

DCAS ADVISORY BOARD on Radiation and Worker Health
Robert Taft Laboratories
1090 Tusculum Ave
Cincinnati OH 45226

November 17, 2020

To All Advisory Board Members,

This is information that has seemed to be forgotten, or omitted from all SEC procedures. Time and time again, NIOSH has willfully denied SEC petitions when they do not have the authority to deny a full evaluation. Equal protection of the law also requires a full evaluation from NIOSH and the Board, with individuals' input. This evaluation is mandated to be in a timely manner.

“ The purpose of the compensation program is to provide for **fair and timely compensation** of covered employees and, where applicable, survivors of such employees, suffering from illnesses incurred by such employees **in the performance of duty** for the Department of Energy (DOE) and certain of its contractors and subcontractors”

Duties of the Board.....”Section 4(b) of Executive Order 13179 establishes that the Board **shall** provide advice to the Secretary, HHS on

- (1) the **development of guidelines** to assess the likelihood that an individual with cancer sustained the cancer **in the performance of duty** at a DOE or an Atomic Weapons Employer (AWE) facility, **and methods 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;**
- (2) **the scientific validity and quality of dose reconstruction efforts performed for purposes of the compensation program;** and
- (3) **upon request by the Secretary, HHS, whether there is a class of employees at any DOE or AWE facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation dose may have endangered the health of members of the class.**

“The Board shall provide advice to the Secretary.” “Subcommittees composed of members and nonmembers of the parent committee may be established with the approval of the Secretary, HHS or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency.”

STATUTORY DUTY BINDING ON BOARD, NIOSH, et al

42 U.S. Code § 7384q. Designation of additional members of special exposure cohort

(a) Advice on additional members

(1) The Advisory Board on Radiation and Worker Health under section 7384o of this title **shall advise the President (Secretary) whether there is a class of employees at any Department of Energy facility who likely were exposed to radiation at that facility but for whom it is not feasible to estimate with sufficient accuracy the radiation dose they received.**

(2) The advice of the Advisory Board on Radiation and Worker Health under paragraph (1) shall be based on exposure assessments by radiation health professionals, information provided by the Department of Energy, and such other information as the Advisory Board considers appropriate.

(3) The President shall request advice under paragraph (1) after consideration of petitions by classes of employees described in that paragraph for such advice. The President shall consider such petitions pursuant to procedures established by the President.

(b) **Designation of additional members** Subject to the provisions of section 7384/(14)(C) of this title, the members of a class of employees at a Department of Energy facility, or at an atomic weapons employer facility, may be treated as members of the Special Exposure Cohort for purposes of the compensation program if the President, upon recommendation of the Advisory Board on Radiation and Worker Health, 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.

(c) Deadlines

(1) Not later than 180 days after the date on which the President (Secretary) receives a petition for designation as members of the Special Exposure Cohort, the Director of the National Institute for Occupational Safety and Health shall submit to the Advisory Board on Radiation and Worker Health a recommendation on that petition, including all supporting documentation.

(2) (A) Upon receipt by the President of a recommendation of the Advisory Board on Radiation and Worker Health that the President should determine in the affirmative that paragraphs (1) and (2) of subsection (b) apply to a class, the President shall have a period of 30 days in which to determine whether such paragraphs apply to the class and to submit that determination (whether affirmative or negative) to Congress.

(B) If the determination submitted by the President under subparagraph (A) is in the affirmative, the President shall also submit a report meeting the requirements of section 7384(14)(C)(ii) of this title.

(C) If the President does not submit a determination required by subparagraph (A) within the period required by subparagraph (A), then upon the day following the expiration of that period, it shall be deemed for purposes of section 7384(14)(C)(ii) of this title that the President submitted the report under that provision on that day.

(d) Access to information

The Secretary of Energy shall provide, in accordance with law, the Secretary of Health and Human Services and the members and staff of the Advisory Board on Radiation and Worker Health access to relevant information on worker exposures, including access to Restricted Data (as defined in section 2014(y) of this title.

(Pub. L. 106–398, § 1 [div. C, title XXXVI, § 3626], Oct. 30, 2000, 114 Stat. 1654, 1654A–504; Pub. L. 107–107, div. C, title XXXI, § 3151(a)(2), Dec. 28, 2001, 115 Stat. 1372; Pub. L. 108–375, div. C, title XXXI, § 3166(b)(1), Oct. 28, 2004, 118 Stat. 2188.)

SEC Rule 42 CFR 83 Binding on parties, but does not over rule statute.

The SEC Rule, Procedures for Designating Classes of Employees as Members of the SEC (42 Code of Federal Regulations, Part 83), PDF pdf icon[132 KB (13 pages)] describes the procedures used to add a class of employees to the SEC.

The Department of Health and Human Services (HHS) created the **SEC procedures rule** to ensure that:

Petitions are submitted by authorized parties

Petitions are justified

Petitions are given uniform, fair, and scientific consideration

Petitioners are given the opportunity to be involved with the petition process

Topics Covered under the SEC Rule:

1. How HHS will determine:
 - if it is feasible to estimate the radiation dose that a class received, and
 - if there is a reasonable likelihood that the radiation dose may have endangered the health of members of the class
2. The procedures that are necessary to add a class of employees to the SEC
3. Individuals and organizations that are qualified to submit an SEC petition on behalf of a class
4. Minimum requirements that must be met for an SEC petition to qualify for consideration
5. Procedures to involve and notify petitioners in the petition process and to allow petitioners to seek administrative reviews of proposed decisions

42 CFR 83.....

Section 3626 of the Act (42 U.S.C. 7384q) authorizes the addition to the Cohort of other classes of employees. This authority has been delegated to the Secretary of HHS by Executive Order 13179.

HHS will consider adding new classes of employees in response to petitions by, or on behalf of, such classes of employees. The procedures specify requirements for petitions and for their consideration. **These requirements are intended to ensure that petitions are submitted by authorized parties, are justified, and receive uniform, fair, scientific consideration.** The procedures are also designed to give petitioners and interested parties opportunity for appropriate involvement in the process, **and to ensure that the process is timely and consistent with requirements specified in EEOICPA.**

42 CFR 83.5 (c) Computation of Time Periods: In this Rule, all prescribed or allowed time periods **will be counted as calendar days from the business day of receipt by the submitter(s),**

the petitioner(s), NIOSH, or HHS. **Receipt by NIOSH, the submitter(s) or petitioner(s) will be either the business day of actual receipt or three (3) business days after initial proof of mailing, whichever time period is shorter. Business days are defined as Monday through Friday, 8 a.m. to 4:30 p.m. est and “legal holiday” will be used as de-fined by the FED. R. CIV. P. 6(a).**

(k) **Petitioner** means an individual or organization that submits a petition on behalf of a class of employees and **qualifies as a petitioner under § 83.7.**

(l) **Radiation** means ionizing radiation, **including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body.**

§ 83.7 Who can submit a petition on be-half of a class of employees? A petitioner or petitioners for a petition must be one or more, up to a maximum of three, of the following:

- (a) One or more DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees, or their survivors; or
- (b) One or more labor organizations representing or formerly having rep-resented DOE, DOE contractor or sub-contractor, or AWE employees, who would be included in the proposed class of employees; or
- (c) One or more individuals or entities authorized in writing by one or more DOE, DOE contractor or subcon-tractor, or AWE employees, who would be included in the proposed class of employees, or their survivors.

§ 83.8 How is a petition submitted? The petitioner(s) must send a petition in writing to NIOSH.

§ 83.9 What information must a petition include?

- (a) All **petitions must** provide identifying and contact information on the petitioner(s). The information required to justify a petition differs, depending on the basis of the petition
- (c) The petition **must include** the following:
 - (1) A proposed class definition specifying:
 - (i) The DOE facility or AWE facility at which the class worked;
 - (ii) The location or locations at the facility covered by the petition (e.g., building, technical area);
 - (iii) The job titles and/or job duties of the class members;
 - (iv) The period of employment relevant to the petition;
 - (v) Identification of any **exposure incident that was unmonitored, unrecorded, or inadequately monitored or recorded**, if such incident comprises the basis of the petition; and
 - (2) **A description of the petitioner’s (petitioners’’) basis for believing records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class of employees with suffi-cient accuracy.** This description **must include one** of the following elements:

- (i) Documentation or statements provided by affidavit indicating that radiation exposures and doses to members of the proposed class were not monitored, either through personal or area monitoring; or
- (ii) Documentation or statements provided by affidavit indicating that radiation monitoring records for members of the proposed class have been lost, falsified, or destroyed; or
- (iii) **A report from a health physicist or other individual with expertise in dose reconstruction documenting the limitations of existing DOE or AWE records on radiation exposures at the facility, as relevant to the petition.** This report **should specify the basis** for believing these documented limitations might prevent the completion of dose reconstructions for members of the class under 42 CFR part 82 and related NIOSH technical implementation guidelines; or
- (iv) **A scientific or technical report**, published or issued by a government agency of the Executive Branch of government or the General Accounting Office, the Nuclear Regulatory Commission, or the Defense Nuclear Facilities Safety Board, or published in a peer-reviewed journal, that identifies dosimetry and related information that are unavailable (due to either a lack of monitoring or the destruction or loss of records) for estimating the radiation doses of employees covered by the petition.

(3) **If the petition is based on an exposure incident** as described under para-graph (c)(1)(v) of this section, the petitioner(s) might be required to provide evidence that the incident occurred, **but only if NIOSH is unable to obtain records or confirmation of the occurrence of such an incident from sources independent of the petitioner(s).**In such cases, **either of the following may qualify as evidence:**

- (i) **Medical evidence** that one or more members of the class may have incurred a high level radiation dose from the incident, such as a depressed white blood cell count associated with radiation exposure or the application of chelation therapy; or
- (ii) **NIOSH will consider evidence provided by affidavit from one or more employees who witnessed the incident.** If the petitioner cannot provide such affidavits because such employees are deceased, prevented by reasons of poor health or impairment, or cannot be identified or located, then the requirement for evidence provided by affidavit can be met by providing such an affidavit from one or more individuals who did not witness the incident, provided the individual was directly informed by one or more employees who witnessed the incident.

(4) The provision of any evidence under this section or other provisions of this part, including one or more affidavits, would not, in and of itself, be sufficient to confirm the facts presented by that evidence. **NIOSH will consider the adequacy and credibility of any evidence provided.**

(5) If, under § 83.15(a), NIOSH has already issued a FEDERAL REGISTER notice scheduling **a Board meeting to consider a petition concerning a class of employees**, then any petitions for such a class of employees submitted following this notice must, under para-graph (c)(2) of this section, present substantially new information that has not

already been considered by NIOSH. For this purpose, NIOSH would find that information has been already considered by NIOSH if it were included in the petition(s) that were already considered by NIOSH or if it were addressed either in the report(s) by NIOSH evaluating such a petition or petitions under § 83.13(c) or in a proposed decision by NIOSH responding to such a petition or petitions under § 83.16(a).

§ 83.10 If a petition satisfies all rel-evant requirements under § 83.9, does this mean the class will be added to the Cohort? Satisfying the informational requirements for a petition does not mean the class will be added to the Cohort. **It means the petition will receive a full evaluation by NIOSH, the Board, and HHS, as described under §§ 83.13 through 83.16.**

§ 83.13 How will NIOSH evaluate petitions, other than petitions by claimants covered under § 83.14?

(a) **NIOSH will collect information on the types and levels of radiation exposures that potential members of the class may have incurred, as specified under 42 CFR 83.14, from the following potential sources, as necessary:**

- (1) The petition or petitions submitted on behalf of the class;
- (2) DOE and AWE facility records and information;
- (3) Potential members of the class and their survivors;
- (4) Labor organizations who represent or represented employees at the facility during the relevant period of employment;
- (5) Managers, radiation safety officials, and other witnesses present during the relevant period of employment at the DOE facility or AWE facility;
- (6) NIOSH records from epidemiological research on DOE populations and records from dose reconstructions conducted under 42 CFR part 82;
- (7) Records from research, dose reconstructions, medical screening programs, and other related activities conducted to evaluate the health and/or radiation exposures of DOE employees, DOE contractor or subcontractor employees, and/or AWE employees; and
- (8) Other sources.

(b) **The Director of OCAS may determine that records and/or information requested from DOE, an AWE, or an-other source to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.**

- (1) Before the Director of OCAS makes such a determination, the source(s) potentially in possession of such records and/or information will be allowed a **reasonable amount of time, as determined by the Director of OCAS, to provide the records and/or information.**
- (2) Such a determination **may take into account the types and quantity of records and/or information requested from the source, as well as any other factors that might be relevant to the judgment** under paragraph (b)(1) of this section of the amount of time that is reasonable to provide the records

and/or information, which would be decided on a case-by-case basis by the Director of OCAS.

(c) **NIOSH will evaluate records and information collected** to make the following determinations:

(1) Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?

(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.**

(ii) In 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. Alternatively, if members of the class were potentially exposed without adequate protection to unmonitored radiation from radiation generating equipment (e.g., particle accelerator, industrial x-ray equipment), in many circumstances, NIOSH would require relevant equipment design and performance specifications or information on maximum emissions.

(iii) In 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.**

(iv) In 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.

(2) How should the class be defined, consistent with the findings of the analysis discussed under paragraph (c)(1) of this section? NIOSH will define the following characteristics of a class, taking into account the class definition proposed by the petition and modified as necessary to reflect the results of the evaluation under paragraph (c)(1) of this section:

- (i) Any of the following employment parameters, as necessary to identify members included in the class: facility, job titles, duties, and/or specific work locations at the facility, the relevant time period, and any additional identifying characteristics of employment; and
- (ii) If applicable, the identification of an exposure incident, when unmonitored radiation exposure during such an incident comprises the basis of the petition or the class definition.

(3) Is there a reasonable likelihood that such radiation dose may have endangered the health of members of the class? If it is not feasible to estimate with sufficient accuracy radiation doses for members of the class, as provided under paragraph (c)(1) of this section, then NIOSH must determine, as required by the statute, that “there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class” (42 U.S.C. 7384q(b)(2)).

- (i) For classes of employees that may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures, such as nuclear criticality incidents or other events involving similarly high levels of **exposures resulting from the failure of radiation protection controls**, NIOSH will assume for the purposes of this section that **any duration of unprotected exposure could cause a specified cancer, and hence may have endangered the health of members of the class**. Presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, will satisfy the health endangerment criterion.
- (ii) For health endangerment not established on the basis of a discrete incident, as described under paragraph (c)(3)(i) of this section, **NIOSH will specify a minimum duration of employment to satisfy the health endangerment criterion as having been employed for a number of work days aggregating at least 250 work days within the parameters established for the class or in combination with work days within the parameters established for one or more other classes of employees in the Cohort.**

(d) NIOSH will submit a report of its evaluation findings to the Board and to the petitioner(s). The report will include the following elements:

- (1) An identification of the relevant petitions;
- (2) A proposed definition of the class or classes of employees to which the evaluation applies, and a summary of the basis for this definition, including, as necessary:

- (i) **Any justification** that may be needed for the inclusion of groups of employees who were not specified in the original petition(s);
 - (ii) The identification of any groups of employees who were identified in the original petition(s) **who should constitute a separate class of employees**; or
 - (iii) The **merging of multiple petitions that represent a single class of employees**;
- (3) The **proposed class definition will address** the following employment parameters:
- (i) The **DOE facility** or the AWE facility that employed the class;
 - (ii) The **job titles and/or job duties and/or work locations** of class members;
 - (iii) The **period of employment** within which a class member must have been employed at the facility under the job titles and/or performing the job duties and/or working in the locations specified in this class definition;
 - (iv) If applicable, **identification of an exposure incident**, when potential radiation exposure during such an incident

§ 83.15 How will the Board consider and advise the Secretary on a petition?

- (a) **NIOSH will publish a notice in the FEDERAL REGISTER providing notice of a Board meeting at which a petition will be considered, and summarizing the petition to be considered by the Board at the meeting and the findings of NIOSH from evaluating the petition.**
- (b) **The Board will consider the petition and the NIOSH evaluation report at the meeting, to which the petitioner(s) will be invited to present views and information on the petition and the NIOSH evaluation findings.**
- (c) **In considering the petition, the Board may obtain and consider additional information not addressed in the petition or the initial NIOSH evaluation report.**
- (d) **NIOSH may decide to further evaluate a petition, upon the request of the Board. If NIOSH conducts further evaluation, it will report new findings to the Board and the petitioner(s).**
- (e) **Upon the completion of NIOSH evaluations and deliberations of the Board concerning a petition, the Board will develop and transmit to the Secretary a report containing its recommendations. The Board's report will include the following:**
 - (1) The identification and inclusion of the relevant petition(s);
 - (2) The definition of the class of employees covered by the recommendation;
 - (3) **A recommendation as to whether or not the Secretary should designate the class as an addition to the Cohort;**
 - (4) **The relevant criteria under § 83.13(c) and findings and information upon which the recommendation is based**, including NIOSH evaluation reports, information provided by the petitioners, any other information considered by the Board, and the deliberations of the Board.

“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 that could have been incurred in plausible circumstances** * * *” (emphasis added). 42 CFR 83.13(c)(1)(i). In this case, “plausible circumstances” is not substituting for “sufficient accuracy” as suggested, since the **operative concept here is the ability to estimate the maximum radiation dose**. The identification of **plausible circumstances qualifies how such doses would be estimated**. It means that NIOSH is **not required to utilize unlikely, unreasonable, or illogical scenarios to estimate radiation doses**.

“NIOSH dose reconstruction program provides the benefit of the doubt to the claimant in identifying plausible scenarios, to ensure that dose reconstructions do not underestimate doses.”

“HHS interprets “sufficient accuracy” in practical terms as **sufficiently accurate to assure the fair adjudication of claims**. NIOSH dose reconstructions provide this assurance **by using methods that build on the factual and scientific bases using two principal measures that are designed to overestimate every employee’s dose**.”

“These two measures taken together, **claimant-favorable assumptions and the estimation of probability of causation at the upper 99 percent credibility limit**, produce a **doubly upper-bounded estimate of the employee’s radiation dose**. By these measures, whenever it is feasible for NIOSH to estimate radiation doses for a cancer claimant, NIOSH is almost certain to be overestimating the actual radiation doses.”

GAP 2006..... Government Accountability Project National Office
1612 K Street, NW Suite #1100 • Washington, D.C. 20006
202.408.0034 • March 20, 2006

John Howard, MD Director National Institute for Occupational Safety and Health
200 Independence Ave, SW Washington, DC 20201

RE: Comments on HHS Interim Final Rule--Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (RIN 920-AA13)

“The Conference Report to the FY 05 Defense Authorization Act (H. Rep.108-767) provided additional **legally binding guidance** regarding what must take place within this 180 day time period:

*“To ensure that applications to be a SEC member are processed promptly, new timelines have been included. **Within 180 days of receipt of a petition for designation as members of a SEC, the Director of NIOSH must submit to the Advisory Board a recommendation on that petition, including all supporting documentation. During the 180 period when NIOSH is preparing the petition for review by the Advisory Board, NIOSH should identify all deficiencies in the petition within the first 30 days. When the President receives an affirmative recommendation from the Advisory Board to designate a class to the SEC, the President shall have a period of***

30 days in which to accept or reject the recommendation and notify Congress. If the President does not send a determination notice within 30 days, and if there is an affirmative Board recommendation, the class recommended to be a SEC will automatically become a SEC, subject to a 30 day notification period in Congress.” (emphasis added)

“We urge HHS to include a provision which requires NIOSH to submit its petition to the Advisory Board, or on before the 180th day, and if it fails to meet this deadline to have the Secretary of HHS send a letter to the petitioner and the impacted Congressional delegation and the Committees of Jurisdiction that **NIOSH is missing its statutory deadline, the reason for missing the deadline, and the expected date of compliance.** Further, to the extent the reason is driven by NIOSH’s contractor failing to comply with deadlines or not meeting required deliverables, then the contractor’s costs associated with non performance should be disallowed in their entirety.”

“Receipt of a SEC petition will be treated as a mere “submission,” and until it is “qualified” as meeting the informational and procedural requirements under 42 CFR Part 83, it will not be deemed a “petition” subject to the 180-day time limits.

This part of the IFR is **completely at odds with the Conference Report which states that “During the 180-day period when NIOSH is preparing the petition for review by the Advisory Board, NIOSH should identify all deficiencies in the petition within the first 30 days.”** This language **directs NIOSH to resolve both petition qualification and evaluation within the 180-day time frame, and does not authorize NIOSH to qualify petitions outside of the 180-day time period.** HHS’s IFR conveniently ignored the Conference Report language, and never reconciled the conflict between the IFR and the plain language of the Conference Report.

The HHS definition of “petition” is inconsistent with the 180-day time limits set forth in the Conference Report (H. Rep. 108-767) for both the qualification and evaluation of the SEC Petition.”

CONCLUSION.....

The Board has a duty to follow the statutory duties, this includes recommending the SEC members to be added. The Board also has a duty to ensure that the SEC determination is within the 180 days criteria which includes the ‘qualification period’ the Working Group subcommittee evaluation, and the working group reporting directly to the entire Board, not NIOSH.

The Advisory Board has the duty to determine if the dose reconstruction is scientific valid, and quality of the dose reconstruction within a timely manner.

Please address why the working group and the Advisory Board has ignored the mandated binding law and only follows policy/procedures that are not binding.

Respectfully submitted,

Donna Hand Worker Advocate and Authorized Representative
7028 W Waters Ave PMB 349 Tampa Fl 33634
608 921 9940 Fax 866 695 9917