



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

MAY 15 2015

Dear Ms.

Thank you for your request, on behalf of yourself and co-petitioner _____, for an administrative review of the December 7, 2012, determination not to add a class of employees from the Weldon Spring Plant, Weldon Spring, Missouri, 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.

After reviewing the administrative record in this case, the panel concluded that: (1) HHS substantially complied with the regulatory procedures set out in 42 CFR part 83; (2) the 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 your challenge to the December 7, 2012, decision is without merit, and they have not recommended any change to the decision to deny adding a class of Weldon Spring Plant employees to the SEC.

After review of the administrative review panel's thorough report, I have decided not to revise the December 7, 2012, final decision. I am enclosing a copy of the administrative review panel's final report, which I hope you find helpful. I am sending an identical copy of this letter to _____.

(b) (6), your co-petitioner.

Sincerely,

[Signature on File]

Sylvia M. Burwell

Enclosure



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Sylvia M. Burwell

Enclosure



February 26, 2015

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

RE: Weldon Spring Plant Special Exposure Cohort Administrative Review Panel

Dear Madam Secretary:

On December 7, 2012, as authorized under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. § 7384q(b), the Secretary of the Department of Health and Human Services (HHS) determined that the following class of employees from the Weldon Spring Plant (hereafter "Weldon Spring"), Weldon Spring, Missouri, does not meet the statutory criteria for addition to the Special Exposure Cohort (SEC):

All employees of the Department of Energy, Department of Energy contractors, or subcontractors who worked in any area at the Weldon Spring Plant in Weldon Spring, Missouri, during the applicable covered operational period from January 1, 1957, through December 31, 1967.

Pursuant to 42 U.S.C. § 7384q(b), a class may be designated for addition to the SEC if the Secretary of HHS 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 Weldon Spring employees; accordingly, a determination of health endangerment was not required.

In a letter dated December 12, 2012, petitioners [REDACTED] (b) (6), both surviving [REDACTED] (b) (6) of former Weldon Spring employees, filed a challenge to the December 7, 2012 determination. A copy of the petitioners' 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 of [42 CFR part 83]."

The petitioners' appeal letter states: "We have several challenges to the National Institute of Occupational Safety and Health's administration of the EEOICPA of 2000. We dispute NIOSH claims that there is sufficient information to estimate radiation doses with sufficient accuracy for ALL members of the Mallinckrodt Weldon Spring Plant SEC class for the years of 1957-1966. The following letter demonstrates the justifiable reasons and the necessity for granting a Special Exposure Cohort for the Mallinckrodt Weldon Spring facility in Weldon Spring, MO."

Pursuant to 42 CFR § 83.18(b), the Secretary appointed a panel of three 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, Rosemary S.L. Wong, Ph.D., Michael A. Noska, M.S. and Andrea L. DiCarlo-Cohen, Ph.D., comprise this panel. Our collective expertise includes radiation biology, health physics, immunology, cell biology, radiation dose assessment, and radiation risk analysis.

We were charged with conducting an administrative review of the Secretary's determination not to add a class of Weldon Spring employees to the SEC. This included reviewing the data and information that formed the basis of the December 7, 2012, 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, whether the Secretary's final decision was supported by accurate factual information, and the principal findings and recommendations of NIOSH and the Board. As explained below, we concluded that the petitioners' challenge to the decision is without merit, and we do not recommend any change to the Secretary's determination to deny adding a class of Weldon Spring employees to the SEC.

In conducting our review, pursuant to 42 CFR § 83.18(b), we examined the views and information submitted by the petitioners in the challenge; the NIOSH Evaluation Report for Weldon Spring ("SEC Petition Evaluation Report: Petition SEC-00143, Report Rev. #: 0, April 16, 2010" - hereafter "Weldon Spring Evaluation Report"); the report containing the recommendations of the Board to the Secretary; the recommendations of the Director of NIOSH to the Secretary; and the information presented or submitted to the Board and the deliberations of the Board (and the Board working groups and subcommittees) prior to the issuance of its recommendations. Since 42 CFR § 83.18(a) prohibits petitioners from introducing any new information or documentation that was not previously submitted to NIOSH or to the Board prior to the Board issuing its recommendations, our review was based entirely on the administrative record in this case, as described above.

Structure of Report:

The body of this report contains the following sections: Section A provides a point-by-point analysis of the Secretary's determination, Section B discusses the appeal letter from the petitioners, and Section C represents the conclusion of the panel.

Section A. Point-by-Point Analysis of the Secretary's Determination

A memorandum to the Secretary, approved on December 7, 2012, from the Director of NIOSH states that NIOSH concluded, based on its full research of the class under evaluation, that available monitoring

records, process descriptions and source term data were sufficient to complete and perform individual dose reconstructions for the Weldon Spring class of employees. Accordingly, in this memorandum, NIOSH recommended that the Secretary sign a Determination not to add the class of Weldon Spring employees to the SEC. This conclusion was based, in large part, on the Weldon Spring Evaluation Report, which evaluated the feasibility of completing dose reconstructions for all employees of the Department of Energy, Department of Energy contractors or subcontractors who worked in any area at the Weldon Spring Plant in Weldon Spring, Missouri, for the operational period from January 1, 1957, through December 31, 1967.

The “HHS Determination Concerning a Petition to Add Members to the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000” (HHS Determination), signed by the Secretary on December 7, 2012, forms the basis for the comments made in Section A. Below, the undersigned panel reproduces the specific points made in the HHS Determination (in bold text), and supplies the panel’s analysis of each point (in plain text) below.

A.1. NIOSH determined that the principal source of internal radiation doses for members of the class under evaluation was inhalation of uranium and thorium during routine operations, initial cleanup, and maintenance periods. Ingestion is routinely assessed by NIOSH concurrently with inhalation exposure.

A.1.1. Petitioners do not agree that NIOSH had sufficient thorium air sampling data or that ingestion was routinely assessed. However, the panel finds that ingestion was taken into account via three routes: frank ingestion of contaminated food or drink; frank ingestion from the transfer of contamination from hands to food/drink and; incidental ingestion following inhalation.

A.1.2. While it may not be intuitively obvious, in the field of radiation protection, ingestion of radioactive materials is partially included in the consideration of inhalation and does not only refer to the direct ingestion of materials. According to the International Commission on Radiological Protection (ICRP) 66, *Annals of the ICRP*, 1994, 24(1-3), page 306, “inhaled substances deposited in the airways are cleared by several mechanisms, which lead mainly to the GI tract, the lymphatic system and the blood.”¹ That is, particles which are cleared (exhaled or coughed out) by the lungs can move into the area of the nasopharynx where they are subsequently swallowed, delivering a dose to the GI tract. The models used internationally by dosimetrists are based directly on ICRP 66, and explicitly include the dose to the GI tract from particles, which are inhaled into the lungs and cleared in this manner into the GI tract. This model was referenced by NIOSH in a Technical Basis Document, *Site Profiles for Atomic Weapons Employers that Refined Uranium and Thorium*, 12/13/2006 (Battelle-TBD-6001, pp. 12-14).

¹ ICRP 66 is the document used for internal dose reconstruction and other scientific methods established by the radiation safety scientific community, and is cited in the preamble to HHS dose reconstruction regulations at 42 CFR part 82 as the source of the methodology in the rule. 67 Fed. Reg. 22314, 22316 (May 2, 2002). In addition, regulations at 42 CFR § 82.16(b) specifically direct NIOSH to use ICRP models.

A.1.3. In addition, NIOSH utilized a model for frank ingestion of contamination as described in the NIOSH/OCAS Technical Information Bulletin, *Estimation of Ingestion Intakes*, dated April 13, 2004 (OCAS-TIB-009). This model implies that ingestion from the two routes of intake represents approximately 20% of the activity measured in an air sample. This is based on assumptions for the settling of contamination on surfaces and the transfer of contamination from surfaces to the hand to food.

A.1.4. Thus utilizing air sampling data, NIOSH was able to evaluate both the inhalation dose and the ingestion dose from thorium, as air samples were taken throughout the period of thorium processing from 1963-1966. Therefore, the panel agrees with NIOSH that there was sufficient thorium air sampling data and that ingestion was routinely assessed.

A.2. Measured air concentrations of radon are not available for the operational period. However, the maximum occupational ambient environmental exposure for radon may be calculated using the method in a white paper and discussion at the Board and Board Working Group meetings.

A.2.1. The panel agrees with the assessment of NIOSH that materials that were processed by employees at Weldon Spring – identified as ore concentrates – did not possess a high radium content, since the materials handled at the plant did not include un-milled uranium ores. The Weldon Spring Evaluation Report identifies two buildings in which evolution of radon might have occurred. These include Building 103, in which radon release occurs during acid digestion, and Building 108, where the acid recovery step was completed, and where maximum radon emission would have been expected (See Weldon Spring Evaluation Report, pp. 27-28). In Building 108, the acid recovery step would have been done within a hood that would have vented any radon emission to outside the plant (*id.* at p. 57), reducing the exposure to employees inside the building. If the assumption is made that outside air would then be drawn back into the plant, then the estimated maximum intake would be ~1.3 working level months (WLM) per year, if the employee remained in the building constantly during his/her shift, and for a total work time of 2000 hours/year. Over the course of the entire petition period (11 years), this would amount to a total estimated exposure of 14.3 WLM for an employee working in this building (which would represent the maximum possible employee exposure). The panel therefore finds that the estimate of intake, based on a claimant-friendly 1.3 WLM per year, can be bounded for all members of the cohort.

A.2.2. Further, the panel finds that the calculations carried out in order to estimate radon exposure (using a mathematical model which takes into account, for example, uranium throughput, air exchanges, etc., while not considering that some of the radon would be removed from the work environment) should over-estimate the exposure. In addition, calculations to bound the dose for the entire class rely on modeling of the building that would have been expected to experience the highest level of radon on the site, which is claimant-favorable.

A.2.3. An additional claimant concern was the possibility that radon may have been emitted in the area of the raffinate pits that may have dried out somewhat during the summer months while the plant was still in operation. After considering the information presented to the Board, and those data that were presented in the Weldon Spring Evaluation Report (*id.* at p. 28), the panel agrees with NIOSH's assertion that even if there were some drying of the pits, it would not have been sufficient to generate radon that would have been a concern.

A.3. NIOSH determined that it can reconstruct internal dose with sufficient accuracy for members of the class under evaluation. NIOSH located sufficient personnel monitoring data to support reconstruction of internal uranium and thorium exposures at the Weldon Spring Plant for the evaluated period of January 1, 1957, through December 31, 1967. This feasibility conclusion is based on the collective availability of uranium bioassay (urinalysis) and thorium air sampling data in sufficient quantity and quality for the entire evaluated period to adequately represent the class under evaluation. Supporting information exists related to workplace activities, area monitoring, and associated source terms.

A.3.1. The panel concluded that NIOSH has consistently used very conservative assumptions, even in spite of specific data that would effectively reduce the potential dose to workers. For instance, NIOSH has made the assumption that all uranium processed from 1963 to 1967 was recycled (enriched 1%), even though records show that the vast majority of uranium processed at Weldon Spring was in natural form (Weldon Spring Evaluation Report p.55). This would appear to be a claimant friendly assumption.

A.3.2. As discussed in section A.1 above, thorium air sampling data allowed for the estimation of internal dose both by inhalation and ingestion. Therefore, the panel agrees with the NIOSH position that internal dose could be reconstructed with sufficient accuracy

A.4. NIOSH determined that the principal source of external radiation doses for members of the evaluated class, other than medical X-rays required as a condition of employment, was direct beta-gamma exposures from processing uranium feed stocks to metal and other intermediate products for use at other AEC facilities across the weapons complex. A limited amount of thorium was also processed at the Weldon Spring Plant from November 1963 through 1966.

A.4.1. Direct beta exposures (that would have comprised the majority of the external exposures) are such that although there can be significant exposures to the skin, they do not penetrate to the level of the internal organs. These kinds of exposures represent the main hazard from exposure to uranium without shielding, such as natural and depleted uranium. The panel concurs with NIOSH that beta exposures could be adequately reconstructed based on film badge records for Weldon Spring employees. Gamma exposures resulting from the handling of uranium must also be considered, and the exposure badges, for which records are available, are also capable of monitoring for gamma or photon radiation. In cases where the records are not available, NIOSH

bounded the beta exposures by referencing the Center for Epidemiologic Research (CER) database, which includes nearly 8,000 film badge records for employees from 1957-1967. According to the Weldon Spring Evaluation Report (at pp.62-63), included in these personnel monitoring numbers are data that represent workers exposed to the maximum radiation levels and highest possible exposure scenarios. The panel concurs that the use of claimant-favorable data from the CER database allows for bounding of exposures (both beta and gamma) for all Weldon Spring Plant Employees, when no individual badge records are available.

A.5. Although NIOSH has not located specific parameters associated with occupational medical X-rays (i.e., specific information on the X-ray devices used at the Weldon Spring Plant), NIOSH will bound the occupational medical X-ray dose by using the values and methodology provided in the complex-wide Technical Information Bulletin, Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures (ORAUT-OTIB-0006) and the Calculations and Assumptions Used in ORAUT-TKBS-0028-3 Rev. No. 01 Weldon Spring Plant Technical Basis Document for Occupational Medical Exposure.

A.5.1. The panel finds that the petitioner's concern about the lack of information on occupational and medical x-ray procedures, equipment and examination frequencies has been adequately addressed by NIOSH, and that the information available to NIOSH allows for the bounding of an individual's exposure. On pages 29-30 of the Sanford Cohen and Associates (SC&A), February 10, 2009 draft report ("Review of the NIOSH Site Profile for the Weldon Spring Site in Weldon Spring, Missouri" – SCA-TR-TASK1-0028), it is stated that dose reconstructions of claimants would need to take into account the likelihood of annual chest x-rays (both posterior-anterior and lateral views), for up to 12 years – during the period of 1955 through 1966, as well as the possibility of lumbar spine exams. The panel finds that the added radiation exposure to an employee from these diagnostic procedures was considered by NIOSH, as outlined in *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*, December 21, 2005 (ORAUT-OTIB-0006, Rev. 03 PC-1, page 20 [chest x-ray], and pages 23-26 [lumbar spine]), as well as in *Calculations and Assumptions Used in ORAUT-TKBS-0028-3, Rev. 01 Weldon Spring Plant Technical Basis Document for Occupational Medical Exposure*, dated December 28, 2007, authored by MH Chew and Associates (references to chest x-rays and lumbar spine throughout). The panel asserts that these documents, both of which include multiple considerations of both chest x-rays lumbar spine exams (their expected timing and frequency relative to employment as well as the class of employees that would have likely received them), provide adequate information to perform dose reconstruction for any part of the cohort that might have been expected to have had this kind of diagnostic exposure.

A.5.2. With regard to expected radiation exposures from standard medical x-rays, Table 3-4 (pp. 11-12) in ORAUT-TKBS-0028-3, Rev. 00 (June 24, 2005) provides organ dose estimates as well as skin dose estimate from medical x-ray exposures. These estimates from the Technical Basis Document (TBD) were derived from ORAUT-OTIB-0006 (referenced above), and reflect the changes in x-ray examinations across the time periods of 1955-1970, 1971-1985 and 1986-2002. The panel concurs that this

information provides a sufficient basis to estimate the x-ray exposures and skin and organ doses that would have been expected in Weldon Spring individuals subjected to these standard medical x-rays as part of their employment. Finally, as described in the Weldon Spring Evaluation Report (at p. 63), ORAUT-OTIB-0006 provides entrance kerma for the three most commonly used diagnostic procedures, which the panel agrees can be used in lieu of actual data from employee records, if it is not available. Therefore, the panel agrees that it is possible to accurately estimate the dose received by individual employees from their exposure to medical x-rays used in standard diagnostic tests.

A.6. NIOSH determined that the external dose reconstruction for members of the evaluated class is feasible based on the available personal external monitoring data, the analysis of the film badge results for the various job categories, survey data obtained during studies to determine the time to perform specific job functions and necessary shielding, and if necessary, a determination of missed and unmonitored neutron dose using the methods described in the SEC 143 Evaluation Report for personnel working in buildings that processed uranium (because of the alpha-neutron reaction from uranium tetrafluoride). In addition, doses from the required medical X-rays and ambient environmental doses can be determined with sufficient accuracy for the evaluated class.

A.6.1. The panel concurs that NIOSH utilized all resources available, including a search of its Site Research Database (SRDB) to locate all relevant Weldon Spring documents – NIOSH identified 844 documents, which included historical background on radiation safety program descriptions and policies, external and internal radiation reports, survey and routine monitoring summary reports, description of health and safety-related studies, environmental reports, exposure incident reports and air sample reports.

A.6.2. For personnel external monitoring data, Table 5-8 of the Weldon Spring Evaluation Report (at p. 31) references ORAUT-TKBS-0028-6, Rev. 00 (Figures 6-1 to 6-3) and Radiological Health Handbook, 1998, and lists the beta and gamma emissions of the radionuclides of major external exposure concern for the employees.

A.6.3. For the analysis of film badges for various job categories to monitor beta dose exposures, details regarding the various analyses used and the associated minimum detectable activities are presented in the Technical Basis Document for the Weldon Spring Plant in ORAUT-TKBS-0028-6. NIOSH also had access to the ORAU CER database, which contained data from approximately 1,850 Weldon Spring employees. Data fields include the employee's last name, social security number, date, beta results (i.e., mrem), gamma results (i.e., mrem), total records, number of weeks that the reported doses did not exceed the administrative limits, and the number of weeks the individual was monitored during the year (CER Data, 2009).

A.6.4. Table 6-6 in ORAUT-TKBS-0028-6 (see pp. 15-16) summarized several different formats in which health physics personnel recorded external dosimetry information for the Weldon Spring site. This document included descriptions of personal monitoring summary records and reports, descriptions of how the results were noted in the reports, and NIOSH's interpretation of zeros and blanks in the monitored exposure results.

A.6.4.a. Tables 6-6 and 6-7 in the Weldon Spring Evaluation Report (see p. 47) (referencing data from ORAUT-TKBS-0028-6, Rev. 00 [Table 6-8, p. 18]) provided the annual average gamma and beta dose (mR) by job category from 1957 through 1966. Data included beta and gamma results (mrem), the number of weeks that reported doses didn't exceed administrative limits, and the number of weeks the individual was monitored during the year.

A.6.4.b. The following documents were used in the determination of missed and unmonitored neutron doses: 1) *Estimation of Neutron Dose Rates from Alpha-Neutron Reactions in Uranium and Thorium Compounds*, April, 7, 2005 (ORAUT-OTIB-0024); and 2) *Assignment of Missed Neutron Doses Based on Dosimeter Records*, May 14, 2008 (ORAUT-OTIB-0023).

A.6.4.c. In response to the determination findings regarding required medical X-rays, see Section A.5 above, regarding doses employees received from medical x-rays.

A.6.4.d. With regard to the determination finding concerning ambient environmental doses, an evaluation of the ambient environmental internal radiation doses from releases of particulates/aerosols of uranium, the associated recycled uranium contaminants, and decay products (e.g., thorium-230) is not necessary because the most highly exposed plant employees were monitored by routine uranium bioassay sampling, either individually or as members of a workgroup. Thus, these doses are accounted for in the process-related internal dose evaluations. Additionally, Table 4-12 in ORAUT-TKBS-0028-4 (at p. 29) showed the estimated maximum site-wide ambient dose exposure to workers for years 1957-1967.

A.6.5. The panel, therefore, is in agreement with NIOSH's statement that external dose reconstruction is feasible.

A.7. NIOSH determined that the reconstruction of internal and external doses is feasible for the covered operational period from January 1, 1957, through December 31, 1967.

A.7.1 The panel agrees with the NIOSH determination that reconstruction of internal and external doses is feasible for the covered operational period. See panel's responses in sections A.3, A.4. and A.6. above.

A.8. NIOSH determined that it has access to sufficient Weldon Spring Plant 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 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.

A.8.1 The panel agrees with NIOSH's determination that it had access to sufficient Weldon Spring Plant site-specific information, as has been discussed in the panel responses above.

A.9. The Board concurred with NIOSH's determination.

A.9.1. The panel is in agreement with the Board's concurrence with NIOSH's determination.

Section B. APPEAL LETTER

The Review Panel has also carefully considered all of the challenges identified by petitioners in their appeal Letter dated December 12, 2012. The panel determined that some of the issues raised in the petitioners' appeal letter are outside the scope of our review and, therefore, cannot be addressed in this report (e.g., allegations concerning misconduct of NIOSH Health Physicist, _____, the 2006 Office of Management and Budget (OMB) Passback Memo, and _____; issues concerning FOIA requests, Mallinckrodt-Integrity and Prior SECs; and general allegations concerning flaws in the EEOICPA Program). We have responded to those challenges that are within our purview and a summary, along with our analysis and conclusion, is set out below. Text provided in bold font below represents concerns from the petitioners, as raised in the December 12 2012, appeal letter. The panel's responses to these concerns are in plain text.

B.1. NIOSH Health Physicist,

The petitioners disagree that there is enough data to provide accurate dose reconstructions.

B.1.1. According to the regulations governing the establishment of Special Exposure Cohorts (42 CFR § 83.13(c)(1)(i)):

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 in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose. NIOSH must also determine that it has information regarding monitoring, source, source term, or process from the site where the employees worked to serve as the basis for a dose reconstruction. This basis requirement does not limit NIOSH to using only, or primarily, information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked.

B.1.2. It is the view of this panel that NIOSH had sufficient monitoring data, sufficient data on the source (radionuclides), source term (the amounts of radioactive material) and the workflow processes at Weldon Spring to be able to estimate the maximum radiation dose for every type of

cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class.

B.1.3. Further, the regulations at 42 CFR § 83.13(c)(1)(ii) state that “[i]n many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would require, at a minimum, that NIOSH have access to reliable information on the identity or set of possible identities and maximum quantity of each radionuclide (the radioactive source material) to which members of the class were potentially exposed without adequate protection.”

B.1.4. According to 42 CFR § 83.13(c)(1)(iii), “[i]n many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would also require information describing the process through which the radiation exposures of concern may have occurred and the physical environment in which the exposures may have occurred.”

B.1.5. Finally, 42 CFR § 83.13(c)(1)(iv), states that “[i]n many circumstances, access to personal dosimetry data and area monitoring data is not necessary to estimate the maximum radiation doses that could have been incurred by any member of the class, although radiation doses can be estimated more precisely with such data.”

B.1.6. The physics of radiation and its interactions with matter are sufficiently well understood that information about the source term and the workplace environment are adequate to reconstruct doses. NIOSH has conducted a thorough search for data on all materials that were processed at Weldon Spring and has compiled a detailed inventory of the different types of materials. The panel is in agreement with NIOSH that there are sufficient data available to provide accurate dose reconstructions.

B.2. Advisory Board on Radiation and Worker Health and SC&A:

The petitioners state that “The Advisory Board members and their contractor, SC&A, have not validated every claim made by NIOSH... The Advisory Board and SC&A just take NIOSH’s word without scrutinizing their claims... there was a lack of participation by Advisory Board members... We have received NO representation by the Board from the inception...We did not have ONE full workgroup meeting...NIOSH Health Physicist, _____, promotes denying the SEC status for the Weldon Spring Plant”.

B.2.1. Contrary to the petitioners’ statements, the panel finds that the Board members and their contractor, SC&A, were very diligent in their duties and responsibilities in evaluating the Weldon Spring SEC-00143 petition. At the May 20, 2010, Board meeting, following presentation on the NIOSH recommendation to deny SEC status to the Weldon Spring cohort, three Board members volunteered to be on the Weldon Spring Working Group (WG). The WG was formed to represent the Weldon Spring petitioners during the proceedings in evaluating the Weldon Spring Evaluation Report and SC&A’s evaluation of NIOSH’s Weldon Spring Site Profile document. The Board-supported contractor, SC&A, was tasked to review NIOSH’s Weldon Spring Site Profile (*SC&A Draft: Review of the NIOSH Site Profile for the Weldon Spring Site in Weldon Spring, February 10, 2009 (SCA-TR-TASK1-0028)*) and it identified 28 site profile issues and 9 main SEC issues that needed to be addressed/clarified before a Board recommendation

could be made. Contrary to the petitioners' statement, in light of issues identified by SC&A, there were seven Weldon Spring WG meetings that took place between October, 2010, and September, 2012. All of these meetings occurred before the Board voted to concur with the NIOSH recommendation not to add Weldon Spring employees to an SEC class. The panel found no evidence that any bias was shown by either _____ or any of the Board members during the review of the Weldon Spring Evaluation Report.

B.3. NIOSH and Deadlines:

The petitioners state that "NIOSH did not adhere to the 180-day deadline as stipulated ... NIOSH has placed a statement on their website indicating that NIOSH makes every effort to meet the 180 day deadline but there are circumstances when NIOSH cannot make the deadline."

B.3.1. The panel has looked into the issue of NIOSH missing deadlines for submitting the recommendation for the Weldon Spring SEC designation to the Board. The 180-day deadline requirement referred to in this challenge is set out in both statute (*see* 42 U.S.C. § 7384q(c)(1)) and in the EEOICPA SEC regulations at 42 CFR 83.13(e), and indicates that NIOSH must submit its recommendation and evaluation report to the Board within 180 calendar days of receiving the petition. We understand that an Interim Final Rule amending the procedures for designating a class to the SEC published on December 22, 2005 (70 Fed. Reg. 75949), as well as the references in § 83.13(e) to § 83.11 (which sets out the procedures for qualifying a petition), make clear that the 180 days is counted from when a petition qualifies for evaluation, not from when it is first received by NIOSH.

B.3.2. The panel finds that although the petition was received on April 29, 2009, it was not considered to be "qualified" until September 11, 2009. If one applies the 180-day deadline to this qualification date, then the Weldon Spring Evaluation Report should have been completed by March 10, 2010. The actual report was dated April 16, 2010, making it 37 calendar days (27 business days) late. It is the opinion of the panel that a 27 business day delay in submission of the report is not unreasonable, given the fact that there were seven government holiday days from the time of qualification until the time the report was submitted, and the period of consideration spanned the end-of-year and spring holidays. In addition, neither the statute nor the regulations include a penalty for missing the deadline, and the panel believes that nothing occurred during the 27 business days that would have changed the outcome of the Board's actions or the Secretary's determination (e.g. no new evidence or dose reconstruction methods were discovered). Therefore, the panel finds that HHS substantially complied with their procedures, and that this claim is without basis. Any allegations of missed deadlines with regard to other SEC petitions are outside of the purview of this panel.

B.4. SC&A Review of NIOSH Evaluation Report:

The petitioners state that "After reviewing Sanford Cohen & Associates review of NIOSH's Evaluation Report, there should be no question as to why the Mallinckrodt Weldon Spring

Plant deserves Special Exposure status... It appears that the Advisory Board members did not thoroughly assess the report.”

B.4.1. The draft SC&A Review of the NIOSH Site Profile for Weldon Spring was completed and submitted on February 10, 2009 (SCA-TR-TASK1-0028). SC&A was initially contracted by the Board to develop a site profile for Weldon Spring, and the report was not commissioned in response to the claimant’s initial request to have the plant added to the SEC, as the review was conducted prior to the SEC petition even being filed. The report was needed as information for the Board to evaluate individual dose reconstruction claims for workers at the plant, as opposed to the ability to reconstruct dose for an entire cohort. The panel finds that the Board and WG gave ample consideration to the report during the determination period for the Weldon Spring SEC, in contrast to the claims made by the petitioners, and that dose reconstructions are possible for each member of the cohort.

B.5. Lack of Data:

The petitioners state that “There is a substantial lack of records for the Mallinckrodt Weldon Spring Plant operational period 1957-1966. Most data for Weldon Spring is being utilized from other sites or the remediation period. The following list of submitted evidence by petitioners demonstrates the inability to perform accurate dose reconstructions for this site.” The petitioner continues with a discussion of destruction of the following categories of records: V2161, Weldon Spring Site Visit, Hardcopy Records and Bldg. 415.

B.5.1. Although the panel conducted an extensive and thorough review of the administrative record in this case, the panel has no way to determine whether the V2161 medical files were destroyed or not or whether building 415 was used to burn classified documents. However, the panel acknowledges that NIOSH did find that there might be some periods of time during the operational 1957- 1967 period that hardcopy records of either film badge exposures, urinalysis data, or medical records may not be available for all Weldon Spring employees in the SEC cohort. To address any shortcoming, the panel found that NIOSH utilized all resources available including a thorough search of the Weldon Spring Site Research Database (SRDB) to locate 844 documents pertaining to Weldon Spring which included historical background on the radiation safety program descriptions and policies, external and internal radiation reports, survey and routine monitoring summary reports, description of health and safety-related studies, environmental reports, exposure incident report and air sample reports.

B.5.2. Table 5-8 in Technical Basis Document *Weldon Spring Plant – Occupational Internal Dose*, June 28, 2005 (ORAUT-TKBS-0028-5, p. 21) shows the composite uranium urinalysis summary data for routine monitoring during the years 1958 – 1966 and was generated from the records contained in the ORAU Center for Epidemiological Research (CER) database. This database contained nearly 30,000 uranium urinalysis records collected during the period from 1957-1966 for approximately 1,800 employees. Tables 6-1, 6-2 and 6-3 in the Weldon Spring Evaluation Report (pp. 35-38) provided evidence of adequate source data that can be used to bound the upper exposure dose for any employees lacking monitoring data.

B.5.3. Additionally, NIOSH had access to the ORAU CER database which contains nearly 8,000 film badge records collected from 1957 to 1967 for approximately 1,850 employees. Hardcopy data or CER exposure data from monitored employees can be used to bound the upper exposure dose for any employees lacking exposure data.

B.5.4. The accuracy of the hardcopy data transferred to the CER database was addressed by NIOSH in Tables 7-1, 7-2 and 7-3 in the Weldon Spring Evaluation Report (at pp. 49-51) for the period from 1957 to 1966.

B.5.5. Therefore, the panel finds that this challenge is without merit.

B.6. Thorium Issues:

The petitioners state that large scale production/extraction of thorium-230 occurred on a regular basis at Weldon Spring from 1958-1966.

B.6.1. Weldon Spring handled primarily uranium ore concentrates, which contain very low concentrations of decay products including thorium-230. Thorium-230 was a major component of uranium raffinates in Pits 1 through 3, but this did not represent an exposure hazard in the general operating areas of the plant (Weldon Spring Evaluation Report, at p. 26).

B.6.2. The petitioners also dispute the use of uranium throughput as a method for determining thorium doses. However, based on measurement of raffinates, the decay characteristics of uranium, and assuming 100% equilibrium with uranium-234, it is possible to provide a claimant-friendly estimate of thorium dose. Additional thorium intakes from the processing of natural thorium can be estimated using the methods described above that are based on air sample results.

B.6.3. Therefore, the panel finds that this petitioner statement is without merit.

B.7. Radon Issues:

The petitioners state that “There was no radon monitoring performed at the Mallinckrodt Weldon Spring Plant. Monitoring ceased in 1955. NIOSH’s suggested radon model appears to have uncertainty, too many assumptions, and does not demonstrate sufficient accuracy. NIOSH made several changes to the ventilation rate... There is a basic model with no benchmark data...”

B.7.1. As mentioned in section A.2. of this report, measured air concentrations of radon are not available for the operational period; however, the maximum occupational ambient environmental exposure for radon may be calculated using the method in a white paper and discussion at the Board and Board Working Group meetings. With regard to changes in the ventilation rates, the Board found that these changes were, in fact, claimant favorable, in that the initial exposure rate quoted (~0.076 working level months per operational year), was increased to ~1.3 working level months per year for the final analyses. Although the basic model used to estimate radon dose for the Weldon Spring cohort relies on mathematical

modeling as opposed to benchmark data, the panel believes that the estimates can be accurately applied to the cohort and are claimant favorable. Thus, we find that this claim is without merit.

B.8. Worker Testimony:

The petitioners state that “Numerous accounts of NIOSH not employing worker accounts of undocumented exposures are distressing and not claimant favorable. There were 30 pages of employee testimony for the Weldon Spring site not initially posted with the Review of the NIOSH Site Profile on February 10, 2009, on the CDC website... NIOSH failed to incorporate any of these employee accounts of accidents and explosions into Weldon Spring Plant dose reconstructions.”

B.8.1. The employees testimony is part of Attachment 2: Site Expert Interview Summary (November 6, 2009) from SC&A’s February 10, 2009 draft Review of the NIOSH Weldon Spring site profile report (“DRAFT: Review of the NIOSH Site Profile for the Weldon Spring Site in Weldon Spring, Missouri” – SCA-TR-TASK1-0028).² At the October 19, 2010, Weldon Spring WG meeting, a discussion focused on accidents/incidents reported in employees’ interviews and testimony that were not mentioned in NIOSH’s Weldon Spring Site Report. These issues were also discussed at the Weldon Spring WG meetings on January 25, 2011, and May 9, 2011, and led to NIOSH’s report titled “*NIOSH Evaluation of the Incident/Accident Information Available at the Weldon Spring Plant,*” Rev. 00 (September 12, 2011). This response was discussed at various Weldon Spring WG meetings, in order to address this site-specific/SEC issue along with many others identified by SC&A.

B.8.2. In addition, in the Weldon Spring Evaluation Report, section 4.3 (at pp. 13-14) provides a listing of the nine former Weldon Spring employees and experts that NIOSH interviewed based on their job descriptions and known experience and knowledge about 1) workplace radiation fields, hazards and practices to control worker exposure, 2) potential radionuclide intakes as evidenced by workplace controls, monitoring policies and procedures and bioassay data, and 3) measurements of the beta, photon and neutron exposure to workers. Therefore, the panel finds that the Board adequately addressed the issue of worker testimony during their deliberations and that the petitioner’s claim is without merit.

Section C. Conclusion

C.1. As a result of our administrative review of this case, we have concluded:

1. HHS substantially complied with the regulatory procedures set out in 42 CFR part 83.

² Although we see that Attachment 2 postdates the draft review, it appears that SC&A first issued the draft review on February 10, 2009, and then later reissued it with Attachment 2, without changing the original date of the document.

2. The original 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.

C.2. In summary: Based upon our review of the administrative record in this case, this panel believes that the regulatory procedures have been complied with, that credible sources of information have been used as allowed for under EEOICPA implementing regulations, 42 CFR parts 82 and 83, and that the Secretary, NIOSH, and the Board came to reasonable and appropriate conclusions. In short, we have concluded that petitioners' challenge is without merit, and we see no reason to recommend any change to the determination to deny adding a class of Weldon Spring employees to the SEC.

Respectfully submitted,

[Signature on File]

Rosemary S.L. Wong, Ph.D.,
Program Director, Radiation Research Program
National Cancer Institute
National Institutes of Health

[Signature on File]

Michael A. Noska, M.S.
Captain, USPHS
FDA Radiation Safety Officer and
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[Signature on File]

Andrea L. DiCarlo-Cohen, Ph.D.,
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National Institute of Allergy and Infectious Diseases
National Institutes of Health

Attachment:

Petitioners' Appeal Letter dated December 12, 2012

December 12, 2012

Secretary Kathleen Sebelius
The U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Madame Secretary,

My name is [redacted] I am one of two petitioners seeking Special Exposure Cohort status for the Mallinckrodt Weldon Spring Plant under the Energy Employees Occupational Illness and Compensation Program Act of 2000. Co-petitioner is [redacted]. Pursuant to 42 CFR 83.18, we are respectfully requesting an administrative review of the final decision to deny SEC status for the Mallinckrodt Weldon Spring Plant in Weldon Spring, Missouri.

We have several challenges to the National Institute of Occupational Safety and Health's administration of the EEOICPA of 2000. We dispute NIOSH claims that there is sufficient information to estimate radiation doses with sufficient accuracy for ALL members of the Mallinckrodt Weldon Spring Plant SEC class for the years of 1957-1966. The following letter demonstrates the justifiable reasons and the necessity for granting a Special Exposure Cohort for the Mallinckrodt Weldon Spring facility in Weldon Spring, MO.

NIOSH Health Physicist,

It has been brought to our attention that the NIOSH Health Physicist assigned to our facility, [redacted] is of questionable integrity. Credible internal sources have revealed that [redacted] has fabricated employee testimony/interviews in prior Special Exposure Cohort cases. This information has compromised the entire Special Exposure Cohort process for the Weldon Spring Plant and is grounds for litigation. [redacted] explanations for Weldon Spring was evasive, highly unreliable, lacked credibility, and were not claimant friendly. It was self evident at the early onset that [redacted] (b) (6) was never prepared for discussions or questions imposed upon him. He made numerous last minute efforts to find ways to deny SEC status for the Weldon Spring Plant. It appeared there was an internal directive from the beginning, to deny compensation for Weldon Spring Plant workers and their families.

As petitioners, we have questioned [redacted] (b) (6) inability to remain unbiased and truthful about the data being utilized for the Weldon Spring Plant. One example of his dishonesty is depicted in the NIOSH Evaluation Report. [redacted] (b) (6) references for employee interviews showed 2009h as a WSP Design Engineer. However, in the narrative of the Evaluation Report, this same individual is referenced as a Health Physicist. Weldon Spring did not have Health Physicists.

[redacted] (b) (6) has made false claims that there is no data being used from Weldon Spring's sister plant, Fernald, or other sites. [redacted] (b) (6) stated that only data from Weldon Spring is being utilized for dose reconstructions. The petitioners, as well as many Advisory Board members and SC&A, have caught [redacted] lying on numerous occasions. While NIOSH claims to have Weldon Spring information, the petitioners clearly disagree that there is enough data to provide accurate dose reconstructions. NIOSH has not provided any evidence as requested by petitioners, which presumably means the data does not exist. In addition, when the petitioners ask explicit questions about Weldon Spring data being utilized, we get evasive responses. NIOSH circumvents inquiries to confuse petitioners and never provides reasonable explanations to our concerns. For example, when the petitioners inquired what "raw data" was being used for daily weighted averages and blunders, we received three separate answers. For instance, at previous Advisory Board meetings, NIOSH stated they had 1400 air samples, then changed it to 1400 operations, and then admitted it was actually 1400 calculations. These calculations are not actual data from the Weldon Spring Plant. The petitioners made several attempts to obtain clarification and we only received vague responses. NIOSH finally conceded that the 1400 operations did not refer to Weldon Spring Plant operations, which were implied in earlier discussions. The fact is there is a lack of original source data for this complex plant and it is unfeasible to perform accurate dose reconstructions. Any attempts by NIOSH to "create data" are not adequate. NIOSH has never answered or provided evidence of what "raw data" is being developed for these calculations. NIOSH and Health Physicist, [redacted] are being deceitful to all parties.

Further evidence depicts [redacted] (b) (6) utilizing only limited summaries of thorium dust studies and performing "calculations" to interpret daily weighted averages. These "calculations" are not benchmark data and they

do not meet the terms of representativeness or sufficient accuracy. In addition, many readings from the summaries were not true measurements. Measurements were often extended from other years. NIOSH's determination finding of having thorium air sampling in sufficient quantity and that ingestion for thorium was routinely assessed is completely fabricated. NIOSH claims that there is supporting information that exists for workplace activities and area monitoring, however any existing information is not sufficient or representative. NIOSH had not produced documentation to support their findings and a thorough investigation is necessary to prove NIOSH's inability to perform dose reconstructions for the Weldon Spring Plant. Furthermore, the use of DWA was already deemed "not-claimant favorable" in prior Special Exposure Cohorts, including the Mallinckrodt Drestrehan Plant. If a precedent has been established, then why is the Weldon Spring Plant not receiving equitable consideration?

Furthermore, internal NIOSH emails claimed if data from Weldon Spring were used for dose reconstructions, it would not be claimant friendly. How is creating unsupported data claimant friendly? has produced undeniable deception with petitioners, which ultimately led to him being withdrawn from discussions at Advisory Board meetings.

ADVISORY BOARD ON RADIATION AND WORKER HEALTH AND SC&A

The Advisory Board members and their contractor, SC&A, have not validated every claim made by NIOSH. SC&A received no guidance on outstanding issues by the Board. There has been no investigation into every detail of NIOSH methods, which have already proven to be erroneous. Numerous discrepancies in dose reconstruction were discovered in previous discussions. There is no accountability to NIOSH's deceptive explanations. The Advisory Board and SC&A just take NIOSH's word without scrutinizing their claims. In addition, there was a huge lack of participation by Advisory Board members. The Board did not research or follow up with any questions or concerns about Weldon Spring. We have received NO representation by the Board from the inception. The petitioners were entitled to dedicated workgroup discussions. We did not have ONE full workgroup meeting. Board members assigned to the workgroup were either new or did not show up for discussions and lacked the consideration to see the detriment they imposed on our SEC case.

As the petitioners of the Weldon Spring Plant, we have been disrespected and treated unjustly. There is no closure since several questions have yet to be addressed. In addition, during the last AB meeting, claimant was not allowed to speak and Board members went straight to a vote. Board members lacked the compassion to allow claimants to make a statement. How fair is it to repress claimants' comments? This whole program is flawed beyond comprehension and warrants a scrupulous investigation.

Furthermore, even members of NIOSH have verbally declared that our plant should have received a Special Exposure Cohort status. What a revelation when NIOSH workers doubt their own work and objectivity. Yet, NIOSH Health Physicist, (b) (6), promotes denying the SEC status for the Weldon Spring Plant

NIOSH AND DEADLINES

NIOSH has been allowed to construe and disregard the original intent of the Energy Employees Occupational Illness and Compensation Program Act of 2000. As stipulated in the Act, "Not later than 180 days after the date on which the President receives a petition for designation as members of the Special Exposure Cohort, the Director of the National Institute of Occupational Safety and Health shall submit to the Advisory Board on Radiation and Worker Health a recommendation on that petition, including all supporting documentation."

NIOSH violated mandated law from the initial filing of the Mallinckrodt Weldon Spring Plant SEC petition. NIOSH did not adhere to the 180-day deadline as stipulated. In fact, NIOSH hasn't adhered to the deadline for many Special Exposure Cohort petitions. NIOSH has placed a statement on their website indicating that NIOSH makes every effort to meet the 180 day deadline but there are circumstances when NIOSH can not make the deadline. This is inexcusable. If NIOSH cannot abide by these imposed deadlines, the SEC petition should automatically be granted. There is no oversight on the blatant disregard of congressional intent. NIOSH has been allowed to manipulate this program and it is a disgrace to believe anyone can receive timely compensation. Why does everyone have to abide by deadlines, except NIOSH?

SC&A REVIEW OF NIOSH EVALUATION REPORT

After reviewing Sanford Cohen & Associates review of NIOSH's Evaluation Report, there should be no question as to why the Mallinckrodt Weldon Spring Plant deserves Special Exposure status. The basis for our SEC petition originated from these alarming revelations that prevents NIOSH from accurately and plausibly performing dose reconstructions for Weldon Spring workers. It appears that the Advisory Board members did not thoroughly assess the report. Too much reliance has been placed on NIOSH's proposals for anyone to receive fair and timely consideration for compensation.

PASSBACK MEMO

Many politicians may be familiar with the notorious 2006 OMB pass-back memo, which sought to restrict compensation payout under the Energy Employees Occupational Illness and Compensation Program Act of 2000. NIOSH continues to hold steadfast the directive to refute and deny compensation claims for stricken nuclear workers, which impacts the credibility of this program. A full congressional exploration into NIOSH is essential to eliminating the misuse of this program.

The petitioners received information from [redacted] environmental management, about the types of radioactive materials sent to the Mallinckrodt Weldon Spring Plant. [redacted] provided a substantial summary about the recycled uranium that was received at the plant and the impact these materials would have on dose reconstruction for this site. [redacted] invaluable witness accounts of radioactive materials sent to Weldon Spring was thwarted by NIOSH. Essentially [redacted] was "bought off" so he would not be an expert witness for SEC petitioners at an Advisory Board meeting. Before the meeting, [redacted] a position with their company. NIOSH - immediately stated his employment with [redacted] would be a conflict of interest and refused to allow him to speak on the petitioners' behalf. NIOSH censored his knowledge and imposed a huge liability. NIOSH does not have the authority to dismiss expert testimony. NIOSH undermines the significant impact of recycled uranium on worker dose reconstructions. This mistreatment to petitioners and claimants is unjust.

FOIAS

Claimants and petitioners are at such a disadvantage in fighting for compensation. We have been treated unfairly as the petitioners for Mallinckrodt Weldon Spring. There appears to be no full disclosure of information. The petitioners have made futile attempts to gain access to records being utilized for Weldon Spring. We have submitted numerous FOIA requests and routinely checked the CDC website, as well as conducted extensive hours of research. There is no assurance that we possess all of the information requested. We have submitted countless FOIA requests for ALL data pertaining to Weldon Spring. However, when we submit a FOIA for a specific item, we get more information and there is no explanation as to why it was not in a previous request. After requesting internal emails involving the Weldon Spring Plant, I received approximately 20 pages. This clearly is not ALL of the emails. NIOSH and DOE repress everything and make it impossible for petitioners and claimants to obtain adjudication.

LACK OF DATA

There is a substantial lack of records for the Mallinckrodt Weldon Spring Plant operational period 1957-1966. Most data for Weldon Spring is being utilized from other sites or the remediation period. The following list of submitted evidence by petitioners demonstrates the inability to perform accurate dose reconstructions for this site.

❖ Destruction of Records

• V2161

As mentioned numerous times before, the V2161 shelf list that contained incomplete sets of medical files for WS employees and dust studies have never been located. NIOSH claims these documents were not destroyed, however we have requested them to be brought forward, and NIOSH fails to do so. The reality is that these records were destroyed because the scheduled destruction date had already lapsed. This was already established during the Mallinckrodt Destrehan SEC.

• WELDON SPRING SITE VISIT

A Weldon Spring site visit during May of 1988 demonstrated that prior attempts to locate records during operations at Weldon Spring were unsuccessful. Many records retained had been exposed to the elements. Documents were wet, showed signs of decay, and were illegible.

• HARDCOPY RECORDS

In September 1979, [redacted] evaluated the comparison of work history records vs. the hard copy records that were available at CER. [redacted] discovered that the computerized work

history records did not compare well with the hard copy records that were available. advised that one of the deficiencies found in the computerized work history data is that they do not contain sufficient detail to match jobs that a worker held to the dust exposure studies that exist for jobs in the Uranium Division. It was known that the types of work history records available changed over the period of operation of the Uranium Division. The computerized work history did not appear to be adequate for linking a worker's job to dust exposure he/she received while doing a job. No one document contained all of the work history information. In addition, the linkage to dust exposures was less successful for Weldon Spring since the dust exposure studies only covered jobs held in the manufacturing areas.

- **BLDG 415**
Historical documents show Bldg 415 contained an incinerator, which was used to burn trash and classified documents.

MALLINCKRODT-INTEGRITY AND PRIOR SECS

NIOSH has acknowledged that Mallinckrodt's reporting practices were highly questionable. Mallinckrodt was reluctant to protect its workers from thorium exposure, which was noted in a memo from November 1965. Thorium operations involved hand scooping outside of the hoods, which was also subjected to vigorous air currents. The adequacy of administrative controls such as respirator wearing for routine dust handling operations was questioned. A back-up in vivo counting was recommended, however a reticence was evidenced by MCW staff personnel toward counting any of its "at risk" employees due to potential personnel relations complications. It was very difficult to assess accurately the potential of overexposure. Conventional bioassay techniques were not adequate for monitoring potential thorium exposures. It has been documented that thorium exposures were more than realized at the WS Plant. There were additional documents that were submitted demonstrating Mallinckrodt's reluctance to protect its workers. Mallinckrodt knowingly placed its employees at risk and these workers and their families are entitled to compensation for the sacrifices that were made. Mallinckrodt Destrehan Plant was awarded Special Exposure Cohort status for three separate years of operations. How can anyone conscientiously deny Mallinckrodt Weldon Spring Plant a cohort when a precedent has been established?

THORIUM ISSUES

Thorium-230

Two documents referred to as the Ingle Documents were rejected by NIOSH because the documents were clearly claimant favorable. Both of these documents state that the AEC asked Mallinckrodt in 1955 to extract thorium 230 (ionium) from raffinate residues on a production basis. This pilot work continued on a large-scale production basis at Weldon Spring from 1958-1966. NIOSH has made every effort to discredit these documents. Additionally, NIOSH cited these same Ingle documents and misrepresented the content. How is NIOSH allowed to discount ANY submitted documents that are clearly claimant favorable?

Dosing Thorium Using Uranium Throughput

Several previous SECs have established NIOSH's inability to bound internal thorium intakes with sufficient accuracy and plausibility. Now NIOSH is attempting to dose thorium intakes from uranium throughput. This position should not be accepted because Weldon Spring lacks appropriate data. NIOSH claims to have urinalysis for 1890 employees for the time period 1957-1966. All of the urine data reports contain data from both facilities, Mallinckrodt Destrehan and WS. Weldon Spring Plant only had 600 employees. NIOSH appears to be misleading everyone about how much data they actually have. NIOSH changes terminology to confuse petitioners, claimants, and the Advisory Board. NIOSH claims that thorium air concentrations were routinely recorded which is far from the truth. NIOSH fails to admit there is a lack of data.

Confusion and disagreement sets in on the concept of utilizing a thorium ratio intake to a uranium ratio intake. Are there not different uranium compounds and different classes of solubility? Doesn't uranium and thorium behave chemically in different ways? Don't the compositions change rapidly? Is there a state of equilibrium? What about enriched, depleted, and recycled uranium implications? Doesn't thorium result in larger doses than uranium per unit of radioactive contamination in the air? These questions were never discussed and remain unanswered. Weldon Spring

workers will be dosed on inaccurate and insufficient data. Additionally stated on page 43 of the NIOSH Site Profile for the Weldon Spring Plant, measurement techniques for urinalysis did not provide sufficient information to have a reliable dose assessment when there was a mixture of uranium compounds and uranium isotopes. And NIOSH is going to use this unreliable information to attempt to dose thorium intake? Furthermore, this proposal has never been validated to be accurate, feasible, or claimant favorable. It appears to be another last-ditch effort to deny compensation.

Thorium is more toxic to the body than uranium. As stated in a Fernald document (SRDB: 41375), solubility changes from outside the body vs. inside the body. Insoluble compounds inhaled into the lungs where they remain for long periods of time apparently present the greatest hazard. Thorium compounds are not readily excreted in the urine, which prevents urinalysis from being nearly as good an indicator for thorium inhalation and ingestion as for uranium inhalation and ingestion. Apparently this is because thorium compounds are generally more insoluble and because soluble thorium compounds are converted into insoluble compounds in the body after ingestion or inhalation. How can this attempted approach be feasible or sufficiently accurate, primarily since there is a lack of adequate air concentration for the Mallinckrodt Weldon Spring Plant?

Prior SEC Cohorts have been passed on NIOSH's inability to dose internal thorium and the Weldon Spring Plant deserves the same consideration. NIOSH's proposal is not suitable for dose reconstructions. The Advisory Board has never accepted this NIOSH position for previous Special Exposure Cohorts, but has accepted the proposal for Weldon Spring.

RADON ISSUES

There was no radon monitoring performed at the Mallinckrodt Weldon Spring Plant. Monitoring ceased in 1955. NIOSH's suggested radon model appears to have uncertainty, too many assumptions, and does not demonstrate sufficient accuracy. NIOSH made several changes to the ventilation rate. How many chances does NIOSH get to make things "right"? Where is the guarantee that EVERY single Weldon Spring worker would have an accurate dose reconstruction? This is a basic model with no benchmark data. All of NIOSH's "fixes" will never be implemented because there is no oversight.

WORKER TESTIMONY

We are not the only petitioners arguing NIOSH's lack of utilizing employee testimony. Numerous accounts of NIOSH not employing worker accounts of undocumented exposures are distressing and not claimant favorable. There were 30 pages of employee testimony for the Weldon Spring site not initially posted with the Review of the NIOSH Site Profile on February 10, 2009, on the CDC website. After NIOSH was confronted, the employee interviews were finally posted on November 6, 2009. It is very suspicious that these interviews were not posted with the initial release of the review of the Site Profile. Yet NIOSH failed to incorporate any of these employee accounts of accidents and explosions into Weldon Spring Plant dose reconstructions. The reason is presumably because these incidents cannot be dosed with sufficient accuracy and plausibility by NIOSH. Any claimant favorable information is tossed aside as if it has not merit. Weldon Spring Plant employee summaries may be reviewed at <http://www.cdc.gov/niosh/ocas/pdfs/abrwh/scarpts/sca-weldonsp-ro.pdf> pages 61-91. In addition, numerous employee affidavits have been submitted and discredited at the hands of NIOSH.

EEOICPA PROGRAM-FLAWED

The EEOICPA program is flawed beyond comprehension. A conspiracy has been instilled and immediate congressional intervention is necessary to provide credibility of administering agencies and reaffirm the intent of this compensation program. This entire process has been an emotional roller coaster for claimants, petitioners, and their families. This process repeatedly victimizes these individuals. The bottom line is Weldon Spring Plant dose reconstructions are flawed and inaccurate due to the lack of data that exists for this facility. As discovered in workgroup discussions, WS dose reconstructions were in need of constant corrections. This serious predicament would not have been identified if a petition hadn't been submitted. Any efforts to dose these employees from operations over 60 years ago are just offensive. NIOSH has made too many assumptions due to data deficiencies, which lead to uncertainty and a lack of confidence. How are these assumptions "sufficiently accurate" or "plausible"? NIOSH cannot guarantee they can accurately dose EVERY single worker from the Weldon Spring Plant. The benefit of the doubt is supposed to go to the claimants, yet anyone requesting compensation has to fight overwhelming odds for adjudication. There has been nothing "fair" or "timely" about this process. We will never get back the blood, sweat, and tears that have been devoted to this campaign to compensate those individuals who sacrificed everything for the Nuclear Defense program. We will never get back the lost time with our loved ones. The petitioners for Weldon Spring have never

seen this much science and detail go into any other SEC petition. The congressional intent of this compensation program has been manipulated long enough. **Evidence and discussions prove that NIOSH makes too many assumptions and lacks the ability to perform ACCURATE dose reconstructions.** We request recognition of the numerous deficiencies in NIOSH's proposals. NIOSH claims are not sufficiently supported and not sufficiently accurate or plausible. Weldon Spring claims necessitate adjudication for the price that these workers paid for this country unknowingly under hazardous conditions.

The Advisory Board on Radiation and Worker Health is in need of oversight and direction. Members lack the empathy and vivacity to remain impartial to these workers, petitioners, and their families. Certain members have verbally declared they were sick of listening to numerous sob stories. Everyone one of these claimants and petitioners has a story to tell and are entitled to share. How disrespectful to disregard our feelings and concerns. The lack of Board participation is distressing. Precious time is wasted if the Board does not contribute in discussions or does not investigate petitioner concerns.

Ombudsman to NIOSH, Denise Brock, is very knowledgeable with the Weldon Spring Plant, as she was the first petitioner to get SEC approval for the Mallinckrodt Destrehan Plant cohorts. Brock welcomes any questions or concerns in regards to this plant. Ms. Brock may be reached at CKO7@cdc.gov.

RESOLUTION

As the petitioners for the Mallinckrodt Weldon Spring Plant, we are seeking inclusion of these nuclear weapons workers (1957-1966) in special exposure cohort under the Energy Employees Occupational Illness Compensation Program.

Energy workers at the former Mallinckrodt facility at Weldon Spring were unknowingly exposed to numerous radionuclides and radioactive materials far above the current maximum allowable Federal standards. These workers were exposed to excessive levels of airborne radiation and were not monitored for every radionuclide that was present at the Weldon Spring facility. The Department of Energy has acknowledged that these workers were exposed to plutonium and recycled uranium, which are highly radioactive.

According to the National Institute of Occupational Safety and Health admits that-

- The sufficiency of area monitoring data for thorium is uncertain.
- NIOSH also determined that records related to potential thorium exposure might not be sufficient for adequate reconstruction of internal exposure.
- The Weldon Spring Plant records do not indicate specific analyses to define concentrations of thoron daughter activities.
- There was no monitoring for radon at the Weldon Spring Plant. Monitoring for radon stopped in 1955.
- Measured air concentrations of radon are not available for the operational period.
- Over 50% of the workforce at Weldon Spring was not monitored for all radionuclides.
- There is no benchmark data for thorium or radon.
- The Weldon Spring Plant received shipments of recycled uranium which contained residual transuranic elements (including plutonium and neptunium), fission products (such as technetium), and reactor-produced uranium isotopes (such as uranium-236). Site records do not include the level of detail needed for an accurate estimate of the amount of recycled material received and processed at the Weldon Spring Plant site.
- There was potential for external exposure associated with working in proximity to the Weldon Spring Plant raffinate pits and quarry.
- The use of Daily Weighted Averages is not claimant friendly.
- A routine monitoring program for neutrons did not exist at the Weldon Spring Plant.
- Weldon Spring Plant records lack egress/contamination monitoring.
- Weldon Spring Plant records lack incident/accident reporting.
- NIOSH does not have access to area survey or monitoring records.
- The Health Physicist assigned to Weldon Spring Plant lacks candor and poses a liability in performing accurate dose reconstructions
- Mallinckrodt lacked the integrity of handling and reporting of monitoring data, which ultimately compromises accurate dose reconstructions for the Weldon Spring Plant.

Many Mallinckrodt Weldon Springs Plant workers have died while waiting for adjudication due to the extensive delay in dose reconstructions imposed by NIOSH. NIOSH has made futile attempts to deny compensation to anyone seeking retribution.

Due to the nature of the aforementioned reasons, including the severe lack of records and NIOSH's compromised dose reconstructions and proposals, it is not feasible to conduct accurate dose reconstructions for all employees of the Mallinckrodt Weldon Spring Plant facility from 1957-1966.

Respectfully submitted,

[Signature on File]

[Signature on File]

Mallinckrodt Weldon Spring Plant SEC Co-Petitioner

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