claim, and PC_n is the probability of causation for the nth primary cancer identified in the claim. PC_{total} is the probability that at least one of the primary cancers (cancers 1 through ''n'') was caused by the radiation dose estimated for the claim when Equation 1 is evaluated based on the joint distribution of PC_1, . . ., PC_n.[3] DOL will use the probability of causation value calculated for PC_{total} to adjudicate the claim.

[67 FR 22309, May 2, 2002; 67 FR 62096, Oct. 3, 2002; 84 FR 37591, Aug. 1, 2019]

PART 82—METHODS FOR CONDUCTING DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

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AUTHORITY: 42 U.S.C. 7384n(d) and (e); E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

SOURCE: 67 FR 22330, May 2, 2002, unless otherwise noted.

Subpart A—Introduction

§ 82.0 Background information on this part.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy (''DOE''), its predecessor agencies and certain of its contractors and subcontractors.

[3] Evaluating Equation 1 based on the individual upper 99th percentiles of PC_1, . . ., PC_n approximates the upper 99th percentile of PC_{total} whenever PC_1, . . ., PC_n are highly related, e.g., when a common dose-reconstruction is the only non-negligible source of uncertainty in the individual PC_i's. However, this approximation can overestimate it if other sources of uncertainty contribute independently to the PC_1, . . ., PC_n, whereas treating the joint distribution as fully independent could substantially underestimate the upper 99th percentile of PC_{total} whenever the individual PC_i's are positively correlated.

Among the types of illnesses for which compensation may be provided are cancers. There are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. The regulations that follow under this part apply only to the category of employees described under paragraph (a) of this section.

(a) One category is employees with cancer for whom a dose reconstruction must be conducted, as required under 20 CFR 30.115.

(b) The second category is members of the Special Exposure Cohort seeking compensation for a specified cancer, as defined under EEOICPA. The U.S. Department of Labor (DOL) which has primary authority for implementing EEOICPA, has promulgated regulations at 20 CFR 30.210 and 30.213 that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 3626 of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 82.1 What is the purpose of this part?

The purpose of this part is to provide methods for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction. These methods will be applied by the National Institute for Occupational Safety and Health (NIOSH) in a dose reconstruction program serving claimants under EEOICPA, as identified under § 82.0.

§ 82.2 What are the basics of dose reconstruction?

The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer occurring among the workers. A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure conditions and the type, quality, and completeness of data available to characterize the environment.

(a) If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority in assessing exposure. These monitoring data are interpreted using additional data characterizing the workplace radiation exposures. If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.

(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.

(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model. For internal exposures, this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion.

§ 82.3 What Are the Requirements for Dose Reconstruction Under EEOICPA?

(a) Dose reconstructions are to be conducted for the following covered

employees with cancer seeking compensation under EEOICPA: An employee who was not monitored for exposure to radiation at DOE or Atomic Weapons Employer (AWE) facilities; an employee who was monitored inadequately for exposure to radiation at such facilities; or an employee whose records of exposure to radiation at such facility are missing or incomplete. Technical limitations of radiation monitoring technology and procedures will require HHS to evaluate each employee's recorded dose. In most, if not all cases, monitoring limitations will result in possibly undetected or unrecorded doses, which are estimated using commonly practiced dose reconstruction methods and would have to be added to the dose record.

(b) Section 7384(n)(e) of EEOICPA requires the reporting of radiation dose information resulting from dose reconstructions to the covered employees for whom claims are being adjudicated. DOE is specifically charged with this responsibility but the Department of Health and Human Services (HHS), which will be producing the dose reconstruction information, will report its findings directly to the claimant, as well as to DOL and DOE. HHS will also make available to researchers and the general public information on the assumptions, methodology, and data used in estimating radiation doses, as required by EEOICPA.

§ 82.4 How Will DOL Use the Results of the NIOSH Dose Reconstructions?

Under 42 CFR part 81, DOL will apply dose reconstruction results together with information on cancer diagnosis and other personal information provided to DOL by the claimant to calculate an estimated probability of causation. This estimate is the probability that the cancer of the covered employee was caused by radiation exposure at a covered facility of DOE or an Atomic Weapons Employer (AWE).

Subpart B—Definitions

§ 82.5 Definition of terms used in this part.

(a) *Atomic weapons employer* (AWE) 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.

(b) *Bioassay* means the determination of the kinds, quantities, or concentrations, and in some cases, locations of radioactive material in the human body, whether by direct measurement or by analysis, and evaluation of radioactive material excreted or eliminated by the body.

(c) *Claimant* means the individual who has filed with the Department of Labor for compensation under EEOICPA.

(d) *Covered employee* means, for the purposes of this part, an individual who is or was an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, and for whom DOL has requested HHS to perform a dose reconstruction.

(e) *Covered facility* means any building, structure, or premises, including the grounds upon which such building, structure, or premise is located:

(1) In which operations are, or have been, conducted by, or on behalf of, the DOE (except for buildings, structures, premises, grounds, or operations covered by Executive Order 12344, dated February 1, 1982, pertaining to the Naval Nuclear Propulsion Program); and,

(2) With regard to which the DOE has or had:

(i) A proprietary interest; or,

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services; or

(3) A facility owned by an entity designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA that is or was used to process or produce, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining or milling.

(f) *DOE* means the U.S. Department of Energy, and includes predecessor

agencies of DOE, including the Manhattan Engineering District.

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

(h) *EEOICPA* means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384–7385 [1994, supp. 2001].

(i) *Equivalent dose* is the absorbed dose in a tissue multiplied by a radiation weighting factor to account for differences in the effectiveness of the radiation in inducing cancer.

(j) *External dose* means that portion of the equivalent dose that is received from radiation sources outside of the body.

(k) *Internal dose* means that portion of the equivalent dose that is received from radioactive materials taken into the body.

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

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) resulting in tumors at other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure. This concept is further explained under 42 CFR part 81, which provides guidelines by which DOL will determine probability of causation under EEOICPA.

(o) *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 purposes of this rule, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(p) *Specified cancer* is a term defined in Section 3621(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis), and bone. Pursuant to section 2403 of Public Law 107–20, this definition will include renal cancer effective October 1, 2001.

(q) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(r) *Worst-case assumption* is a term used to describe a type of assumption used in certain instances for certain dose reconstructions conducted under this rule. It assigns the highest reasonably possible value, based on reliable science, documented experience, and relevant data, to a radiation dose of a covered employee.

Subpart C—Dose Reconstruction Process

§ 82.10 Overview of the dose reconstruction process.

(a) Upon receipt of a claims package from the Department of Labor, as provided under 20 CFR part 30, NIOSH will request from DOE records on radiation dose monitoring and radiation exposures associated with the employment history of the covered employee. Additionally, NIOSH may compile data, and information from NIOSH records that may contribute to the dose reconstruction. For each dose reconstruction, NIOSH will include records relevant to internal and external exposures to ionizing radiation, including exposures from medical screening x rays that were required as a condition of employment.

(b) NIOSH will evaluate the initial radiation exposure record compiled to: Reconcile the exposure record with the

reported employment history, as necessary; complete preliminary calculations of dose, based upon this initial record, and prepare to consult with the claimant. Any discrepancies in the employment history information will be reconciled with the assistance of DOE, as necessary.

(c) NIOSH will interview the claimant. The interview may be conducted in one or more sessions. The purpose of the interview is to:

(1) Explain the dose reconstruction process;

(2) Confirm elements of the employment history transmitted to NIOSH by DOL;

(3) Identify any relevant information on employment history that may have been omitted;

(4) Confirm or supplement monitoring information included in the initial radiation exposure record;

(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary;

(6) Identify co-workers and other witnesses with information relevant to the radiation exposures of the covered worker to supplement or confirm information on work experiences, as necessary.

(d) NIOSH will provide a report to the claimant summarizing the findings of the interview, titled: ''NIOSH Claimant Interview under EEOICPA.'' The report will also notify the claimant of the opportunity to contact NIOSH if necessary, by a specified date, to make any written corrections or additions to information provided by the claimant during the interview process.

(e) Information provided by the claimant will be accepted and used for dose reconstruction, providing it is reasonable, supported by substantial evidence, and is not refuted by other evidence. In assessing whether the information provided by the claimant is supported by substantial evidence, NIOSH will consider:

(1) Consistency of the information with other information in the possession of NIOSH, from radiation safety programs, research, medical screening programs, labor union documents, worksite investigations, dose reconstructions conducted by NIOSH under EEOICPA, or other reports relating to the circumstances at issue;

(2) Consistency of the information with medical records provided by the claimant;

(3) Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant; and,

(4) Confirmation of information by co-workers or other witnesses.

(f) NIOSH will seek to confirm information provided by the claimant through review of available records and records requested from DOE.

(g) As necessary, NIOSH will request additional records from DOE to characterize processes and tasks potentially involving radiation exposure for which dose and exposure monitoring data is incomplete or insufficient for dose reconstruction.

(h) NIOSH will review the adequacy of monitoring data and completeness of records provided by DOE. NIOSH will request certification from DOE that record searches requested by NIOSH have been completed.

(i) As necessary, NIOSH will characterize the internal and external exposure environments for parameters known to influence the dose. For internal exposures, examples of these parameters include the mode of intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type. When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science. For external exposures, the radiation type (gamma, x-ray, neutron, beta, or other charged particle) and radiation energy spectrum will be evaluated. When possible, the effect of non-uniformity and geometry of the radiation exposure will be assessed.

(j) For individual monitoring records that are incomplete, NIOSH may assign doses using techniques discussed in § 82.16. Once the resulting data set is complete, NIOSH will construct an occupational exposure matrix, using the

general hierarchical approach discussed in § 82.2. This matrix will contain the estimated annual equivalent dose(s) to the relevant organ(s) or tissue(s), for the period from the initial date of potential exposure at a covered facility until the date the cancer was diagnosed. The equivalent dose(s) will be calculated using the current, standard radiation weighting factors from the International Commission on Radiological Protection.[1]

(k) At any point during steps of dose reconstruction described in paragraphs (f) through (j) of this section, NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met:

(1) From acquired experience, it is evident the estimated cumulative dose is sufficient to qualify the claimant for compensation (*i.e.*, the dose produces a probability of causation of 50% or greater);

(2) Dose is determined using worst-case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,

(3) Research and analysis indicated under steps described in paragraphs (f)–(j) of this section have been completed. Worst-case assumptions will be employed under condition 2 to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose. For all claims in which worst-case assumptions are employed under condition 2, the reasoning that resulted in the determination to limit further research and analysis will be clearly described in the draft of the dose reconstruction results reported to the claimant under § 82.25 and in the dose reconstruction results reported to the claimant under § 82.26.

(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant to review the dose reconstruction results and the basis upon which the results were calculated. This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction. The closing interview may require multiple sessions, if the claimant requires time to obtain and provide additional information, and to allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report. NIOSH will determine whether to grant requests for time to provide additional information, based on whether the requests are reasonable and the claimant is actively seeking the information specified.

(m) Subject to any additional information provided by the claimant and revision of the draft dose reconstruction report under § 82.10(l), the claimant is required to return form OCAS–1 to NIOSH, certifying that the claimant has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form, NIOSH will forward a final dose reconstruction report to DOL, DOE, and to the claimant.

(n) NIOSH will not forward the dose reconstruction report to DOL for adjudication without receipt of form OCAS–1 signed by the claimant or a representative of the claimant authorized pursuant to 20 CFR 30.600. If the claimant or the authorized representative of the claimant fails to sign and return form OCAS–1 within 60 days, or 60 days following the claimant's final provision of additional information and receipt of a revised draft dose reconstruction report under § 82.10 (l), whichever occurs last, after notifying the claimant or the authorized representative, NIOSH may administratively close the dose reconstruction and notify DOL of this action. Upon receiving this notification by NIOSH, DOL may administratively close the claim.

[1] The current weighting factors of the International Commission on Radiological Protection are provided in ICRP 60: ''1990 Recommendations of the International Commission on Radiological Protection.'' Ann. ICRP 21 (1–3):6.

(o) Once actions under § 82.10 (m) are completed, the record for dose reconstruction shall be closed unless reopened at the request of DOL under 20 CFR part 30.

§ 82.11 For which claims under EEOICPA will NIOSH conduct a dose reconstruction?

NIOSH will conduct a dose reconstruction for each claim determined by DOL to be a claim for a covered employee with cancer under DOL regulations at 20 CFR 30.210(b), subject to the limitation and exception noted in § 82.12. Claims for covered employees who are members of the Special Exposure Cohort seeking compensation for a specified cancer, as determined by DOL under 20 CFR 30.210(a), do not require and will not receive a dose reconstruction under this rule.

§ 82.12 Will it be possible to conduct dose reconstructions for all claims?

It is uncertain whether adequate information of the types outlined under § 82.14 will be available to complete a dose reconstruction for every claim eligible under § 82.11.

(a) NIOSH will notify in writing any claimants for whom a dose reconstruction cannot be completed once that determination is made, as well as in the closing interview provided for under § 82.10(l).

(b) Notification will describe the basis for finding a dose reconstruction cannot be completed, including the following:

(1) A summary of the information obtained from DOE and other sources; and, (2) a summary of necessary information found to be unavailable from DOE and other sources.

(c) NIOSH will notify DOL and DOE when it is unable to complete a dose reconstruction for the claimant. This will result in DOL producing a recommended decision to deny the claim, since DOL cannot determine probability of causation without a dose estimate produced by NIOSH under this rule.

(d) A claimant for whom a dose reconstruction cannot be completed, as indicated under this section, may have recourse to seek compensation under provisions of the Special Exposure Cohort (see 20 CFR part 30). Pursuant to section 7384q of EEOICPA, the Secretary of HHS is authorized to add classes of employees to the Special Exposure Cohort. NIOSH will provide the claimant with any information and forms that HHS provides to classes of employees seeking to petition to be added to the Special Exposure Cohort.

§ 82.13 What sources of information may be used for dose reconstructions?

NIOSH will use the following sources of information for dose reconstructions, as necessary:

(a) DOE and its contractors, including Atomic Weapons Employers and the former worker medical screening program;

(b) NIOSH and other records from health research on DOE worker populations;

(c) Interviews and records provided by claimants;

(d) Co-workers of covered employees, or others with information relevant to the covered employee's exposure, that the claimant identified during the initial interview with NIOSH;

(e) Labor union records from unions representing employees at covered facilities of DOE or AWEs; and,

(f) Any other relevant information.

§ 82.14 What types of information could be used in dose reconstructions?

NIOSH will obtain the types of information described in this section for dose reconstructions, as necessary and available:

(a) *Subject and employment information*, including:

(1) Gender;

(2) Date of birth; and,

(3) DOE and/or AWE employment history, including: job title held by year, and work location(s): including site names(s), building numbers(s), technical area(s), and duration of relevant employment or tasks.

(b) *Worker monitoring data*, including:

(1) External dosimetry data, including external dosimeter readings (film badge, TLD, neutron dosimeters); and,

(2) Pocket ionization chamber data.

(c) *Internal dosimetry data*, including:

(1) Urinalysis results;

(2) Fecal sample results;

(3) In Vivo measurement results;
(4) Incident investigation reports;
(5) Breath radon and/or thoron results;
(6) Nasal smear results;
(7) External contamination measurements; and
(8) Other measurement results applicable to internal dosimetry.
(d) *Monitoring program data,* including:
(1) Analytical methods used for bioassay analyses;
(2) Performance characteristics of dosimeters for different radiation types;
(3) Historical detection limits for bioassay samples and dosimeter badges;
(4) Bioassay sample and dosimeter collection/exchange frequencies;
(5) Documentation of record keeping practices used to record data and/or administratively assign dose; and,
(6) Other information to characterize the monitoring program procedures and evaluate monitoring results.
(e) *Workplace monitoring data,* including:
(1) Surface contamination surveys;
(2) General area air sampling results;
(3) Breathing zone air sampling results;
(4) Radon and/or thoron monitoring results;
(5) Area radiation survey measurements (beta, gamma and neutron); and,
(6) Fixed location dosimeter results (beta, gamma and neutron); and,
(7) Other workplace monitoring results.
(f) *Workplace characterization data,* including:
(1) Information on the external exposure environment, including: radiation type (gamma, x-ray, proton, neutron, beta, other charged particle); radiation energy spectrum; uniformity of exposure (whole body vs partial body exposure); irradiation geometry;
(2) Information on work-required medical screening x rays; and,
(3) Other information useful for characterizing workplace radiation exposures.
(g) *Information characterizing internal exposures,* including:
(1) Radionuclide(s) and associated chemical forms;
(2) Results of particle size distribution studies;
(3) Respiratory protection practices; and
(4) Other information useful for characterizing internal exposures.
(h) *Process descriptions for each work location,* including:
(1) General description of the process;
(2) Characterization of the source term (i.e., the radionuclide and its quantity);
(3) Extent of encapsulation;
(4) Methods of containment;
(5) Other information to assess potential for irradiation by source or airborne dispersion radioactive material.

§ 82.15 How will NIOSH evaluate the completeness and adequacy of individual monitoring data?

(a) NIOSH will evaluate the completeness and adequacy of an individual's monitoring data provided by DOE through one or more possible measures including, but not limited to:
(1) Comparisons with information provided by claimants, co-workers, and other witnesses;
(2) Comparisons with available information on area monitoring, production processes, and radiologic protection programs;
(3) Comparisons with information documented in the records of unions representing covered employees;
(4) Comparisons with data available on co-workers; and
(5) Reviews of DOE contractor record systems.
(b) NIOSH will evaluate the instruments and procedures used to collect individual monitoring data to determine whether they adequately characterized the radiation environments in which the covered employee worked, (adequately for the purpose of dose reconstruction,) based on present-day scientific understanding. For external dosimeter measurements, this includes an evaluation of the dosimeter response to the radiation types (gamma, x-ray, neutron, beta, or other charged particle) and the associated energy spectrum. For internal exposure, the methods used to analyze bioassay samples will be reviewed to determine

their ability to detect the radionuclides present in the work environment. An analysis of the monitoring or exchange frequencies for the monitoring programs will also be conducted to determine the potential for undetected dose.

§ 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?

(a) For external dosimeter results that are incomplete due to historical record keeping practices, NIOSH will use commonly practiced techniques, such as those described in the NIOSH Research Issues Workshop,[2] to estimate the missing component of dose and to add this to the total dose estimate. For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation, using available monitoring results from other time periods close to the period in question, or based on monitoring data on other workers engaged in similar tasks.

(b) NIOSH will review historical bioassay sample detection limits and monitoring frequencies to determine, when possible, the minimum detectable dose for routine internal dose monitoring programs. This ''missed dose'' will establish the upper limit of internal dose that a worker could have received for periods when bioassay sample analysis results were below the detection limit. Using ICRP biokinetic models, NIOSH will estimate the internal dose and include an associated uncertainty distribution.

§ 82.17 What types of information could be used to supplement or substitute for individual monitoring data?

Three types of information could be used:

(a) Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment; or,

(b) A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area radiation and radioactive contamination survey results, air sampling data; or,

(c) A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices.

§ 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?

(a) The calculation of dose from ingested, inhaled or absorbed radioactivity involves the determination of the types and quantities of radionuclides that entered the body. NIOSH will use the results of all available bioassay monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program. If bioassay monitoring data are unavailable or inadequate, the dose reconstruction will rely on the results of air sampling measurements, radiation sources, work processes and practices, and incidents involving radiation contamination, as necessary.

(b) NIOSH will calculate the dose to the organ or tissue of concern using the appropriate current metabolic models published by ICRP. Using data available to NIOSH, the models will be based on exposure conditions representative of the work environment. When NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration. When the cancer covered by a claim is in a tissue not covered by existing ICRP models, NIOSH will use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant. For internal exposures, NIOSH will select the highest dose estimate from among the

[2] NIOSH [1995]. NIOSH research issues workshop: epidemiologic use of nondetectable values in radiation exposure measurements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 224647 (NTIS—PB 95189601).

modeled organs or tissues that do not concentrate the radionuclide.

(c) Internal doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.

§ 82.19 How will NIOSH address uncertainty about dose levels?

The estimate of each annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate. This information will be used by DOL in the calculation of probability of causation, under HHS guidelines for calculating probability of causation estimates at 42 CFR 81. In this way, claimants will receive the benefit of the doubt in cases in which the actual dose may have exceeded the best estimate calculated by NIOSH.

Subpart D—Reporting and Review of Dose Reconstruction Results

§ 82.25 When will NIOSH report dose reconstruction results, and to whom?

NIOSH will report dose reconstruction results to DOL and to the claimant, as provided for under § 82.10. Draft results will be reported to the claimant upon tentative completion of the dose reconstruction. Final results will be reported to the claimant, DOL and DOE after NIOSH receives certification from the claimant that the claimant has completed providing information to NIOSH for the dose reconstruction (Form OCAS–1).

§ 82.26 How will NIOSH report dose reconstruction results?

(a) NIOSH will provide dose reconstruction results to the claimant, DOL, and DOE in a report: ''NIOSH Report of Dose Reconstruction under EEOICPA.'' The report itself will not provide information on probability of causation, which DOL must calculate to determine a recommended decision on the claim.

(b) The report will include the following information, as relevant:

(1) Annual dose estimates (or a fraction thereof) related to covered employment for each year from the date of initial radiation exposure at a covered facility to the date of cancer diagnosis;

(2) Separate dose estimates for acute and chronic exposures, different types of ionizing radiation, and internal and external doses, providing internal dose information only for the organ or tissue relevant to the primary cancer site(s) established in the claim;

(3) Uncertainty distributions associated with each dose estimated, as necessary;

(4) Explanation of each type of dose estimate included in terms of its relevance for estimating probability of causation;

(5) Identification of any information provided by the claimant relevant to dose estimation that NIOSH decided to omit from the basis for dose reconstruction, justification for the decision, and if possible, a quantitative estimate of the effect of the omission on the dose reconstruction results; and

(6) A summary and explanation of information and methods applied to produce the dose reconstruction estimates, including any factual findings and the evidence upon which those findings are based.

(c) As provided under § 82.10(l), NIOSH staff will conduct a closing interview with claimants to explain the dose reconstruction report.

§ 82.27 How can claimants obtain reviews of their NIOSH dose reconstruction results by NIOSH?

(a) Claimants can seek reviews of their dose reconstruction through the processes established by DOL under 20 CFR 30. DOL will request NIOSH to review dose reconstructions under the following conditions, as provided under 20 CFR 30.318:

(1) DOL may determine that factual findings of the dose reconstruction do not appear to be supported by substantial evidence; or,

(2) Although the methodology established by HHS under this Part is binding on DOL, DOL may determine that arguments concerning the *application* of this methodology should be considered by NIOSH.

(b) NIOSH may review completed dose reconstructions on its own initiative and with the assistance of DOL to

identify denied claims when either of the following circumstances arise:

(1) NIOSH obtains records or information on radiation exposures of DOE or AWE employees that could substantially increase the level of radiation doses estimated in the completed dose reconstructions; or

(2) NIOSH changes a scientific element underlying dose reconstructions according to the provisions of Subpart E of this rule and the change could substantially increase the level of radiation doses estimated in the completed dose reconstructions.

(c) When NIOSH completes the review of a dose reconstruction, NIOSH will provide a report describing the basis for the review, the methods employed in the review, and the review findings to the claimant, DOL, and DOE.

§ 82.28 Who can review NIOSH dose reconstruction files on individual claimants?

(a) Claimants and DOL will be provided individual dose reconstruction files, upon request. Claimants should note, however, that a complete summary of the data and methods used in a dose reconstruction will be included in the ''NIOSH Report of Dose Reconstruction under EEOICPA''.

(b) Researchers and the public will be provided limited access to NIOSH dose reconstruction files, subject to provisions and restrictions of the Privacy Act for the protection of confidential information on individuals.

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

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83.15 How will the Board consider and advise the Secretary on a petition?
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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?
83.18 How can petitioners obtain an administrative review of a final decision by the Secretary?
83.19 How can the Secretary cancel or modify a final decision to add a class of employees to the Cohort?

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

SOURCE: 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.