UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANNON YOUNG and KEVIN YOUNG, **Plaintiffs,** **v.** **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,** **Defendant.**	**Civil Action No. 17-2428 (JDB)**

MEMORANDUM OPINION

Plaintiffs Shannon and Kevin Young, sons of a former Department of Energy ("DOE") contract employee who died of cancer, seek compensation for their father's death under the Energy Employees Occupational Illness Compensation Program Act ("EEOICPA"). The Department of Labor ("DOL") denied their claim for compensation after determining that there was a less-than-even chance that their father's prostate cancer was caused by radiation exposure during his DOE employment. Plaintiffs dispute that finding, arguing that it was based on an incomplete "radiation dose reconstruction" prepared by the National Institute for Occupational Safety and Health ("NIOSH"), a component agency of the Department of Health and Human Services ("HHS"). This incomplete dose reconstruction, plaintiffs contend, was conducted under an HHS policy regarding the feasibility of dose estimates that is both contrary to the EEOICPA and arbitrary and capricious, in violation of the Administrative Procedure Act ("APA"). Pending before the Court are the parties' cross-motions for summary judgment. For the reasons stated below, the Court will grant summary judgment to HHS and deny plaintiffs' cross-motion for summary judgment.

Background

I. Statutory and Regulatory Framework

Congress passed the EEOICPA in 2000 to ensure that former DOE employees and contractors who "performed duties uniquely related to the nuclear weapons production and testing programs" receive "efficient, uniform, and adequate compensation for . . . radiation-related health conditions." 42 U.S.C. § 7384(a)(8). Part B authorizes a payment of $150,000 and medical benefits to surviving family members of employees who died from cancer related to radiation exposure from their work at covered DOE facilities. See id. §§ 7384l(1)(B), 7384l(9), 7384n(b), 7384s(a)(1). DOL has primary responsibility for administering the program and adjudicating claims for compensation. See Exec. Order No. 13,179, 65 Fed. Reg. 77,487, 77,488 (Dec. 7, 2000); 20 C.F.R. § 30.1.

"There are two methods set forth in the statute for claimants to establish that a cancer incurred by a covered worker is compensable under EEOICPA." 42 C.F.R. § 83.0. The first method is to establish that the employee's cancer was "at least as likely as not" related to employment at the covered facility (i.e., the probability of causation was at least fifty percent). 42 U.S.C. § 7384n(b); 20 C.F.R. §§ 30.210–13.[1] This begins with the "dose reconstruction" process, which involves estimating the amount of radiation to which an employee was exposed while

[1] The Court notes that the version of 20 C.F.R. § 30.210 in the 2020 annual edition of the Code of Federal Regulations ("CFR")—which sets forth the criteria for eligibility for compensation under Part B of the EEOICPA—appears to erroneously omit a portion of the regulatory text that appeared in previous versions of the regulation. Effective April 9, 2019, DOL "updated a cross-reference to reflect the changed location of the regulatory provision defining the term specified cancer from § 30.5(ff) to § 30.5(gg)." See 84 Fed. Reg. 3,026, 3,030, 3,049 (Feb. 9, 2019). However, it seems that the update inadvertently resulted in the deletion of § 30.210(a)(1)(i) and (ii). Compare 20 C.F.R. § 30.210(a)(1) (2019), with 20 C.F.R. § 30.210(a)(1) (2020). The Court believes this was unintentional because it resulted in the deletion of the word "or" at the end of § 30.210(a)(1), without which § 30.210(a) makes no sense. To the extent that the 2020 version can be read coherently, it has a drastically different meaning from previous versions and is inconsistent with the EEOICPA. The Court doubts that DOL would have upended the regulatory scheme without explanation. Moreover, the 2020 version of § 30.214 continues to reference the deleted provisions, suggesting that the deletion was a mistake. The Court therefore relies on the 2019 annual edition of the CFR available at https://www.govinfo.gov/content/pkg/CFR-2019-title20-vol1/pdf/CFR-2019-title20-vol1.pdf.

working at a covered facility. 42 U.S.C. § 7384n(d). The second method is to establish that the employee contracted one of twenty-two specified types of cancer and is a member of the "Special Exposure Cohort" ("SEC")—meaning the employee worked at particular covered facilities during specific periods of time. Id. §§ 7384l(9)(A), (14), (17), 7384q; 20 C.F.R. § 30.5(gg).

A. Dose Reconstruction

The EEOICPA requires the President to designate a federal agency (other than DOE) to "establish by regulation methods for arriving at reasonable estimates of the radiation doses received by" employees at covered DOE facilities for whom radiation monitoring records are inadequate or incomplete. 42 U.S.C. § 7384n(d). Although DOL is responsible for ultimately adjudicating EEOICPA claims, the President designated HHS to administer the dose reconstruction process. See Exec. Order No. 13,179, 65 Fed. Reg. at 77,488 (ordering HHS Secretary to "promulgate regulations establishing . . . methods, pursuant to [§ 7384n(d)], for arriving at and providing reasonable estimates of the radiation doses received by individuals applying for assistance under this program for whom there are inadequate records of radiation exposure"). HHS subsequently promulgated regulations "provid[ing] methods for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction," and the agency tasked NIOSH with making those estimates. 42 C.F.R. § 82.1. HHS interprets the term "reasonable estimates" to mean "estimates calculated using a substantial basis of fact and the application of science-based, logical assumptions to supplement or interpret the factual basis." Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, 67 Fed. Reg. 22,314, 22,317 (May 2, 2002).

"The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment." 42 C.F.R. § 82.2. Then, "methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer occurring among the workers." Id. NIOSH estimates both "internal" and "external" radiation doses. Id. § 82.5 (j)–(k). An "internal" radiation dose is radiation exposure "from radioactive materials taken into the body," id. § 82.5(k), whereas an "external" dose is exposure "from radiation sources outside of the body," id. § 82.5(j). To estimate doses, NIOSH uses a "hierarchy of methods" depending on the "data available to characterize the environment." Id. § 82.2; see also id. § 82.14.

If individual worker monitoring data (i.e., bioassay data) is available, NIOSH gives that data the highest priority. Id. §§ 82.2(a), 82.14(b)–(c). But when individual monitoring is not available or adequate, NIOSH may use monitoring data from coworkers with "comparable activities and relationships to the radiation environment" to develop a coworker model. 42 C.F.R. §§ 82.2(b), 82.17(a). Alternatively, NIOSH may develop an exposure model from "a quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information" such as air sampling data. 42 C.F.R. § 82.17(b); see also id. §§ 82.2(b), 82.14(e).

The individual, coworker, or workplace monitoring data is "interpreted using additional data characterizing the workplace radiation exposures." 42 C.F.R. § 82.2(a); see also id. §§ 82.2(b), 82.14(f)–(g). To get this workplace characterization data, NIOSH "characterize[s] the internal and external exposure environments for parameters known to influence the dose." 42 C.F.R. § 82.10(i). "For internal exposures, examples of these parameters include the mode of

intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type." Id. "When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science." Id.

To determine "default" values for workplace exposure parameters, NIOSH uses a "maximum dose" approach. See Decl. of Timothy D. Taulbee ("Taulbee Decl.") [ECF No. 37-1] ¶¶ 13, 15.[2] That is, "[w]hen NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration." 42 C.F.R. § 82.18(b). In other words, if NIOSH cannot precisely determine workplace exposure parameters, it uses "assumptions that represent the worst case conditions." Id. § 82.2(a). For example, one parameter is the "solubility class" of the radioactive material, which "categorize[s] how fast the inhaled radioactive material transfers from the lungs into the remainder of the body and is subsequently excreted in urine and measured via bioassay." Taulbee Decl. ¶ 15. In a case where "the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process." 42 C.F.R. § 82.2(a).

In sum, when NIOSH lacks adequate information to establish workplace exposure parameters (such as solubility class), NIOSH will attempt to use scientifically defensible assumptions to develop a dose reconstruction model capable of providing the maximum dose that could have been incurred by the organ under consideration in plausible circumstances. NIOSH

[2] The Court will occasionally cite to two declarations that HHS filed to assist the Court in understanding the administrative record. See Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 285 (D.C. Cir 1981) (finding that agency affidavits that are "explanatory of the original record" may be considered).

uses the maximum dose approach both because it is claimant-favorable and for efficiency reasons. See 67 Fed. Reg. at 22,316, 22,317; see also Taulbee Decl. ¶ 13. Since this approach "gives the benefit of the doubt to claimants," it "tend[s] to overestimate radiation doses for employees." Id. at 22,317.

If adequate individual, coworker, or workplace monitoring data is not available, NIOSH may—as a last resort—"rely substantially on process description information to analytically develop an exposure model." 42 C.F.R. § 82.2(c); see also id. § 82.14(h). Put differently, NIOSH may develop a "quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices." 42 C.F.R. § 82.17(c). For internal exposures, an exposure model based on process description information includes factors such as "the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion." Id. § 82.2(c). NIOSH compiles its analysis of available data for each covered facility, along with any coworker and exposure models, in a "site profile" or a Technical Basis Document ("TBD"). 42 U.S.C. § 7384w-1; Decl. of David E. Allen ("Allen Decl.") [ECF No. 37-2] ¶¶ 14–17. Information in TBDs can help NIOSH health physicists complete dose estimates when a worker's personal monitoring data is unavailable or incomplete. Allen Decl. ¶ 14; AR 7579–7580.[3]

To summarize, NIOSH reconstructs radiation doses using personal radiation monitoring data, coworker radiation monitoring data, or workplace monitoring data—in that order of priority—and interprets that data using additional data characterizing the workplace exposure

[3] Citations to "AR" refer to the administrative record. See Joint App'x [ECF No. 45].

environment, such as particle size distribution. See 42 C.F.R. § 82.14 (listing the types of information used in dose reconstructions). When NIOSH does not have adequate information to ascertain workplace exposure parameters with precision, it will use worst-case assumptions—if they are scientifically defensible—to create a dose reconstruction model capable of providing the maximum dose to which the organ under consideration could have been exposed in plausible circumstances. And if NIOSH does not have adequate personal, coworker, or workplace monitoring data, it may rely substantially on process description information to develop an exposure model capable of providing the maximum dose. See id. § 82.2(c).

Yet it is "uncertain whether adequate information of the types outlined under § 82.14 will be available to complete a dose reconstruction for every claim eligible." Id. § 82.12. As explained above, NIOSH may sometimes rely substantially on process description information to "provide the basis for a reasonable estimate." 67 Fed. Reg. at 22,324; see also id. at 22,325 ("In some cases, limited information about the radiation source term (type and quantity of radioactive material) and the process in which it was used, without any individual monitoring records, will be sufficient to complete a dose reconstruction."). But if "this basic information is lacking," then "NIOSH may not be able to establish reasonable estimates." 67 Fed. Reg. at 22,324. If a dose reconstruction "cannot be completed," NIOSH will notify the claimant, DOL, and DOE. 42 C.F.R. § 82.12. Such a scenario "result[s] in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH . . . ." Id. Claimants seeking compensation for one of twenty-two specified cancers may still be eligible for compensation under the SEC provision, and NIOSH will assist such claimants in preparing a petition to be added to the SEC. Id.

Assuming there is enough basic information to produce a reasonable dose estimate, NIOSH will calculate an internal dose. Id. § 82.18(a). To do so, NIOSH applies the employee's duration and rate of exposure (based on individual work history) to the applicable dose reconstruction model "to calculate the maximum amount of radioactive material the worker potentially inhaled and/or ingested during the span of employment at a covered facility." Taulbee Decl. ¶ 23; see also Allen Decl. ¶ 18; AR 7583. Then, NIOSH applies this quantity to metabolic models published by the International Committee on Radiological Protection (ICRP) to calculate the maximum possible dose to the particular organ of concern. See Taulbee Decl. ¶ 23; AR 7583.[4] Once NIOSH has estimated a dose, it attaches a "probability distribution that accounts for the uncertainty of the estimate," which is used by DOL to calculate the probability of causation. 42 C.F.R. § 82.19. "In this way, claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH." Id.

HHS provides completed dose reconstructions to DOL, which then applies the dose reconstruction results together with certain medical and personal information provided by the claimant to calculate an estimated probability that the employee's cancer was caused by his employment at a covered DOE facility. 42 C.F.R. § 82.4; 20 C.F.R. §§ 30.213(a)–(b), 30.305. A probability of causation greater than or equal to fifty percent qualifies claimants for compensation. 20 C.F.R. § 30.213.

[4] "When the cancer covered by a claim is in a tissue not covered by existing ICRP models, NIOSH will use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant." 42 C.F.R. § 82.18(b). This means that "[f]or internal exposures, NIOSH will select the highest dose estimate from among the modeled organs or tissues that do not concentrate the radionuclide." Id.

B. Special Exposure Cohort

Workers who qualify as members of the Special Exposure Cohort do not need to go through the dose reconstruction process in order to receive compensation. 42 C.F.R. § 82.11; 20 C.F.R. § 30.115(a). In essence, it is presumed that occupational radiation more likely than not caused such a worker's cancer. To qualify as a member of the SEC, an employee must meet the specific facility and work period requirements for an "SEC class" and have had at least one of twenty-two specified cancers. 42 U.S.C. §§ 7384l(9)(A), (14), (17); 20 C.F.R. § 30.5(gg) (listing twenty-two cancer types). As a result, some workers may be part of an "SEC class" but not qualify for membership in the SEC because they have not had one of the specified cancers.

The EEOICPA designated groups of workers at four particular facilities as members of an SEC class. 42 U.S.C. § 7384l(14). The Act also authorized the President to designate additional groups of workers as an SEC class if he determines that "(1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class." Id. § 7384q(b).[5] In short, if it is feasible to estimate with sufficient accuracy the radiation dose for a class of workers, those workers will not be deemed an SEC class and will instead go through the dose reconstruction process. But if it is not feasible to estimate the radiation dose for the class with sufficient accuracy, then HHS must also find that it is likely that the radiation dose may have endangered the health of class members. NIOSH is responsible for evaluating petitions to add classes of employees to the SEC. See 42 C.F.R. §§ 83.6, 83.13. When assessing SEC petitions, NIOSH asks whether the dose reconstruction methods set out in 42 C.F.R. pt. 82 can be used to estimate the radiation dose the class received with sufficient accuracy. See Procedures for

[5] The President then delegated this power to HHS. See Exec. Order No. 13,179, 65 Fed. Reg. at 77,488.

Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule, 69 Fed. Reg. 30,764, 30,765 (May 28, 2004) ("42 CFR Part 82 provides the methods by which NIOSH is conducting dose reconstructions . . . . [and these] methods . . . will be directly considered by HHS in reviewing petitions to add classes of employees to the Cohort.").

When evaluating a proposed SEC class, NIOSH must have sufficient information to characterize the radiation environment, and that information must adequately represent the exposure scenarios for all workers in the proposed class. See id. § 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 sufficient information to "estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose."); see also Allen Decl. ¶ 24. Although NIOSH is not limited to using only information from the specific facility under consideration, "a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked." Id. Therefore, NIOSH must 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." 42 C.F.R. § 83.13(c)(1)(i).

The kinds of information needed for NIOSH to conclude that it can estimate doses for a class with sufficient accuracy is the same as the kinds of information needed to complete a dose reconstruction under 42 C.F.R. pt. 82: personal monitoring data, coworker monitoring data, workplace monitoring data, and process description information. See id. § 83.13(c)(1)(ii)–(iv). This kind of data is necessary to support the development of dose reconstruction models capable

of providing the maximum dose that could have been incurred in plausible circumstances. See id. § 83.13(c)(1)(i). In sum, "the initial evaluation of information sufficiency and representativeness for the end goal of developing a dose reconstruction method capable of producing a maximum value under plausible circumstances for dose estimates is the objective of an SEC petition evaluation." Allen Decl. ¶ 21. When an SEC petition is filed after a TBD has been completed, NIOSH will review the TBD to assess the sufficiency and representativeness of the information that forms the basis for any dose reconstruction model. See id. (citing AR 7338–7341; AR 6426–6427, 6429). After NIOSH evaluates an SEC petition, it will use its findings to create or revise the relevant TBD. See id.

* * *

Thus, the regulatory scheme to assess claims for compensation under the EEOICPA operates on two different tracks. One track is the dose reconstruction process under 42 U.S.C. § 7384n, whereby HHS provides reasonable internal and external radiation dose estimates to DOL, which then estimates the probability that the employee's cancer was caused by occupational radiation. The second track—the fast track—is inclusion in the SEC by having one of twenty-two cancers and being part of a class of workers that HHS or Congress has designated to the SEC under 42 U.S.C. § 7384q or 42 U.S.C. § 7384l(14), respectively. Decisions concerning both dose reconstruction and SEC designation are subject to review by the Advisory Board on Radiation and Worker Health ("Advisory Board"), which includes scientists, physicians, and workers. 42 U.S.C. §§ 7384o, 7384n(d)(2), 7384q.

II. Factual Background

Plaintiffs' father Arnold Young ("Young") was a DOE contract employee at Electro Metallurgical Company ("Electro Met") from 1941 to 1945 and at the Linde Ceramics Plant from

1956 to 1971. AR 8179. Both were covered DOE facilities under the EEOICPA. Id. Young was diagnosed with prostate cancer on March 21, 1984, and died on August 5, 1985. Id. at 8182; Ex. 1 to Compl. ("Notice of Final Decision") [ECF No. 1-6] at 2. Prostate cancer does not qualify an employee for the SEC. See 42 C.F.R. § 83.0; 20 C.F.R. § 30.5(gg) (listing the twenty-two types of cancers that qualify for the SEC, none of which is prostate cancer).

A. Young's 2011 Dose Reconstruction

In 2011, Young's surviving spouse, Dorothy Young, filed a claim for benefits under Part B of the EEOICPA. See AR 8178–8179. Her claim was denied on April 18, 2012, because DOL, relying in part on a NIOSH dose reconstruction, determined that the probability that Young's cancer was related to his employment was less than 50 percent. See Notice of Final Decision at 2–3. Because there was no individual monitoring data for Young at Electro Met, the Electro Met portion of the 2011 dose reconstruction relied on information and exposure models in a Technical Basis Document ("TBD") first developed in 2007. AR 8183, 8186.[6]

B. Electro Met SEC Class Designation

In May 2012, HHS designated all DOE employees and contractors at Electro Met from August 13, 1942, through December 31, 1947, as an SEC class because NIOSH could not estimate the internal radiation dose for those employees "with sufficient accuracy." AR 5408. Specifically, HHS determined that "[i]nternal monitoring data, work area radiological monitoring data, and source term data are not sufficient to provide a sufficiently accurate estimate of the bounding internal dose during this early period at the Electro Metallurgical site." AR 5409.

[6] The Electro Met TBD was technically published in 2011 because prior to that, it was an appendix in a larger document rather than a standalone TBD. But the change was in format only. The 2011 Electro Met TBD contained the same internal and external dose reconstruction models as the 2007 appendix. See AR 8464–8471, 6486–6493.

This decision was made in response to a petition filed in 2008, which sought to designate Electro Met workers as an SEC class. AR 5837. In evaluating whether class members' radiation doses could be estimated with sufficient accuracy, NIOSH scrutinized the dose reconstruction methods in the Electro Met TBD. AR 5847. The Electro Met TBD contained an internal dose model that was based on a limited number of air samples taken in 1948 and 1949. AR 9371. But in 2012, after an extensive three-year evaluation process, NIOSH uncovered new information which showed that "the internal dose related data collected after 1947 cannot be extrapolated to exposures occurring prior to 1948 at Electro Metallurgical." AR 5838. Further, the only pre-1947 air samples available were "completely at odds with the later data" because the concentrations were much lower than samples taken after safety practices improved—and so these samples were unreliable. AR 5537–5541. NIOSH therefore concluded that "neither the bioassay nor the early limited air sampling data are sufficient to bound the dose at Electro Metallurgical for the August 13, 1942 through December 31, 1947" period. AR 5865.

Next, NIOSH considered using limited coworker data but concluded that the samples were not sufficiently high-quality or representative. AR 5538-89, 5766-67. And NIOSH even considered using process description information, but it was unable to locate relevant documents. AR 6139. Hence, NIOSH did not have sufficient information to build a dose reconstruction model capable of providing the maximum (i.e., bounding) internal dose for the period before 1948. See AR 5866 ("[I]t is not possible to completely reconstruct internal radiation doses for the period from August 13, 1942 through December 31, 1947."). The Advisory Board agreed with NIOSH's findings and recommended that HHS designate this class of Electro Met employees as an SEC class, which HHS did in 2012. AR 5408.

C. 2015 Revision to Electro Met TBD

Following the class designation, NIOSH continued to revise existing dose reconstruction methods for Electro Met in light of information discovered during the SEC petition evaluation process. See Allen Decl. ¶ 45. In 2015, NIOSH issued a new TBD to be used in preparing dose reconstructions for Electro Met workers—a "total rewrite of the document." AR 5369. The 2015 Electro Met TBD changed the dose reconstruction process for Electro Met workers in two major ways. First, NIOSH terminated its use of the internal exposure model that was developed in 2007. After citing its conclusion (from the SEC petition evaluation) that "it is not feasible to estimate internal exposures with sufficient accuracy for all workers at the site for the period August 13, 1942 through December 3, 1947," NIOSH explained that "unmonitored internal exposures during this time period cannot be reconstructed." AR 5383. NIOSH would, however, still reconstruct the internal dose for employees during this time period if there was any "personal monitoring data" available for them. Id. Second, the new dose reconstruction process "incorporated a re-evaluation of data and information [from] the SEC review process," which resulted in "an increased external dose estimate for all claims" completed using the earlier TBD. AR 5366 (emphasis added).

HHS evaluated the effects of the revision of the Electro Met TBD on previously completed claims and determined that twenty-five of those claims met the criteria for inclusion in the SEC while thirty-nine did not. AR 5366–5367. Dorothy Young's claim was one of the thirty-nine. Although Arnold Young was now part of an SEC class, he did not qualify as a member of the SEC because he had not been diagnosed with one of the twenty-two specified cancers. See AR 7576–78; see also 42 C.F.R. § 83.0; 20 C.F.R. § 30.5(gg). Employees who are part of an SEC class but do not qualify for the SEC do not enjoy the presumption that their cancer is related to occupational radiation. Instead, "[f]or any claimant referred to NIOSH who is a member of the [SEC class] and

has a cancer not defined as a 'specified cancer' under EEOICPA (and so is not eligible for compensation under EEOICPA without a dose reconstruction), NIOSH will continue to attempt to complete a dose reconstruction, using whatever information is available about that member's entire work history." 69 Fed. Reg. at 30,776. "However, NIOSH is not authorized under EEOICPA to administratively assign radiation doses to employees for whom radiation doses cannot be estimated using methods of dose reconstruction." Id.

D. Young's 2016 Dose Reconstruction

In 2016, plaintiffs each filed a survivor's claim for benefits under the EEOICPA as the surviving adult children of Arnold Young. AR 7556; AR 7574. NIOSH revised its 2011 dose reconstruction due to the addition of new survivors to the claim and in order to reflect the changes in the TBDs for Electro Met and the Linde Ceramics Plant. AR 7578. Young's 2016 dose reconstruction differed from his 2011 dose reconstruction in two meaningful ways. First, "[t]he assigned internal dose decreased due to the special exposure cohort (SEC) for Electro Metallurgical." AR 7579. As in 2011, NIOSH lacked personal monitoring records for Young. AR 7578. In 2011, NIOSH had relied on the internal exposure model that was later removed from the Electro Met TBD in 2015. AR 8183. But by 2016, NIOSH had determined that it was not feasible to reconstruct internal radiation exposures for Electro Met employees from August 13, 1942, through December 31, 1947, and it had terminated use of the 2007 internal exposure model. AR 7579. Hence, "no internal dose [could] be assigned to Mr. Young for his employment at Electro Metallurgical." Id. Young's internal dose also decreased due to changes in the TBD for the Linde Ceramics Plant. Id. Second, although Young's total internal dose estimate decreased, "the assigned external dose increased . . . in accordance with the revised technical basis document

for the Electro Metallurgical Company and the technical basis document for the Linde Ceramics Plant." Id.

DOL, applying Young's new 2016 dose reconstruction, determined that there was a 49.18 percent probability that Young's prostate cancer was related to his employment at the covered facilities. Notice of Final Decision at 3. Because the probability of causation was less than fifty percent, plaintiffs' claims for survivor benefits were not compensable. Id. at 6–7.

III. Litigation History

On November 9, 2017, plaintiffs brought this action against DOL and HHS under the APA, asking the Court to compel DOL to re-adjudicate their claim after HHS provided a "complete dose reconstruction"—meaning one that included an internal dose estimate for Young's time at Electro Met. Compl. [ECF No. 1] ¶¶ 7, 105. The Court dismissed plaintiffs' initial complaint for lack of standing and failure to allege a cause of action because plaintiffs had not challenged a particular HHS regulation or final agency action, explaining that "without a change in the underlying technical basis document, policy, or regulations, these requested remedies would lead to precisely the same result" and would therefore not redress the harm alleged. See Young v. U.S. Dep't of Labor, No. 17-2428 (JDB), 2018 WL 3941948, at *3–5 (D.D.C. Aug. 16, 2018).

Plaintiffs then filed an amended complaint challenging "HHS's policy that where a determination has been made that a dose estimate cannot be performed with 'sufficient accuracy' for purposes of [designating a class of workers to the] SEC . . . HHS will not prepare a dose estimate for use in dose reconstructions . . . [for] claimants that are not eligible for the SEC." Am. Compl. [ECF No. 17] ¶ 49. Plaintiffs asked the Court to order HHS to revise its TBDs and to stop relying on the "sufficient accuracy" standard used in the SEC class designation process under § 7384q to determine the feasibility of making "reasonable" dose estimates under § 7384n. Id.

¶ 50. HHS and DOL moved to dismiss plaintiffs' amended complaint for lack of standing and failure to state a claim. Defs.' Mot. to Dismiss Am. Compl. [ECF No. 19]. Following oral argument, the Court granted the motion to dismiss as to DOL but denied the motion as to HHS. Young v. U.S. Dep't of Labor, No. 17-2428 (JDB), 2020 WL 1557170, at *15 (D.D.C. Apr. 1, 2020); Order (Apr. 1, 2020) [ECF No. 30].

On October 13, 2020, HHS filed a motion for summary judgment. Def.'s Mot. for Summ. J. ("Def.'s Mot.") [ECF No. 37]. Plaintiffs cross-moved for summary judgment. Pls.' Cross-Mot. for Summ. J. ("Pls.' Cross-Mot.") [ECF No. 39]. Both motions are now fully briefed and ripe for consideration.

Legal Standard

"Because of the limited role federal courts play in reviewing . . . administrative decisions, the typical Federal Rule 56 summary-judgment standard does not apply" to the parties' cross-motions for summary judgment. Conservation L. Found. v. Ross, 422 F. Supp. 3d 12, 27 (D.D.C. 2019). Instead, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The 'entire case' on review is a question of law," id., and summary judgment is the proper mechanism for review, Ctr. for Food Safety v. Salazar, 898 F. Supp. 2d 130, 138 (D.D.C. 2012). The Court's role "is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." Ass'n of Priv. Sector Colls. & Univs. v. Duncan, 110 F. Supp. 3d 176, 184 (D.D.C. 2015) (quoting Univ. of Mass. v. Kappos, 903 F. Supp. 2d 77, 84 (D.D.C. 2012)), aff'd, 640 Fed. App'x 5 (D.C. Cir. 2016)

Under the APA, the Court must "hold unlawful and set aside agency action, findings, and conclusions found to be," among other things, "arbitrary, capricious, an abuse of discretion, or

otherwise not in accordance with law; . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2). In short, plaintiffs must show that the challenged action was arbitrary and capricious or otherwise not in accordance with law. The bar for arbitrary and capricious action is high: "[i]t is not enough . . . that the court would have come to a different conclusion from the agency," Conservation L. Found., 422 F. Supp. 3d at 27–28, nor can the court "substitute its own judgment for that of the agency," id. at 28 (quoting Oceana, Inc., v. Pritzker, 24 F. Supp. 3d 49, 58 (D.D.C. 2014)). Similarly, courts have found abuse of discretion "if there is no evidence to support the decision or if the decision was based on an improper understanding of the law." Id. at 27 (quoting Kazarian v. USCIS, 596 F.3d 1115, 1118 (9th Cir. 2010)). To survive APA review, there need only be a "rational connection between the facts found and the choice made." Id. (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

Analysis

I. Standing

HHS claims that plaintiffs lack standing to challenge the agency's determination that it could not estimate Young's occupational radiation exposure with sufficient accuracy because they were not directly or concretely injured by the agency's radiation dose reconstruction methods. See Def.'s Mot. at 36–37. HHS also asserts that this assessment was not a final agency action as required to establish standing under the APA. See Reply of Def. HHS in Supp. of Mot. for Summ. J. & Opp'n to Pls.' Cross-Mot. for Summ. J. ("Def.'s Reply") [ECF No. 41] at 13–17. The Court disagrees.

To establish constitutional standing, a party must demonstrate an injury in fact, fairly traceable to the challenged conduct, that is redressable by a favorable judicial decision. Spokeo,

Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016); Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992). An injury in fact must be "concrete and particularized and actual or imminent, not conjectural or hypothetical." Spokeo, 136 S. Ct. at 1548 (internal quotation marks omitted). A concrete injury is "direct, real, and palpable—not abstract." Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin., 489 F.3d 1279, 1292 (D.C. Cir. 2007). A particularized injury is "personal, individual, distinct, and differentiated." Id. An actual or imminent injury is "certainly impending and immediate—not remote, speculative, conjectural, or hypothetical." Id. at 1293. Furthermore, the "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right in vacuo—is insufficient to create Article III standing." Summers v. Earth Island Inst., 555 U.S. 488, 496 (2009).

Plaintiffs claim to have been injured when DOL denied their claim for compensation under the EEOICPA, which they allege resulted from HHS's unlawful failure to produce a reasonable internal dose estimate for their father. Pls.' Cross-Mot. at 14–15. HHS argues that this claimed injury is not concrete because neither the statute nor the implementing regulations entitle plaintiffs to a complete dose reconstruction—meaning, in this case, one that includes an internal dose estimate. Def.'s Mot. at 37. But plaintiffs argue the opposite. Although the Court will ultimately reject plaintiffs' readings of the statute and regulations, that does not mean plaintiffs lack standing. If plaintiffs were to prove that HHS exceeded its legal authority by not providing a reasonable internal dose estimate, they would be able to show a corresponding injury.

As the Court previously explained in rejecting HHS's standing challenge at the motion to dismiss stage, "the EEOICPA confers the concrete benefit of compensation to qualifying claimants . . . and plaintiffs have alleged that HHS failed to abide by a procedural requirement (the use of methods for arriving at reasonable estimates) in the administrative process that determines

whether they qualify for the concrete benefit of compensation." Young, 2020 WL 1557170, at *7. Moreover, "[s]uch a procedural injury in the adjudication of plaintiffs' EEOICPA compensation claim satisfies the injury-in-fact requirement." Id. To be sure, when a statute gives the administering agency "unfettered discretion" in determining who will receive a benefit, the denial of that benefit cannot give rise to standing. Wash. Legal Clinic for the Homeless v. Barry, 107 F.3d 32, 36 (D.C. Cir. 1997) (quoting Bd. of Regents of State Colls. v. Roth, 408 U.S. 564, 567 (1972)). But the EEOICPA does not afford such discretion to DOL administrators to adjudicate claims; instead, it gives explicit instructions as to the criteria claimants must meet to be eligible for compensation. Pls.' Cross-Mot. at 26; 20 C.F.R. § 30.210. And the indirectness of HHS's influence on DOL's adjudication of plaintiffs' EEOICPA claim does not undermine standing, since HHS's dose estimation methods influence whether plaintiffs receive compensation from DOL. Young, 2020 WL 1557170, at *9.

Plaintiffs also allege that they were improperly denied their property interest in the compensation that would flow from a successful EEOICPA claim. Pls.' Cross-Mot. at 25. There is no due process deprivation-of-property claim in plaintiffs' complaint, and they cannot now amend their complaint through their opposition brief. See Def.'s Reply at 17 (citing Jo v. Dist. of Columbia, 582 F. Supp. 2d 51, 64 (D.D.C. 2008)). But plaintiffs' explanation of their proffered property interest in the EEOICPA benefit does bolster their argument that they were concretely injured by the denial of their claims.

HHS does not explicitly challenge the causation or redressability prongs of standing under Article III. The redressability requirement is relaxed for plaintiffs in cases alleging procedural injury and requires two causal links: between the procedural step at issue and the substantive government decision, and between that decision and plaintiffs' claimed injury. Young, 2020 WL

1557170, at *7 (citing Ctr. for Biological Diversity v. EPA, 861 F.3d 174, 182 (D.C. Cir. 2017)). The first of those links is satisfied by plaintiffs' allegations that HHS's dose reconstruction shaped DOL's adjudication of their EEOICPA claim; the second is met by their assertion that the denial of that claim resulted in a loss of compensation. The Court therefore finds that plaintiffs have established Article III standing and now moves to assessing plaintiffs' standing under the APA.

The APA limits review of agency action to "[actions] made reviewable by statute and final agency action for which there is no other adequate remedy in a court." Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 882 (1990) (quoting 5 U.S.C. § 704). A "final" agency action must: (1) "mark the consummation of the agency's decisionmaking process" and "not be of a merely tentative or interlocutory nature"; and (2) "be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 178 (1997) (internal quotation marks omitted). Plaintiffs purport to challenge two decisions by HHS: the "decision to deny reasonable dose estimates to certain claimants" and the decision "to direct NIOSH not to estimate certain doses in the revised technical basis document for Electro Metallurgical." Pls.' Cross-Mot. at 23. But HHS asserts that plaintiffs have failed to establish that any legal consequences resulted from either decision, since HHS's work only informs the ultimate adjudication by DOL. Def.'s Reply at 15.

To begin, the Court finds that HHS's actions satisfy the first prong of the Bennett test. Plaintiffs argue that HHS has an agency policy not to estimate a radiation dose if it previously determined it could not do so "with sufficient accuracy." Am. Compl. ¶ 2. This policy, according to plaintiffs, is a consummation of the agency's decision-making process. See Am. Compl. ¶¶ 3, 23–24. Plaintiffs contend that because this decision is detailed in HHS's final rule regarding the designation of SECs and published in the Federal Register in response to public comment, it is

correctly characterized as a final action. See id. ¶ 3; see also Soundboard Ass'n v. FTC, 888 F.3d 1261, 1267 (D.C. Cir. 2018). The Court agrees. Plaintiffs also cite the Electro Met TBD revision—which stated that internal dose estimates could not be reconstructed for unmonitored Electro Met workers from August 13, 1942 through December 3, 1947—as a final action appropriate for review by this Court. Am. Compl. ¶¶ 11, 24; Pls.' Cross-Mot. at 23. Such a guidance document is not tentative or interlocutory or only a particular official's opinion—rather, it is reflective of HHS's consideration of this particular issue. See Soundboard Ass'n, 888 F.3d at 1271.

Turning to the second Bennett prong, plaintiffs assert that legal consequences clearly flowed from HHS's determination not to estimate doses for certain workers—namely, that this caused their DOL application for EEOICPA benefits to be denied. Pls.' Cross-Mot. at 24. Defendants deny this contention, arguing instead that the dose reconstruction is only one piece of DOL's adjudication of EEOICPA claims and that it is speculative to assert that a revised dose estimate would result in a different outcome. Def.'s Reply at 14–16. While defendants are correct that it is ultimately the province of DOL to approve or deny EEOICPA claims, DOL has no authority to determine the method by which radiation exposure is measured and cannot therefore change the result of plaintiffs' dose reconstruction. See Still v. Dep't of Lab., No. 17-CV-1420 (DLF), 2020 WL 1853299, at *4 (D.D.C. Apr. 13, 2020).

Plaintiffs do not have the burden to prove that, but for a more favorable dose reconstruction, their EEOICPA petition would have been granted. "A plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." Sugar Cane Growers Coop. of Fla. v.

Veneman, 289 F.3d 89, 94–95 (D.C. Cir. 2002); see also Lujan, 504 U.S. at 572 n.7 (holding that a person living next to a licensed dam "ha[d] standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered").

Plaintiffs make a plausible argument that HHS's allegedly unlawful failure to estimate an internal dose for Young was the basis for the DOL's denial of their EEOICPA claim. With a partial dose reconstruction, plaintiffs could not demonstrate a greater than 50 percent likelihood that their father's cancer was caused by occupational radiation exposure. Defendant dismisses this argument as speculative, but this assertion beggars belief. Plaintiffs' calculated probability was 49.18 percent, a mere 0.82 percent away from the necessary figure. Am. Compl. ¶ 48. While not certain, plaintiffs' claim that an adjustment to the dose estimation would likely increase the probability enough to make up the difference is colorable. Accordingly, the Court finds that plaintiffs have sufficiently established their standing to bring this case under the APA.

II. Merits

A. The Decision Not to Estimate Internal Doses for Unmonitored Workers at Electro Met from 1942 Through 1947 Was Not Contrary to the EEOICPA

To start, plaintiffs argue that HHS violated the EEOICPA by deciding not to estimate internal radiation doses for unmonitored Electro Met workers who are part of the SEC class but who do not qualify as members of the SEC. See Pls.' Cross-Mot. at 1–3. Plaintiffs claim that § 7384n of the EEOICPA obligates HHS to provide an internal dose estimate for each worker, id. at 32–33, and to provide a "reasonable" internal dose estimate even if the dose cannot be estimated with "sufficient accuracy," id. at 5–12.

1. § 7384n of the EEOICPA Does Not Require a Dose Estimate in Every Case

Plaintiffs claim that § 7384n(d) of the EEOICPA requires NIOSH to estimate an internal dose. See Pls.' Cross-Mot. at 14–15, 32–33. In their reply, plaintiffs double down on this position, asserting that "there is no statutory authority for the notion that a reasonable dose estimate might be impossible based on a lack of basic information." Pls.' Reply to Def.'s Opp'n to Pls.' Mot. for Summ. J ("Pls.' Reply") [ECF No. 44] at 3. According to plaintiffs, "HHS is not asked in the EEOICPA statute whether reasonable dose estimates can be prepared," but is instead directed to determine how dose estimates will be prepared. Id. The Court is not persuaded.

Under the EEOICPA, HHS is required to "establish by regulation methods for arriving at reasonable estimates of radiation doses received" by workers whose personal monitoring data is nonexistent or inadequate. 42 U.S.C. § 7384n(d)(1). Read plainly, the statute does not require the agency to provide a completed dose estimate in every case, just to establish methods designed to produce reasonable estimates. Plaintiffs offer no support for their strained interpretation of § 7384n(d), and the Court finds none. The fact that HHS is tasked with determining how to arrive at reasonable estimates does not mean that reasonable external and internal estimates are possible in every case. If NIOSH has so little data that it cannot produce an estimate "using a substantial basis of fact," see 67 Fed. Reg. at 22,317, surely § 7384n(d) does not require NIOSH to make a baseless guess and deem it "reasonable." Indeed, plaintiffs seem to concede that a reasonable estimate could be impossible when they state that "[u]nless the evidence is so sparce [sic] that such an estimate can be only described as speculation and conjecture, a reasonable dose should be estimated." See Pls.' Reply at 22.

Moreover, the dose reconstruction regulations expressly contemplate that complete dose reconstructions may sometimes be impossible. In order to characterize the radiation environment, NIOSH seeks out various types of information, which are detailed at 42 C.F.R. § 82.14. The

regulations note that "[i]t is uncertain whether adequate information of the types outlined under § 82.14 will be available to complete a dose reconstruction for every claim." 42 C.F.R. § 82.12. In some cases, NIOSH may rely substantially on process description information to "provide the basis for a reasonable estimate." 67 Fed. Reg. at 22,324; see also id. at 22,325 ("In some cases, limited information about the radiation source term (type and quantity of radioactive material) and the process in which it was used, without any individual monitoring records, will be sufficient to complete a dose reconstruction."). But if "this basic information is lacking," then "NIOSH may not be able to establish reasonable estimates." 67 Fed. Reg. at 22,324. Further, the regulations acknowledge that when NIOSH cannot estimate any internal or external dose for an employee's entire work history, "[t]his will result in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH." Id. Plaintiffs concede that "the potential that a dose estimate might not be possible is set forth in the regulation" but stress that "it has no counterpart in the statute." See Pls.' Reply at 3. Apparently, plaintiffs believe that the regulations violate the statute. But plaintiffs have not brought an APA challenge against § 82.12. And, as explained above, such a challenge would fail.

2. § 7384n of the EEOICPA Does Not Require NIOSH to Produce a "Reasonable" Dose Estimate Where NIOSH Lacks Information to Estimate the Dose With "Sufficient Accuracy"

The Court now turns to plaintiffs' closely related contention that HHS unlawfully refuses to estimate a dose unless the estimate is "sufficiently accurate," which plaintiffs claim is a more rigorous standard than "reasonable." See Pls.' Cross-Mot. at 5–12. Plaintiffs assert that although § 7384n requires NIOSH to make "reasonable" internal dose estimates, NIOSH will not estimate an internal dose (absent personal monitoring data) if it has determined that it cannot do so with

"sufficient accuracy" for purposes of designating an SEC class under § 7384q. See id. According to plaintiffs, however, the fact that NIOSH cannot estimate a dose with "sufficient accuracy" does not mean it cannot make a "reasonable" estimate. See id. at 6 ("[T]here are times when NIOSH can reasonably estimate a dose but that dose is so uncertain that an SEC should nevertheless be established."). Plaintiffs further contend that HHS's decision in the 2015 Electro Met TBD not to estimate internal doses from 1942 to 1947 (absent personal monitoring data) resulted from this overarching "policy" and thus defied HHS's statutory mandate. Id. at 33. The Court disagrees.

To be sure, the bare definitions of "reasonable estimate" and "with sufficient accuracy" diverge. HHS interprets the term "reasonable estimates" in § 7384n to mean "estimates calculated using a substantial basis of fact and the application of science-based, logical assumptions to supplement or interpret the factual basis." 67 Fed. Reg. at 22,317. By contrast, HHS regulations state that radiation doses can be estimated "with sufficient accuracy" under § 7384q if HHS has "access to sufficient information to estimate the maximum radiation dose . . . that could have been incurred in plausible circumstances by any member of the class, or . . . to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose." 42 C.F.R. § 83.13(c)(1)(i). Based on these definitions alone, the "sufficient accuracy" standard may appear narrower and more specific. See Young, 2020 WL 1557170, at *14.

But in reality, if NIOSH does not have sufficient information to estimate the maximum radiation dose for a class or to estimate the radiation doses of class members more precisely, then NIOSH does not have the information needed to develop a dose reconstruction model capable of providing the maximum dose potentially received by an individual worker in the class. And

without such a model or adequate personal monitoring data, NIOSH cannot reasonably estimate the dose incurred by the organ relevant to the worker's cancer. See supra at 4–8.[7]

Again, the "basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment." 42 C.F.R. § 82.2. The best way to do that is to use a worker's personal monitoring data, id. § 82.2(a), but if such data is nonexistent or inadequate, NIOSH will attempt to use coworker or exposure models to complete dose estimates, id. § 82.2(b)–(c). As explained above, the information needed for NIOSH to conclude that it can estimate doses for a class with sufficient accuracy under 42 C.F.R. pt. 83 is the same information needed to complete a dose reconstruction under 42 C.F.R. pt. 82: personal, coworker, workplace monitoring data, or process description information. See supra at 10. This kind of data is necessary to create dose reconstruction models capable of providing the maximum dose that could have been received by a worker in plausible circumstances—or, if adequate personal monitoring data is available, a more precise dose. Id.; see also 42 C.F.R. § 83.13(c)(1)(i).

In other words, the starting point for producing a reasonable dose estimate for an individual worker under 42 C.F.R. pt. 82 and evaluating a SEC petition under 42 C.F.R. pt. 83 is the same: to determine whether NIOSH has sufficient information to complete a dose reconstruction. Therefore, if NIOSH finds that it does not have sufficient information to characterize the radiation

[7] Although the term "maximum dose" is associated with the evaluation of an SEC class (i.e., determining whether radiation dose can be estimated with "sufficient accuracy" asks whether there is "sufficient information to estimate the maximum radiation dose"), the maximum dose approach is embedded in the dose reconstruction regulations at 42 C.F.R. pt. 82. See supra at 5.

environment for a class of workers, then it cannot produce a reasonable dose estimate for an individual worker within that class (absent personal monitoring data).[8]

Nevertheless, plaintiffs insist that NIOSH can produce a "reasonable" dose estimate for an individual class member even when NIOSH lacks both (1) sufficient information to create a dose reconstruction model capable of providing the maximum dose that could have been received by a class member in plausible circumstances and (2) sufficient personal monitoring data to estimate a dose more precisely. See Pls.' Cross-Mot. at 6–7. Although their arguments are a bit difficult to discern, plaintiffs appear to contend that Congress used different terms in § 7384n ("reasonable estimates") and § 7384q ("with sufficient accuracy") to signal different standards for determining the feasibility of estimating an individual employee's dose during the dose reconstruction process and for evaluating whether a class should be added to the SEC. See id. at 5–12. Yet as plaintiffs acknowledge, HHS already answered this same comment in the final rule for designating classes to the SEC. See Pl.'s Cross-Mot. at 11 (citing 69 Fed. Reg. at 30,769). HHS explained:

> The statutory provisions concerning the development of dose reconstruction methods (42 U.S.C. 7384n(d)) are concerned with how dose reconstructions are to be done, not a determination as to whether or not they can be done. It is implicit, nonetheless, that these dose reconstructions must be "feasible to estimate with sufficient accuracy." It appears to HHS that the use of this phrase under provisions for considering the addition of classes of employees to the Cohort, and the omission of this phrase under provisions concerning dose reconstruction, simply reflects the fact that these two separate provisions of EEOICPA address different but complementary circumstances.

69 Fed. Reg. at 30,769.

[8] HHS explains this point well when it notes that, in the absence of personal monitoring data, "[t]he dose reconstruction process, either for the purposes of providing a reasonable dose estimate for an individual worker or determining if it is feasible to estimate the radiation dose for a class of workers, requires sufficient information to build a coworker or exposure model to calculate the maximum dose incurred for all workers." Def.'s Mot. at 26. Accordingly, "if NIOSH does not have sufficient information to build a coworker or exposure model, then NIOSH is unable to model the highest exposure scenario for reconstructing the maximum dose for all workers or a reasonable dose estimate for any single unmonitored worker." Id. (citing 69 Fed. Reg. at 30,769).

Plaintiffs assert that this statement established a policy that "fail[s] to give effect to the clear language" of the EEOICPA. See Pls.' Cross-Mot. at 27–28. But here the Court agrees with HHS. Given the relationship between the dose reconstruction process and SEC petition evaluations, it does appear that the use of the phrase "with sufficient accuracy" in § 7384q but not in § 7384n reflects the fact that these provisions "address different but complementary circumstances." 69 Fed. Reg. at 30,769. HHS did not fail to give effect to the language "reasonable estimate"—it merely observed that NIOSH cannot produce a reasonable estimate without sufficient information to build a dose reconstruction model capable of providing the maximum dose or a more precise estimate. The term "reasonable estimate" still has a unique meaning. To produce a reasonable dose estimate, NIOSH must not only have sufficient information to build a model but must also take analytical steps to use that information to build a model and ultimately to estimate a dose. See Allen Decl. ¶ 21. For example, NIOSH must properly combine that information with any appropriate assumptions to develop a model, apply the employee's work history to the model to calculate the amount of radioactive material ingested or inhaled, and apply the resulting quantity to metabolic models to calculate the dose to the relevant organ. See supra at 4–8. The SEC petition evaluation process, on the other hand, "ends with a finding of whether sufficient information is available to complete dose reconstruction." Allen Decl. ¶ 21.

Next, plaintiffs argue that not estimating an internal dose when it cannot be estimated with "sufficient accuracy" is a "direct violation of the language of the dose reconstruction statute, section 7384n, which acknowledges the uncertainties involved and requires 'reasonable' dose estimates in spite of those uncertainties." Pls.' Cross-Mot. at 14–15. In other words, plaintiffs contend, "[t]he statute provides that HHS will promulgate regulations that establish how HHS will

prepare reasonable dose estimates in spite of a lack of 'basic information about the radiation environment.'" Pls.' Reply at 3. But plaintiffs misread the statute. Under § 7384n(d), NIOSH must establish methods for arriving at reasonable dose estimates when there is inadequate personal monitoring data. However, NIOSH needs some type of "basic information" in order to produce a reasonable estimate, such as coworker monitoring data, workplace monitoring data, or even (in some cases) process description information. See 42 C.F.R. § 82.12. The statute does not require NIOSH to prepare a reasonable estimate in spite of all uncertainties; rather, it requires a reasonable estimate when NIOSH lacks personal monitoring data but still has sufficient information to estimate the dose.[9]

Hence, NIOSH did not violate § 7384n. True, NIOSH's determination that it could not reconstruct Electro Met internal doses for a five-year period was made in the context of deciding whether to designate an SEC class. But this does not mean that, in revising the Electro Met TBD and performing Young's 2016 dose reconstruction, NIOSH refused to make reasonable internal dose estimates even though it could have done so. Rather, NIOSH determined that it lacked sufficient information to characterize the radiation environment during an early period at Electro Met. That was a reasonable conclusion based on the facts and science, consistent with the EEOICPA.

* * *

[9] Similarly, although NIOSH may use worst-case assumptions when there is uncertainty as to workplace exposure parameters, NIOSH still needs basic information to produce a reasonable dose estimate; it cannot rely entirely on default values. See Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Notice of Proposed Rulemaking, 68 Fed. Reg. at 11,294, 11,296 (Mar. 7, 2003) ("NIOSH has established the use of maximum doses based on worst-case assumptions in its dose reconstruction program whenever sufficient information is available to support this approach and the additional information needed for a more precise estimate is unavailable.").

The Court concludes that HHS did not violate the EEOICPA by deciding not to estimate internal radiation doses for unmonitored Electro Met workers who are part of the SEC class but do not qualify as members of the SEC.

B. The Decision Not to Produce Internal Dose Estimates for Unmonitored Workers at Electro Met from 1942 Through 1947 Was Not Arbitrary and Capricious

Plaintiffs contend not only that NIOSH shirked its statutory obligation to provide reasonable dose estimates but also that its determination that it could not produce such estimates was arbitrary and capricious. See Pls.' Cross-Mot. at 17, 33. To set aside an agency action as arbitrary and capricious, a court must find that the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or that the agency's action was "so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Conservation L. Found., 422 F. Supp. 3d at 27 (quoting State Farm, 463 U.S. at 43). Applying this standard, the Court concludes that NIOSH's decision was not arbitrary and capricious.

1. NIOSH Rationally Determined That It Lacked Sufficient Information to Estimate an Internal Dose

The Administrative Record establishes that NIOSH reasonably concluded, after extensive scientific analysis, that it lacked sufficient information to build an internal radiation exposure model characterizing the radiological environment at Electro Met from August 13, 1942, through December 31, 1947. As a result, NIOSH could not produce a reasonable internal dose estimate for Young or similarly situated workers. During the SEC evaluation process, NIOSH and the Advisory Board uncovered new information that undermined the scientific assumption supporting the internal dose exposure model that formed the basis for Young's 2011 dose reconstruction. See Allen Decl. ¶¶ 36–39 (compiling AR citations). That faulty assumption was that the radiological

conditions at Electro Met remained constant from 1943 to 1953, which had enabled NIOSH to build an exposure model for the entire period based on air samples collected in 1948 and 1949. Id. ¶ 36.

First, NIOSH discovered a report stating that "many changes were made to the industrial hygiene procedures at Electro Met prior to . . . October 1, 1947," which called into question NIOSH's prior assertion that air samples from 1948 and 1949 accurately represented radiological conditions for earlier years. Id. ¶ 37; AR 6432. Second, NIOSH found that there were "very few samples" of air concentrations from before 1947. Furthermore, NIOSH determined that the "air data collected in this early period is completely at odds with the later data. They are much, much lower. It is thousands of times higher when you look at those later time frames after the supposed improvements happened." Def.'s Mot. at 31–32 (quoting AR 5537–41); Allen Decl. ¶ 38. This was confounding and cast doubt on the foundational assumption of the 2011 internal dose reconstruction. Allen Decl. ¶ 38. Hence, NIOSH and the Advisory Board concluded that neither the post-1947 air samples (from 1948 and 1949) nor the limited pre-1947 air samples (from 1943 and 1944) were sufficient to build a new exposure model. AR 5537–5540, 5858; see also Taulbee Decl. ¶ 23. ("[I]f the breathing zone air sampling data only covers a short period of time, and the exposure conditions before or after that time period were not similar (e.g., changes to uranium metal processing, ventilation, or to radiation protection practices at the facility), then the utility of these breathing zone air monitoring data may not be sufficient to developing an exposure model for the time period of interest.").

Without air concentration data on which to build an exposure model, NIOSH considered alternatives. NIOSH explored whether it could use 67 urinalysis (i.e., bioassay) samples taken from 24 workers in 1944 to develop a coworker model, but concluded that the samples were not

representative or of adequate quality. AR 5766, 7454, 7456; Allen Decl. ¶ 40. NIOSH also attempted the last-resort dose reconstruction method: using process description and source term information. NIOSH asked DOE to locate "additional information regarding the possible processing of uranium ore and thorium activities at [Electro Met]." AR 6465. But DOE's search did not produce any relevant documents, see AR 6139, and so NIOSH had extremely limited information concerning the quantity and processing of uranium ore, see Allen Decl. ¶ 41. NIOSH and the Advisory Board could not even draw basic conclusions about the nature of production activities because all they had were "intermittent pieces, scraps and pieces" of "production information data over time for this facility." AR 5565–66. Indeed, the Advisory Board Chairman commented that "without sort of some good source or production data . . . I think it is really hard to draw conclusions." AR 5566.

Hence, when NIOSH stated in the 2015 Electro Met TBD that "it is not feasible to estimate internal exposures with sufficient accuracy . . . for the period August 13, 1942 through December 31, 1947," it meant that NIOSH did not have sufficient information to establish a coworker or exposure model for estimating internal doses for unmonitored workers. AR 5371, 5383, 5409; see also AR 7583 ("NIOSH has determined and the Secretary of [HHS] has concurred, that it is not feasible to reconstruct internal radiation exposures for all [AWE] employees who worked at [Electro Met] from August 13, 1942 through December 31, 1947, inclusive for Mr. Young."). Because NIOSH could not characterize the radiation environment, the "basic principle of dose reconstruction" was absent. NIOSH therefore could not produce a reasonable dose estimate.

NIOSH's reasonable determination is a scientific decision entitled to deference. The Supreme Court has held that "[w]hen examining this kind of scientific determination . . . a reviewing court must generally be at its most deferential." Balt. Gas & Elec. Co. v. Nat. Res. Def.

Council, 462 U.S. 87, 103 (1983) (considering the Nuclear Regulatory Commission's "zero-release" assumption); see also Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 375–77 (1989) (where analysis "requires a high level of technical expertise," courts must defer to informed discretion of agency) (citation omitted). Similarly, the D.C. Circuit has instructed that "[a]gency determinations based upon highly complex and technical matters are entitled to great deference." West Virginia v. EPA, 362 F.3d 861, 871 (D.C. Cir. 2004) (citation and quotation marks omitted). In this context, a reviewing court holds the agency only to "certain minimal standards of rationality." Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA, 686 F.3d 803, 810 (D.C. Cir. 2012) (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36–37 (D.C. Cir. 1976) (en banc)).

Plaintiffs counter that their challenge is entirely "a matter of interpretation of statutory language and does not involve scientific judgments." Pls.' Cross-Mot. at 31. They are wrong. Plaintiffs challenge NIOSH's failure to produce an internal dose estimate for Young's time at Electro Met and the record demonstrates that the decision not to estimate internal doses at Electro Met for the 1942 to 1947 period was the result of scientific analysis. Plaintiffs cannot escape deference by framing this entire case as a "legal question." See Marsh, 490 U.S. at 376–77 ("[W]e cannot accept respondents' supposition that review is of a legal question and that the [Army] Corps' decision 'deserves no deference.'").

Indeed, plaintiffs' own strategy demonstrates that NIOSH's decision was a scientific judgment. They second-guess NIOSH's scientific expertise, arguing that NIOSH could have estimated a dose greater than zero. See Pls.' Cross-Mot. at 19. They point to two findings from the Advisory Board's technical contractor that plaintiffs contend "would provide some scientific justification for certain dose estimates." Id. But the technical experts considered these findings, weighed them with other evidence, and concluded that this limited information did not support

construction of an internal exposure model. AR 5572–74, 5577. For instance, plaintiffs point to urinalysis sampling from 1944—where approximately half of the results were recorded as zero—but the Advisory Board concurred with NIOSH's finding that two months of data in 1944 "may not represent overall facility operations." AR 5766–67. Plaintiffs' assertion that "a reasonable estimate can be established" from these findings contradicts their statement that they are not asking the Court to second guess complex scientific decisions. See Pls.' Cross-Mot. at 19–20.

Plaintiffs further contend that NIOSH's determination that it could not estimate an internal dose for Young was contrary to the regulatory regime, which "gives the benefit of the doubt to the claimant when there is uncertainty" arising from DOE's failure to properly monitor workers. Id. at 6–7. But plaintiffs overstate the scope of the "benefit of the doubt" approach. They claim that HHS made an "unrestrained commitment to give claimants the benefit of the doubt," id. at 9, and that the "absence of information regarding worker radiation exposure should never be used against a worker in this program," id. at 5. Not so. Rather, the regulations give claimants the benefit of the doubt at a few specific stages of the dose reconstruction process. If NIOSH cannot precisely determine certain workplace exposure parameters, such as solubility class, it uses worst-case assumptions to give claimants the benefit of the doubt. 42 C.F.R. §§ 82.2(a), 82.18(b); 67 Fed. Reg. at 22,324. And when applying the worker's annual radiation quantity to a metabolic model in order to determine the dose to the relevant organ, NIOSH will select the model "that best approximates the model needed, while giving the benefit of the doubt to the claimant." 42 C.F.R. § 82.18(b). Finally, once NIOSH has estimated a dose, it attaches a "probability distribution" to account for the uncertainty of the estimate so that "claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH." Id. § 82.19. Plaintiffs do not dispute that they received the benefit of the doubt at these stages of the

2016 dose reconstruction process. See Def.'s Mot. at 30–31; Def.'s Reply at 10–11. And as HHS explains, "[t]he benefit of the doubt approach . . . does not require NIOSH to build a radiation exposure model where technical and scientific experts have concluded that there is insufficient information to build a model or to use a model that lacks a substantial basis in fact or logical assumptions." Def.'s Reply at 11.

Similarly, plaintiffs argue that "[a] program which resolves the absence of evidence in favor of the claimant should not conclude that a lack of evidence requires no dose estimate or a zero dose estimate." Pls.' Cross-Mot. at 2; see also id. at 14–15 ("It cannot be 'reasonable' to assign the worker what amounts to a zero dose when you are required to give that worker the benefit of the doubt and you know that a zero dose is not reasonable."). But as explained above, the dose reconstruction regulations do not always resolve the absence of evidence in favor of the claimant. To the contrary, the regulations contemplate that when basic information is absent, NIOSH cannot and will not complete a dose reconstruction—which may result in denial of the claim. 42 C.F.R. § 82.12.

The Court notes that, in deciding the motion to dismiss, it concluded that "plaintiffs have plausibly alleged that it is arbitrary and capricious, or otherwise unlawful, to assign Mr. Young an internal dose of zero when the data suggests he was likely exposed to more radiation than workers from 1948 who are receiving internal dose estimates for their time at Electro Metallurgical." Young, 2020 WL 1557170, at *14. But now, having reviewed the administrative record, the Court cannot conclude that Young was likely exposed to more radiation than Electro Met workers from 1948. The record shows that air sample values from 1943 and 1944 were actually much lower than those from later years, after supposed improvements to facility hygiene were made. See Allen Decl. ¶ 38 ("It is impossible to estimate the air concentrations prior to 1948 with any certainty.").

Hence, it was not arbitrary and capricious for NIOSH to determine that it lacked sufficient information to estimate an internal dose for Young's time at Electro Met. Plaintiffs seem to argue that when NIOSH cannot estimate a dose, it should assign some dose value greater than zero. See Pls.' Cross-Mot. at 2, 14–15.[10] But plaintiffs do not explain how NIOSH would determine that value, why such a value would be scientifically defensible, or where the EEOICPA authorizes NIOSH to administratively assign radiation doses to employees for whom radiation doses cannot be reasonably estimated.

2. HHS Adequately Considered Alternatives

Plaintiffs' position is that NIOSH can arrive at reasonable internal dose estimates even when it cannot determine the maximum (i.e., bounding) dose. See Pls.' Cross-Mot. at 2. But HHS already considered—and reasonably rejected—alternatives to a "maximum dose" approach to dose reconstruction. During the rulemaking for 42 C.F.R. pt. 83, the SEC regulation, HHS and the Advisory Board considered various options, including estimating a minimum dose, to mitigate the impact of an SEC class designation on unmonitored workers who are not eligible to be compensated through the SEC process. AR 3801, 3835–3840, 4868–4869, 3286–3291, 3501–3512, 3151.

The minimum dose approach was initially considered in the context of the health endangerment criterion for designating a SEC. See Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the EEOICPA; Notice of Proposed

[10] HHS argues that there are scientifically defensible reasons to assign Young a zero internal dose. See Def.'s Mot. at 34–35. There is no indication that Young worked at the Area Plant where all the uranium operations occurred. AR 5372, 8291; Taulbee Decl. ¶ 26 ("The minimum occupational radiation dose to energy employees can be zero because not all workers at a covered facility are exposed to radioactive materials."). Moreover, because the Area Plant did not become operational until April 1943, Young could have only been exposed to radiation from April 1943 to October 7, 1945. Since he was a welder, it is unlikely that he would have spent any prolonged period inside the Area Plant to incur any internal exposure. See AR 5754.

Rulemaking, 67 Fed. Reg. 42,962, 42,963–64 (June 25, 2002) (exploring the possibility that "the process of determining that dose reconstructions are not feasible should provide information to determine imprecisely the potential level of radiation to which the class could have been exposed"). Later, the Advisory Board considered whether this concept could be employed for workers who are part of an SEC class but do not qualify for the SEC. See AR 3388–3394, 3501–3509. But Advisory Board members expressed concerns with estimates that lack "an upper-bound estimate radiation dose." AR 3508–09. And in the context of the health endangerment assessment, the Advisory Board concluded that "the proposed [minimum dose] method for estimating whether the cohort met the criterion for 'health endangerment' was not adequately justified and could lead to arbitrary and unfair decisions." AR 3153. In contrast, HHS adopted the claimant-favorable maximum dose approach to dose reconstruction in order to avoid such arbitrary and unfair decisions. See 67 Fed. Reg. at 22,316. HHS also adopted the approach for efficiency reasons. Id. at 22,317. Ultimately, HHS omitted the "minimum dose" concept, concluding that "[l]acking a factual basis for establishing such a cap or upper bound to the possible level of radiation exposure, NIOSH cannot quantitatively evaluate health endangerment." 68 Fed. Reg. at 11,297; see also Taulbee Decl. ¶ 25.

HHS also considered whether "changes in the dose reconstruction regulations should be made to address any potential conflict between [42 C.F.R. pt. 83] and 42 CFR 82 that could leave some claimants ineligible for either individual dose reconstruction or special cohort status." AR 8655. But HHS concluded that the dose reconstruction rule in 42 C.F.R. pt. 82 did not need to be revised because it was not in conflict with 42 C.F.R. pt. 83. 69 Fed. Reg. at 30,777. Since the dose reconstruction methods under 42 C.F.R. pt. 82 are concerned with how dose reconstructions can be done, it is implicit that there must be sufficient information to support the development of

a dose reconstruction method that is capable of producing the maximum radiation dose. See id. at 30,769. When sufficient information is not available, then it is not feasible to estimate a radiation dose with sufficient accuracy, and it is also not feasible to estimate the radiation dose for individual workers. Id.; 42 C.F.R. § 82.12. Moreover, NIOSH considered whether it could administratively assign radiation doses greater than zero when those doses could not be reasonably estimated. But "NIOSH is not authorized under EEOICPA to administratively assign radiation doses to employees for whom radiation doses cannot be estimated using methods of dose reconstruction." 69 Fed. Reg. at 30,776.

In the end, plaintiffs have not identified any data or alternative that HHS failed to examine. The record establishes that NIOSH lacked sufficient information to estimate maximum internal doses for employees during the early period at Electro Met. Furthermore, HHS considered estimating non-zero minimum doses but rationally rejected that approach. Accordingly, it cannot be said that HHS "failed to consider an important aspect" of agency action. State Farm, 463 U.S. at 43.

CONCLUSION

For all these reasons, the Court will grant defendant's motion for summary judgment and deny plaintiffs' cross-motion for summary judgment. A separate order has been issued on this date.

/s/
JOHN D. BATES
Senior United States District Judge

Dated: August 6, 2021