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| | Effective Date: | (9/24/02) |
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| Performing and Reporting Dose Reconstructio | ns | Page 1 of 20 |
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Subject Expert: Grady Calhoun x4377

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RECORD OF ISSUE/REVISIONS

| ISSUE AUTHORIZATION DATE | EFFECTIVE DATE | REV. NO. | DESCRIPTION |
|--------------------------------|-------------------|-------------|--|
| 9/24/02 | 9/24/02 | 0 | New document to establish program guidelines for performing dose reconstruction. Initiated by Grady Calhoun. |

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1.0 <u>PURPOSE</u>

The purpose of this procedure is to provide guidance for the Office of Compensation Analysis and Support (OCAS) staff and its technical support contractors in the performance, review, and documentation of dose reconstructions for covered employees with cancer per the requirements of 42 CFR 82, "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000."

2.0 <u>SCOPE</u>

This procedure applies to OCAS personnel and its technical support contractors involved in performing dose reconstructions for covered employees.

3.0 <u>REFERENCES</u>

- 3.1 OCAS-IG-001, "External Dose Reconstruction Implementation Guide"
- 3.2 OCAS-IG-002, "Internal Dose Reconstruction Implementation Guide"
- 3.3 Energy Employees Occupational Illness Compensation Program Act (EEOICPA)
- 3.4 42 CFR 82, "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000: Interim Final Rule With Request for Comments."
- 3.5 20 CFR 30, "Performance of Functions Under This Chapter; Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program; Final Rule."

4.0 **RESPONSIBILITIES**

<u>Records Management Team Leader</u> - Oversees the receipt and maintenance of data provided by the Department of Labor and the Department of Energy, processes requests for additional information, and maintains records of all correspondence associated with dose reconstructions.

Health Physicist - Performs and reviews dose reconstructions.

OCAS Health Science Administrator - Oversees the dose reconstruction process.

5.0 GENERAL

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy, its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. As provided below, there are two categories of covered employees with cancer under EEOICPA for whom compensation may be provided. This procedure applies only to the category of employees described under 5.1.

- 5.1 Employees with cancer for whom a dose reconstruction must be conducted, as required under 20 CFR 30.115.
- 5.2 Members of the Special Exposure Cohort seeking compensation for a specified cancer, as

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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.

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 facilities. Technical limitations of radiation monitoring technology and procedures will require evaluations of 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.

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 limitations of available data.

The procedures and level of effort involved in dose reconstructions depend in part on the quantity and quality of available dose monitoring information, the conditions under which radiation exposure arose, and the forms of radiation to which the individual was exposed. If individuals for whom dose estimates are needed were monitored using present day technology and received only external radiation doses, dose reconstruction could be very simple. It might only require summing the radiation doses recorded from radiation badges and adding estimated potential "missed" doses resulting from the limits of detection of monitoring badges.

Dose reconstruction can require extensive research and analysis. Such work is required if radiation doses were not monitored or there is uncertainty about the monitoring methods involved; if there was potential for internal doses through the ingestion, inhalation or absorption of radioactive materials; or i the processes and circumstances involved in the radiation exposures were complex. For the most complex dose reconstructions, research and analyses may include determining or assuming specific characteristics of the monitoring procedures; identifying events or processes that were unmonitored; identifying the types and quantities of radioactive materials involved; evaluating production processes and safety procedures employed; identifying the locations and activities of exposed persons; identifying comparable exposure circumstances for which data is available to make assumptions; and conducting a variety of complex analyses to interpret the data compiled or estimated.

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.

For each dose reconstruction, 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 will be included.

Dose reconstructions will be performed in a conservative manner such that uncertainties concerning data quality or dose are handled in a manner favorable to the claimant.

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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

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, defau 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.

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.

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.

An iterative process is used to expedite the processing of claims to ensure that dose reconstructions are completed in a claimant-friendly manner. If using an individual's minimum realistic exposure, or a portion of an individual's exposure (internal, external, or internal and external combined) results in a high probability of causation, then no further evaluation will be performed. Conversely, if the worst-case exposure (internal plus external) scenario results in a low probability of causation, then no further evaluation will be performed on those cases where the probability of causation is not evidently clear. Attachment 1, "Dose Reconstruction Flow Process" illustrates the decision logic used during the dose reconstruction process.

- 6.0 PROCEDURE
- 6.1 Claim Receipt

Records Management Team

- 6.1.1 Receive, process and maintain the claims provided by the DOL in accordance with OCAS-PR-002, "Processing Compensation Claims."
- 6.1.2 Request records from the DOE on radiation dose monitoring and radiation exposures associated with the employment history of the covered employee.
- 6.1.3 Notify OCAS Health Science Administrator or designee when personnel exposure information is received.

Health Physicist

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6.2 <u>Evaluate Available Data/Information</u>

- 6.2.1 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, consider:
 - 6.2.1.1 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
 - 6.2.1.2 Consistency of the information with medical records provided by the claimant;
 - 6.2.1.3 Consistency of the information with practices or exposures demonstrated by the dose reconstruction record developed for the claimant
 - 6.2.1.4 Confirmation of information by co-workers or other witnesses
- 6.2.2 Attempt to confirm information provided by the claimant through review of available records and records requested from DOE.
- 6.2.3 As necessary, 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.
- 6.2.4 Compile any data, and information from NIOSH records that may contribute to the dose reconstruction.
- 6.2.5 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.
- 6.2.6 Any discrepancies in the employment history information will be reconciled with the assistance of DOE, as necessary.
- 6.2.7 Use the following sources of information for dose reconstructions, as necessary:
 - 6.2.7.1 DOE and its contractors, including Atomic Weapons Employers and the Former Worker Medical Screening Program
 - 6.2.7.2 NIOSH and other records from health research on DOE worker populations
 - 6.2.7.3 Interviews and records provided by claimants
 - 6.2.7.4 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
 - 6.2.7.5 Labor union records from unions representing employees at covered facilities of DOE or AWEs
 - 6.2.7.6 Any other relevant information
- 6.2.8 Obtain the types of information described in this section for dose reconstructions, as necessary and available:

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6.2.8.1 Subject and employment information, including:

- (A) Gender
- (B) Date of birth
- (C) DOE and/or AWE employment history, including: job title held by year, and work location(s): Including site name(s), building number(s), technical area(s), and duration of relevant employment or tasks.
- 6.2.8.2 Worker monitoring data, including:
 - (A) External dosimetry data, including external dosimeter readings (film badge, TLD, neutron dosimeters)
 - (B) Pocket ionization chamber data

6.2.8.3 Internal dosimetry data, including:

- (A) Urinalysis results
- (B) Fecal sample results
- (C) In Vivo measurement results
- (D) Incident investigation reports
- (E) Breath radon and/or thoron results
- (F) Nasal smear results
- (G) External contamination measurements
- (H) Other measurement results applicable to internal dosimetry
- 6.2.8.4 Monitoring program data, including:
 - (A) Analytical methods used for bioassay analyses
 - (B) Performance characteristics of dosimeters for different radiation types
 - (C) Historical detection limits for bioassay samples and dosimeter badges
 - (D) Bioassay sample and dosimeter collection/exchange frequencies
 - (E) Documentation of record keeping practices used to record data and/or administratively assign dose
 - (F) Other information to characterize the monitoring program procedures and evaluate monitoring results.
- 6.2.8.5 Workplace monitoring data, including:
 - (A) Surface contamination surveys
 - (B) General area air sampling results
 - (C) Breathing zone air sampling results
 - (D) Radon and/or thoron monitoring results
 - (E) Area radiation survey measurements (beta, gamma and neutron)
 - (F) Fixed location dosimeter results (beta, gamma and neutron)
 - (G) Other workplace monitoring results
- 6.2.8.6 Workplace characterization data, including:
 - (A) Information on the external exposure environment, including: Radiation type (gamma, x-ray, neutron, beta, other charged particle); radiation energy spectrum; uniformity of exposure (whole body vs partial body exposure)
 - (B) Information on work-required medical screening x-rays
 - (C) Other information useful for characterizing workplace radiation exposures
- 6.2.8.7 Information characterizing internal exposures, including:

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- (A) Radionuclide(s) and associated chemical forms
- (B) Results of particle size distribution studies
- (C) Respiratory protection practices
- (D) Other information useful for characterizing internal exposures
- 6.2.8.8 Process descriptions for each work location, including:
 - (A) General description of the process
 - (B) Characterization of the source term (i.e., the radionuclide and its quantity)
 - (C) Extent of encapsulation
 - (D) Methods of containment
 - (E) Other information to assess potential irradiation by source or potential for airborne radioactive material
- 6.2.9 Evaluate the completeness of an individual's monitoring data provided by DOE through one or more possible measures including, but not limited to:
 - 6.2.9.1 Comparisons with information provided by claimants, co-workers, and other witnesses
 - 6.2.9.2 Comparisons with available information on area monitoring, production processes, and radiologic protection programs
 - 6.2.9.3 Comparisons with information documented in the records of unions representing covered employees
 - 6.2.9.4 Comparisons with data available on co-workers
 - 6.2.9.5 Reviews of DOE contractor record systems.
- 6.2.10 As appropriate, 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.
 - 6.2.10.1 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.
 - 6.2.10.2 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.
 - 6.2.10.3 An analysis of the monitoring, or exchange frequencies for the monitoring program(s), will also be conducted to determine the potential for undetected dose.
- 6.2.11 For external dosimeter results that are incomplete due to historical record keeping practices, use commonly practiced techniques to estimate the missing component of dose and to add this to the total dose estimate.
- 6.2.12 For monitoring periods where external dosimetry data are missing from the records, 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.
- 6.2.13 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

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a worker could have received for periods when bioassay sample analysis results were below the detection limit.

- 6.2.14 Using ICRP biokinetic models, estimate the internal dose and include an associated uncertainty distribution.
- 6.2.15 The following types of information can be used to supplement or substitute individual monitoring data:
 - 6.2.15.1 Monitoring data from co-workers, if it is determined they had a common relationship to the radiation environment
 - 6.2.15.2 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 survey results, air sampling data
 - 6.2.15.3A 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

6.3 Claimant Interview

NIOSH Interviewer

- 6.3.1 Interview the claimant. The interview may be conducted in one or more sessions. The purpose of the interview is to:
 - 6.3.1.1 Explain the dose reconstruction process
 - 6.3.1.2 Confirm elements of the employment history transmitted to NIOSH by DOL
 - 6.3.1.3 Identify any relevant information on employment history that may have been omitted
 - 6.3.1.4 Confirm or supplement monitoring information included in the initial radiation exposure record
 - 6.3.1.5 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
 - 6.3.1.6 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.

6.4 Document Claimant Interview

- 6.4.1 Document the claimant interview on the "NIOSH Claimant Interview under EEOICPA."
- 6.5 <u>Provide Interview Report to Claimant</u>
 - 6.5.1 Provide a report to the claimant summarizing the findings of the interview, titled: "NIOSH Claimant Interview under EEOICPA."
 - 6.5.2 Notify the claimant, in the report, of the opportunity to contact NIOSH if necessary, by a

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specified date, to make any written corrections or additions to information provided by the claimant during the interview process.

6.6 Claim Evaluation

OCAS Health Science Administrator (or designee)

6.6.1 Assigns claim to Health Physicist for evaluation.

Health Physicist

6.6.2 Ensure that all the following criteria have been met:

- 6.6.2.1 The claimant meets the definition of covered employee and the Department of Labor has verified the covered employment period for the claimant.
- 6.6.2.2 Documentation exists stating that the claimant has or has had a covered cancer.
- 6.6.3 If either of the previous criteria are not met, then additional information is required prior to performing a dose reconstruction. Notify OCAS Health Science Administrator.

6.7 Internal Dose Calculation Methodology

- 6.7.1 In accordance with the guidance provided in the NIOSH Implementation Guide for Internal Dosimetry, 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.
- 6.7.2 When exposure conditions cannot be established with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration.
- 6.7.3 Internal doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.
- 6.7.4 The calculation of dose from ingested, inhaled or absorbed radioactivity involves the determination of the types and quantities of radionuclides that entered the body. Use the results of all available bioassay monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program.
- 6.7.5 If bioassay monitoring data are unavailable, 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.
- 6.7.6 When the cancer covered by a claim is in a tissue not covered by existing ICRP models, use the ICRP model that best approximates the model needed, while giving the benefit of the doubt to the claimant.
- 6.7.7 For internal exposures, select the highest dose estimate from among the modeled organs or tissues that do not concentrate the radionuclide

6.8 External Dose Calculation Methodology

6.8.1 In accordance with the guidance provided in the NIOSH Implementation Guide for External Dosimetry, calculate the dose to the organ or tissue of concern. Using data available to NIOSH, the dose will be based on exposure conditions representative of the work

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environment.

- 6.8.2 When exposure conditions cannot be established with sufficient specificity, the dose calculation will assume exposure conditions that maximize the dose to the organ under consideration.
- 6.8.3 External doses will be calculated for each year of exposure from the date of initial exposure to the date of cancer diagnosis.
- 6.8.4 The calculation of external dose involves the determination of the types and energies of radiation present as well as the direction from which the radiation entered the body. Use the results of all available external monitoring information as appropriate, based on assessment of the technical characteristics of the monitoring program.

6.9 Initial Dose Evaluation

The first step in performing an initial dose evaluation is to review the available exposure data and the specified primary cancer(s). For cases in which only a secondary cancer is listed, the dose to all possible primary cancer sites, as listed in Table 1 of 42 CFR 81, must be calculated. A judgement must then be made whether internal or external sources contributed the larger dose to the specified organ(s). This information will be used to determine which portion of the dose reconstruction will be performed first. The work activity and the types and sources of radiation to which an individual was potentially exposed must be evaluated. For example, external radiation would be the primary concern for an individual working with encapsulated radioactive material such as cladded fuel parts or radiation sources. Internal exposure would be the primary concern if an individual worked with un-encapsulated radioactive material, worked in airborne radioactivity areas, or worked with un-contained chemical operations.

In addition to the radioactive material or radiation encountered in the workplace, the affected organ(s) and the potential routes of exposure to the organ(s) must be evaluated. For example, internal exposure is probably the highest contributor of dose to the lung for individuals working with uranium or transuranic elements with a relatively small emission of penetrating radiation. Conversely, an organ such as the prostate gland has very little likelihood of receiving significant dose from internal deposition of actinides because it is not an organ of significant accumulation.

Once the most probable source of irradiation is determined, an evaluation of the potential dose is performed. Guidelines for performing internal and external dose reconstructions are found in OCAS-IG-001, "External Dose Reconstruction Implementation Guide" and OCAS-IG-002, "Internal Dose Reconstruction Implementation, worst-case assumptions will be used to provide an overestimate of the dose. Probability of causation calculations will be performed to determine if this overestimated radiation dose will result in a high or low probability of causation.

- 6.9.1 If the overestimated dose results in an estimated probability of causation less than 50%, then perform a similar assessment for the other source of irradiation. For example, if the internal exposure evaluation was performed first, complete an external exposure evaluation.
 - 6.9.1.1 If the sum of the internal and external doses results in a probability of causation of less than 50%, then the evaluation is complete. A report must be written per the requirements of step 6.12.
 - 6.9.1.2 If the sum of the internal and external doses results in a probability of causation above 50%, then the dose reconstruction must be further refined.

6.10 Secondary Dose Evaluation

Using the route of exposure (internal or external) resulting in the highest dose to the specified

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organ(s), perform a secondary dose evaluation. The secondary evaluation uses an underestimated dose or even a partial dose to the organ or tissue of interest.

- 6.10.1 If the underestimated dose results in a high probability of causation (i.e., >50%), then no further evaluation is necessary. Prepare a report per step 6.12.
- 6.10.2 If the dose results in an estimated probability of causation less than 50%, then perform a similar assessment for the other source of irradiation. For example, if the internal exposure evaluation was performed first, complete an external exposure evaluation.
 - 6.10.2.1 If the sum of the internal and external doses results in a probability of causation greater than 50%, then the evaluation is complete. A report must be written per the requirements of step 6.12.
 - 6.10.2.2 If the sum of the internal and external doses results in a probability of causation of less than 50%, then the dose reconstruction must be further refined.

6.11 Refining Dose Reconstruction

The dose reconstruction process is an iterative one. Successive reconstructions will contain increasing detail. This process will continue until the dose clearly results in an estimated high or low probability of causation <u>OR</u> all relevant, available data has been used in the calculation.

At any point during the dose reconstruction, 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:

- 6.11.1 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);
- 6.11.2 Dose is determined using worst-case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,
- 6.11.3 All available data has been used.

Worst-case assumptions will be employed under condition in step 6.11.2 of this section 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.

6.12 Report Preparation

- 6.12.1 An overview of the dose reconstruction must be included in the, "NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).
- 6.12.2 The report will include the following information, as relevant:
 - 6.12.2.1 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
 - 6.12.2.2 Separate dose estimates for acute and chronic exposures, different types of ionizing radiation, and internal and external doses, providing dose information for the organ or

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tissue relevant to the primary cancer site(s) established in the claim

- 6.12.2.3 Uncertainty distributions associated with each dose estimated, as necessary
- 6.12.2.4 Explanation of each type of dose estimate included in terms of its relevance for estimating probability of causation
- 6.12.2.5 Identification of any information provided by the claimant relevant to dose estimation that was omitted 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
- 6.12.2.6 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
- 6.12.2.7 For all claims in which worst-case assumptions are employed under the conditions of 6.11.2, the reasoning that resulted in the determination to limit further research and analysis will be clearly described in the dose reconstruction results reported to the claimant and the DOL.
- 6.12.2.8 The estimate of each annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate.
- 6.12.3 Once the resulting data set is complete, construct an occupational exposure matrix, using the general hierarchical approach discussed in step 5.0.
 - 6.12.3.1 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.
 - 6.12.3.2 The equivalent dose(s) will be calculated using the current, standard radiation weighting factors from the International Commission on Radiological Protection.

Note: All dose reconstructions must be reviewed and approved by an OCAS Health Physicist.

6.12.4 If the dose reconstruction was completed by a contract Health Physicist then the report must be forwarded to an OCAS Health Physicist for review. If the dose reconstruction was completed by an OCAS Health Physicist, then it must be forwarded to an OCAS Health Physicist, then it must be forwarded to an OCAS Health Physicist other than the one performing the dose reconstruction.

6.13 Dose Reconstructions that Cannot Be Completed

- 6.13.1 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 step 6.16.
- 6.13.2 Notification will describe the basis for finding a dose reconstruction cannot be completed, including the following:
 - 6.13.2.1 A summary of the information obtained from DOE and other sources; and,
 - 6.13.2.2 A summary of necessary information found to be unavailable from DOE and other sources.

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- 6.13.3 Notify DOL when it is not possible to complete a dose reconstruction for the claimant.
- 6.13.4 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.

6.14 Report Review

OCAS Reviewing Health Physicist

- 6.14.1 Review the dose reconstruction report for technical accuracy and to ensure that the requirements of 6.12.2 are included.
- 6.14.2 Designate approval by signing the "Dose Reconstruction Reviewed by" block of the "NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)."
- 6.14.3 Return reports not meeting appropriate requirements to the Health Physicist who performed the dose reconstruction.

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Administrative Support

6.15 Draft Report Distribution

6.15.1 Provide the claimant with a copy of the draft dose reconstruction report to be provided to DOL.

Health Physicist

- 6.16 Closing Interview with Claimant
 - 6.16.1 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 allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report
 - 6.16.2 Grant requests for time to provide additional information, based on whether the requests are reasonable and the claimant is actively seeking the information specified
 - 6.16.3 Subject to any additional information provided by the claimant and revision to the dose reconstruction report, the claimant is required to return form OCAS-1 to NIOSH, certifying that he/she has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form, forward a final dose reconstruction report to DOL, DOE, and to the claimant. The report itself will not provide information on probability of causation, which DOL must calculate to determine a recommended decision on the claim.

Records Management Team/Health Physicist

6.17 Preparation of Administrative Record

The information to be included in the Administrative Record, as applicable, is as follows:

- 6.17.1 Acknowledgment Letter to Claimant (Letter #1)
- 6.17.2 DOE Request Form (2 page)
- 6.17.3 DOE Request Sent Letter to Claimant (Letter #2)
- 6.17.4 60 Days Overdue Letter to DOE
- 6.17.5 DOE Receipt
- 6.17.6 Letter to Claimant Preparing them for the CATI (Includes Script) (Letter #3)
- 6.17.7 Letter to Claimant with completed CATI Draft Report
- 6.17.8 Letter to Claimant with completed CATI Update Report
- 6.17.9 Letter to Claimant with completed Dose Reconstruction Draft Report
- 6.17.10 Letter to Claimant with completed Dose Reconstruction Final Report

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- 6.17.11 Internal Correspondence (Correspondence Initiated by OCAS Staff)
- 6.17.12 External Correspondence (Correspondence Initiated by Outside Entity)
- 6.17.13 DOL Supplemental Information (Category non-specific)
- 6.17.14 DOL Supplemental Information (Employment Verification)
- 6.17.15 DOL Supplemental Information (Racial Ethnic Identification)
- 6.17.16 DOL Supplemental Information (Medical Information)
- 6.17.17 DOL Supplemental Information (Smoking Information)
- 6.17.18 DOL Amended NIOSH Referral Summary Document
- 6.17.19 DOL Supplemental Information (Dose Information)
- 6.17.20 DOE Response
- 6.17.21 Phone Conversation Report
- 6.17.22 OCAS-1 Form
- 6.17.23 Authorization Forms from Claimant Contacts (i.e. forms, letters, or documentation)
- 6.17.24 Supporting documentation for final dose calculations which may include:
 - 6.17.24.1 Spreadsheets containing calculations used for <u>final</u> dose estimates
 - 6.17.24.2 Applicable portions of environmental reports used
 - 6.17.24.3 Reports from dose calculation programs showing <u>final</u> results of dose estimates
 - 6.17.24.3 Any other documentation used in final dose estimate
- 6.17.25 Excel Spreadsheet for input into IREP
- 6.17.26 Printout of IREP run performed by NIOSH

Administrative Support

6.18 Final Report Distribution

- 6.18.1 Forward a final dose reconstruction report to the claimant and DOE.
- 6.18.2 Forward administrative record to DOL.

Note: Do 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, 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.

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6.19 Claim Closing

6.19.1 Once actions under section 6.16.2 are completed, the record for dose reconstruction shall be closed unless reopened at the request of DOL under 20 CFR part 30.

6.20 Review of Completed Dose Reconstructions

- 6.20.1 Completed dose reconstructions may be reviewed with the assistance of DOL to identify denied claims when either of the following circumstanced arise:
 - 6.20.1.1 Additional records or information are obtained pertaining to radiation exposures of DOE or AWE employees that could substantially increase the level of radiation doses estimated in the completed dose reconstructions
 - 6.20.1.2 A scientific element underlying dose reconstructions is changed 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
- 6.20.2 When a review of a dose reconstruction is completed, 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.

7.0 <u>RECORDS</u>

The following records are generated as applicable.

7.1 NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

8.0 **DEFINITIONS**

- 8.1 Atomic Weapons Employer an entity, other than the United States, that--
 - 8.1.1 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,
 - 8.1.2 is designated by the Secretary of Energy as an atomic weapons employer for purposes of the compensation program.
- 8.2 <u>Bioassay</u> 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.
- 8.3 <u>Claimant</u> the individual who has filed with the Department of Labor for compensation under EEOICPA.
- 8.4 <u>Covered Employee</u> An individual with cancer specified below if, and only if, that individual is determined to have sustained that cancer in the performance of duty in accordance with section 3623(b) of EEOICPA.
 - 8.4.1 A Department of Energy employee who contracted that cancer after beginning employment at a Department of Energy facility.
 - 8.4.2 A Department of Energy contractor employee who contracted that cancer after beginning employment at a Department of Energy facility.

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- 8.4.3 An atomic weapons employee who contracted that cancer after beginning employment at an atomic weapons employer facility.
- 8.4.4 An individual with cancer specified in steps (9.4.1), (9.4.2), or (9.4.3) shall be determined to have sustained that cancer in the performance of duty for purposes of the compensation program if, and only if, the cancer specified was at least as likely as not related to employment at the facility, as determined in accordance with the guidelines established in 42 CFR 81.
- 8.5 <u>Covered Facility</u> any building, structure, or premises, including the grounds upon which such building, structure, or premise is located:
 - 8.5.1 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,
 - 8.5.2 With regard to which the DOE has or had:
 - 8.5.2.1 A proprietary interest; or,
 - 8.5.2.2 Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services; or
 - 8.5.3 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.
- 8.6 <u>DOE</u> means the U.S. Department of Energy, and includes predecessor agencies of DOE, including the Manhattan Engineering District.
- 8.7 <u>Department of Energy contractor employee</u> means any of the following:
 - 8.7.1 An individual who is or was in residence at a Department of Energy facility as a researcher for one or more periods aggregating at least 24 months.
 - 8.7.2 An individual who is or was employed at a Department of Energy facility by--
 - 8.7.2.1 an entity that contracted with the Department of Energy to provide management and operating, management and integration, or environmental remediation at the facility; or,
 - 8.7.2.2 a contractor or subcontractor that provided services, including construction and maintenance, at the facility.
- 8.8 <u>Department of Energy facility</u> means any building, structure, or premise, including the grounds upon which such building, structure, or premise is located. Refer to 9.5, "Covered Facility."
- 8.9 <u>DOL</u> The U.S. Department of Labor
- 8.10 <u>Dose Reconstruction</u> the process by which the radiation dose received by an individual is estimated. The result of a dose reconstruction is not intended to replace the dose of record or be the absolute dose which the individual received.
- 8.11 EEOICPA means the Energy Employees Occupational Illness Compensation Program Act of 2000, 42 U.S.C. 7384-7385 [1994, supp. 2001].

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- 8.12 <u>Equivalent dose</u> 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.
- 8.13 <u>External dose</u> that portion of the equivalent dose that is received from radiation sources outside of the body.
- 8.14 <u>Internal dose</u> that portion of the equivalent dose that is received from radioactive materials taken into the body.
- 8.15 <u>NIOSH</u> the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.
- 8.16 <u>Primary cancer</u> 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.
- 8.17 <u>Probability of causation</u> 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.
- 8.18 <u>Radiation</u> 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.
- 8.19 <u>Specified cancer</u> a term defined in section 3621(17) of EEOICPA and 20 CFR part 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.
- 8.20 <u>Uncertainty distribution</u> 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.
- 8.21 <u>Worst Case</u> -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.

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ATTACHMENT 1 Dose Reconstruction Flow Process (Page 1 of 1)