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§ 81.2 Provisions of EEOICPA concerning this part.

EEOICPA imposes several general requirements concerning the development of these guidelines. It requires that the guidelines produce a determination as to whether it is at least as likely as not (a 50% or greater probability) that the cancer of the covered employee was related to radiation doses incurred by the employee in the performance of duty. It requires the guidelines be based on the radiation dose received by the employee, incorporating the methods of dose reconstruction to be established by HHS. It requires determinations be based on the upper 99 percent confidence interval (credibility limit) of the probability of causation in the RadioEpidemiological tables published under section 7(b) of the Orphan Drug Act (42 U.S.C. 241 note), as such tables may be updated. EEOICPA also requires HHS consider the type of cancer, past health-related activities, the risk of developing a radiation-related cancer from workplace exposure, and other relevant factors. Finally, it is important to note EEOICPA does not include a requirement limiting the types of cancers to be considered radiogenic for these guidelines.

Subpart B—Definitions

§ 81.4 Definition of terms used in this part.

(a) Covered employee, for purposes of this part, means 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.

(b) *Dose and dose rate effectiveness factor (DDREF)* means a factor applied to a risk model to modify the dose-risk relationship estimated by the model to account for the level of the dose and the rate at which the dose is incurred. As used in IREP, a DDREF value of greater than one implies that chronic or low doses are less carcinogenic per unit of dose than acute or higher doses.

(c) *Dose-response relationship* means a mathematical expression of the way that the risk of a biological effect (for example, cancer) changes with increased exposure to a potential health hazard (for example, ionizing radiation).

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

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

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

(g) *Interactive RadioEpidemiological Program (IREP)* means a computer software program that uses information on the dose-response relationship, and specific factors such as a claimant's radiation exposure, gender, age at diagnosis, and age at exposure to calculate the probability of causation for a given pattern and level of radiation exposure.

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

(i) *Inverse dose rate effect* means a phenomenon in which the protraction of an exposure to a potential health hazard leads to greater biological effect per unit of dose than the delivery of the same total amount in a single dose. An inverse dose rate effect implies that the dose and dose rate effectiveness factor (DDREF) is less than one for chronic or low doses.

(j) *Linear energy transfer (LET)* means the average amount of energy transferred to surrounding body tissues per unit of distance the radiation travels through body tissues (track length). Low LET radiation is typified by gamma and x rays, which have high penetrating capabilities through various tissues, but transfer a relatively small amount of energy to surrounding tissue per unit of track length. High LET radiation includes alpha particles and neutrons, which have weaker penetrating capability but transfer a larger amount of energy per unit of track length.

(k) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and

Prevention, United States Department of Health and Human Services.

(l) *Non-radiogenic cancer* means a type of cancer that HHS has found not to be caused by radiation, for the purposes of this regulation.

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

(o) *RadioEpidemiological Tables* means tables that allow computation of the probability of causation for various cancers associated with a defined exposure to radiation, after accounting for factors such as age at exposure, age at diagnosis, and time since exposure.

(p) *Relative biological effectiveness (RBE)* means a factor applied to a risk model to account for differences between the amount of cancer effect produced by different forms of radiation. For purposes of EEOICPA, the RBE is considered equivalent to the radiation weighting factor.

(q) *Risk model* means a mathematical model used under EEOICPA to estimate a specific probability of causation using information on radiation dose, cancer type, and personal data (e.g., gender, smoking history).

(r) *Secondary site* means a body site to which a primary cancer has spread (metastasized).

(s) *Specified cancer* is a term defined in §7384(l)(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, renal cancers, 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 B), and bone.

(t) *Uncertainty* is a term used in this rule to describe the lack of precision of a given estimate, the extent of which depends upon the amount and quality of the evidence or data available.

(u) *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.

(v) *Upper 99 percent confidence interval* is a term used in EEOICPA to mean credibility limit, the probability of causation estimate determined at the 99th percentile of the range of uncertainty around the central estimate of probability of causation.

Subpart C—Data Required To Estimate Probability of Causation

§81.5 Use of personal and medical information.

Determining probability of causation may require the use of the following personal and medical information provided to DOL by claimants under DOL regulations 20 CFR part 30:

(a) Year of birth

(b) Cancer diagnosis (by ICD–9 code) for primary and secondary cancers

(c) Date of cancer diagnosis

(d) Gender

(e) Race/ethnicity (if the claim is for skin cancer or a secondary cancer for which skin cancer is a likely primary cancer)

(f) Smoking history (if the claim is for lung cancer or a secondary cancer for which lung cancer is a likely primary cancer)

§81.6 Use of radiation dose information.

Determining probability of causation will require the use of radiation dose information provided to DOL by the National Institute for Occupational Safety and Health (NIOSH) under HHS regulations 42 CFR part 82. This information will include annual dose estimates for each year in which a dose was incurred, together with uncertainty distributions associated with