

**§ 83.11 What happens to petition submissions that do not satisfy all relevant requirements under §§ 83.7 through 83.9?**

(a) NIOSH will notify the petitioner(s) of any requirement that is not met by the submission, assist the petitioner(s) with guidance in developing relevant information, and provide 30 calendar days for the petitioner(s) to revise the submission accordingly.

(b) After 30 calendar days from the date of notification under paragraph (a) of this section, NIOSH will notify any petitioner(s) whose submission remains unsatisfactory of the proposed finding of NIOSH that the submission fails to meet the specified requirements and the basis for this finding.

(c) A petitioner may request in writing a review of a proposed finding within 7 calendar days of notification under paragraph (b) of this section. Petitioners must specify why the proposed finding should be reversed, based on the petition requirements and on the information that the petitioners had already submitted. The request may not include any new information or documentation that was not included in the completed submission. If the petitioner obtains new information within this 7 day period, the petitioner should provide it to NIOSH. NIOSH will consider this new information as a revision of the submission under paragraph (a) of this section.

(d) Three HHS personnel, appointed by the Director of NIOSH, who were not involved in developing the proposed finding will complete reviews within 30 work days of the request for such a review. The Director of NIOSH will consider the results of the review and then make a final decision as to whether the submission satisfies the requirements for a petition.

(e) Proposed findings established by NIOSH under paragraph (b) of this section will become final decisions in 8 calendar days if not reviewed under paragraph (d) of this section.

(f) Based on new information, NIOSH may, at its discretion, reconsider a decision that a submission does not satisfy the requirements for a petition.

[70 FR 75952, Dec. 22, 2005]

**§ 83.12 How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?**

(a) NIOSH will notify the petitioner(s) in writing that it has selected the petition for evaluation. NIOSH will also provide the petitioner(s) with information on the steps of the evaluation and other processes required pursuant to these procedures.

(b) NIOSH will combine separate petitions and evaluate them as a single petition if, at this or at any point in the evaluation process under §§ 83.13 and 83.14, NIOSH finds such petitions represent the same class of employees.

(c) NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition. Each evaluation plan will include the following elements:

(1) An initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation conducted under § 83.13 or § 83.14; and

(2) A list of activities for evaluating the radiation exposure potential of the class and the adequacy of existing records and information needed to conduct dose reconstructions for all class members under 42 CFR part 82.

(d) NIOSH may initiate work to evaluate a petition immediately, prior to presenting the petition and evaluation plan to the Board.

(e) NIOSH will publish a notice in the FEDERAL REGISTER notifying the public of its decision to evaluate a petition.

**§ 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 another 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 comprises the basis of the class definition;

(v) If necessary, any other parameters that serve to define the membership of the class; and

(vi) For a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a minimum duration of employment within the parameters of the class for inclusion in the class, as defined under paragraph (c)(3) of this section;

(4) A summary of the findings concerning the adequacy of existing

records and information for reconstructing doses for individual members of the class under the methods of 42 CFR part 82, and a description of the evaluation methods and information upon which these findings are based; and

(5) For a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a summary of the basis for establishing the duration of employment requirement with respect to health endangerment.

**§ 83.14 How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR part 82?**

(a) NIOSH may establish two classes for evaluation, to permit the timely adjudication of the existing cancer claim:

(1) A class of employees defined using the research and analyses already completed in attempting the dose reconstruction for the employee identified in the claimant's petition; and

(2) A class of co-workers similar to the class defined under paragraph (a)(1) of this section, to be defined by NIOSH on the basis of further research and analyses, using the procedures under § 83.13.

(b) NIOSH will determine the health endangerment criteria for adding the class under paragraph (a)(1) of this section to the Cohort, using the procedures under § 83.13. NIOSH will report to the Board and to petitioner(s) the results of this determination, together with its finding under 42 CFR part 82 that there was insufficient information to complete the dose reconstruction. HHS will consider this finding under 42 CFR part 82 sufficient, without further consideration, to determine that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy.

(c) NIOSH will evaluate the petition as it may concern a class of co-workers, as described under paragraph (a)(2) of this section, according to the procedures under § 83.13.

**§ 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. In considering the petition, both NIOSH and the members of the Board will take all steps necessary to prevent the disclosure of information of a personal nature, concerning the petitioners or others, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

(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.

**§ 83.16 How will the Secretary decide the outcome(s) of a petition?**

(a) The Director of NIOSH will propose a decision to add or deny adding any class or classes of employees to the Cohort, including an iteration of the