, 2016

The Honorable Sylvia M. Burwell
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Pantex Plant Special Exposure Cohort Administrative Review Panel

Dear Madam Secretary:

BACKGROUND

On September 30, 2013, as authorized under the Energy Employees Occupational Illness Compensation Act of 2000 (EEOICPA), 42 U.S.C. § 7384q(b), the Secretary of the Department of Health and Human Services (HHS) at that time, Kathleen Sebelius (hereafter "the Secretary") determined that the following class of employees does not meet the statutory criteria for addition to the Special Exposure Cohort (SEC):

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

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 the Secretary's decision in this case was the determination that it is feasible to estimate with sufficient accuracy the radiation doses encountered by employees at the Pantex Plant in Amarillo Texas (hereinafter "Pantex"); accordingly, a determination of health endangerment was not required.

CONTEST OF DECISION

In a letter dated November 14, 2013, petitioner [REDACTED], filed a challenge to the September 30, 2013, 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 SEC, 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 Panel wishes to provide a full and satisfactory response to the petitioner. Although we cannot answer the questions raised in the petitioner's appeal letter that are outside the scope of our review, we have responded to those questions that are within our purview. We interpret the letter as raising two relevant points:

1. An allegation that there is "...no evidence that records adequate for dose reconstruction were found or considered for all those employees at risk following documented exposure to radiation";
2. An allegation that "For production, maintenance and waste remediation workers, the exposures appear to have been direct and indirect, routinely unguarded, uncommonly monitored, [and] mostly unrecorded..."

The Panel addresses these allegations through its review of the National Institute for Occupational Safety and Health (NIOSH) findings, which were incorporated into the Secretary's September 30, 2013, determination.

ADMINISTRATIVE REVIEW PANEL

Pursuant to 42 CFR § 83.18(b), the Secretary appointed a panel of three Department of Health and Human Services (HHS) personnel, independent of the 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, John Koerner, MPH, CIH, Francesca Macchiarini, MS, PhD, and Donald Miller, MD, comprise that panel. Our collective expertise includes radiation medicine, occupational radiation protection, industrial hygiene, health physics, radiation exposure, dose assessment and dose reconstruction, and radiation risk analysis. The panel was charged with conducting an administrative review of the determination not to add a class of Pantex employees to the SEC, which included reviewing the data and information that formed the basis of the prior decision.

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 Report, 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 petitioner from introducing any new information or documentation, our review was based entirely on the administrative record in this case, as described above. The Panel did not have access to any classified material; the review was conducted based solely on the unclassified material.

STANDARD OF REVIEW AND MAIN CONCLUSION

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. We also reviewed the principal findings and recommendations of NIOSH and the Board. As explained below, we concluded that petitioner's challenge does have merit and, thus, we recommend a revision to the Secretary's September 30, 2013, determination that denied adding a class of Pantex employees to the SEC.

SUMMARY OF THE PRIOR DETERMINATION

A memorandum to the Secretary, dated September 13, 2013, from the Director of NIOSH states that NIOSH concluded that dose reconstruction is feasible for all Pantex employees who worked from January 1, 1951, through December 31, 1957. This finding was based on the full administrative record, including the NIOSH Evaluation Report for the Pantex Plant, SEC Petition Evaluation Report: Petition SEC-00068, Report

Rev. #0, (August 8, 2008), (hereafter "Pantex Evaluation Report"), which evaluated the feasibility of reconstructing doses for all employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, from January 1, 1951, through December 31, 1957. Specifically, this memorandum states as follows:

Based on its full review of the SEC petition 00068, NIOSH determined:

- 1. The principal source of internal radiation dose for workers at Pantex during the years from 1951-1957, was depleted uranium.*
- 2. It was confirmed that there were no weapons system dismantlements before 1958. Fresh depleted uranium (DU) forms were handled, but there is no evidence of exposure potential because of the negligible amount of oxidation present. The burn pits and hydroshot testing involved DU, but there are sufficient air sampling data available to NIOSH to support dose reconstruction. The Board concurred with NIOSH's finding that dose reconstruction for internal uranium exposures during the period from 1951 through 1957 is feasible.*
- 3. Consequently, NIOSH finds it is feasible to estimate, with sufficient accuracy, the internal dose for workers at the Pantex Plant from January 1, 1951, through December 31, 1957.*
- 4. NIOSH has access to sufficient personnel monitoring and workplace monitoring data to bound potential external exposures for workers at the Pantex Plant during the period from January 1, 1951, through December 31, 1957. NIOSH also finds it is feasible to reconstruct occupational medical dose, when appropriate, for this period. Consequently, NIOSH finds that it is feasible to estimate, with sufficient accuracy, the total external dose and occupational medical dose for the class of employees covered by this evaluation.*
- 5. In sum, NIOSH determined that it has access to sufficient site-specific 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 workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957; or (2) estimate the internal and external radiation doses to workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957, more precisely than a maximum dose estimate. The Board also concurred with this determination.*

FINDINGS OF THE ADMINISTRATIVE REVIEW PANEL

The Panel recognizes that the radiation protection practices used at Pantex from 1951

to 1957, while inferior to today's best practices, were consistent with the practices in widespread use at the time. With respect to the five points above, we have separated out each of NIOSH's findings and conclusions into individual bullet points, and provide the following comments for each bullet point as part of our review and analysis:

- A. *The principal source of internal radiation dose for workers at Pantex during the years from 1951-1957, was depleted uranium.*

The Panel agrees that the principal source of internal radiation dose for workers at Pantex during the years from 1951-1957 was depleted uranium. However, it was not the only source; tritium was also a source and first arrived at Pantex in late 1956 or early 1957. See Technical Basis Document ORAUT-TKBS-0013-1, "Pantex Plant – Introduction", Rev. 02, (May 11, 2007), at 8. Further, the Technical Basis Document ORAUT-TKBS-0013-5, "Pantex Plant – Occupational Internal Dose", Rev. 01, (June 22, 2007), § 5.2.2.1 at 20 (hereafter "ORAUT-TKBS-0013-5"), notes that "DU manufactured after 1952 could have contained contaminants from movement of recycled U and DU throughout the Portsmouth, Paducah, K-25, Y-12 complex. Exact levels of contaminants in Pantex DU have not been discovered and probably varied from batch to batch." This section of ORAUT-TKBS-0013-5 also notes plutonium (²³⁹Pu), neptunium (²³⁷Np) and technetium (⁹⁹Tc) as contaminants.

- B. *There were no weapons system dismantlements before 1958.*

The Panel agrees that there were no weapon dismantlements prior to 1958.

- C. *Fresh depleted uranium (DU) forms were handled.*

The Panel agrees that fresh depleted uranium (DU) forms were handled.

- D. *There is no evidence of exposure potential because of the negligible amount of oxidation present [on the DU forms].*

The Panel disagrees that there is no evidence of exposure potential because of the negligible amount of oxidation present on the DU forms. The Technical Basis Document ORAUT-TKBS-0013-2, "Pantex Plant - Site Description", Rev. 02, (May 8, 2007) § 2.6 at 16, states that, "During assembly, the DU was *relatively* clean and there was minimal removable contamination." (Emphasis added). This statement is annotated (annotation [9]). Annotation [9] states, "Assemblies involved new, clean components that were *generally* free of radioactive contamination. Contamination tests were routinely done on new components and results were *usually* negative." *Id.* at 18) (emphasis added). In § 2.3.1, in the discussion of early Pantex operations, this report states, "Because these DU components were new at the time of assembly, this analysis *assumed* that removable DU oxide contamination on the components was minimal." *Id.* at 8 (emphasis added). The evidence demonstrates that there was some degree of contamination. Therefore, the explicit assumption in the analysis that DU contamination was minimal is not justified. This assumption is further weakened by the lack of worker monitoring or exposure records to support it.

- E. The burn pits and hydroshot testing involved DU, but there are sufficient air sampling data available to NIOSH to support dose reconstruction.*

The Panel disagrees that there are sufficient air sampling data to support dose reconstruction for employees involved with various burn pit and hydroshot testing operations. In the Data Capture Document: Discovery and Review, "Documented Communication ... on Weapons Disassembly Operations at Pantex," Project Document Number 030086460 (May, 26, 2011) at 4, the interviewee specifically stated that, "... Mark 6 units tended to have considerable DU oxidation." No air samples appear to have been collected to assess this potential exposure route. Additionally, for burning pad and firing site operations, air samples were collected, but only in the operations bunker area. "The burning pad operators were part of the transportation group and operating the burning pad was just a part-time task - a few hours approximately once a week. The ash was scooped up and put into 10 to 20 gallon cans for burial. The workers wore half-face, HEPA filtered masks during the collection of the ash." Data Capture Document: Discovery and Review, Project Document Number 030001035, (August 24, 2004) at 3 (hereafter "Telephone Interview of June 16, 2004"). Although the interviewee believed that these workers were subject to bioassay, there is no evidence in the record of such and no personal air samples or dosimetry were collected on anyone performing burning pad and firing site operations.

Further, with respect to the hydroshot firing sites, Telephone Interview of June 16, 2004 states, "After a denotation [sic], the operators would retrieve instruments from the firing site while the driver was returning to the area, then they all would leave. The total exposure time was less than a half-hour. The cloud from the detonations was quite visible." *Id.* Since air samples collected at the time were within the operations bunker and later air samples were collected by drones at altitude, these samples should not be used as objective data to accurately estimate or support the exposure of operators, firemen, truck drivers, firing site technicians, and others as they conducted ash removal and instrumentation retrieval following a burn or detonation as these samples do not represent actual exposure. Furthermore, the only air samples collected were area samples that would not accurately reflect breathing zone concentrations of those in the operations bunker or others as described above.

Finally, given the limited radiation controls applied during that period, the very different operations and devices handled, the near total absence of bioassay or other exposure assessment data from the period, the Panel concludes that there are significant limitations in applying data from later operations in the assessment of the exposures for operations in earlier time periods.

- F. The Board concurred with NIOSH's finding that dose reconstruction for internal uranium exposures during the period from 1951 through 1957 is feasible.*

The Panel agrees that the Board concurred with NIOSH's finding that dose reconstruction for internal uranium exposures during the period from 1951 through 1957 is feasible.

- G. *NIOSH finds it is feasible to estimate, with sufficient accuracy, the internal dose for workers at the Pantex Plant from January 1, 1951, through December 31, 1957.*

There were no contamination areas established in the early years, and individuals were allowed to eat, drink, or smoke in the work areas. S. Cohen & Associates: Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program – Draft Pantex Plant Site Expert Interview Summary, Rev. 0, (July 25, 2011) at 23 (hereafter “Pantex Plant Site Expert Interview Summary”). “In the early days, workers could have water or coffee on the bench at their work location during assembly. Workers would take their lunches into the work area and drink coffee while they were working on weapons up to the mid-1980s. The plant also allowed smoking on parts of the line and in break areas. These were common practices. Everyone knew about it and no one ever questioned it.” *Id.* at 23-24. Therefore, the Panel believes that there was substantial opportunity for oral and respiratory ingestion of uranium as a result of common work practices. ORAUT-TKBS-0013-5, § 5.2.2.1 at 21 notes that “there is no evidence that workers were routinely monitored for uranium before 1991.”

There are no personnel monitoring data upon which to base a dose reconstruction for internal uranium exposure. There is evidence of potential routes for oral and respiratory ingestion of uranium as a result of common work practices. NIOSH's assumption that removable DU oxide contamination on the components was minimal is therefore only an assumption. As noted above in response to (A), there was also potential for internal exposure to unknown amounts of ²³⁹Pu, ²³⁷Np and ⁸⁹Tc contaminants.

Minimal air sampling data are available for the operations bunker area for the burning pad and firing site operations. See bullet (E), above for further discussion. Because (a) there was a substantial opportunity for oral and respiratory ingestion of uranium as a result of common work practices, (b) there are no personnel dosimetry data for exposure during routine work practices (workers were not routinely monitored for uranium) and (c) the air sampling data used as surrogate data are not adequate to bound exposure, the panel concludes that it is not feasible to estimate, with sufficient accuracy, the internal dose for workers at Pantex from January 1, 1951, through December 31, 1957.

- H. *NIOSH has access to sufficient personnel monitoring and workplace monitoring data to bound potential external exposures for workers at the Pantex Plant during the period from January 1, 1951, through December 31, 1957.*

The Technical Basis Document ORAUT-TKBS-0013-6, “Pantex Plant – Occupational External Dose”, Rev. 01, (June 22, 2007), § 6.4 and Table 6-1, at

11-12 (hereafter "ORAUT-TKBS-0013-6"), shows that external dose data (dosimeter doses) during the period 1951-1957 are available only for radiographers. Between 1951 and 1957, only radiographers were monitored routinely, and no more than three individuals per year were monitored. At this time, there were "a few hundred personnel at the plant." Pantex Plant Site Expert Interview Summary at 17.

The job of radiographers was different from all other Pantex workers. Radiographers were not exposed to radiation because the x-ray machines were enclosed in shielded cabinets. In an interview with a former Pantex employee, a worker's response to a question about the use of lead aprons is summarized as, "X ray machines were enclosed in cabinets and were surveyed routinely" (See Data Capture Document: Discovery and Review, "Documented Communication on Dosimetry and Radiological Controls at the Pantex site," Project Document Number 030032527, (April 7, 2008) at 4, (hereafter "Documented Communication"). The same individual also noted that, "all of the X-ray machines were placed in enclosed cabinets," implying that there was no potential for exposure to radioactivity. *Id.* at 4. Similarly, ORAUT-TKBS-0013-6, § 6.5.5.6, at 37, states that "radiography machines were inside shielded facilities."

ORAUT-TKBS-0013-6, § 6.5.4.1, at 25-26, states "significant beta exposures to Pantex workers were rarely detected by film badges or thermoluminescent dosimeters, based on a review of shallow and deep dosimetry data." This statement regarding beta exposures cannot refer to workers other than radiographers in the period 1951-1957, as only radiographers were issued dosimeters during this time period.

ORAUT-TKBS-0013-6, § 6.7.1, at 43, advises, "For years before 1959, when no measured gamma dose equal to or greater than 40 mrem was measured, use the median dose for 1960 for each year of employment." However, for the period 1951-1957, the only monitored workers who could have had measured gamma doses were radiographers, whose job was different from all other Pantex workers. There are no dosimetry data for the hundreds of other workers at the site.

Other Pantex workers were exposed to radiation. ORAUT-TKBS-0013-6, § 6.6.2, at 40, notes that, for the sample of 316 claims by Pantex workers evaluated, "most of the collective dose was received by assembly, inspection, and warehouse operators." (See also *Id.* at 41, Table 6-16.) None of these workers were issued dosimeters during the period 1952-1957. ORAUT-TKBS-0013-6, § 6.4, at 11-12. In addition, the record establishes that there were "ladies doing inventory of devices and receiving significant exposure." Documented Communication at 5. The Panel is unable to identify evidence in the record that this scenario is incorrect or was disproven. The Pantex Plant Site Expert Interview Summary at 16, states, "Workers routinely functioned outside of their job titles performing work for which they had appropriate clearance and qualifications. For example, office staff sometimes transported material and parts from storage or labs to assembly points, or the reverse. Production

Technicians assisted with inventories. When available, personnel helped out where they were needed." None of these workers were issued dosimeters during the period 1952-1957. ORAUT-TKBS-0013-6, § 6.4 at 11-12.

ORAUT-TKBS-0013-6, § 6.5.4.1, at 25, states "A bare slab source of DU contributes an $H_p(0.07)$ dose of approximately 200 mrad/hr at the surface (BRH 1970) compared to an $H_p(10)$ dose of approximately 2 mrad/hr (ORAUT 2004a)." "Beta radiation from DU could contribute to extremity and skin dose to workers unless precautions were taken to protect workers from the radiation. Protective clothing and gloves provide a protection factor of 2 or more, depending on the thickness (DOE 2000)." *Id.* No information on protective clothing for workers is provided in the record for the period 1951-1957, except for the mention that "Lead aprons were available to early radiography workers at Pantex. ... the use of lead aprons was not included in procedures until the mid-1980s." ORAUT-TKBS-0013-6, § 6.5.5.6, at 37. "One long-term worker indicated that when he initially started work at Pantex in the early days, they did not wear gloves or lead aprons, or use shielding. Nowadays, Pantex would require a worker to wear lead aprons, leaded glasses, and leaded gloves. During pit vault inventories, one worker reported wearing street clothes, safety shoes, and safety glasses, while his coworker wore cotton coveralls with underclothes underneath." Pantex Plant Site Expert Interview Summary at 24. Even when provided, use of protective clothing was not standard procedure in the 1950s. "Although lead aprons were provided to workers, there was no requirement to wear them; thus, not all workers wore them. No training on the aprons was provided." *Id.* at 25. The panel is unable to identify any evidence that Pantex workers other than radiography workers were provided with any protective clothing or gloves, or that their use was required.

It is apparent from the record that there were substantial changes in the use of protective clothing and radiation monitoring after 1958, so data from later years cannot be applied appropriately to earlier years as surrogate data for dose reconstruction. ORAUT-TKBS-0013-6, § 6.5.2, at 16 states, "Pantex Plant dosimetry methods evolved with the development of improved technology and a better understanding of the complex radiation fields encountered in the workplace." During 1952-1957, a Safety Engineer "oversaw Radiation Safety in addition to several other safety disciplines." Pantex Plant Site Expert Interview Summary, at 17. A health physicist was not hired until about 1970. *Id.*

Even after 1957, when plutonium was present at the plant, workers were not appropriately educated with respect to radiation hazards: "The workers had no concept of the degree of hazard. Originally, the workers were not aware they were working with plutonium. The plant was not required to tell the workers what they were working with." *Id.* at 18. Even in later years, when dosimeters were issued to other workers and not just radiographers, compliance was not universal. "The actual use of extremity dosimeters at Pantex has not always been rigorously managed, and there were times when workers did not wear the assigned extremity dosimeters." ORAUT-TKBS-0013-6, § 6.7.6, at 50.

Because (a) only radiographers were monitored during the period 1951-1957,

(b) radiographers were not exposed to radiation because the x-ray machines were enclosed in shielded cabinets, (c) other workers were exposed to radiation but were not monitored, (d) there is no evidence that workers other than radiographers were provided with protective clothing during the period 1951-1957, and (e) work practices changed after this time period so that surrogate data from a later time period cannot be used to reconstruct the dose that Pantex employees encountered during an earlier time period, the Panel concludes that it is not feasible to estimate, with sufficient accuracy, the external dose for workers at Pantex from January 1, 1951, through December 31, 1957.

Also see discussion under (J), below.

- I. NIOSH finds it is feasible to reconstruct occupational medical dose, when appropriate, for this period.*

The Panel agrees that it is feasible to reconstruct occupational medical dose, when appropriate, for the period from January 1, 1951, through December 31, 1957.

- J. NIOSH finds that it is feasible to estimate, with sufficient accuracy, the total external dose and occupational medical dose for the class of employees covered by this evaluation.*

The Panel believes that it is feasible to reconstruct occupational medical dose for workers at the Pantex Plant from January 1, 1951, through December 31, 1957, but the Panel concludes that it is not feasible to estimate, with sufficient accuracy, the total external dose for the class of employees during this same time period.

- K. In sum, NIOSH determined that it has access to sufficient site-specific 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 workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957; or (2) estimate the internal and external radiation doses to workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957, more precisely than a maximum dose estimate.*

The Panel concludes (a) that there is insufficient site-specific information to estimate the maximum internal and external radiation dose for every type of cancer for which radiation doses that could have been incurred under plausible circumstances by workers at Pantex for the time period from January 1, 1951, through December 31, 1957, and (b) that there is insufficient site-specific information to estimate the internal and external radiation doses to workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957, more precisely than a maximum dose estimate.

The Panel has made this determination based on:

1. The presence of uranium, tritium, and possibly other radionuclides in the plant during that period.

2. The limited radiation controls applied during that period.
3. The conduct of operations with exposure potential beyond radiography, such as handling DU forms, various burning pad and hydroshot operations and other non-characterized operations.
4. The near total absence of bioassay or other exposure assessment data from the period.
5. Limitations in applying objective data from later operations given the very different operations and devices handled, controls in place, and sophistication of the overall radiation safety program

L. *The Board also concurred with this determination.*

The Panel agrees that the Board concurred with NIOSH's determination.

ADMINISTRATIVE REVIEW PANEL CONCLUSIONS

In our review of this case, we have concluded that:

1. HHS complied with the regulatory procedures set out in 42 CFR part 83;
2. The Secretary's prior decision was not supported by factually accurate information;
3. There were errors of fact or omission in the principal findings and recommendations of NIOSH and the Board;
4. Therefore, the petitioner's two relevant allegations raised in the appeal have merit.

SUMMARY AND RECOMMENDATIONS

Based upon our review of the administrative record in this case, this Panel believes that the regulatory procedures have been complied with as set out in the EEOICPA implementing regulations at 42 CFR parts 82 and 83. However, the Secretary's decision to deny SEC status to the workers at the Pantex Plant for the time period from January 1, 1951, through December 31, 1957, was not supported by factually accurate information.

The Administrative Review Panel has concluded that the petitioner's challenge has merit, and we recommend that you revise the September 30, 2013, determination that denied SEC status to the class of employees who worked at the Pantex Plant from January 1, 1951, through December 31, 1957.

Respectfully submitted,

Signature on File

Francesca Macchiarini, MS, PhD
Radiation and Nuclear Countermeasure Program
National Institute of Allergies and Infectious Diseases
National Institutes of Health

Signature on File

Donald L. Miller, MD FACR
Chief Medical Officer for Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration

Signature on File

John F. Koerner, MPH, CIH
Chief, Chemical, Biological, Radiological, Nuclear, and Explosives Branch
Office of Emergency Management
Assistant Secretary for Preparedness and Response

Attachment:

Petitioner's Appeal Letter dated November 14, 2013



November 14, 2013

To: Jennifer M. Cannistra
Ex. Sec'y DHHS
Room 603H
200 Independence Ave, S.W.
Washington, DC 20201

Re: Secretary's determination excluding from Pantex SEC workers employed 1951 - 1957

Petitioner's Request for an Administrative Review [#SEC00068]

Our prior letter of November 6, 2013 sought additional information illuminating the empirical basis for the NIOSH recommendation to the Secretary. Both what we received and failed to receive justifies this appeal for reconsideration of the Secretary's exclusion from the existing SEC of those employed at Pantex in the years 1951 through 1957.

The fast and courteous reply, we gratefully acknowledge, directed us to the published record: two transcripts and the regulations on conflict of interest. A review of that material reveals no evidence that records adequate for dose reconstruction were found or considered for **all** those employees at risk following documented exposure to radiation. Thus, in addition to recollections of interviewed workers from that era,¹ we reviewed EPA's Pantex Superfund Site Report of 09/10/2013 on activities begun in 1951. This generated two unanswered questions:

- Waste management was restricted to the site, requiring **remediation workers** on site. Ought not the record display the presence of these workers and the absence of their records, and recollection or notation of the presence or absence of personal protective equipment and environmental monitoring (personal or area) for these workers?
- Waste waters and solids included "**depleted uranium**". (EPA p5) and "**releases to soils ... pose a direct contact risk to onsite workers.**" (EPA

¹ The writer, in [REDACTED] interviewed Pantex workers, family and peers in evaluating community resources of the Texas-New Mexico region, noted in commendations of the Attorney General, State of New Mexico and USEPA.

p4) Other than a discussion of natural background sources, why is there no discussion in the transcripts of this **additional** exposure issue?

The publicly-accessible transcripts [6/18/13 & 7/17/13] of meetings of the Board and it's Investigating committee provide **no evidence that radiation records of all workers including remediation workers from the era in contention were discussed or sought.**

Pantex never was just a warehouse or passive shipping point. In the second transcript of 7/17/13, Fitzgerald makes clear to the Board what actual industrial activity took place from the beginnings of operations, which necessarily resulted in radiation exposure: the "first depleted uranium forms arrived at Pantex in 1951 ... they were mating the depleted uranium with high explosives." [p58]

In the first transcript of 6/18/13, the Chair of the Investigating committee, Mr. Clawson, says [pp35-36] that exposures [by implication of all workers] "were never discussed at that time ... because the uranium and the HE were bonded together" The inference is that in this process the physical state of the uranium permitted complete contaminant containment. This belief is refuted by Mr. Fitzgerald.

Fitzgerald discusses [pp 37-45] **visual evidence of oxidation**, which he characterizes as being "minor". BEIR reports of the National Academy of Science on the sources and effects of low levels of radiation, with which he is familiar, lead us to assume that he must mean "minor" relative to the function of the weapon, not as a source of chronic radiation exposure. Even the low levels of radiation from radioactive flakes resulting from oxidation and deposited in the respiratory system during long-term continuous exposure and contact with the metallic source may result in significant elevated risk.

Fitzgerald does note exposure-resulting "incidents". [p43] These "**incidents**" occurred in "**mating high explosives to depleted uranium.**" [p45] He asserted that "major handling" may not have taken place during mating. Apparently, "major" events as judged by Mr. Fitzgerald [p44], did not include this revealing assessment: "**you could lift the unit up and the DU would just fall out.**" [p54]

For production, maintenance and waste remediation workers, the exposures appear to have been direct and indirect, routinely unguarded, uncommonly monitored, mostly unrecorded, to be assessed not empirically, but by **extremes of professional judgment** expressed in the construction and application of hypothetical models of population exposure, supposedly enabling calculations of probabilities of causation for any individual in the population.

The Secretary ought to note the absence of any discussion by the Board in its public transcript of this subjective process of judgment in which numbers are used in an arithmorphic fallacy noted and rejected by a joint committee of the National Institutes of Health and the National Academy of Science as an **inappropriate, un-heuristic exercise.**

It is true that the joint committee does not write laws, and the agency is bound to the law. However, 1) it is a mistake, **an error**, not to report their opinion to the Congress, and 2)

October 7, 2016

The Honorable Sylvia M. Burwell
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Pantex Plant Special Exposure Cohort Administrative Review Panel

Dear Madam Secretary:

In our letter of February 19, 2016, we noted the standard of review that applies to appeals filed under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). Specifically, pursuant to 42 CFR § 83.18(b), administrative review panels “shall consider whether HHS substantially complied with the procedures of [42 CFR part 83], the factual accuracy of the information supporting the final decision, and the principal findings and recommendations of NIOSH and those of the Board. . . .” Using this standard, in our original report, we stated the following conclusions:

1. HHS complied with the regulatory procedures set out in 42 CFR part 83;
2. The Secretary’s prior decision was not supported by factually accurate information;
3. There were errors of fact or omission in the principal findings and recommendations of the National Institute for Occupational Safety and Health (NIOSH) and the Advisory Board on Radiation and Worker Health (the Board).
4. Therefore, the petitioner’s two relevant allegations raised in the appeal have merit.

On September 21, 2016, we had the opportunity to engage in a productive conversation with NIOSH regarding these conclusions, and we offer this addendum to our letter to further clarify our second and third conclusions. As articulated by John Howard, Director of NIOSH, in his letter of July 1, 2016, what we have characterized as factual errors is an acknowledgement that certain data and facts regarding the history of early operations at the Pantex Plant do not exist or are substantially conflicting in the record available to us. From our review of the administrative record as provided to us by NIOSH, we were unable to agree with the recommendations of NIOSH and the Board that internal dose reconstruction is possible for employees in the January 1, 1951, through December 31, 1957 time period. To be clear, our conclusions focus on and are derived from the record. These conclusions in no way reflect negatively upon the scientific integrity of NIOSH, NIOSH scientists, the Board, or the important work that they perform.

The Panel’s unanimous conclusions, based upon the standard of review, reflect only the insufficiency of the record, which does not permit us to confirm “the factual accuracy of the

The Honorable Sylvia M. Burwell—Page 2

information supporting the final decision.” 42 CFR § 83.18(b). Furthermore, the omissions in the data and historical facts were such that we could not confirm that the record supported “the principal findings and recommendations of NIOSH and those of the Board. . . .” *Id.*

We would like to take this opportunity to thank NIOSH, particularly Mr. Stuart Hinnefeld and Dr. James Neton, for a productive conversation about this issue. They care passionately about this important program, and serve you and the affected energy employees well. We would also like to thank Dr. Wanda Jones for facilitating the September 21, 2016, conversation with NIOSH, as well as skillfully managing the administrative review process.

Thank you for the opportunity to serve on this interesting and important panel.

Respectfully submitted,

Signature on File

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TO: Dr. Wanda Jones

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

DATE: October 24, 2016

SUBJECT: Pantex Plant Special Exposure Cohort (SEC) Petition Administrative Review
Panel's Final Recommendation to the Secretary

Thank you for sharing the Pantex Plant SEC Petition Administrative Review Panel's ("the Panel") October 7, 2016, letter to the Secretary. I particularly want to thank you for facilitating a meeting between NIOSH and the Panel on September 21, 2016. During that meeting, the Panel clarified its findings and discussed the basis for its conclusions. As an outcome of the meeting, NIOSH now understands the Panel's finding that the administrative record is insufficient to permit them to confirm the factual accuracy of the information supporting the Secretary's final decision, the principal findings and recommendations of NIOSH, and those of the Advisory Board.

In light of the Panel's conclusions, NIOSH concurs that it is appropriate for the Secretary to conclude that it is not feasible to reconstruct internal exposures to uranium during the years 1951 through 1957. Therefore, NIOSH also recommends that the Secretary revise her prior decision and add the following class of Pantex Plant workers to the SEC:

"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 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 SEC."

I would like to thank the Panel members for their hard work and dedication to this administrative review. It is clear to me and others at NIOSH that the Panel members took this matter very seriously and conducted a thorough and complete review of the record and issues before them.

Thank you again for your assistance with the administrative review process, and congratulations on your new assignment. I hope we will work together again in the future.