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

[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.

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.

(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.

[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).

§ 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 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.