Subpart E—Updating the Scientific Elements Underlying Dose Reconstructions

§ 82.30 How will NIOSH inform the public of any plans to change scientific elements underlying the dose reconstruction process to maintain methods reasonably current with scientific progress?

Periodically, NIOSH will publish a notice in the FEDERAL REGISTER notifying the public of plans to change scientific elements underlying the dose reconstruction process under EEOICPA to reflect scientific progress. Notice will include a summary of the planned changes and the expected completion date for such changes.

§ 82.31 How can the public recommend changes to scientific elements underlying the dose reconstruction process?

(a) At any time, the public can submit written recommendations to NIOSH for changes to scientific elements underlying the dose reconstruction process, based on relevant new research findings and technological advances. NIOSH will provide these recommendations to the Advisory Board on Radiation and Worker Health to be addressed at a public meeting of the Advisory Board, with notification provided to the source of the recommendations. Recommendations should be addressed to: Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, Ohio 45226.

(b) The public can also submit recommendations by e-mail. Instructions will be provided on the NIOSH Internet homepage at *www.cdc.gov/niosh/ocas.*

§ 82.32 How will NIOSH make changes in scientific elements underlying the dose reconstruction process, based on scientific progress?

NIOSH will present proposed changes to the Advisory Board on Radiation and Worker Health prior to implementation. These proposed changes will be summarized in a notice published in the FEDERAL REGISTER. The public will have the opportunity to comment on proposed changes at the meeting of the Advisory Board and/or in written comments submitted for this purpose. NIOSH will fully consider the comments of the Advisory Board and of the public before deciding upon any changes.

§ 82.33 How will NIOSH inform the public of changes to the scientific elements underlying the dose reconstruction process?

(a) NIOSH will publish a notice in the FEDERAL REGISTER informing the public of changes and the rationale for the changes. This notice will also provide a summary of the recommendations and comments received from the Advisory Board and the public, as well as responses to the comments.

(b) NIOSH may take into account other factors and employ other procedures than those specified in this subpart, if circumstances arise that require NIOSH to implement a change more immediately than the procedures in this subpart allow.

PART 83—PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Sec.

Subpart B—Definitions

Subpart C—Procedures for Adding Classes of Employees to the Cohort

AUTHORITY: 42 U.S.C. 7384q; E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

SOURCE: At 69 FR 30780, May 28, 2004, unless otherwise noted.

Subpart A—Introduction

§83.0 Background information on the procedures in this part.

The Energy Employees Occupational Illness Compensation Program Act, as amended (''EEOICPA'' or ''the Act''), 42 U.S.C. 7384–7385, provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of DOE, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. 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. The first is to establish that the cancer is at least as likely as not related to covered employment at a DOE or Atomic Weapons Employer (''AWE'') facility pursuant to guidelines issued by the Department of Health and Human Services (''HHS''), which are found at 42 CFR part 81. The second method to establish that a cancer incurred by a covered worker is compensable under EEOICPA is to establish that the worker is a member of the Special Exposure Cohort (''the Cohort'') and suffered a specified cancer after beginning employment at a DOE facility or AWE facility. In Section 3621(14) of EEOICPA (42 U.S.C. 7384l(14)) Congress included certain classes of employees in the Cohort. 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.

§83.1 What is the purpose of the procedures in this part?

EEOICPA authorizes the President to add classes of employees to the Cohort, while providing Congress with the opportunity to review and expedite or reverse these decisions. The President delegated his authority to the Secretary of HHS. This part specifies the procedures by which HHS will determine whether to add new classes of employees from DOE and AWE facilities to the Cohort. 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. The procedures are not intended to provide a second opportunity to qualify a claim for compensation, once HHS has completed the dose reconstruction and DOL has determined that the cancer subject to the claim was not ''at least as likely as not'' caused by the estimated radiation doses. DOL has established procedures separate from those covered by this part, under 20 CFR part 30, for cancer claimants who want to contest the factual determinations or how NIOSH conducted their dose reconstructions.

§ 83.2 How will DOL use the designations established under the procedures in this part?

DOL will adjudicate compensation claims for members of classes of employees added to the Cohort according to the same general procedures that apply to the statutorily defined classes of employees in the Cohort. Specifically, DOL will determine whether the claim is for a qualified member of the Cohort with a specified cancer, pursuant to the procedures set forth in 20 CFR part 30.

Subpart B—Definitions

§ 83.5 Definitions of terms used in the procedures in this part.

(a) *Advisory Board on Radiation and Worker Health (''the Board'')* is a federal advisory committee established under EEOICPA and appointed by the President to advise HHS in implementing its responsibilities under EEOICPA.

(b) *Atomic Weapons Employer (''AWE'')* is a statutory term of EEOICPA which means any entity, other than the United States, that:

(1) Processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling: and,

(2) Is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(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 defined by the FED. R. CIV. P. 6(a).

(d) *Class of employees* means, for the purposes of this part, a group of employees who work or worked at the same DOE facility or AWE facility, and for whom the availability of information and recorded data on radiation exposures is comparable with respect to the informational needs of dose reconstructions conducted under 42 CFR part 82.

(e) *HHS* is the U.S. Department of Health and Human Services.

(f) *DOE* is the U.S. Department of Energy, which includes predecessor agencies of DOE, including the Manhattan Engineering District.

(g) *DOL* is the U.S. Department of Labor.

(h) *Employee,* for the purposes of these procedures, means a person who is or was, for the purposes of EEOICPA, an employee of DOE, a DOE contractor or subcontractor, or an Atomic Weapons Employer.

(i) *NIOSH* is the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(j) *OCAS* is the Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(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. A single petition shall only include up to three petitioners.

(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. For the purposes of the proposed procedures, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(m) *Secretary* is the Secretary of Health and Human Services.

(n) *Specified cancer,* as is defined in Section 3621(17) of EEOICPA (42 U.S.C. 7384l(17)) and the DOL regulation implementing EEOICPA (20 CFR 30.5(dd)), means:

(1) Leukemia (other than chronic lymphocytic leukemia) provided that onset of the disease was at least two years after initial occupational exposure;

(2) Lung cancer (other than in situ lung cancer that is discovered during or after a post-mortem exam);
(3) Bone cancer;
(4) Renal cancers;
(5) The following diseases, provided onset was at least 5 years after first exposure:
(i) Multiple myeloma;
(ii) Lymphomas (other than Hodgkin's disease);
(iii) Primary cancer of the:
(A) Thyroid;
(B) Male or female breast;
(C) Esophagus;
(D) Stomach;
(E) Pharynx;
(F) Small intestine;
(G) Pancreas;
(H) Bile ducts;
(I) Gall bladder;
(J) Salivary gland;
(K) Urinary bladder;
(L) Brain;
(M) Colon;
(N) Ovary;
(O) Liver (except if cirrhosis or hepatitis B is indicated).
(6) The specified diseases designated in this section mean the physiological condition or conditions that are recognized by the National Cancer Institute under those names or nomenclature, or under any previously accepted or commonly used names or nomenclature.
(o) Survivor means a surviving spouse, child, parent, grandchild and grandparent of a deceased covered employee as defined in EEOICPA.

[69 FR 30780, May 28, 2004, as amended at 70 FR 75952, Dec. 22, 2005; 72 FR 37459, July, 10, 2007]

Subpart C—Procedures for Adding Classes of Employees to the Cohort

§ 83.6 Overview of the procedures in this part.

The procedures in this part specify who may petition to add a class of employees to the Cohort, the requirements for such a petition, how a petition will be selected for evaluation by NIOSH and for the advice of the Board, and the process NIOSH, the Board, and the Secretary will use to consider a petition, leading to the Secretary's final determination to accept or deny adding a class to the Cohort. The rule provides for petitions in two distinct circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant, under 42 CFR part 82, and finds that the dose reconstruction cannot be completed, because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer. As required by EEOICPA (42 U.S.C. 7384l(14)(c)(ii)), the procedures in this part include formal notice to Congress of any decision by the Secretary to add a class to the Cohort, and the opportunity for Congress to expedite or change the outcome of the decision within 180 days.

§ 83.7 Who can submit a petition on behalf 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 represented DOE, DOE contractor or subcontractor, 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 subcontractor, 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. A petition must provide identifying and contact information on the petitioner(s) and information to justify the petition, as specified under §83.9. Detailed instructions for preparing and submitting a petition, including an optional petition form, are available from NIOSH through direct request (1–800–35–

NIOSH) or on the Internet at *www.cdc.gov/niosh/ocas.*

§ 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. If the petition is by a claimant in response to a finding by NIOSH that the dose reconstruction for the claimant cannot be completed, then the petition must provide only the justification specified under paragraph (b) of this section. All other petitions must provide only the information specified under paragraph (c) of this section. The informational requirements for petitions are also summarized in Table 1 at the end of this section.

(b) The petition must notify NIOSH that the claimant is petitioning on the basis that NIOSH found, under 42 CFR 82.12, that the dose reconstruction for the claimant could not be completed due to insufficient records and information.

(c) The petition must include the following:

(1) A proposed class definition[1] specifying:

(i) The DOE facility or AWE facility[2] 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 sufficient 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 paragraph (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). Such evidence would not be required at the time the petition is submitted and the

[1] HHS will determine the final class definition(s) for each petition (see §83.16).

[2] Depending on the factual circumstances present, a facility that meets the definition of an AWE facility or DOE facility covered under EEOICPA (42 U.S.C. 7384l(5) and (12)) could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing numerous buildings or structures, including the grounds upon which it is located.

petitioner(s) would be directly informed of the need for this supplemental information. 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.[3]

(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 paragraph (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).

TABLE 1 FOR §83.9: SUMMARY OF INFORMATIONAL REQUIREMENTS FOR ALL PETITIONS

[Petitioner(s) must submit identifying and contact information and either A. or B. of this table.]

A. The claimant's authorization of the petition, based on NIOSH having found it could not complete a dose reconstrucitn for the claimant submitting the petition; or.	B. (1) A proposed class definition identifying: (i) Facility, (ii) relevant locations at the facility; (iii) job titles/duties, (iv) period of employment, and if relevant, (v) exposure incident. (2) The basis for infeasibility of dose reconstruction; either: (i) lack of monitoring; or (ii) destruction, falsification, or loss of records; or (iii) expert report; or (iv) scientific or technical report.

§83.10 If a petition satisfies all relevant 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. The role of the petitioner(s) is to identify classes of employees that should be considered for addition to the Cohort.

[3] An affidavit may be from a petitioner but HHS does not require that an affidavit be from a petitioner.

§ 83.11 What happens to petitions 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 petition, assist the petitioner(s) with guidance in developing relevant information, and provide 30 calendar days for the petitioner(s) to revise the petition accordingly.

(b) After 30 calendar days from the date of notification under paragraph (a) of this section, NIOSH will notify any petitioner(s) whose petition remains unsatisfactory of the proposed finding of NIOSH that the petition 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 30 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 petition. If the petitioner obtains new information within this 30-day period, the petitioner should provide it to NIOSH. NIOSH will consider this new information as a revision of the petition 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 petition satisfies the requirements for a petition.

(e) Proposed findings established by NIOSH under paragraph (b) of this section will become final decisions in 31 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 petition does not satisfy the requirements for a petition.

(g) A petitioner whose petition has been found not to satisfy the requirements for a petition under either paragraph (d) or (e) of this section may submit to NIOSH a new petition for the identical class of employees at any time thereafter on the basis of new information not provided to NIOSH in the original petition. In such a case, the petitioner is required to fully readdress all the requirements of §§ 83.7–83.9 in the petition.

[70 FR 75952, Dec. 22, 2005, as amended at 72 FR 37459, July 10, 2007]

§ 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 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 specifying, for each class defined in the report, whether NIOSH finds that it is feasible to estimate the radiation doses of members of the class with sufficient accuracy, 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.

(e) The NIOSH report under paragraph (d) of this section shall be completed within 180 calendar days of the receipt of the petition by NIOSH. The procedure for computing this time period is specified in §83.5(c). In addition, the computing of 180 calendar days shall not include any days during which the petitioner may be revising the petition to remedy deficiencies identified by NIOSH under §83.11(a) or (b), nor shall it include any days during which the petitioner may request a review of a proposed finding under §83.11(c) or during the conduct of such a review under §83.11(d).

[69 FR 30780, May 28, 2004, as amended at 72 FR 37459, July 10, 2007]

§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 relevant criteria, as specified under §83.13(c), and a summary of the information and findings on which the proposed decision is based. This proposed decision will take into consideration the evaluations of NIOSH and the report and recommendations of the Board, and may also take into consideration information presented or submitted to the Board and the deliberations of the Board. In the case of a petition that NIOSH has determined encompasses more than one class of employees, the Director of NIOSH will issue a separate proposed decision for each separate class of employees.

(b) The Secretary will make the final decision to add or deny adding a class to the Cohort, including the definition of the class, after considering information and recommendations provided to the Secretary by the Director of NIOSH and the Board. HHS will transmit a report of the decision to the petitioner(s), including an iteration of the relevant criteria, as specified under §83.13(c), and a summary of the information and findings on which the decision is based. HHS will also publish a notice summarizing the decision in the FEDERAL REGISTER.

(c) If, under §83.15(e), the Board recommends that the Secretary designate a class covered by the petition as an addition to the Cohort, and if, under paragraph (b) of §83.16, the Secretary decides to deny adding the class, as defined by the Board, to the Cohort, then the Secretary will submit to Congress a determination that the statutory criteria specified under 42 U.S.C. 7384q(b)(1) and (2) have not been met for adding the class to the Cohort. The Secretary will submit this determination to Congress within 30 calendar days following receipt by the Secretary of the recommendation of the Board.

[70 FR 75953, Dec. 22, 2005]

§ 83.17 How will the Secretary report a final decision to add a class of employees to the Cohort and any action of Congress concerning the effect of the final decision?

(a) If the Secretary designates a class of employees to be added to the Cohort, the Secretary will transmit to Congress a report providing the designation, the definition of the class of employees covered by the designation, and the criteria and findings upon which the designation was based.[4]

(b) If, under §83.15(e), the Board recommends that the Secretary designate a class covered by the petition as an addition to the Cohort, and if, under paragraph (b) of §83.16, the Secretary decides to add a class to the Cohort that is inclusive of the class as defined by the Board, then the Secretary will transmit to Congress the report specified in paragraph (a) of this section within 30 calendar days following receipt by the Secretary of the recommendation of the Board.

[4] See 42 U.S.C. 7384l(14)(C)(ii).

(c) A designation of the Secretary will take effect 30 calendar days after the date on which the report of the Secretary under paragraph (a) of this section is submitted to Congress, or is deemed to have been submitted to Congress,[5] unless Congress takes an action that reverses or expedites the designation.

(d) After either the expiration of the congressional review period or notification of final congressional action, whichever comes first, the Secretary will transmit to DOL and to the petitioner(s) a report providing the definition of the class and one of the following outcomes:

(1) The addition of the class to the Cohort; or

(2) The result of any action by Congress to reverse or expedite the decision of the Secretary to add the class to the Cohort.

(e) The report specified under paragraph (d) of this section will be published on the Internet at *http://www.cdc.gov/niosh/ocas* and in the FEDERAL REGISTER.

[69 FR 30780, May 28, 2004, as amended at 70 FR 75953, Dec. 22, 2005]

§83.18 How can petitioners obtain an administrative review of a final decision by the Secretary?

(a) HHS will allow petitioners to contest only a final decision to deny adding a class to the Cohort or a health endangerment determination under §83.13(c)(3)(ii). Such challenges must be submitted in writing within 30 calendar days and must include evidence that the final decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures of this part. Challenges may not introduce new information or documentation concerning the petition or the NIOSH or Board evaluation(s) that was not submitted or presented by the petitioner(s) or others to NIOSH or to the Board prior to the Board's issuing its recommendations under §83.15.

(b) A panel of three HHS personnel, independent of NIOSH and appointed by the Secretary, will conduct an administrative review based on a challenge submitted under paragraph (a) of this section and provide recommendations of the panel to the Secretary concerning the merits of the challenge and the resolution of issues contested by the challenge. Reviews by the panel will consider, in addition to the views and information submitted by the petitioner(s) in the challenge, the NIOSH evaluation report(s), the report containing the recommendations of the Board issued under §83.15, and recommendations of the Director of NIOSH to the Secretary. The reviews may also consider information presented or submitted to the Board and the deliberations of the Board prior to the issuance of the recommendations of the Board under §83.15. The panel shall consider whether HHS substantially complied with the procedures of this part, the factual accuracy of the information supporting the final decision, and the principal findings and recommendations of NIOSH and those of the Board issued under §83.15.

(c) The Secretary will decide whether or not to revise a final decision contested by the petitioner(s) under this section after considering information and recommendations provided to the Secretary by the Director of NIOSH, the Board, and from the HHS administrative review conducted under paragraph (b) of this section. HHS will transmit a report of the decision to the petitioner(s).

(d) If the Secretary decides under paragraph (c) of this section to change a designation under §83.17(a) of this part or a determination under §83.16(c) of this part, the Secretary will transmit to Congress a report providing such change to the designation or determination, including an iteration of the relevant criteria, as specified under §83.13(c), and a summary of the information and findings on which the decision is based. HHS will also publish a notice summarizing the decision in the FEDERAL REGISTER.

[5] Under 42 U.S.C. 7384q(c)(2)(C), if the Secretary does not submit within 30 days the determination required under paragraph (a) of §83.17 of this part, then on the following day, ''it shall be deemed'' that the Secretary submitted the report specified under paragraph (b) of §83.17 of this part.

(e) A new designation of the Secretary under this section will take effect 30 calendar days after the date on which the report of the Secretary under paragraph (d) of this section is submitted to Congress, unless Congress takes an action that reverses or expedites the designation. Such new designations and related congressional actions will be further reported by the Secretary pursuant to paragraphs (d) and (e) of § 83.17.

[70 FR 75953, Dec. 22, 2005]

§ 83.19 How can the Secretary cancel or modify a final decision to add a class of employees to the Cohort?

(a) The Secretary can cancel a final decision to add a class to the Cohort, or can modify a final decision to reduce the scope of a class added by the Secretary, if HHS obtains records relevant to radiation exposures of members of the class that enable NIOSH to estimate the radiation doses incurred by individual members of the class through dose reconstructions conducted under the requirements of 42 CFR part 82.

(b) Before canceling a final decision to add a class or modifying a final decision to reduce the scope of a class, the Secretary intends to follow evaluation procedures that are substantially similar to those described in this part for adding a class of employees to the Cohort. The procedures will include the following:

(1) Publication of a notice in the FEDERAL REGISTER informing the public of the intent of the Secretary to review the final decision on the basis of new information and describing procedures for this review;

(2) An analysis by NIOSH of the utility of the new information for conducting dose reconstructions under 42 CFR part 82; the analysis will be performed consistently with the requirements for analysis of a petition by NIOSH under §§ 83.13(c)(1) and (2), and 83.13(c)(2) and (3);

(3) A recommendation by the Board to the Secretary as to whether or not the Secretary should cancel or modify his final decision that added the class to the Cohort, based upon a review by the Board of the NIOSH analysis under paragraph (b)(2) of this section and any other relevant information considered by the Board;

(4) An opportunity for members of the class to contest a proposed decision to cancel or modify the prior final decision that added the class to the Cohort, including a reasonable and timely effort by the Secretary to notify members of the class of this opportunity; and

(5) Publication in the FEDERAL REGISTER of a final decision to cancel or modify the prior final decision that added the class to the Cohort.

[69 FR 30780, May 28, 2004. Redesignated at 70 FR 75953, Dec. 22, 2005]

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Application for Approval

Subpart C—Fees

Subpart D—Approval and Disapproval

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