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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.

(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 codes[3]) 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. [1991] Department of Health and Human Services Publication No. (PHS) 91–1260, U.S. Government Printing Office, Washington D.C.