



Federal Register

**Thursday,
May 2, 2002**

Part IV

Department of Health and Human Services

42 CFR Parts 81 and 82

**Guidelines for Determining the
Probability of Causation and Methods for
Radiation Dose Reconstruction Under the
Employees Occupational Illness
Compensation Program Act of 2000; Final
Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 81

RIN 0920-ZA01

Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This rule implements select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA" or "Act"). The Act requires the promulgation of guidelines, in the form of regulations, for determining whether an individual with cancer shall be found, "at least as likely as not," to have sustained that cancer from exposure to ionizing radiation in the performance of duty for nuclear weapons production programs of the Department of Energy and its predecessor agencies. The guidelines will be applied by the U.S. Department of Labor, which is responsible for determining whether to award compensation to individuals seeking federal compensation under the Act.

DATES: *Effective Date:* This final rule is effective May 2, 2002.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone 513-841-4498 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA"), 42 U.S.C. 7384-7385 [1994, supp. 2001], established a compensation program to provide a lump sum payment of \$150,000 and medical benefits as compensation to covered employees suffering from designated illnesses (i.e. cancer resulting from radiation exposure, chronic beryllium disease, or silicosis) incurred as a result of their exposures while in the performance of duty for the Department of Energy ("DOE") and certain of its vendors, contractors, and subcontractors. This legislation also

provided for payment of compensation to certain survivors of covered employees.

EEOICPA instructed the President to designate one or more federal agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179 titled Providing Compensation to America's Nuclear Weapons Workers, which assigned primary responsibility for administering the compensation program to the Department of Labor ("DOL"). 65 FR 77,487 (Dec. 7, 2000). DOL published an interim final rule governing its administration of EEOICPA on May 25, 2001 (20 CFR Parts 1 and 30).

The Executive Order directed the Department of Health and Human Services ("HHS") to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop guidelines to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or Atomic Weapons Employer ("AWE") facility. These "Probability of Causation" guidelines are the subject of this final rule, and were initially proposed for public comment in a notice of proposed rulemaking published on October 5, 2001.

(2) HHS is also to establish methods to estimate radiation doses ("dose reconstruction") for certain individuals with cancer applying for benefits under the DOL program, and HHS is to implement these methods in a program of dose reconstruction for EEOICPA claims. HHS published these methods as an interim final rule under 42 CFR part 82 on October 5, 2001, and is publishing them as a final rule simultaneously in this issue of the **Federal Register**. HHS is presently applying these methods to conduct the program of dose reconstruction required by EEOICPA.

(3) HHS is to staff the Advisory Board on Radiation and Worker Health and provide it with administrative and other necessary support services. The Board, a federal advisory committee, was appointed by the President in November 2001. It was first convened on January 22, 2001, and is advising HHS in implementing its roles under EEOICPA described here.

(4) Finally, HHS is to develop and apply procedures for considering petitions by classes of employees at DOE or AWE facilities seeking to be added to the Special Exposure Cohort established under EEOICPA. Employees included in the Special Exposure Cohort

who have a specified cancer and meet other conditions, as defined by EEOICPA and DOL regulations (20 CFR 30), qualify for compensation under EEOICPA. HHS has developed proposed procedures for considering Special Exposure Cohort petitions which will be published soon in the **Federal Register**. HHS will obtain public comment and a review by the Advisory Board on Radiation and Worker Health before these procedures are made final and implemented.

As provided for under 42 U.S.C. 7384p, HHS is implementing its responsibilities with the assistance of the National Institute for Occupational Safety and Health ("NIOSH"), an institute of the Centers for Disease Control and Prevention, HHS.

B. Purpose of Probability of Causation Guidelines

Under EEOICPA, a covered employee seeking compensation for cancer, other than as a member of the Special Exposure Cohort seeking compensation for a specified cancer, is eligible for compensation only if DOL determines that the cancer was "at least as likely as not" (a 50% or greater probability) caused by radiation doses incurred in the performance of duty while working for DOE and/or an atomic weapons employer (AWE) facility. These guidelines provide DOL with the procedure to make these determinations, and specify the information DOL will use.

HHS notes that EEOICPA does not authorize the establishment of new radiation protection standards through the promulgation of these guidelines, and these guidelines do not constitute such new standards.

C. Statutory Requirements for Probability of Causation Guidelines

EEOICPA has several general requirements concerning the development of these guidelines. It requires the guidelines provide for determinations that are 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 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 to consider the type of cancer, past health-related activities, the risk of developing a radiation-related cancer from workplace exposure, and other relevant factors. 42 U.S.C. 7384n(c). It is also important to

note EEOICPA does *not* include a requirement limiting the types of cancers to be considered radiogenic for these guidelines.

D. Understanding Probability of Causation

Probability of Causation is a technical term generally meaning an estimate of the percentage of cases of illness caused by a health hazard among a group of persons exposed to the hazard. This estimate is used in compensation programs as an estimate of the probability or likelihood that the illness of an individual member of that group was caused by exposure to the health hazard. Other terms for this concept include "assigned share" and "attributable risk percent".

In this rule, the potential hazard is ionizing radiation to which U.S. nuclear weapons workers were exposed in the performance of duty; the illnesses are specific types of cancer. The probability of causation (PC) is calculated as the risk of cancer attributable to radiation exposure (RadRisk) divided by the sum of the baseline risk of cancer to the general population (BasRisk) plus the risk attributable to the radiation exposure, then multiplied by 100 percent, as follows:

$$\frac{\text{RadRisk}}{\text{RadRisk} + \text{BasRisk}} \times 100\% = \text{PC}$$

This calculation provides a percentage estimate between 0 and 100 percent, where 0 would mean 0 likelihood that radiation caused the cancer and 100 would mean 100 percent certainty that radiation caused the cancer.

Scientists evaluate the likelihood that radiation caused cancer in a worker by using medical and scientific knowledge about the relationship between specific types and levels of radiation dose and the frequency of cancers in exposed populations. Simply explained, if research determines that a specific type of cancer occurs more frequently among a population exposed to a higher level of radiation than a comparable population (a population with less radiation exposure but similar in age, gender, and other factors that have a role in health), and if the radiation exposure levels are known in the two populations, then it is possible to estimate the proportion of cancers in the exposed population that may have been caused by a given level of radiation.

If scientists consider this research sufficient and of reasonable quality, they can then translate the findings into a series of mathematical equations that estimate how much the risk of cancer in a population would increase as the dose

of radiation incurred by that population increases. The series of equations, known as a dose-response or quantitative risk assessment model, may also take into account other health factors potentially related to cancer risk, such as gender, smoking history, age at exposure (to radiation), and time since exposure. The risk models can then be applied as an imperfect but reasonable approach to determine the likelihood that the cancer of an individual worker was caused by his or her radiation dose.

E. Development and Use of the RadioEpidemiological Tables and Interactive RadioEpidemiological Program

In 1985, in response to a congressional mandate in the Orphan Drug Act, a panel established by the National Institutes of Health developed a set of Radioepidemiological Tables. The tables serve as a reference tool providing probability of causation estimates for individuals with cancer who were exposed to ionizing radiation. Use of the tables requires information about the person's dose, gender, age at exposure, date of cancer diagnosis and other relevant factors. The tables are used by the Department of Veterans Affairs (DVA) to make compensation decisions for veterans with cancer who were exposed in the performance of duty to radiation from atomic weapon detonations.

The primary source of data for the 1985 tables is research on cancer-related deaths occurring among Japanese atomic bomb survivors from World War II.

The 1985 tables are presently being updated by the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention¹ to incorporate progress in research on the relationship between radiation and cancer risk. The draft update has been reviewed by the National Research Council² and by NIOSH. DOL will employ the updated version of the tables, with modifications important to claims under EEOICPA (described below under "G" and in response to public comments under "II"), as a basis for determining probability of causation for employees covered under EEOICPA.

A major scientific change achieved by this update is the use of risk models developed from data on the occurrence of cancers (cases of illness) rather than the occurrence of cancer deaths among

Japanese atomic bomb survivors. The risk models are further improved by being based on more current data as well. Many more cancers have been modeled in the revised report. The new risk models also take into account factors that modify the effect of radiation on cancer, related to the type of radiation dose, the amount of dose, and the timing of the dose.

A major technological change accompanying this update, which represents a scientific improvement, is the production of a computer software program for calculating probability of causation. This software program, named the Interactive RadioEpidemiological Program (IREP), allows the user to apply the NCI risk models directly to data on an individual employee. This makes it possible to estimate probability of causation using better quantitative methods than could be incorporated into printed tables. In particular, IREP allows the user to take into account uncertainty concerning the information being used to estimate probability of causation. There typically is uncertainty about the radiation dose levels to which a person has been exposed, as well as uncertainty relating levels of dose received to levels of cancer risk observed in study populations.

Accounting for uncertainty is important because it can have a large effect on the probability of causation estimates. DVA, in their use of the 1985 Radioepidemiological Tables, uses the probability of causation estimates found in the tables at the upper 99 percent credibility limit. This means when DVA determines whether the cancer of a veteran was more likely than not caused by radiation, they use the estimate that is 99 percent certain to be greater than the probability that would be calculated if the information on dose and the risk model were perfectly accurate.

Similarly, these HHS guidelines, as required by EEOICPA, will use the upper 99 percent credibility limit to determine whether the cancers of employees are at least as likely as not caused by their occupational radiation doses. 42 U.S.C. 7384n(c)(3)(A). This will help minimize the possibility of denying compensation to claimants under EEOICPA for those employees with cancers likely to have been caused by occupational radiation exposures.

F. Use of IREP for Energy Employees

The risk models developed by NCI and CDC for IREP provide the primary basis for developing guidelines for estimating probability of causation under EEOICPA. They directly address 33 cancers and most types of radiation

¹ Draft Report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000.

² A Review of the Draft Report of the NCI-CDC Working Group to Revise the "1985 Radioepidemiological Tables", National Research Council.

exposure relevant to employees covered by EEOICPA. These models take into account the employee's cancer type, year of birth, year of cancer diagnosis, and exposure information such as years of exposure, as well as the dose received from gamma radiation, x rays, alpha radiation, beta radiation, and neutrons during each year. Also, the risk model for lung cancer takes into account smoking history and the risk model for skin cancer takes into account race/ethnicity. None of the risk models explicitly accounts for exposure to other occupational, environmental, or dietary carcinogens. Models accounting for these factors have not been developed and may not be possible to develop based on existing research. Moreover, DOL could not consistently or efficiently obtain the data required to make use of such models.

IREP models do not specifically include cancers as defined in their early stages: carcinoma in situ (CIS). These lesions are becoming more frequently diagnosed, as the use of cancer screening tools, such as mammography, have increased in the general population. The risk factors and treatment for CIS are frequently similar to those for malignant neoplasms, and, while controversial, there is growing evidence that CIS represents the earliest detectable phase of malignancy.³ Therefore, for determining compensation under EEOICPA, HHS requires that CIS be treated as a malignant neoplasm of the specified site.

Cancers identified by their secondary sites (sites to which a malignant cancer has spread), when the primary site is unknown, raise another issue for the application of IREP. This situation will most commonly arise when death certificate information is the primary source of a cancer diagnosis. It is accepted in medicine that cancer-causing agents such as ionizing radiation produce primary cancers. This means, in a case in which the primary site of cancer is unknown, the primary site must be established by inference to estimate probability of causation.

HHS establishes such assignments in these guidelines, based on an evaluation

³Kerlikowski, K, J Barclay, D Grady, EA Sickles, and V Ernster. "Comparison of risk factors for ductal carcinoma in situ and invasive breast cancer." *J. Natl. Canc. Inst.* 89:76-82, 1997.

Grippo, PJ, and EP Sandgren. "Highly invasive transitional cell carcinoma of the bladder in a simian virus 40 T-antigen transgenic mouse model." *Am. J. Pathol.* 157:805-813, 2000.

Correa P, "Morphology and natural history of cancer precursors" Chapter 4 in: *Cancer Epidemiology and Prevention*, 2nd Edition, D Schottenfeld and JF Fraumeni, Jr, eds. New York: Oxford University Press, 1996.

of the relationship between primary and secondary cancer sites using the National Center for Health Statistics (NCHS) Mortality Database for years 1995-1997. Because national cancer incidence databases (e.g., the National Cancer Institute's Surveillance, Epidemiology and End Results program) do not contain information about sites of metastasis, the NCHS database is the best available data source at this time to assign the primary site(s) most likely to have caused the spread of cancer to a known secondary site. For each secondary cancer, HHS identified the set of primary cancers producing approximately 75% of that secondary cancer among the U.S. population (males and females were considered separately). The sets are tabulated in this rule (Table 1). DOL will determine the final assignment of a primary cancer site for an individual claim on a case-by-case basis, as the site among possible primary sites which results in the highest probability of causation estimate.

Employees diagnosed with two or more primary cancers also raise a special issue for determining probability of causation. Even under the assumption that the biological mechanisms by which each cancer is caused are unrelated, uncertainty estimates about the level of radiation delivered to each cancer site will be related. While fully understanding this situation requires statistical training, the consequence has simple but important implications. Under this rule, instead of determining the probability that each cancer was caused by radiation independently, DOL will perform an additional statistical procedure following the use of IREP to determine the probability that at least one of the cancers was caused by the radiation. This approach is important to the claimant because it would determine a higher probability of causation than would be determined for either cancer individually.

G. Limitations of IREP for Energy Employees

NCI is developing IREP to serve the needs of DVA in deciding cancer compensation claims for veterans. This means IREP has to be adapted in various ways to meet the needs of DOL, because the radiation exposure experience of employees covered by EEOICPA differs substantially.

Some employees covered by EEOICPA were exposed to radon and other sources of high linear energy transfer (LET) radiation. This type of radiation exposure has unique properties affecting cancer risk, which are not addressed in

the risk models included in IREP. Specifically, the IREP risk models do not account for a possible inverse dose-rate effect for high-LET radiation exposures. This effect means at any particular dose level, especially higher dose levels, a dose of high LET radiation incurred gradually over time is more likely to cause cancer than the same total dose incurred quickly or at once. A substantial body of research supports this finding, including studies of uranium miners,⁴ patients exposed to bone-seeking radium alpha particles,⁵ and research on the cancer effects of high LET radiation in animals.⁶ Because high-LET radiation is an important type of radiation exposure among employees covered by EEOICPA, NIOSH has modified IREP to include uncertainty associated with the assumption of an inverse dose-rate effect for these exposures.

The DOE workforce has been exposed to various types of neutron energies and these exposures are frequently documented in the worker's dosimetry records. The relative biological effectiveness (RBE) of radiation exposure, a factor in cancer risk models that accounts for the differing level of cancer risk associated with different forms of radiation, varies as a function of neutron energy.⁷ This variation in RBE related to differing neutron energy is not accounted for in the current version of IREP, which contains a single neutron RBE distribution. Therefore, NIOSH has modified IREP for DOE workers to include different RBE distributions for neutrons of various energies.

The currently public draft of IREP does not incorporate a unique lung cancer model for radon exposure, which is an important exposure for some workers covered under EEOICPA. Using epidemiologic evidence on the lung carcinogenicity of radon exposures, NCI

⁴Hornung RW, Meinhardt TJ. Quantitative risk assessment of lung cancer in U.S. uranium miners. *Health Phys* 52: 417-430, 1987.

Lubin JH, Boice JD Jr, Edling C, et al. Radon-exposed underground miners and the inverse dose-rate (protraction enhancement) effects. *Health Phys* 69:494-550, 1995.

⁵Mays CW, Spiess H. Bone sarcomas in patients given radium-224. In: *Radiation Carcinogenesis: Epidemiology and Biological Significance*. Boice JD Jr, Fraumeni JF Jr (eds): New York: Raven Press, pp 241-252, 1984.

⁶Luebeck EG, Curtis SB, Cross FT, Moolgavkar SH. Two-stage model of radon-induced malignant lung tumors in rats: effects of cell killing. *Radiat. Res.* 145:163-173, 1996.

Hall EJ, Miller RC, Brenner DJ. Neoplastic transformation and the inverse dose-rate effect for neutrons. *Radiat. Res.* 128 (Suppl): S75-S80, 1991.

⁷International Commission on Radiological Protection (ICRP) 60: "1990 Recommendations of the International Commission on Radiological Protection." *Ann. ICRP* 21 (1-3): 1-201.

has incorporated a lung cancer model for radon exposures into IREP. The data source for this model is the analysis conducted by the federal Radiation Exposure Compensation Act Committee.⁸

NIOSH has changed IREP to modify an assumption for non-leukemia cancers that low-level acute radiation doses (defined in IREP as doses between 3 and 30 cSv) cause less risk, per unit of dose, than higher level acute doses. NIOSH will use an uncertainty distribution for the dose and dose rate effectiveness factor (DDREF) that more heavily weights a DDREF of one, reducing the distinction in risk effects for low-level acute doses. A recent study of the Japanese atomic bomb survivors supports this change.⁹

Additionally, some employees covered by EEOICPA were required, as a condition of employment, to undergo routine medical screening with x rays. The dose resulting from these x rays will be included in their dose reconstruction. This required NIOSH to add to IREP an RBE distribution appropriate to the low-energy form of radiation produced from some of these x rays.¹⁰

Research has found bone cancer risk substantially and significantly elevated among animals and humans exposed to certain forms of high-LET radiation.¹¹ Although Japanese A-bomb survivor risk models for bone cancer have been used for a plutonium risk assessment,¹² they are based on highly unstable risk models. Therefore, NIOSH is using in IREP the risk model recommended in the NCI-IREP documentation, which is based on all residual cancers, including bone.

Limitations of current research and development have prevented NIOSH from considering and implementing all

possible improvements to IREP at this time. In the future, NIOSH may make additional changes in IREP to address differences in radiation-related cancer risk between Japanese atomic bomb survivors and employees involved in nuclear weapons production. Some research has shown substantial differences in risk for certain cancers, such as brain cancer and multiple myeloma¹³. The radiation-related risk of these cancers is significantly elevated among employees involved in nuclear weapons production, whereas it is not among the Japanese study population. The IREP risk models for these cancers were produced using data from the Japanese study population.

Similarly, it may be possible to improve the fit of IREP risk models to employees covered by EEOICPA with respect to differences between the frequency of certain cancers in the general population in the United States versus Japan. The IREP risk models include a simplistically derived factor (risk transfer) that accounts for these differences, based on expert judgment. For some cancers, such as breast and stomach cancer, sufficient research may exist to improve this factor. In addition, where current IREP risk models could be replaced with risk models based on studies of U.S. DOE workers, or other U.S. populations, this factor could be omitted entirely. The potential future use of risk models based on studies of U.S. DOE workers may also eliminate limitations arising because data are sparse for certain cancers among the Japanese atomic bomb survivors, such as most specific types of leukemia. Using data on the Japanese cohort, the effect on risk of age at time of exposure to radiation, an important modifier of leukemia risk, cannot be estimated for specific types of leukemia, except chronic myeloid leukemia. It can only be estimated for other leukemia types by using a general leukemia model that combines data from cases of different types of leukemia.

Finally, NIOSH may make modifications in cancer risk models in IREP, as appropriate and if feasible, to account for the changing frequency among the general population (baseline rates) of certain types of cancer in the United States. Certain types of cancer (e.g., lung cancer among women, breast

cancer) have become more frequent in recent decades. Similarly, NIOSH may make modifications in cancer risk models to reflect the differing frequency of certain types of cancer among different racial and ethnic groups in the United States (e.g., multiple myeloma). The effect of these modifications, at such time as they may become available, would be to improve the accuracy of probability of causation estimates.

H. Procedures for Review and Public Comment on NIOSH-IREP

As described under Section G above, some current and potential future changes to the cancer risk models in IREP are particularly appropriate for addressing the radiation exposures and statutory requirements of claimants under EEOICPA. As a result, the version of IREP to include NIOSH modifications will be unique and distinguished as "NIOSH-IREP." This version, which DOL will use to estimate probability of causation under EEOICPA, will be reviewed by the Advisory Board on Radiation and Worker Health. NIOSH-IREP is available for public review on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html. It includes documentation of underlying risk models and calculations. The public can obtain complete information about NIOSH-IREP by contacting NIOSH at its toll-free telephone information service: 1-800-35-NIOSH (1-800-356-4674).

The public may comment on NIOSH-IREP at any time. Comments can be submitted by e-mail to OCAS@CDC.GOV, or by mailing written comments to: NIOSH-IREP Comments, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, Ohio 45226. All comments will be considered. In addition, NIOSH will forward all substantive comments to the Advisory Board on Radiation and Worker Health, which will have an ongoing role to review and advise NIOSH on possible changes to NIOSH-IREP, as described in this rule.

I. Operating Guide for NIOSH-IREP

DOL will use procedures specified in the NIOSH-IREP Operating Guide to calculate probability of causation estimates under EEOICPA. The guide provides current, step-by-step instructions for the operation of NIOSH-IREP. The procedures include entering personal, diagnostic, and exposure data; setting/confirming appropriate values for variables used in calculations; conducting the calculation; and, obtaining, evaluating, and reporting results.

⁸ Final Report of the Radiation Exposure Compensation Act Committee, submitted to the Human Radiation Interagency Working Group, July 1996 (Appendix A), 30 pp (plus Figures).

⁹ Pierce DA and Preston DL "Radiation-related cancer risks at low doses among atomic bomb survivors." *Radiat. Res.* 154:178-186, 2000.

¹⁰ ICRU Report 40: The quality factor in radiation protection. *Internat. Commission on Radiat. Units and Meas.*, 33 pp, 1986.

Hall EJ. "Linear energy transfer and relative biological effectiveness" Chapter 9 in *Radiobiology for the Radiobiologist*, 4th Edition. Philadelphia: J.B. Lippincott, 1994.

¹¹ International Agency for Research on Cancer (IARC). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 78 *Ionizing Radiation, Part 2: Some Internally Deposited Radionuclides*. Lyon, France: IARC Press, 595 pp, 2001.

¹² Grogan HA, Sinclair WK, and Voillequé PG. "Risks of fatal cancer from inhalation of 239,240plutonium by humans: a combined four-method approach with uncertainty evaluation" *Health Physics* 80:447-461, 2001.

¹³ Alexander V and DiMarco JH. "Reappraisal of brain tumor risk among U.S. nuclear workers: a 10-year review." *Occupational Medicine: State of the Art Reviews* 16(2):289-315, 2001.

Cardis E, Gilbert ES, Carpenter L, et al. "Effects of low doses and low dose rates of external ionizing radiation: cancer mortality among nuclear industry workers in three countries." *Radiat. Res.* 142:117-132, 1995.

An initial version of the NIOSH–IREP Operating Guide is available to the public online on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html. The public can obtain printed copies by contacting NIOSH at its toll-free telephone information service: 1–800–35–NIOASH (1–800–356–4674).

II. Summary of Public Comments

On October 5, 2001, HHS proposed guidelines for determining probability of causation under EEOICPA (42 CFR 81; see 66 FR 50967). HHS initially solicited public comments from October 5 to December 4, 2001. The public comment period was reopened subsequently from January 17, 2002 to January 23, 2002 for public comments, and from January 17, 2002 to February 6, 2002, for comments from the Advisory Board on Radiation and Worker Health (67 FR 2397).

HHS received comments from 12 organizations and 24 individuals. Organizations commenting included several labor unions representing DOE workers, a community based organization, an administrative office of the University of California, several DOE contractors, and several federal agencies. A summary of these comments and HHS responses is provided below. These are organized by general topical area.

A. Appropriateness of Adapting Compensation Policy Used for Atomic Veterans

One commenter requested explanation of the appropriateness of adapting existing compensation policy for atomic veterans to a compensation program for nuclear weapons workers. The comment appears to question whether this existing policy for atomic veterans is an appropriate starting point from which to develop compensation policy under EEOICPA. In the notice of proposed rulemaking, HHS had solicited public comment on whether it had appropriately adapted compensation policy for atomic veterans to meet the needs of this workforce, which has a substantially different occupational and radiation exposure experience.

Congress determined the veteran's compensation policy as a starting point for HHS. It did so by requiring the determination of probability of causation based on radiation doses and the use of the NIH Radioepidemiological Tables, and by requiring that the cancer covered in a claim be determined to be "at least as likely as not" caused by radiation doses incurred in the performance of duty, based on the upper 99 percent credibility limit. These are

defining features of compensation policy for atomic veterans.

The public should also recognize that the Radioepidemiological Tables required years to initially develop and then additional years to update (the update is not completed). Without this critical, highly sophisticated element developed for the veterans' program, it would not have been possible to establish and implement a policy for nuclear weapons workers in a timely fashion.

HHS adapted these policies for nuclear weapons workers through two prominent measures, discussed in the notice of proposed rulemaking and below. HHS included provisions to allow NIOSH to adapt the cancer risk models in the latest version of the NIH Radioepidemiological Tables to reflect the unique radiation exposure experience of nuclear weapons workers. And HHS established transparent, objective procedures for DOL to handle a variety of circumstances in which various information relevant to determining probability of causation will be unknown. The majority of comments received on this rule suggest most commenters view as appropriate the measures HHS has taken to adapt existing compensation policy to this new program.

B. Compensability

Various comments relating to the use of these guidelines were received. Specifically, HHS received comments on: awarding compensation based upon a proportional level of probability of causation; the use of the upper 99 percent confidence limit to estimate probability of causation; awarding compensation for employees who incurred radiation doses within regulated radiation safety limits; automatically qualifying employees who incurred doses in excess of the maximum allowable radiation dose under Atomic Energy Commission regulations; waiving dose reconstruction and probability of causation for employees with rare cancers; and automatically compensating employees for whom DOE is unwilling or unable to provide employment records.

The development and use of these guidelines for determining compensability and the benefit structure are statutorily mandated and therefore these comments were not adopted.

One commenter suggested prohibiting the use of probability of causation findings as proof of fault in litigation. This suggestion was not adopted because prohibiting the use of probability of causation findings for litigation purposes is not authorized by

the statute. However, because these findings will be based on NIOSH dose reconstructions, which will not always produce complete or best estimates of the actual doses received by an individual,¹⁴ HHS does not believe these findings should be used for any purpose other than the adjudication of claims under EEOICPA.

C. Need for Peer Review

Several commenters recommended that HHS obtain peer review of the cancer risk models that comprise NIOSH–IREP, and of changes to NIOSH–IREP, as it is updated based on progress in the underlying sciences. Several commenters recognized that the Advisory Board on Radiation and Worker Health is intended by HHS as one means of obtaining such peer review, but the commenters raised concerns about whether the Board would have sufficient expertise for this purpose.

HHS recognizes the importance of peer review. Consequently, as indicated above, the National Cancer Institute obtained peer review of IREP by the National Research Council. NCI and NIOSH have made modifications in IREP consistent with this peer review. NIOSH has also obtained peer-review by independent subject matter experts of changes developed by NIOSH to adapt IREP to the experience of nuclear weapons workers. These peer-reviews are posted on the NIOSH website and are also available to the public by request.

In addition, the Advisory Board on Radiation and Worker Health will be reviewing the cancer risk models in NIOSH–IREP, as indicated above and in the notice of proposed rulemaking. Contrary to the public comments noted above, HHS finds the Board has appropriate expertise for such a review, including eminent physicians and scientists from the field of health physics. Moreover, the Board maintains the option to commission additional independent scientists to participate in the Board's review. HHS also has the option to obtain additional peer reviews by the National Academy of Sciences, as recommended by some commenters.

In response to comments recommending peer review and to the recommendations of the Advisory Board on Radiation and Worker Health discussed below, HHS has added a new requirement to this rule to affirm the commitment of HHS to involve the

¹⁴ For explanation of these possible limitations of NIOSH dose reconstructions, see the discussion under "II. Summary of Public Comments; A. Purpose of the Rule" in the preamble of 42 CFR Part 82 (the HHS dose reconstruction rule).

Board in peer-review of future decisions to change NIOSH-IREP and to ensure this process is open to public participation. These provisions, which were previously contained in the preamble of the notice of proposed rulemaking, are now incorporated into the rule itself under § 81.12.

One commenter recommended HHS extend the comment period of the rule to provide the public with additional time to review NIOSH-IREP.

As indicated in the notice of proposed rulemaking and above, the public can comment on NIOSH-IREP at any time. The rule comment period applies only to provisions of the rule itself.

D. Updating NIOSH-IREP to Remain Current With Science

Commenters supported the intent of HHS to update NIOSH-IREP as scientific progress enables HHS to improve the cancer risk models. Two commenters recommended that DOL apply updates to NIOSH-IREP retrospectively to claims that were denied on the basis of a probability of causation finding that might change as a result of the update.

Under 42 CFR 81.12 NIOSH will notify the public and DOL when changes to NIOSH-IREP are completed and explain the effect of changes on probability of causation estimates. This will enable DOL and claimants with denied claims to identify denied claims potentially affected by the changes and evaluate the effect of this new information.

E. Chemical or Non-Occupational Radiation Exposures as Risk Factors

Some nuclear weapons workers were exposed to potential and known chemical carcinogens as well as radiation in the performance of duty. Several commenters urged that cancer risk models in NIOSH-IREP take into account the effects that these combined or "mixed" exposures might have on risk associated with radiation exposure.

There is no adjustment in NIOSH-IREP for chemical exposures. It is not clear that the state of science presently could support risk adjustments that account for possibly differing roles of chemical exposures. A second, probably overriding, practical concern is whether this compensation program for nuclear weapons workers, which already requires the collection and consideration of large amounts of information, could produce fair, timely decisions with the addition of a substantial new informational burden. New information would be required for each claim regarding the type, level, duration, and timing of relevant

chemical exposures, as well as the use of administrative measures and protective equipment to protect exposed workers.

Despite these limitations, NIOSH will consider taking into account the effect of mixed exposures at such time as this may become scientifically supportable and feasible. HHS has added section 81.10(b)(4) to specifically include this possibility.

Several other commenters made similar but distinct recommendations to modify the cancer risk models in NIOSH-IREP to account for cancer risks that might be independent of radiation risks, arising from occupational and community exposures to chemicals or non-occupational exposures to radiation. Some commonplace examples of such exposures might include exposures to solvents or preservatives used at work or home, radon in the home, second-hand tobacco smoke, or sun exposure. The recommendation relates to the fact that groups have different "background" risks of cancers depending on their exposure to these various carcinogens. Groups with higher than normal background risks might be shown in studies of radiation risks to have lower increases in cancer risk attributable to radiation. Likewise, groups with lower than normal background risks might be shown to have higher increases in risk attributable to radiation, depending on the form of interaction between radiation exposures and these other cancer risk factors.

It is not scientifically supportable or feasible to adjust NIOSH-IREP risk models for the multitude of occupational and community exposures. The carcinogenic risks associated with most chemical exposures, and the appropriate form of their interaction with radiation, have not been adequately quantified. Moreover, DOL generally would not have access to exposure data on the individual's exposure to chemicals or radiation in the community. As discussed above, access to data on occupational exposures to chemicals is also infeasible at this time.

F. Covered Exposures

A few commenters recommended changes in the set of exposures included by this rule to contribute to the probability of causation calculation.

Several commenters recommended against HHS including medical screening x rays administered to nuclear weapons employees as a condition of employment. Similar comments were received on the interim final HHS dose reconstruction rule (42 CFR 82) as well. Commenters argue that the benefit of

these exposures justifies their attendant risks, and therefore they should not contribute to the acceptance of a claim for compensation.

HHS will not exclude radiation exposures resulting from these occupationally required medical screening x rays. The important factor in this decision is that the exposures were incurred "in the performance of duty," as specified by EEOICPA. The employees were required to receive these x ray screenings and hence were exposed to radiation in performing this duty.

Several commenters recommended HHS include cancer risks associated with chemical exposures and in effect calculate a probability of causation related to all occupational exposures, rather than radiation exposures alone.

HHS cannot include the cancer risks associated with chemical exposures in the calculation of probability of causation. EEOICPA explicitly limits these guidelines and DOL to making determinations as to whether the cancer subject to a claim was caused by radiation doses incurred in the performance of duty (see § 7384(n)(c) of EEOICPA).

G. Covered Illnesses

HHS received several comments addressing the exclusion or inclusion of illnesses covered by these guidelines.

Several commenters noted that EEOICPA only covers cancers but should cover other or all illnesses. A second commenter recommended that probability of causation should be determined for inherited genetic effects (among offspring of covered workers).

The probability of causation guidelines cover only cancers because this is a statutory requirement of EEOICPA (see discussion of statutory requirements above). Moreover, science has not progressed sufficiently to permit probability of causation determinations for many radiogenic illnesses other than cancers; specifically not for inherited genetic effects.

Readers should note, however, that part B of EEOICPA, which provides lump sum payments of \$150,000 as well as medical benefits, provides coverage for chronic beryllium disease and silicosis (when incurred by workers exposed in connection with mining of tunnels for atomic weapons tests or experiments in Nevada or Alaska), two well documented occupational illnesses. Part B also provides for medical monitoring of covered workers with beryllium sensitivity. In addition, part D of EEOICPA provides assistance through a worker advocacy program administered by DOE to assist nuclear

weapons workers with illnesses that might have resulted from toxic occupational exposures who are seeking state workers' compensation benefits. Panels of expert physicians appointed by HHS will review the medical records in connection with each of these cases and make a determination as to whether the illness was likely to have been caused by toxic occupational exposures.

Another commenter recommended that HHS not permit probability of causation to be determined for cancers in situ—that is, cancers that have yet to spread to neighboring tissues. In other words, the comment recommends assigning a probability of causation of zero to individuals with this early stage of cancer.

HHS is retaining the procedures it proposed for estimating probability of causation for carcinomas in situ, treating them within NIOSH-IREP identically to invasive cancers. Although more research is needed, some studies have shown the risk factors for a carcinoma in situ are similar to cancer at a later stage. In addition, for any given individual, it is not possible to determine which carcinomas in situ will progress to become invasive cancers.

H. Radiation Dose Threshold for Calculating Probability of Causation

Several commenters recommended HHS establish a radiation dose threshold below which DOL would deny the claim without calculating probability of causation. One commenter proposed NIOSH-IREP be modified to take into account alternative theories of radiation effects at low cumulative doses. The commenters argue that it is unknown whether cancers can be caused at radiation doses below 10 to 20 rem. In addition, several commenters note that claims for rare cancers, for which there is likely to be a high level of uncertainty about the dose-risk relationship, would have unfair advantage over claims for more common cancers, due to the use of the 99 percent credibility limit.

The National Research Council, which reviewed IREP, noted concern about the effect of uncertainty with respect to rare cancers. NCI has responded to this concern by grouping rare cancers in more general cancer categories, for which there is a more robust research basis for quantifying risk.

HHS does not find that any further measures are necessary, particularly the application of a threshold. The issue of whether or not there is a threshold for causation of cancer by radiation is controversial. Moreover, the issue is avoided by the practical approach taken

in this rule. Doses resulting in a probability of causation finding of 50 percent or greater are determined based on current and cumulative epidemiologic findings. The NCI solution of grouping rare cancers addresses the concern about high levels of uncertainty for rare cancers.

I. Non-Radiogenic Cancers

One commenter recommended against the proposed rule's consideration of chronic lymphocytic leukemia (CLL) as non-radiogenic (§ 81.30). This provision requires DOL to assign a probability of causation of zero for a claim for CLL. The commenter asserts that it cannot be proven that this form of leukemia is non-radiogenic.

As discussed in the notice of proposed rulemaking and below, CLL is widely considered non-radiogenic by the radiation health research community and is not covered by other radiation compensation programs. Moreover, there is no risk model appropriate to CLL, nor data to support the development of such a risk model. Consequently, it is not possible to calculate probability of causation for CLL and it is both appropriate and necessary to consider CLL as non-radiogenic for the purposes of this rule.

J. Documentation of NIOSH-IREP

Several commenters recommended NIOSH fully document the risk models and calculations of NIOSH-IREP so that the basis for its calculations are fully transparent. One commenter added that in this documentation, NIOSH should explain how different sources of uncertainty are taken into account.

NIOSH agrees with the comment and, as indicated in the notice of proposed rulemaking, is committed to maintaining and providing full documentation on NIOSH-IREP. To a substantial extent, this documentation is directly available to the public while using or examining NIOSH-IREP. The software, which is accessible for public use from the NIOSH homepage on the internet, has a feature that allows the user to call-up the formulae and information underlying each calculation. The user can also call-up graphic illustrations (pie charts) that quantitatively depict the role of different sources of uncertainty in contributing to the overall uncertainty calculated for use in a probability of causation estimate.¹⁵ As noted above,

¹⁵ The uncertainty distributions for the various sources of uncertainty involved in a probability of causation estimate are combined in NIOSH-IREP using a Monte Carlo simulation program that draws values randomly, repeatedly from each distribution

the documentation is also available in print form by contacting NIOSH.

K. Current Technical Elements of NIOSH-IREP

HHS received a variety of comments on specific aspects of the cancer risk models in NIOSH-IREP. While these risk models are not themselves subject to this rulemaking, HHS is committed to receiving and responding to public comments on NIOSH-IREP, and making improvements as appropriate. As indicated in § 81.12 of this rule, recommendations for modifications to NIOSH-IREP will be addressed routinely through a public process involving the Advisory Board on Radiation and Worker Health. Hence, HHS addresses current comments submitted during the rulemaking comment period below, but notes that some of these issues may receive further consideration subsequent to this rulemaking, once HHS has obtained advice on these issues by the Advisory Board. The Advisory Board has received these public comments for review.

One commenter generically recommended against making use in NIOSH-IREP of cancer risk models developed for determining probability of causation for atomic veterans. As discussed above and in the notice of proposed rulemaking, most of the risk models in IREP were developed based on the exposure and disease experience of Japanese survivors of the atomic bomb detonations in World War II. The commenter finds the differences between the exposure conditions of these survivors and those of nuclear weapons employees too great to support probability of causation determinations for the latter.

HHS recognizes the substantial differences between the radiation exposure experiences of these two populations and discussed these differences above and in the notice of proposed rulemaking. To address these differences, NIOSH has adapted the available risk models to the extent feasible and supportable using current science. The difference in exposure characteristics is also part of the rationale for the provisions of this rule supporting updates of NIOSH-IREP, as scientific progress allows additional improvements. One of the specified goals of such updates is to use, as this becomes feasible, risk findings derived from occupational health studies of nuclear weapons workers.

Nonetheless, NIOSH maintains that the current scientific basis applied in

to derive a single, representative uncertainty distribution.

NIOSH-IREP is the best available at this time and that its use is both reasonable and fair. As discussed throughout this rule, NIOSH has taken into account, whenever feasible, recognized limitations in the current state of relevant sciences.

Several commenters recommended changes in the way the lung cancer risk model adjusts risk according to the individual's smoking history. The risk model produces a higher probability of causation that lung cancer was caused by radiation for a non-smoker than a smoker, at a given level and pattern of radiation exposure.

One commenter indicated that the probability of causation estimate for a heavy smoker should be much lower than currently estimated by the risk model. The other commenters recommended the opposite, that NIOSH should eliminate adjustment for smoking history. They assert research indicates that smoking may have a multiplicative effect on lung cancer risk, when combined with radiation exposure. If this research were proven correct, then smoking history would not affect the contribution of radiation to cancer risk, and could indeed be omitted from consideration.

The adjustment for smoking history in NIOSH-IREP has been adopted from the approach developed by NCI, and fully takes into account the cumulative body of research evaluating the interaction between smoking and radiation risks, as well as leading scientific views on this research. The NCI review of relevant literature, and a scientific consensus panel opinion (UNSCEAR 2000¹⁶), conclude that the best-supported risk models to evaluate the form of interaction between smoking and radiation are based on meta-analyses of radon-exposed workers. Combined analyses of these studies suggest that the most appropriate form of interaction is sub-multiplicative (i.e., the excess relative risk from radiation exposure among smokers is less than the excess relative risk among non-smokers), but greater than additive (Lubin and Steindorf 1995). NCI used this scientific basis to develop an uncertainty distribution for the form of interaction between smoking and radiation in the lung cancer risk models that is centered on a sub-multiplicative model (i.e., a model which assumes the excess

relative risk of cancer per unit of radiation dose is lower for individuals who smoke more), but includes the possibility of either a multiplicative model (i.e., that excess relative risk per unit of radiation dose is the same for various levels of smoking, including non-smokers) or a super-multiplicative model (i.e., that excess relative risk per unit dose is higher for individuals who smoke more). As with all assumptions, this uncertainty distribution is subject to modification in future revisions of NIOSH-IREP, pending the availability of new scientific information.

Several commenters recommended against use of a factor that reduces cancer risk for workers who were exposed to radiation at older ages. In support of this recommendation, they contend atomic bomb survivor and occupational studies do not find an inverse relationship for adults between age at time of radiation exposure and cancer risk.

NIOSH is using in NIOSH-IREP the NCI approach to adjusting radiation risk estimates for different exposure ages. This approach is based on new epidemiological analyses of atomic bomb survivors who were of working age when exposed during the blast, and uses an approach recommended by an international expert committee (Pierce et al. 1993, UNSCEAR 2000¹⁷). It addresses all solid cancers except skin and thyroid. Thus, for most cancers NIOSH-IREP relies on direct evidence from the A-bomb survivors exposed as adults rather than as children. NCI did not incorporate any age at exposure effect for the following cancers: acute myeloid leukemia, chronic myeloid leukemia, lung cancer (non-radon exposures), and female genital cancers other than ovary. The NCI models do incorporate a trend of decreasing risk per unit dose with increasing age at exposure for the following cancer sites: acute lymphocytic leukemia, all leukemia other than chronic lymphocytic, basal cell carcinoma, and cancers of thyroid. For radon exposures and lung cancer, there is no direct adjustment for exposure age: risks are dependent on time since last exposure and on age at diagnosis. The effect of this adjustment is that, at a constant "time since last exposure", the risk decreases for increasing age at last exposure; however, for constant "age at

diagnosis", the risk increases for increasing age at last exposure. For all other cancers, the NCI models incorporate a trend of decreasing risk per unit dose for exposure ages between 15 and 30, and assume constancy (no effect of age) thereafter.

There is substantial evidence from several key studies in addition to those of the A-bomb cohort that suggests radiation risk for many cancers decreases with increasing age at exposure. These include studies of breast cancer among x-ray tuberculosis patients (Boice et al. 1991¹⁸), of thyroid cancer among medically- and occupationally-exposed populations (summarized in UNSCEAR 2000a3), and of skin cancer (UNSCEAR 2000b3). While some studies of DOE workers suggest no effect or find increased relative risk estimates for certain cancers from exposure to radiation at older ages, this information is insufficient to support the selection of appropriate cancers and an appropriate method for quantitatively incorporating this information into risk adjustments in NIOSH-IREP. As indicated in the rule, HHS will re-evaluate this issue in future revisions of NIOSH-IREP, as warranted by advances in scientific information.

Several commenters recommended adding a risk adjustment factor to NIOSH-IREP to account for a possible "healthy survivor effect" presently unaccounted for in the research on Japanese atomic bomb survivors. The theory underlying this comment is that atomic bomb survivors may be healthier than the general public and less likely to incur cancer. Therefore, according to this theory, it would be mistaken to equate the level of increased cancer risk from radiation among this robustly healthy population to the level of increased cancer risk among the U.S. population, with its normal distribution of health. If this were proven correct, the risk models in NIOSH-IREP should

¹⁵ Lubin JH, Boice JD Jr, Edling C, et al. 1995. Lung cancer risk in radon-exposed miners and estimation of risk from indoor exposure. *J. Natl. Canc. Inst.* 87:817-827.

¹⁸ Boice JD Jr, Engholm G, Kleinerman RA, et al. 1991. Frequent chest x-ray fluoroscopy and breast cancer incidence among tuberculosis patients in Massachusetts. *Radiat. Res.* 125:214-222.

United National Scientific Committee on the Effects of Atomic Radiation. 2000a. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 338-343.

United National Scientific Committee on the Effects of Atomic Radiation. 2000b. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 402.

Richardson DB, Wing S, Hoffmann W. 2001. Cancer risk from low-level ionizing radiation: the role of age at exposure. *Occupat. Med.: State of the Art Reviews* 16:191-218.

¹⁶ United National Scientific Committee on the Effects of Atomic Radiation. 2000. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 201-203.

Lubin JH and Steindorf K. 1995. Cigarette use and the estimation of lung cancer attributable to radon in the United States. *Radiat. Res.* 141:79-85.

¹⁷ Pierce DA, Preston DL. 1993. Joint analysis of site-specific cancer risks for the A-bomb survivors. *Radiat. Res.* 137:134-142.

United National Scientific Committee on the Effects of Atomic Radiation. 2000. Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, Volume II: Effects; p. 208.

be adjusted to increase the level of cancer risk caused by a unit of radiation dose, since the U.S. population would presumably be more susceptible than the Japanese survivor population to the cancer-causing effects of radiation.

The possible existence of a healthy survivor effect has been theorized by some researchers (Stewart and Kneale 1990¹⁹), and has been determined by others to be of small magnitude or non-existent (Little and Charles 1990, NCRP 1997). The NCI determined that insufficient information on the possible effect of this bias is available for use the IREP program. NIOSH, in consultation with the Advisory Board on Radiation and Worker Health, will consider whether to add an adjustment factor to future versions of NIOSH-IREP to account for a possible healthy survivor effect, if supported by new scientific information. HHS notes such a finding would be equally relevant for claimants under EEOICPA and under the Atomic Veterans Compensation Program, and thus should be decided by scientific consensus between these two programs whose relevant policies are both determined by HHS.

Several commenters recommended changing the factor in NIOSH-IREP that reduces cancer risk for workers who were exposed to low linear energy transfer (LET)²⁰ radiation at low dose rates (workers who received many small doses of radiation, versus fewer large doses). They cite reports by the Nuclear Regulatory Commission and the International Agency for Research on Cancer as finding no relationship between the rate at which low LET radiation doses are incurred and the risk of cancer.

HHS agrees that this is an area of substantial uncertainty. Many studies suggest that risks are reduced for particular cancers when doses are fractionated or received at low dose-rate, while other studies suggest no effect of dose-rate or dose fractionation on radiation risk.

NIOSH-IREP accounts for this uncertainty. For chronic exposures, NIOSH-IREP adopts the approach used in the final revision of the NCI-IREP program, which more heavily weights a probability that there is no attenuation

¹⁹ Stewart AM, and Kneale GW. 1990. A-bomb radiation and evidence of late effects other than cancer. *Health Phys.* 58:729-735.

Little MP, and Charles MW. 1990. Bomb survivor selection and consequences for estimates of population cancer risks. *Health Phys.* 59:765-775.

National Council on Radiation Protection and Measurements (NCRP). 1997. Uncertainties in fatal cancer risk estimates used in radiation protection. NCRP report 126. 112 pp.

²⁰ See § 81.4 in rule for a definition of LET.

of risk at low dose rates of exposure. This uncertainty distribution also includes a small probability that dose-rate reduction or dose fractionation enhances, rather than reduces, radiation risk.

One commenter recommends that NIOSH-IREP account for a possible inverse relationship between exposure to low doses of high LET radiation and cancer risk. The commenter cites recent research suggesting that individuals who incurred high LET radiation doses at lower rates had higher risk of cancer, compared with individuals who incurred the same cumulative doses at higher rates.

As indicated in the notice of proposed rulemaking and above, NIOSH has incorporated the possibility of this inverse relationship into NIOSH-IREP for both neutron and low-LET exposures. Based on reviews of subject matter experts, the revised version of NIOSH-IREP includes a small probability of an inverse dose-rate effect for alpha radiation exposures as well.

One commenter noted that a linear-quadratic model of the dose-risk relationship is not equivalent to use of a dose-rate correction factor to reduce the per-unit contribution of low doses to cumulative risk of cancer. The commenter recommended either using a dose-rate correction factor to keep these model elements separate, or alternatively to explain why it is appropriate to use the linear-quadratic model to mimic a reduced cancer risk effect at low dose rates.

This comment is contradicted by several research groups, including the NCI-IREP working group, the NIH Ad Hoc Working Group which initially developed the Radioepidemiological Tables (NIH 1985²¹), and the Committee on Biological Effects of Ionizing Radiation (BEIR)V. The BEIR V committee explicitly states that "[Dose rate] reductions should be applied only to the non-leukemia risks, as the leukemia risks already contain an implicit DREF [dose rate effectiveness factor] owing to the use of the linear-quadratic model"²². The theoretical basis for this equivalence is the observation that the use of a linear-quadratic dose assumption applies a reduction in risk that is equivalent to using a dose-and-dose-rate reduction

²¹ National Institutes of Health (NIH). 1985. Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables. US DHHS. NIH Publication No. 85-2748, p. 88.

²² National Research Council. 1990. Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V. National Academy Press, Washington, DC. 421 pp., p.174.

factor of about two, which has been commonly recommended by advisory groups for modeling leukemia risk.

One commenter recommended NIOSH change the dose and dose rate effectiveness factor (DDREF) for leukemia (for low LET radiation exposure) to three. This would reduce by two-thirds the probability of causation estimates for workers with leukemia who accrued their cumulative radiation doses slowly. The commenter cites two studies to support this recommendation.

NIOSH-IREP uses the models developed by the NCI Working Group for leukemia risk from low-LET exposure. As discussed previously, rather than incorporating a DDREF of greater than one for leukemia risk models, the dose-response function for leukemia is of the linear-quadratic form. This corresponds approximately to a DDREF of two for leukemia risk at low compared to high doses and dose rates. This approach has been recommended by several expert committees, referenced above.^{6,7} While findings from individual epidemiological studies may vary from this approach, these individual study findings are subject to the limitations of the studies. For this reason, risk modeling requires consideration of the totality of scientific evidence regarding the effects of dose protraction. Consistent with the extensive expert analyses cited above, NIOSH-IREP uses a linear-quadratic model with uncertainty in the model parameters, which best captures the uncertainties associated with the effects at low doses and dose rates.

One commenter recommends NIOSH obtain peer review for the radiation weighting factors used in NIOSH-IREP. These weighting factors take into account the differing biological effect potency of different types of radiation in inducing cancer. The commenter states that a factor of 40 used for alpha radiation in NIOSH-IREP, that this is "too conservative" (i.e., results in probability of causation estimates that would be higher than scientifically justified), and notes that the International Commission on Radiological Protection (ICRP) intends to lower its recommended weight for alpha radiation from 20 to 10.

The commenter misunderstands how information on the biological effectiveness of radiation types is used in NIOSH-IREP. The ICRP and other leading expert groups recommend weighting factors in the form of point estimates to summarize the differing biological effectiveness of various types of radiation for use by radiation protection programs. These programs

require a point estimate to calculate appropriate safety criteria that can be applied to protect populations. On the other hand, the task involving NIOSH-IREP is to calculate probability of causation for individual claims, taking into account sources of scientific uncertainty. There is substantial uncertainty of science in describing the biological effectiveness of various types of radiation, and in part due to this uncertainty, there are differences in the review findings of ICRP, the International Commission on Radiation Units and Measurements, and the National Council on Radiation Protection and Measurements. In addition, some radiation exposures are incompletely addressed by the reviews by these expert groups.

To evaluate scientific uncertainty, NIOSH analyzed the reviews of biological effectiveness of radiation by each of the expert committees cited above and, where these reviews were incomplete, other expert reviews and primary research as well. Based on this analysis, NIOSH established the central tendency of "relative biological effectiveness" for each type of radiation and assigned a probability distribution to describe the scientific uncertainty about the central tendency estimate. To calculate probability of causation, NIOSH-IREP will apply these resulting uncertainty distributions derived by NIOSH, instead of point estimate weighting factors, to account for the differing biological effectiveness of various radiation types.

The NIOSH analysis of relative biological effectiveness described here has been summarized in a scientific paper, peer-reviewed by subject matter experts, and revised accordingly. It is available to the public, along with the peer-review comments, from the NIOSH homepage on the internet or by direct request to NIOSH (addresses provided above)²³.

One commenter questions how the lung cancer model for radon in NIOSH-IREP compares with the recommendations of the Committee on Health Risks of Exposure to Radon (BEIR VI)²⁴.

As discussed in the notice of proposed rulemaking and above, the lung cancer model for radon in NIOSH-

IREP was developed based on an analysis of risk by the Radiation Exposure Compensation Act (RECA) Committee²⁵, as recommended by the National Research Council review of the NCI IREP software. The RECA committee recommended scientific methods for adapting the radon and lung cancer risk models derived from uranium miner research to compensation decisions. These research findings were an important component of the BEIR VI analyses as well.

L. HHS Dose Reconstruction Program (42 CFR 82)

HHS received several comments addressed to this rule that relate to HHS dose reconstructions under EEOICPA. In some cases, the comments were directed to this rule because dose reconstruction results serve as inputs to calculate probability of causation. The HHS rule establishing methods for dose reconstruction, 42 CFR Part 82, is being published simultaneously in this issue of the **Federal Register**.

Several commenters recommended that these guidelines prescribe the selection of uncertainty distributions associated with radiation dose information supplied by the NIOSH dose reconstruction.

As discussed in the dose reconstruction rule, uncertainty distributions associated with the dose information will indeed be defined by NIOSH in its individual dose reconstruction final reports provided to DOL, the claimant, and DOE. This information, also included in the electronic dose files provided to DOL by NIOSH, will be imported into NIOSH-IREP by DOL when it calculates probability of causation.

These uncertainty distributions associated with dose information cannot be generically prescribed by these guidelines. This information will vary substantially depending on radiation exposure circumstances and informational sources associated with each claim. Therefore, NIOSH will be defining the use of appropriate uncertainty distributions on a claim-by-claim basis, based on technical procedures established by NIOSH to implement the HHS dose reconstruction rule.

One commenter recommended NIOSH use a default assumption that characterizes radiation doses as chronic rather than acute. The commenter indicated that the radiation doses

incurred by many workers are more accurately characterized as chronic using traditional definitions.

NIOSH will characterize radiation doses as chronic when it has information to substantiate this designation. However, in most cases NIOSH is unlikely to have sufficient information to make this distinction. For these cases, NIOSH will continue to characterize doses as acute as the default assumption, since this gives claimants the benefit of the doubt. As discussed above, this rule, consistent with the requirement of EEOICPA to calculate probability of causation at the upper 99 percent credibility limit, gives claimants the benefit of the doubt with respect to uncertainty. The use of chronic as a default assumption would reduce the level of probability of causation calculated for some claims.

One commenter recommended NIOSH-IREP include as an input radiation doses from nuclides (types of radiation) associated with particle accelerators.

The radiation weighting factors included in NIOSH-IREP cover the vast majority of exposures that have occurred or will occur in the claimant population. Exposures to the most unusual radiation exposure types, such as protons and other accelerator produced particles, will be addressed on an individual basis, as specified by NIOSH. It would not be useful to construct a priori probability distributions for these radiation types without knowledge of the range of energies likely to be involved in an actual exposure. Probability distributions developed for these unusual radiation types will be incorporated into the probability of causation calculation for affected claimants by DOL through a user-definable feature of NIOSH-IREP. NIOSH will define the probability distribution to be applied by DOL and summarize its technical basis in the dose reconstruction report.

One commenter questioned how NIOSH would know the energies of neutron doses, since this information will not always be available from DOE or AWE records.

As discussed in the interim final and final dose reconstruction rules, NIOSH will assign the energies for claims in which this specific information is unknown. NIOSH will give the benefit of the doubt to the claimant in making such assignments, such that the energy selected is consistent with available information and represents the case most favorable to the claimant for calculating probability of causation.

²³ The paper was originally titled: "Proposed Radiation Weighting Factors for Use in Calculating Probability of Causation for Cancers" and is now published with revisions and more extensive explanation under the title: "Relative Biological Effectiveness Factors (RBE) for Use in Calculating Probability of Causation of Radiogenic Cancers."

²⁴ National Research Council. 1999. Health Effects of Exposure to Radon: BEIR VI. National Academy Press, Washington, DC. 500 pp.

²⁵ Final Report of the Radiation Exposure Compensation Act Committee, submitted to the Human Radiation Interagency Working Group, July 1996 (Appendix A), 30 pp (plus Figures).

One commenter recommended that NIOSH combine the internal and external dose reconstruction data into single annual dose values.

It is unclear how this suggested change would be useful. Moreover, it would rarely be feasible. It would be feasible only when radiation doses in a given year are limited to a single type of radiation and the uncertainty distributions for the external and internal doses are identical.

Several commenters questioned why HHS added a parameter to the definition of "covered employee," under § 81.4 of the proposed rule, that is not specified in EEOICPA. HHS specified more narrowly than EEOICPA that a covered employee, for the purposes of the HHS rules, is a DOE or AWE employee for whom DOL has requested HHS perform a dose reconstruction.

This distinction results practically from the separate responsibilities of DOL and HHS in implementing EEOICPA. DOL is solely responsible for initially reviewing each claim, evaluating whether the claim represents a covered employee with a covered illness, and determining whether or not the claim requires a dose reconstruction. The only claims DOL will forward to HHS for dose reconstructions are those involving a covered employee with a cancer not covered by provisions of the Special Exposure Cohort. Hence, HHS retains its proposed definition in this rule to be clear that NIOSH will only conduct dose reconstructions under EEOICPA for the subset of claims submitted by DOL to HHS for dose reconstructions. This is intended to avoid the possible confusion and delay that would arise if claimants or the public were to directly submit to NIOSH requests for dose reconstructions.

M. Special Exposure Cohort

HHS received several comments that provide recommendations, criteria, or concerns related to adding members to the Special Exposure Cohort established under EEOICPA. These comments fall outside the scope of this rule and address related but separate procedures to be established by HHS.

As discussed above, HHS is proposing procedures by which it will consider petitions by classes of employees at DOE or AWE facilities to be added to the cohort, with the advice of the Advisory Board on Radiation and Worker Health. These procedures will be published soon in the **Federal Register**. The proposed HHS procedures and their accompanying explanation address the comments received and directly solicit additional public comments, which HHS will fully

consider in establishing final procedures.

N. DOL Responsibilities Under EEOICPA

HHS received several comments that relate to DOL responsibilities under EEOICPA and thus fall outside the scope of this rule.

One commenter recommended that claimants be provided with full documentation of the basis for the probability of causation estimate determined for their claim by DOL.

DOL will provide the claimant with a recommended decision which will explain the decision based upon the probability of causation. In addition, NIOSH will provide the claimant with complete documentation on the dose reconstruction conducted for the claim, which, together with the DOL report, provides the claimant with a complete set of the claim-related data and information used to calculate probability of causation.

The claimant would not, however, automatically receive documentation of the formulae and underlying research basis for the cancer risk models applied to the claim in NIOSH-IREP. This information is highly technical and complex and is unlikely to be of value to most claimants. Claimants who desire this information, however, can obtain it either from NIOSH-IREP, from the NIOSH homepage, or by contacting NIOSH directly (see contact information above). Some details of IREP documentation are only available at this time from NCI but will be incorporated into NIOSH informational resources as soon as possible.

One commenter recommended that claimants be permitted to submit affidavits in lieu of medical records when necessary.

DOL determines what types of information can constitute medical evidence of a diagnosis of cancer (see 20 CFR 30.211.). More details can be obtained by contacting DOL.

One commenter recommended that staff working for contractor support services offsite from the DOE facility should be treated as covered employees under EEOICPA. The comment identifies workers providing offsite laundry services as an example of such support staff. As discussed above, DOL is responsible for determining whether an individual is a covered employee within the scope of coverage defined by Congress in EEOICPA. Individuals who are concerned that certain employee groups involved in nuclear weapons production or related activities might be excluded from coverage under EEOICPA

should consult DOL, which makes these determinations.

III. Review and Recommendations of the Advisory Board on Radiation and Worker Health

As discussed above, the Advisory Board on Radiation and Worker Health is required by Section 7384(n)(c) of EEOICPA to conduct a technical review of these HHS guidelines. The Board reviewed the guidelines during public meetings on January 22–23 and February 5, 2002. In preparation for the meeting, the Board members individually reviewed the notice of proposed rulemaking as well as the HHS interim final rule providing the methods of dose reconstruction (42 CFR 82) that govern the estimation of radiation doses to be used under these guidelines. The members also reviewed public comments on these rules and written comments by subject matter experts who evaluated technical elements of NIOSH-IREP. In addition, NIOSH staff members gave formal presentations on the HHS rules, implementation procedures, and related issues during the Board meetings. The transcripts and minutes of these meetings are included in the NIOSH docket for this rule and are available to the public.

All of the Board members participated in the technical review of these guidelines and they unanimously concurred in establishing the Board findings and recommendations. The Board organized its findings and recommendations to correspond with the three general questions for public comment HHS identified in the notice for proposed rulemaking. The findings and recommendations are provided below, together with responses by HHS to the recommendations:

Board Comment #1: The Board agrees that the NIOSH guidelines and procedures for probability of causation determinations have been developed using the best and most current scientific information relating radiation exposures to cancer risks. The use of current recommendations from independent expert bodies lends strength to the approach proposed by NIOSH. The NIOSH approach also implements the spirit of concern for nuclear workers that was inherent in the legislation underlying this compensation program. In this context, the NIOSH guidelines and procedures provide an appropriate application of existing science to the compensation process.

HHS Response: No response is necessary, but it may be helpful to readers to explain the Board's reference to the "spirit of concern." HHS has

implemented the "spirit of concern" to which the Board refers by consistently and reasonably giving the benefit of the doubt to nuclear weapons workers, whenever feasible, with respect to policy decisions and technical procedures involving factual or scientific unknowns and uncertainty.

Board Comment #2: "The Board has also noted the differences between the approach being used in this compensation program and that of the Atomic Veterans Act. There are significant differences in the categories of compensation covered by the two acts. In some cases, the Atomic Veterans Act required primarily that the claimants were present in a specific area, had one of the specified cancers, and were therefore compensated. This proposed rule is an effort to address much more complicated situations and to face the reality that simple exposure to radiation does not automatically presume the development of disease. The Board recognizes the excellent efforts of NIOSH staff and their subject matter experts in bringing the best known current science to an appropriate method for translating experience gained in the veterans exposure calculations to this civilian nuclear worker proposal."

HHS Response: No response necessary.

Board Comment #3: "The Board also agrees that the proposed NIOSH procedures appropriately allow for the incorporation of new scientific information into the compensation procedures as this new information becomes available. However, given the limited time that the Board has had to review the details of the probability of causation procedures and the potential impact of changes in the NIOSH IREP on compensation decisions, the Board recommends that the regulations be amended to formalize the role of the Board in reviewing any substantial changes in these procedures (i.e., the NIOSH IREP). This change should include publication of the planned changes in the **Federal Register**, an appropriate opportunity for public comment, and then review by this Board before finalization. Although these actions are included in the Preamble "Background," (Section III, Subsection I, Paragraph 3) of 42 CFR Part 81, making them part of the rule itself would formalize the updating process, significantly strengthening assurance that review of revisions by the Board will occur."

HHS Response: HHS accepts this recommendation by the Board. Accordingly, as discussed above in response to public comments on peer-

review, HHS has moved provisions for peer-review involving the Board from the preamble of the notice of proposed rulemaking into the body of the rule itself. These provisions can be found at 42 CFR 81.12.

IV. Summary of the Rule

Congress, in enacting EEOICPA, created a new Energy Employees Occupational Illness Compensation Program to ensure an efficient, uniform, and adequate compensation system for certain employees. Through Executive Order 13179, the President assigned primary responsibility for administering the program to DOL. The President assigned various technical responsibilities for policymaking and assistance to HHS. Included among these is promulgation of this rule to establish guidelines DOL will apply to adjudicate cancer claims for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. Sections 81.20–81.25 and 81.30 provide guidelines for determining the probability of causation with respect to all known cancers.

In the summary below, HHS indicates all the changes in provisions of this rule made since the notice of proposed rulemaking. These occur under §§ 81.10(b) and 81.12.

Introduction

Sections 81.0 and 81.1 briefly describe how this rule relates to DOL authorities under EEOICPA and the assignment of authority for this rule to HHS. Section 81.2 summarizes the specific provisions of EEOICPA directing HHS in the development of this rule.

Definitions

This section of the regulation defines the principal terms used in this part. It includes terms specifically defined in EEOICPA that, for the convenience of the reader of this part, are repeated in this section. The citation to EEOICPA has been revised to reflect the codification of the Act in the United States Code.

Data Required To Estimate Probability of Causation

Sections 81.5 and 81.6 identify the sources and types of personal, medical, and radiation dose information that would be required by this regulation. Claimants will provide personal and medical information to DOL under DOL regulations 20 CFR Part 30. NIOSH will provide radiation dose information pursuant to 20 CFR Part 30. NIOSH will

develop the dose information required pursuant to the HHS regulation under 42 CFR Part 82, which was promulgated on October 5, 2001 as an interim final rule and is being promulgated as a final rule simultaneously with this final rule in this issue of the **Federal Register**. The application of this personal, medical, and radiation dose information to estimate probability of causation is described generally under §§ 81.22–81.25.

Requirements for Risk Models Used To Estimate Probability of Causation

Sections 81.10 and 81.11 describe the use of cancer risk models and uncertainty analysis underlying the NIH RadioEpidemiological Tables in their current, updated form, which is a software program named the "Interactive RadioEpidemiological Program" (IREP). NIOSH–IREP, the version of IREP to be used by DOL to implement this rule, is discussed extensively in the notice of proposed rulemaking and above. These sections also propose criteria by which the risk models in NIOSH–IREP may be changed to ensure that probability of causation estimates calculated for EEOICPA claimants represent the unique exposure and disease experiences of employees covered by EEOICPA. In response to public comments, a criterion discussed above has been added to § 81.10. This criterion authorizes NIOSH to modify NIOSH–IREP to account for new understanding of the potential interaction between cancer risks associated with occupational exposures to chemical carcinogens and radiation-related cancer effects (see § 81.10(b)(4)).

Section 81.12 was added in response to comments and describes the procedure to update NIOSH–IREP. NIOSH may periodically revise NIOSH–IREP to add, modify, or replace cancer risk models, improve the modeling of uncertainty, and improve the functionality and user-interface of NIOSH–IREP. Principal sources of potential improvements in cancer risk models include new epidemiologic research on DOE employee populations and periodic updates from scientific committees evaluating such research (e.g., the Committee on Biological Effects of Ionizing Radiation).

Improvements may also be recommended by the Advisory Board on Radiation and Worker Health, scientific reviews relevant to or addressing this program, public comment, or by DOL, which is the principal user and hence may require functional changes and improvements in the user-interface.

Substantive changes to NIOSH–IREP (changes that would substantially affect

estimates of probability of causation calculated using NIOSH-IREP, including the addition of new cancer risk models) will be submitted to the Advisory Board on Radiation and Worker Health for review. Proposed changes provided to the Advisory Board for review will also be made available to the public, which will have opportunity to comment and have its comments considered by NIOSH and the Board.

To facilitate public participation in updating NIOSH-IREP, NIOSH will periodically publish a notice in the **Federal Register** informing the public of proposed substantive changes to NIOSH-IREP currently under development, the status of the proposed changes, and the expected completion dates. NIOSH will also publish a notice in the **Federal Register** notifying DOL and the public of the completion of substantive changes to NIOSH-IREP. In the notice, NIOSH will address relevant public comments and recommendations from the Advisory Board received by NIOSH.

Guidelines To Estimate Probability of Causation

Sections 81.20 and 81.21 require DOL to use NIOSH-IREP to estimate probability of causation for cancers for which probability of causation estimates can be calculated using available cancer risk models. Section 81.21 also requires DOL to assume carcinoma in situ (ICD-9²⁶ codes 230-234), neoplasms of uncertain behavior (ICD-9 codes 235-238), and neoplasms of unspecified nature (ICD-9 code 239) are malignant, for purposes of estimating probability of causation.

Sections 81.22-81.25 provide general guidelines for the use of NIOSH-IREP and specific applications to accommodate special circumstances anticipated. The special circumstances include claims in which: (1) The primary site of a metastasized cancer is unknown; (2) the subtype of leukemia presented lacks a single, optimal risk model in NIOSH-IREP; and (3) two or more primary cancers are presented, requiring further statistical adjustment of probability of causation estimates calculated using NIOSH-IREP.

The procedure concerning subtypes of leukemia (2) is needed because of a

limitation of the data on Japanese atomic bomb survivors, as discussed above and in the notice of proposed rulemaking. The general leukemia model in IREP allows for adjustment for age at exposure, which is an important modifier of leukemia risk. The data are too sparse, however, to allow for such an adjustment with respect to specific types of leukemia, with the exception of chronic myeloid leukemia. Since it is not possible to determine which factor, age at exposure or leukemia subtype, is more important to determining probability of causation for most specific types of leukemia, the guidelines require use of both the general model and the specific model. The guidelines require DOL to use the findings of whichever model produces the higher probability of causation estimate.

Section 81.30 specifies one cancer to be considered non-radiogenic for the purposes of this rule: chronic lymphocytic leukemia (ICD-9 Code: 204.1). DOL would assign a value of zero to the probability of causation for a claim based on this type of leukemia. There is general consensus among the scientific and medical communities that treatment of this leukemia as non-radiogenic is appropriate, and such treatment is consistent with other radiation illness compensation programs.

V. Significant Regulatory Action (Executive Order 12866)

This rule is a "significant regulatory action," within the meaning of Executive Order 12866, because it raises novel or legal policy issues arising out of the legal mandate established under EEOICPA. The rule is designed to establish objective guidelines, grounded in current science, to support DOL in the adjudication of applicable claims seeking compensation for cancer under EEOICPA. The guidelines will be applied by DOL to calculate a reasonable, scientifically supported determination of the probability that a cancer for which a claimant is seeking compensation was as likely as not caused by radiation doses incurred in the performance of duty by the covered employee. The financial cost to the federal government of applying these guidelines is covered under administrative expenses estimated by DOL under its rule (see FR 28948, May 25, 2001).

The rule carefully explains the manner in which the regulatory action is consistent with the mandate for this action under § 3623(c) of EEOICPA and implements the detailed requirements concerning this action under this

section of EEOICPA. The rule does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in section 3(f)(1) of the Executive Order 12866. This rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR Parts 1 and 30. DOL has determined that its rule fulfills the requirements of Executive Order 12866 and provides estimates of the aggregate cost of benefits and administrative expenses of implementing EEOICPA under its rule (see FR 28948, May 25, 2001).

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, not-for-profit organizations, and small non-governmental units, and small not-for-profit organizations. HHS certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. This rule affects only DOL, HHS, and some individuals filing compensation claims under EEOICPA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on and to obtain OMB approval of any regulation that requires ten or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements. It provides guidelines only to the U.S. Department of Labor (DOL) for adjudicating compensation claims and thus requires no reporting or record keeping. Information required by DOL to apply these guidelines is being provided by HHS and by individual claimants to DOL under DOL regulations 20 CFR 30. Thus, HHS has determined that the PRA does not apply to this rule.

VIII. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report to Congress promulgation of this rule. The report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in

²⁶ICD-9 is a version of the standard system of classifying diseases that will be used by IREP. The most recent version of this system, ICD-10, will not be used because the cancer risk models have been constructed using ICD-9.

See: The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91-1260, U.S. Government Printing Office, Washington, D.C.

an annual effect on the economy of \$100 million or more. However, this rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR Parts 1 and 30. DOL has determined that its rule is a "major rule" because it will likely result in an annual effect on the economy of \$100 million or more.

IX. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector, "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or tribal governments in the aggregate, or by the private sector.

X. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the Federal court system. Probability of causation may be an element in reviews of DOL adverse decisions in the United States District Courts pursuant to the Administrative Procedure Act. However, DOL has attempted to minimize that burden by providing claimants an opportunity to seek administrative review of adverse decisions, including those involving probability of causation. HHS has provided a clear legal standard for DOL to apply regarding probability of causation. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

XI. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

XII. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the

environmental health and safety effects of this rule on children. HHS has determined that the rule would have no effect on children.

XIII. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect on them.

XIV. Effective Date

The Secretary has determined, pursuant to 5 U.S.C. 553(d)(3), that there is good cause for this rule to be effective immediately to avoid undue hardship on and facilitate payment to eligible claimants.

List of Subjects in 42 CFR Part 81

Cancer, Government Employees, Probability of Causation, Radiation Protection, Radioactive Materials, Workers' Compensation.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services is amending 42 CFR to add Part 81 to read as follows:

PART 81—GUIDELINES FOR DETERMINING PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Sec.

81.0 Background.

81.1 Purpose and Authority.

81.2 Provisions of EEOICPA concerning this part.

Subpart B—Definitions

81.4 Definition of terms used in this part.

Subpart C—Data Required To Estimate Probability of Causation

81.5 Use of personal and medical information

81.6 Use of radiation dose information.

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

81.10 Use of cancer risk assessment models in NIOSH-IREP.

81.11 Use of uncertainty analysis in NIOSH-IREP.

81.12 Procedure for updating NIOSH-IREP.

Subpart E—Guidelines To Estimate Probability of Causation

81.20 Required use of NIOSH-IREP.

81.21 Cancers requiring the use of NIOSH-IREP.

81.22 General guidelines for use of NIOSH-IREP.

81.23 Guidelines for cancers for which primary site is unknown.

81.24 Guidelines for leukemia.

81.25 Guidelines for claims involving two or more primary cancers.

81.30 Non-radiogenic cancers.

Appendix A to Part 81—Glossary of ICD-9 codes and their cancer descriptions.

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

Subpart A—Introduction

§ 81.0 Background.

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, 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 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 probability of causation must be estimated or determined, 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 *et seq.* that identify current members of the Special Exposure Cohort and requirements for compensation. Pursuant to section 7384(q) of EEOICPA, the Secretary of HHS is authorized to add additional classes of employees to the Special Exposure Cohort.

§ 81.1 Purpose and Authority.

(a) The purpose of this regulation is to establish guidelines DOL will apply to adjudicate cancer claims for covered employees seeking compensation for cancer, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer. To award a claim, DOL must first determine that it is at least as likely as not that the cancer of the employee was caused by radiation doses incurred by the employee in the performance of

duty. These guidelines provide the procedures DOL must apply and identify the information DOL will use.

(b) Section 7384(n)(b) of EEOICPA requires the President to promulgate these guidelines. Executive Order 13179 assigned responsibility for promulgating these guidelines to the Secretary of HHS.

§ 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 each dose estimate. Dose estimates will be distinguished by type of radiation (low linear energy transfer (LET), protons, neutrons, alpha, low-energy x-ray) and by dose rate (acute or chronic) for external and internal radiation dose.

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

§ 81.10 Use of cancer risk assessment models in NIOSH IREP.

(a) The risk models used to estimate probability of causation for covered employees under EEOICPA will be based on risk models updated from the 1985 NIH Radioepidemiological Tables. These 1985 tables were developed from analyses of cancer mortality risk among the Japanese atomic bomb survivor cohort. The National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) are updating the tables, replacing them with a sophisticated analytic software program. This program, the Interactive RadioEpidemiological Program (IREP)¹,

models the dose-response relationship between ionizing radiation and 33 cancers using morbidity data from the same Japanese atomic bomb survivor cohort. In the case of thyroid cancer, radiation risk models are based on a pooled analysis of several international cohorts^{1a}.

(b) NIOSH will change the risk models in IREP, as needed, to reflect the radiation exposure and disease experiences of employees covered under EEOICPA, which differ from the experiences of the Japanese atomic bomb survivor cohort. Changes will be incorporated in a version of IREP named NIOSH-IREP, specifically designed for adjudication of claims under EEOICPA. Possible changes in IREP risk models include the following:

- (1) Addition of risk models to IREP, as needed, for claims under EEOICPA (e.g., malignant melanoma and other skin cancers)
- (2) Modification of IREP risk models to incorporate radiation exposures unique to employees covered by EEOICPA (e.g., radon and low energy x rays from employer-required medical screening programs, adjustment of relative biological effectiveness distributions based on neutron energy).
- (3) Modification of IREP risk models to incorporate new understanding of radiation-related cancer effects relevant to employees covered by EEOICPA (e.g., incorporation of inverse dose-rate relationship between high LET radiation exposures and cancer; adjustment of the low-dose effect reduction factor for acute exposures).
- (4) Modification of IREP risk models to incorporate new understanding of the potential interaction between cancer risk associated with occupational exposures to chemical carcinogens and radiation-related cancer effects.
- (5) Modification of IREP risk models to incorporate temporal, race and ethnicity-related differences in the frequency of certain cancers occurring generally among the U.S. population.
- (6) Modifications of IREP to facilitate improved evaluation of the uncertainty distribution for the probability of causation for claims based on two or more primary cancers.

(b) NIOSH-IREP will operate according to the same general protocol as IREP for the analysis of uncertainty. It will address the same possible sources of uncertainty affecting probability of causation estimates, and in most cases will apply the same assumptions incorporated in IREP risk models. Different procedures and assumptions will be incorporated into NIOSH-IREP as needed, according to the criteria outlined under § 81.10.

(c) NIOSH-IREP will operate according to the same general protocol as IREP for the analysis of uncertainty. It will address the same possible sources of uncertainty affecting probability of causation estimates, and in most cases will apply the same assumptions incorporated in IREP risk models. Different procedures and assumptions will be incorporated into NIOSH-IREP as needed, according to the criteria outlined under § 81.10.

§ 81.11 Use of uncertainty analysis in NIOSH-IREP.

(a) EEOICPA requires use of the uncertainty associated with the probability of causation calculation, specifically requiring the use of the upper 99% confidence interval

(credibility limit) estimate of the probability of causation estimate. As described in the NCI document,² uncertainty from several sources is incorporated into the probability of causation calculation performed by NIOSH-IREP. These sources include uncertainties in estimating: radiation dose incurred by the covered employee; the radiation dose-cancer relationship (statistical uncertainty in the specific cancer risk model); the extrapolation of risk (risk transfer) from the Japanese to the U.S. population; differences in the amount of cancer effect caused by different radiation types (relative biological effectiveness or RBE); the relationship between the rate at which a radiation dose is incurred and the level of cancer risk produced (dose and dose rate effectiveness factor or DDREF); and, the role of non-radiation risk factors (such as smoking history).

(b) NIOSH-IREP will operate according to the same general protocol as IREP for the analysis of uncertainty. It will address the same possible sources of uncertainty affecting probability of causation estimates, and in most cases will apply the same assumptions incorporated in IREP risk models. Different procedures and assumptions will be incorporated into NIOSH-IREP as needed, according to the criteria outlined under § 81.10.

§ 81.12 Procedure to update NIOSH-IREP.

(a) NIOSH may periodically revise NIOSH-IREP to add, modify, or replace cancer risk models, improve the modeling of uncertainty, and improve the functionality and user-interface of NIOSH-IREP.

(b) Revisions to NIOSH-IREP may be recommended by the following sources:

- (1) NIOSH,
- (2) The Advisory Board on Radiation and Worker Health,
- (3) Independent reviews of NIOSH-IREP or elements thereof by scientific organizations (e.g., National Academy of Sciences),
- (4) DOL,
- (5) Public comment.

(c) NIOSH will submit substantive changes to NIOSH-IREP (changes that would substantially affect estimates of probability of causation calculated using NIOSH-IREP, including the addition of new cancer risk models) to the Advisory Board on Radiation and Worker Health for review. NIOSH will obtain such review and address any recommendations of the review before completing and implementing the change.

¹ NIOSH-IREP is available for public review on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html.

^{1a} Ron E, Lubin JH, Shore RE, et al. "Thyroid cancer after exposure to external radiation: a pooled analysis of seven studies." *Radiat. Res.* 141:259-277, 1995.

² Draft Report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000, p. 17-18, p. 22-23.

(d) NIOSH will inform the public of proposed changes provided to the Advisory Board for review. HHS will provide instructions for obtaining relevant materials and providing public comment in the notice announcing the Advisory Board meeting, published in the **Federal Register**.

(e) NIOSH will publish periodically a notice in the **Federal Register** informing the public of proposed substantive changes to NIOSH-IREP currently under development, the status of the proposed changes, and the expected completion dates.

(f) NIOSH will notify DOL and publish a notice in the **Federal Register** notifying the public of the completion and implementation of substantive changes to NIOSH-IREP. In the notice, NIOSH will explain the effect of the change on estimates of probability of causation and will summarize and address relevant comments received by NIOSH.

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

Subpart E—Guidelines To Estimate Probability of Causation

§ 81.20 Required use of NIOSH-IREP.

(a) NIOSH-IREP is an interactive software program for estimating

probability of causation for covered employees seeking compensation for cancer under EEOICPA, other than as members of the Special Exposure Cohort seeking compensation for a specified cancer.

(b) DOL is required to use NIOSH-IREP to estimate probability of causation for all cancers, as identified under §§ 81.21 and 81.23.

§ 81.21 Cancers requiring the use of NIOSH-IREP.

(a) DOL will calculate probability of causation for all cancers, except chronic lymphocytic leukemia as provided under § 81.30, using NIOSH-IREP.

(b) Carcinoma in situ (ICD-9 codes 230-234), neoplasms of uncertain behavior (ICD-9 codes 235-238), and neoplasms of unspecified nature (ICD-9 code 239) are assumed to be malignant, for purposes of estimating probability of causation.

(c) All secondary and unspecified cancers of the lymph node (ICD-9 code 196) shall be considered secondary cancers (cancers resulting from metastasis of cancer from a primary site). For claims identifying cancers of the lymph node, Table 1 in § 81.23 provides guidance for assigning a primary site and calculating probability of causation using NIOSH-IREP.

§ 81.22 General guidelines for use of NIOSH-IREP.

DOL will use procedures specified in the NIOSH-IREP Operating Guide to

calculate probability of causation estimates under EEOICPA. The guide provides current, step-by-step instructions for the operation of IREP. The procedures include entering personal, diagnostic, and exposure data; setting/confirming appropriate values for variables used in calculations; conducting the calculation; and, obtaining, evaluating, and reporting results.

§ 81.23 Guidelines for cancers for which primary site is unknown.

(a) In claims for which the primary cancer site cannot be determined, but a site of metastasis is known, DOL will calculate probability of causation estimates for various likely primary sites. Table 1, below, indicates the primary cancer site(s) DOL will use in NIOSH-IREP when the primary cancer site is unknown.

Table 1

Primary cancers (ICD-9 codes³) for which probability of causation is to be calculated, if only a secondary cancer site is known. “M” indicates cancer site should be used for males only, and “F” indicates the cancer site should be used for females only. A glossary of cancer descriptions for each ICD-9 code is provided in Appendix A to this part.

Secondary cancer (ICD-9 code)	ICD-9 code of likely primary cancers
Lymph nodes of head, face and neck (196.0) ...	141, 142 (M), 146 (M), 149 (F), 161 (M), 162, 172, 173, 174 (F), 193 (F).
Intrathoracic lymph nodes (196.1)	150 (M), 162, 174 (F).
Intra-abdominal lymph nodes (196.2)	150 (M), 151 (M), 153, 157 (F), 162, 174 (F), 180 (F), 185 (M), 189, 202 (F).
Lymph nodes of axilla and upper limb (196.3) ...	162, 172, 174 (F).
Inguinal and lower limb lymph nodes (196.5)	154 (M), 162, 172, 173 (F), 187 (M).
Intrapelvic lymph nodes (196.6)	153 (M), 154 (F), 162 (M), 180 (F), 182 (F), 185 (M), 188.
Lymph nodes of multiple sites (196.8)	150 (M), 151 (M), 153 (M), 162, 174 (F).
Lymph nodes, site unspecified (196.9)	150 (M), 151, 153, 162, 172, 174 (F), 185 (M).
Lung (197.0)	153, 162, 172 (M), 174 (F), 185 (M), 188 (M), 189.
Mediastinum (197.1)	150 (M), 162, 174 (F).
Pleura (197.2)	150 (M), 153 (M), 162, 174 (F), 183 (F), 185 (M), 189 (M).
Other respiratory organs (197.3)	150, 153 (M), 161, 162, 173 (M), 174 (F), 185 (M), 193 (F).
Small intestine, including duodenum (197.4)	152, 153, 157, 162, 171, 172 (M), 174 (F), 183 (F), 189 (M).
Large intestine and rectum (197.5)	153, 154, 162, 174 (F), 183 (F), 185 (M).
Retroperitoneum and peritoneum (197.6)	151, 153, 154 (M), 157, 162 (M), 171, 174 (F), 182 (F), 183 (F).
Liver, specified as secondary (197.7)	151 (M), 153, 154 (M), 157, 162, 174 (F).
Other digestive organs (197.8)	150 (M), 151, 153, 157, 162, 174 (F), 185 (M).
Kidney (198.0)	153, 162, 174 (F), 180 (F), 185 (M), 188, 189, 202 (F).
Other urinary organs (198.1)	153, 174 (F), 180 (F), 183 (F), 185 (M), 188, 189 (F).
Skin (198.2)	153, 162, 171 (M), 172, 173 (M), 174 (F), 189 (M).
Brain and spinal cord (198.3)	162, 172 (M), 174 (F).
Other parts of nervous system (198.4)	162, 172 (M), 174 (F), 185 (M), 202.
Bone and bone marrow (198.5)	162, 174 (F), 185 (M).
Ovary (198.6)	153 (F), 174 (F), 183 (F).
Suprarenal gland (198.7)	153 (F), 162, 174 (F).
Other specified sites (198.8)	153, 162, 172 (M), 174 (F), 183 (F), 185 (M), 188 (M).

³ The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II.

(b) DOL will select the site producing the highest estimate for probability of causation to adjudicate the claim.

§ 81.24 Guidelines for leukemia.

(a) For claims involving leukemia, DOL will calculate one or more probability of causation estimates from up to three of the four alternate leukemia risk models included in NIOSH-IREP, as specified in the NIOSH-IREP Operating Guide. These include: "Leukemia, all types except CLL" (ICD-9 codes: 204-208, except 204.1), "acute lymphocytic leukemia" (ICD-9 code: 204.0), and "acute myelogenous leukemia" (ICD-9 code: 205.0).

(b) For leukemia claims in which DOL calculates multiple probability of causation estimates, as specified in the NIOSH-IREP Operating Guide, the probability of causation estimate DOL assigns to the claim will be based on the leukemia risk model producing the highest estimate for probability of causation.

§ 81.25 Guidelines for claims including two or more primary cancers.

For claims including two or more primary cancers, DOL will use NIOSH-IREP to calculate the estimated probability of causation for each cancer individually. Then DOL will perform the following calculation using the probability of causation estimates produced by NIOSH-IREP:

EQUATION 1

$$\text{Calculate: } 1 - \{ \{ 1 \times PC_1 \} \times \{ 1 - PC_2 \} \times \dots \times$$

$\{ 1 - PC_n \} \} = PC_{\text{total}}$, where PC_1 is the probability of causation for one of the primary cancers identified in the claim, PC_2 is the probability of causation for a second primary cancer identified in the 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 .⁴ DOL will use the probability of causation value calculated for PC_{total} to adjudicate the claim.

§ 81.30 Non-radiogenic cancers

The following cancers are considered non-radiogenic for the purposes of EEOICPA and this part. DOL will assign a probability of causation of zero to the following cancers:

- (a) Chronic lymphocytic leukemia (ICD-9 code: 204.1)
- (b) [Reserved]

⁴ Evaluating Equation 1 based on the individual upper 99th percentiles of PC_1, \dots, PC_n approximates the upper 99th percentile of PC_{total} whenever PC_1, \dots, 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, \dots, 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.

APPENDIX A TO PART 81—GLOSSARY OF ICD-9 CODES AND THEIR CANCER DESCRIPTIONS ¹

ICD-9 code	Cancer description
140	Malignant neoplasm of lip.
141	Malignant neoplasm of tongue.
142	Malignant neoplasm of major salivary glands.
143	Malignant neoplasm of gum.
144	Malignant neoplasm of floor of mouth.
145	Malignant neoplasm of other and unspecified parts of mouth.
146	Malignant neoplasm of oropharynx.
147	Malignant neoplasm of nasopharynx.
148	Malignant neoplasm of hypopharynx.
149	Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx.
150	Malignant neoplasm of esophagus.
151	Malignant neoplasm of stomach.
152	Malignant neoplasm of small intestine, including duodenum.
153	Malignant neoplasm of colon.
154	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
155	Malignant neoplasm of liver and intrahepatic bile ducts.
156	Malignant neoplasm of gall bladder and extrahepatic bile ducts.
157	Malignant neoplasm of pancreas.
158	Malignant neoplasm of retroperitoneum and peritoneum.
159	Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum.
160	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses.
161	Malignant neoplasm of larynx.
162	Malignant neoplasm of trachea, bronchus and lung.
163	Malignant neoplasm of pleura.
164	Malignant neoplasm of thymus, heart, and mediastinum.
165	Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs.
170	Malignant neoplasm of bone and articular cartilage.
171	Malignant neoplasm of connective and other soft tissue.
172	Malignant melanoma of skin.
173	Other malignant neoplasms of skin.
174	Malignant neoplasm of female breast.
175	Malignant neoplasm of male breast.
179	Malignant neoplasm of uterus, part unspecified.
180	Malignant neoplasm of cervix uteri.
181	Malignant neoplasm of placenta.
182	Malignant neoplasm of body of uterus.
183	Malignant neoplasm of ovary and other uterine adnexa.
184	Malignant neoplasm of other and unspecified female genital organs.
185	Malignant neoplasm of prostate.
186	Malignant neoplasm of testis.

APPENDIX A TO PART 81—GLOSSARY OF ICD-9 CODES AND THEIR CANCER DESCRIPTIONS¹—Continued

ICD-9 code	Cancer description
187	Malignant neoplasm of penis and other male genital organs.
188	Malignant neoplasm of urinary bladder.
189	Malignant neoplasm of kidney and other unspecified urinary organs.
190	Malignant neoplasm of eye.
191	Malignant neoplasm of brain.
192	Malignant neoplasm of other and unspecified parts of nervous system.
193	Malignant neoplasm of thyroid gland.
194	Malignant neoplasm of other endocrine glands and related structures.
195	Malignant neoplasm of other and ill-defined sites.
196	Secondary and unspecified malignant neoplasm of the lymph nodes.
197	Secondary malignant neoplasm of the respiratory and digestive organs.
198	Secondary malignant neoplasm of other tissue and organs.
199	Malignant neoplasm without specification of site.
200	Lymphosarcoma and reticulosarcoma.
201	Hodgkin's disease.
202	Other malignant neoplasms of lymphoid and histiocytic tissue.
203	Multiple myeloma and other immunoproliferative neoplasms.
204	Lymphoid leukemia
205	Myeloid leukemia.
206	Monocytic leukemia.
207	Other specified leukemia.
208	Leukemia of unspecified cell type.

¹ The International Classification of Diseases Clinical Modification (9th Revision) Volume I&II. [1991] Department of Health and Human Services Publication No. (PHS) 91-1260, U.S. Government Printing Office, Washington, D.C.

Dated: April 10, 2002.
Tommy G. Thompson,
Secretary, Department of Health and Human Services.
 [FR Doc. 02-10764 Filed 4-30-02; 8:45 am]
BILLING CODE 4160-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 82
RIN 0920-ZA00

Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This rule implements select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 (“EEOICPA” or “Act”). The Act requires the promulgation of methods, in the form of regulations, for estimating the dose levels of ionizing radiation incurred by workers in the performance of duty for nuclear weapons production programs of the Department of Energy and its predecessor agencies. These “dose reconstruction” methods will be applied by the National Institute for Occupational Safety and Health, which is responsible for producing the radiation dose estimates that the U.S.

Department of Labor will use in adjudicating certain cancer claims under the Act.

DATES: *Effective Date:* This final rule is effective May 2, 2002.

Compliance Dates: Affected parties are required to comply with the information collection requirements in § 82.10 May 2, 2002.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone 513-841-4498 (this is not a toll-free number). Information requests may also be submitted by e-mail to OCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act of 2000 (“EEOICPA”), 42 U.S.C. 7384-7385 [1994, supp. 2001], established a compensation program to provide a lump sum payment of \$150,000 and medical benefits as compensation to covered employees suffering from designated illnesses (i.e. cancer resulting from radiation exposure, chronic beryllium disease, or silicosis) incurred as a result of their exposures while in the performance of duty for the Department of Energy (“DOE”) and certain of its vendors, contractors, and subcontractors. This law also provided

for payment of compensation to certain survivors of covered employees.

EEOICPA instructed the President to designate one or more federal agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179, titled Providing Compensation to America’s Nuclear Weapons Workers, which assigned primary responsibility for administering the compensation program to the Department of Labor (“DOL”). 65 FR 77487 (Dec. 7, 2000). DOL published an interim final rule governing DOL’s administration of EEOICPA on May 25, 2001 (20 CFR parts 1 and 30).

The executive order directed the Department of Health and Human Services (“HHS”) to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop methods to estimate radiation doses (“dose reconstruction”) for certain individuals with cancer applying for benefits under the DOL program. These methods are the subject of this rule. HHS is also to apply these methods to conduct the program of dose reconstructions required by EEOICPA. This program is delegated to the National Institute for Occupational Safety and Health (“NIOSH”), an institute of the Centers for Disease Control and Prevention.

(2) HHS is also to develop guidelines to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or atomic