

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

NOV 0 2 2018

Dear

Thank you for your request for an administrative review of the December 21, 2016, determination not to add a class of employees from the Blockson Chemical Company, Joliet, Illinois, 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 employees of the Department of Health and Human Services (HHS), 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.

After reviewing the administrative record in this case, the panel concluded that: (1) HHS complied with the regulatory procedures set out in 42 CFR part 83; (2) the Secretary's prior decision was supported by factually accurate information; and (3) there were no errors of fact or of omission in the principal findings and recommendations of NIOSH and the Advisory Board on Radiation and Worker Health. In summary, the panel concluded that your challenge to the December 21, 2016, decision should not be sustained and it has recommended no change to that decision to deny adding a class of Blockson Chemical Company employees to the SEC.

After review of the administrative review panel's thorough report, I have decided not to revise the December 21, 2016, final decision. I am enclosing a copy of the administrative review panel's final report, which I hope you find helpful.

Sincerely, [Signature on File]

Alex M. Azar II

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

October 4, 2018

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

RE: Blockson Chemical Company Petition SEC-00225 - Special Exposure Cohort Administrative Review Panel

Dear Mr. Secretary:

BACKGROUND

The Blockson Chemical Company (also known as Olin Mathieson, but referred to as Blockson hereunder) in Joliet, Illinois extracted and processed uranium from phosphate ores, beginning in the 1950s. Radiation exposure to workers at Blockson constituted conditions that could be considered as possible grounds for compensation under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). As described below, successive Special Exposure Cohort (SEC) petitions, SEC-00058 (which was merged with SEC-00045) and SEC-00225, were submitted to the National Institute of Occupational Safety and Health (NIOSH) for review of the exposure conditions and for consideration with respect to compensation under the EEOICPA.

Petition SEC-00058

Petition SEC-00058 sought the creation of an SEC that would include All Atomic Weapons Employer (AWE) workers at the Blockson Chemical Company from January 1, 1951, to December 31, 1962. The NIOSH Evaluation Report (ER) for SEC-00058 was issued in July 2007. That evaluation was based on the assumption that uranium production at the Blockson Chemical site ended in March 1962. However, in March 2010, based on information regarding the Blockson uranium production and contract periods, the facility listing for Blockson was changed by the Department of Labor (DOL)¹ and/or the Department of Energy² to an exposure

¹ Document SRDB 146542, p. 4 (of pdf). The designation references the date June 20, 1960. For the purposes of this recommendation, the Panel assumes that this was a typographical error, and the intended date was June 30, 1960. Note that citations throughout this report correspond to the names of electronic files in the NIOSH administrative record.

² Document SRDB 106641, p. 4 (of pdf).

period of March 1951 through June 30, 1960. See Blockson ER Final 090815, page 9.

Based on its own technical evaluation, NIOSH recommended that internal dose reconstruction for members of the proposed class was feasible, thus negating the need for creation of an SEC. However, a majority of the Advisory Board on Radiation and Worker Health (the Board) found it was not feasible to reconstruct radiation doses associated with exposure to radon gas and its short-lived progeny with sufficient accuracy for the period from March 1, 1951, to June 30, 1960. Subsequently, both the Board and NIOSH recommended the designation of an SEC and on September 3, 2010, as authorized by EEOICPA, 42 U.S.C. § 7384q, the Secretary of Health and Human Services (HHS) at that time, Kathleen Sebelius, designated Blockson petition SEC-00058 for addition to the SEC. See id. at pages 9-10; see also SRDB 146542.

This designation was made pursuant to 42 U.S.C. § 7384q, in which a class may be designated for addition to the SEC if the Secretary determines, upon recommendation of 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 decision was the determination that it was not feasible to estimate with sufficient accuracy the radiation doses encountered by employees at Blockson during the specified time-period. See id.

Blockson Petition SEC-00225

On February 24, 2015, NIOSH received another SEC petition for the Blockson Chemical Company site and qualified the petition for further evaluation on May 5, 2015. The petition, SEC-00225, requested that NIOSH evaluate whether "All maintenance and operations personnel who worked in any area at Blockson Chemical Co. in Joliet, Illinois, from July 1, 1960, through December 31, 1991," should be added to the SEC. NIOSH determined that it could not differentiate doses received by different categories of employees, so it modified the petitioner-requested class to include all employees, i.e., "All employees who worked in any area at the Blockson Chemical Co. site in Joliet, Illinois, during the period from July 1, 1960, through December 31, 1991." NIOSH determined through its research that it had access to sufficient monitoring records, process descriptions, and source-term data to estimate radiation doses to employees, thus negating the need and requirement to create an SEC. The Board confirmed their agreement with the NIOSH findings on October 20, 2016. See NIOSH OD Recommendation to HHS.

On December 21, 2016, the Secretary of HHS at that time, Sylvia M. Burwell, determined that Blockson petition SEC-00225 did not meet the statutory criteria for addition to the SEC.

REQUEST FOR ADMINISTRATIVE REVIEW

In a letter date-stamped by HHS on May 16, 2017,

wrote to Ann

Agnew, Executive Secretary to HHS, to discuss their earlier submitted request for an

administrative review of SEC-00225 and the fact that they subsequently learned their appeal had not been received in a timely matter for consideration. A copy of petitioners' appeal letter is attached. In their letter of May 16, the petitioners submitted evidence regarding the timely submission of their request for review. The request was deemed timely filed by HHS.

The petitioners' appeal letter focused on two points: 1) the apparent failure of NIOSH and the Board to address the radioactive material and concomitant doses due to the continued presence of equipment as mentioned in the 1978 Formerly Utilized MED/EC Sites Remedial Action Program Radiological Survey of the site conducted by Argonne National Laboratories (ANL)³, and 2) the actual date on which Atomic Energy Commission (AEC) contract work at the facility ceased. Regarding the latter issue, which the Panel construed to be of primary importance, the petitioners wrote: "We still feel, at a minimum, considering the above facts, the SEC should be extended back to the original contract ending date of March 31, 1962." In effect, such an extension would increase the length of time of the exposure period from June 30, 1960, to March 31, 1962, thus allowing for the inclusion of their father into an SEC.

ADMINISTRATIVE REVIEW PANEL

In October 2017, pursuant to 42 CFR § 83.18(b), the Secretary appointed a panel of three HHS personnel, independent of NIOSH, to conduct an administrative review and provide recommendations concerning the merits of the request and the resolution of the issues contested by the request. The undersigned, Steven L. Simon, PhD, Eric J. Bernhard, PhD, and James J. Cherniack, Certified Health Physicist, comprise that panel. Our collective expertise includes health physics, radiation exposure, radiation biology, dose assessment and dose reconstruction, radiation oncology, and radiation risk analysis.

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

³ Document SRDB 23615. To address this issue, which the Panel interprets as not the main area of concern, the Panel reviewed the evaluation report generated by NIOSH and found that the 1978 ANL survey was used to calculate the bounding doses to facility workers. See Blockson ER Final 090815, at pp. 17, 19-20, 23, 28, 30-32. In particular, see section 7.4.1 of the ER (addressing "Equipment and Production Buildings Onsite after Production Ended") which concludes: "For purposes of bounding exposure to AEC-related residues during the period under evaluation, the conservative assumption is made that all radiation measurements made in Building 55 are assumed to indicate levels arising from residual radioactivity remaining from AEC operations." *Id.* at 33. In addition, the administrative record clearly shows that the 1978 ANL survey findings were presented to the Board by Dr. James Neton, Associate Director for Science, NIOSH, at the November 19, 2015 meeting of the Board. *See* 2015_11_19 Board transcript, at pp. 6-30; Blockson Chemical Co. SEC Presentation (November 2015, Oakland CA) (slides 13-18).

petitioners from introducing any new information or documentation, our initial review was based entirely on the administrative record in this case, as described above.

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 and factual information. We also reviewed the principal findings and recommendations of NIOSH and the Board.

We believe that this Panel was broadly charged with conducting an administrative review of the Secretary's determination not to add a class of Blockson employees to SEC-00225 for the period of July 1, 1960, through December 31, 1991, and the basis for that determination. Implicit in the SEC-00225 determination, however, is that there was no active uranium extraction during that period and that exposure was only from constrained (unavailable and/or undisturbed) residual radioactivity in the facility. However, the Panel took under consideration what we believe was the petitioner's actual request (though stated in indefinite terms): In SEC-00225, change the defined time interval to be two adjacent periods, the first being a period of exposure due to AEC contract work for uranium extraction (July 1, 1960, to March 31, 1962) followed by a subsequent period (April I, 1962, to December 31, 1991) when exposure was only due to constrained residual radioactivity. Based on our interpretation of the petitioners' letter, we defined our tasks to be two-fold: (i) review the finding of NIOSH and the Board that dose reconstruction for July 1, 1960, through December 31, 1991, was feasible under the assumption that only exposure to constrained or undisturbed residual radioactivity was involved, and (ii) review the documentation that AEC contract activities had actually ceased by June 30, 1960, as well as documentation related to whether there was any unconstrained residual activity (activity available for human exposure) still present at Blockson after July 1, 1960.

As part of what we, the Panel, believed to be our charge, we conducted an extensive review and analysis of the administrative record documents provided to us in regard to the operating status of the uranium processing operations at Blockson between July 1, 1960 and March 31, 1962. In those documents, we found contradictory evidence and no confirmation that operations had ceased. Consequently, on May 1, 2018, we preliminarily concluded that the Secretary had insufficient evidence that AEC operations had ceased at Blockson.

In September 2018, we received a copy of a letter dated September 4, 2018, from Rachel P. Leiton, Director, Division of Energy Employees Occupational Illness Compensation, Department of Labor (DOL) to Mr. Stuart Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, giving information previously unavailable to us. That letter elucidated that the Department of Labor has the sole legal authority, conferred by Executive Order 13179, § 2(a)(i), to make determinations regarding covered periods for work sites under EEOICPA. Moreover, the letter explained that the DOL had made the determination that uranium processing operations and, therefore, AEC activities at Blockson, had ceased by June 1960, based on an official AEC document located in a collection of Department of Energy historical records held in Grand

Junction, Colorado. This AEC document, which is a table entitled "Receipts of U308 from Phosphate and Other Miscellaneous Domestic Sources," was included as Exhibit C of petitioners' appeal letter, and also part of the administrative record (Document SRDB 40645). Validation of the source of that table had not previously been available to us for review, nor had we been made aware of its official provenance. The Iawful and final decision by the DOL that uranium operations had ceased during the period for which we had earlier determined there was no reliable documentation considerably changes the outcome of our analysis and our preliminary conclusions.

ADMINISTRATIVE REVIEW PANEL CONCLUSIONS

After thorough review of the administrative record documents provided, we, the Panel, have come to a final conclusion regarding the petitioners' main issue on appeal.⁴

We agree with the determination that estimation of dose by the NIOSH is feasible for the period during which exposure only occurred from constrained residual activity. This is our primary conclusion.

Because we were unaware of the provenance of the main evidence establishing the official period of uranium extraction operations, we considered recommending the addition to the SEC of a class of employees who worked at Blockson between July 1, 1960, and March 31, 1962. Such a recommendation would have been based on the conclusion that it may not have been feasible to estimate with sufficient accuracy the radiation dose that the class of Blockson employees received during this time-period. However, in light of the information provided in the letter from DOL, this Panel no longer supports that contention.

In summary, this Panel supports the NIOSH finding that dose reconstruction is feasible in the period defined in SEC-00225 under the strict assumption that exposure resulted only from constrained and undisturbed residual activity, which DOL concluded was the case in designating the operational and residual periods at Blockson. Consequently, because we believe dose reconstruction was feasible during this time, this Panel supports Secretary Burwell's prior decision to deny SEC status for the class of employees who worked at Blockson during the period July 1, 1960, to March 31, 1962, and we recommend that this prior decision be upheld.

SUMMARY AND RECOMMENDATION

The findings and conclusions presented here are based on the Panel's review of the administrative record available to it, and on additional information provided by DOL in September of this year to provide context to the record.

Consequently, our main conclusions are:

⁴ The Panel additionally concluded that the first issue raised by petitioners related to the 1978 ANL survey did not have merit. See supra, note 3.

- 1. HHS complied with the regulatory procedures set out in 42 CFR part 83;
- 2. The Secretary's prior decision was supported by factually accurate information;
- There were no errors of fact or of omission in the principal findings and recommendations of NIOSH and the Board;
- 4. The petitioners' appeal, therefore, does not have merit.

Respectfully submitted,

[Signature on File]

Steven L. Simon, PhD
Staff Scientist
Epidemiology and Biostatistics Program
Division of Cancer Epidemiology and Genetics
National Cancer Institute/National Institutes of Health

[Signature on File]

Eric J. Bernhard, PhD
Chief, Radiotherapy Development Branch
Radiation Research Program
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[Signature on File]

James J. Cherniack, CHP
Laser Safety Officer
Engineering Branch
Winchester Engineering and Analytical Center
Office of Regulatory Affairs
U.S. Food and Drug Administration

Attachments:

Petitioners' Appeal Letter date-stamped May 16, 2017 (without exhibits)

Request of Administrative Review-2017 SEC-00225

Per my recent conversation with Janet East, please find attached, our original appeal for administrative review of SEC-00225 for Blockson Chemical

. We were told that the case was closed because we failed to file an appeal in the time required. However, we do have the letter from the U.S. Post Office attached indicating package as received on 1/23/2017. (a full week within the 30 day limit). The letter from the post office indicates it was signed for at

11:06 am on 1/23/2017 and assigned a Firm Book ID Label #5103-OSHJ8818-1756-

I also spoke with Vanessa Jones and she could not tell where it was delivered. Vanessa also advised me to put this to the attention of Jamar Hawkins, since he is the person that directs the mail to the appropriate departments. This time I will follow up immediately after the package is signed for to make sure it was delivered to the correct department. If there is any way you or someone in your department could call or email me to verify you received this that would also be greatly appreciated.

Thank you in advance for your assistance,

7334.

REQUEST FOR ADMINISTRATIVE REVIEW ~ 2017

SEC - 00225

We still have the following concerns that were not addressed in our SEC petition for Blockson Chemical.

- The SEC petition was apparently considered due to residual contamination that would result from all equipment still being on site as mentioned in 1978 Argonne study- See Exhibit B. This was also mentioned as part of the reason for SEC consideration in a letter from Congressman Bill Foster and from Congressman Adam Kinzinger to NiOSH – See Exhibit A. There was no mention made of the equipment still being on-site as of 1978 by the Advisory Board and NiOSH during the Blockson SEC discussion.
 - During the Advisory Board and NIOSH meeting, the main topic of discussion was the Gypsum Waste Pile on site. They all seemed to agree this was of little concern. They also said there was a <u>very, very low level of contamination</u>, barely above background level in approximately five locations at Blockson. This however seems to contradict the 1978 Argonne Report that mentions over forty-seven hot spots and eleven other areas all clearly in excess of background levels See Exhibit B.
- The one page document receipts of U308 was the sole report that was relied on to change Blockson ending date from 1962 to 1960, even though the first ten years of dose reconstructions were based on data indicating a contract end date of 1962. (This shortened the coverage period by twenty-one months.)
 See exhibit C.

Reports indicate that either party could terminate contract early, with written notice So far no one has been able to provide a copy of the written notice of request for early termination by Biockson. We have also not seen any documents supporting a contract end date of 1960, other than in this one page unsupported document of unknown origin. This one page document was considered precise and above reproach by D.O.L and D.O.E and was also considered official written notice of early termination by Rachel Leiton, Director D.O.L.

However, we have found a 6 page report with a cover letter from US Atomic Energy Commission dated 1955 that seems to contradict certain items in the one page "precise and above reproach" U308 Report. This 6 page report indicates apparent errors in the one page U308 Report — See Exhibit D.

Briefly the errors are as follows and are highlighted in yellow on both reports:

The one page report indicates production for Texas City in March 1954, however all production ended in 1953, with a total of only three months of production and only 300-400 lbs of U308 produced according to the 6 page report. The Texas City SEC even

extended the production coverage period another twenty-one months beyond this date, (September 30, 1955), even though nothing was produced during leach zone studies. This does not seem to fit the definition of Atomic Weapons Employer as applied to Blockson – See Exhibit F

The one page report indicates international Mining and Chemical produced 853 lbs of U308 in FY 1954, which was actually 6,242 lbs per 6 page report. The one page report also indicates none was produced in FY 1955, which was actually 5,880 lbs produced per 6 page report. If any part of the one page document of unknown origin is incorrect, the accuracy of the entire document is questionable.

Ombudsman Malcom Nelson D.O.L. in a 2014 email response to our concerns also questioned the reliance of the one, one page report, stating it would be hard to imagine DEEOIC crediting such evidence if it were submitted by a claimant. See Exhibit E.

We still feel, at a minimum, considering the above facts, the SEC should be extended back to

the original contract ending date of march 31, 1962.