DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 81

[Docket Number CDC–2019–0050; NIOSH–329]

RIN 0920–AA74

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

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule.

SUMMARY: The Department of Health and Human Services (HHS) is revising its regulations to update references to the International Classification of Disease (ICD) codes from ICD–9–CM to ICD–10–CM, and remove outdated references to chronic lymphocytic leukemia from Energy Employees Occupational Illness Compensation Program regulations. These technical amendments have no effect on the cancer eligibility requirement under the Program because all cancer types are eligible to receive a dose reconstruction from NIOSH. Thus, no eligible claimant will be adversely impacted by this rulemaking.

DATES: This rule is effective on August 1, 2019. Comments must be received by September 30, 2019.

ADDRESSES: You may submit comments, identified by “RIN 0920–AA74,” by any of the following methods:


• Mail: NIOSH Docket Office, 1090 Tusculum Avenue, MS C–48, Cincinnati, OH 45226–1998.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and search for CDC–2019–0050.

FOR FURTHER INFORMATION CONTACT:
Rachel Weiss, Program Analyst; 1090 Tusculum Ave., MS C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

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D. Executive Order 13132 (Federalism)
E. Executive Order 12955 (Protection of Children From Environmental Health Risks and Safety Risks)
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G. Executive Order 13045 (Children’s Right to Environmental Health and Safety Risks)

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this rulemaking.

All relevant comments submitted will be available for examination in the docket for this rulemaking both before and after the closing date for comments. All relevant comments will be posted without change to Docket CDC–2019–0050 at http://www.regulations.gov including any personal information provided.

All relevant communications received on or before the closing date for comments will be fully considered by HHS.

II. Background

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) 1 was established to provide financial compensation and prospective medical benefits to employees for illness caused by exposure to radiation, beryllium, silica, and toxic substances during their employment at facilities of the Department of Energy, its predecessor agencies, and certain of its contractors and vendors. It is administered by the Department of Labor’s Office of Workers’ Compensation Programs (OWCP) with radiation dose reconstructions for claims involving radiogenic cancers provided by CDC’s National Institute for Occupational Safety and Health (NIOSH). For these radiogenic cancer claims, OWCP is responsible for developing a claim file upon receipt of an application for benefits under EEOICPA from a claimant. The claim file includes, among other things, employment history and an International Classification of Disease (ICD) diagnosis code(s) indicating the type and location of a radiogenic cancer for the claimant. After a claim file is developed, OWCP then transmits the claim file to NIOSH, which uses that information to estimate the amount of radiation (radiation “dose”) the worker might have received during covered employment. OWCP then makes determinations regarding the likelihood that an individual’s cancer is associated with workplace radiation exposures using a number of factors, including the radiation doses estimated by NIOSH. Existing HHS regulations in 42 CFR part 81 require the use of International Classification of Disease, 9th Revision, Clinical Modification (ICD–9–CM) codes to identify specific cancer types used in making these determinations.

The World Health Organization (WHO) develops diagnostic codes for the identification of health conditions; these ICD codes are periodically updated to reflect advances in health and medicine. WHO developed the 10th

1 42 U.S.C. 7384n(c).
version (ICD–10) to replace the 9th in
1999. CDC’s National Center for Health
Statistics developed the ICD–10–CM
classification, which is a “clinical
modification” of WHO’s ICD–10 codes,
for use in coding and classifying disease
in the clinical setting. Since the
development of the ICD–10–CM codes,
health facilities and other organizations,
including OWCP, have relied on HHS’
Centers for Medicare & Medicaid
Services (CMS) to provide “general
equivalence mapping” between ICD–9–
CM codes and ICD–10–CM codes.
However, CMS will discontinue that
service on September 30, 2019.3

Accordingly, OWCP informed NIOSH in
January 2019 that it will be unable to
continue providing both ICD–9–CM and
ICD–10–CM codes in the claim files
without potentially causing delay to
claim processing. Therefore, the ICD–9–
CM codes in part 81 must be replaced
with ICD–10–CM codes to bring the
regulations up to date and allow NIOSH
to efficiently develop dose estimates
and improve the overall efficiency in
claim processing.

Updating the ICD codes and
references in part 81 will inform the
claimant population of the current
diagnosis codes used in the
compensation program and the dose
reconstruction process. This rulemaking
will benefit the population of energy
workers who submit claims to OWCP
for benefits under EEOICPA by allowing
NIOSH to complete radiation dose
reconstructions in support of OWCP’s
adjudication of the claims in a timely
manner. This technical amendment has
no effect on the cancer eligibility
requirement under the dose
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because all cancer types are eligible to
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rulemaking.

In addition to updating the ICD codes,
NIOSH will also remove outdated
references to chronic lymphocytic
leukemia (CLL) from part 81. Until
promulgation of a final rule in 2012,3
CLL was not covered under the
EEOICPA program. The 2012 final rule
removed 42 CFR 81.30, which excluded
this cancer, thereby allowing claimants
to seek compensation through the dose
reconstruction process. That rulemaking
mistakenly did not remove other

3 See https://www.cms.gov/Medicare/Coding/

4 Final Rule; Guidelines for Determining
Probability of Causation Under the Energy
Employees Occupational Illness Compensation
Program Act of 2000; Revision of Guidelines on
Non-Radiogenic Cancers, February 6, 2012 (77 FR
5711).

54 CFR 162.1002(c)(2).

6 Final Rule; Guidelines for Determining
Probability of Causation Under the Energy
Employees Occupational Illness Compensation
Program Act of 2000; Revision of Guidelines on
Non-Radiogenic Cancers, February 6, 2012 (77 FR
5711).
definition of “ICD–10–CM,” to include a reference and web link.

In existing § 81.5(b), the term “ICD–9” is replaced with “ICD–10–CM.” In §§ 81.21, 81.23, and 81.24, all references to ICD–9 codes are changed to ICD–10–CM codes. In §§ 81.21(a) and 81.24(a), outdated references to CLL are also removed. Finally, Appendix A is removed in its entirety because it is a glossary of ICD–9 codes and their cancer descriptions, and such reference tables, including tables of ICD–10 codes and their cancer descriptions, are readily available online.

VI. Regulatory Assessment Requirements

A. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim final rule is not being treated as a “significant” action under E.O. 12866. It updates references and ICD codes in existing 42 CFR part 81 to allow better administrative efficiency in the processing of dose reconstruction claims. The rule does not result in costs to the Program, claimants, or any other interested parties. Accordingly, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

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

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771 requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs. HHS has determined that this rulemaking is cost-neutral because it does not require any new action by stakeholders. The rulemaking ensures that the dose reconstructions developed by the Program can be conducted efficiently.

Because OMB has determined that this rulemaking is not significant, pursuant to E.O. 12866, and because it does not impose costs, OMB has determined that this rulemaking is exempt from the requirements of E.O. 13771. Thus it has not been reviewed by OMB.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The rule affects only Federal agencies and certain individuals covered by EEOICPA. Therefore, HHS certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 et seq., requires an agency to invite public comment on and to obtain OMB approval of any rule of general applicability that requires recordkeeping, reporting, or disclosure requirements.

NIOSH has obtained approval from OMB to collect information from claimants under “Energy Employees Occupational Illness Compensation Program Act Dose Reconstruction Interviews and Forms (EEOICPA)” (OMB Control No. 0920–0530, exp. January 31, 2022), which covers information collected under 42 CFR part 81. This rulemaking does not change the reporting burden on any respondents.

E. 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 the promulgation of this rule to Congress prior to its effective date. 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 an annual effect on the economy of $100 million or more.

F. 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.

G. 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. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

H. 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.”

I. 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.

J. 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.

K. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the interim final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 81

Interim Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 81 as follows:

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

1. The authority citation for part 81 continues to read as follows:


2. Amend § 81.4 as follows:

(a) In paragraph (l), remove the reference “20 CFR 30.5(dd)” and add in its place “20 CFR 30.5(gg)

The addition reads as follows:

§ 81.4 Definition of terms used in this part.

<table>
<thead>
<tr>
<th>Secondary cancer (ICD–10–CM code)</th>
<th>ICD–10–CM code of likely primary cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph nodes of head, face and neck (C77.0)</td>
<td>C01, C02, C07(M), C08(M), C09(M), C10(M), C14(F), C32(M), C33, C34, C43, C44, C50(F), C73(F), D03, C15(M), C33, C34, C50(F).</td>
</tr>
<tr>
<td>Infrathoracic lymph nodes (C77.1)</td>
<td>C15(M), C16(M), C18, C25(F), C33, C34, C50(F), C53(F), C61(M), C64, C65, C66, C68, C82(F), C84(F) (excluding C84.6, C84.7), C85(F), C86(F) (excluding C86.5, C86.6), C91.4(F), C96(F).</td>
</tr>
<tr>
<td>Intrathoracic lymph nodes (C77.2)</td>
<td>C33, C34, C43, C50(F), D03.</td>
</tr>
<tr>
<td>Lymph nodes of axilla and upper limb (C77.3)</td>
<td>C19(M), C20(M), C21(M), C33, C34, C43, C44(F), C60(M), C63(M), D03.</td>
</tr>
<tr>
<td>Intrapelvic lymph nodes (C77.5)</td>
<td>C18(M), C19(F), C20(F), C21(F), C33(M), C34(M), C53(F), C54(F), C61(M), C67.</td>
</tr>
<tr>
<td>Lymph nodes of multiple sites (C77.8)</td>
<td>C15(M), C16(M), C18, C33, C34, C50(F).</td>
</tr>
<tr>
<td>Lymph nodes, site unspecified (C77.9)</td>
<td>C15(M), C16, C18, C33, C34, C43, C50(F), C61(M), D03.</td>
</tr>
<tr>
<td>Lung (C78.0)</td>
<td>C18, C33, C34, C43(M), C50(F), C61(M), C67(M), C64, C65, C66, C68, D03(M).</td>
</tr>
<tr>
<td>Mediastinum (C78.1)</td>
<td>C15(M), C33, C34, C50(F).</td>
</tr>
<tr>
<td>Pleura (C78.2)</td>
<td>C15(M), C18(M), C33, C34, C43, C50(F), C56(F), C57(F), C61(M), C64(M), C65(M), C66(M), C68(M).</td>
</tr>
<tr>
<td>Other respiratory organs (C78.3)</td>
<td>C15(M), C18(M), C33, C34, C50(F), C61(M), C64(M), C65(M), C66(M), C68(M).</td>
</tr>
<tr>
<td>Small intestine, including duodenum (C78.4)</td>
<td>C15, C18, C32, C33, C34, C44(M), C50(F), C61(M), C73(F).</td>
</tr>
<tr>
<td>Large intestine and rectum (C78.5)</td>
<td>C17, C18, C25, C33, C34, C43, C50(F), C56(F), C57(F), C61(M), C64(M), C65(M), C66(M), C68(M), D03(M).</td>
</tr>
<tr>
<td>Liver, specified as secondary (C78.7)</td>
<td>C18, C19(M), C20, C21, C33, C34, C50(F), C56(F), C57(F), C61(M).</td>
</tr>
<tr>
<td>Other digestive organs (C78.8)</td>
<td>C16, C18, C19(M), C20(M), C21(M), C25, C33, C34, C50(F).</td>
</tr>
<tr>
<td>Kidney (C79.0)</td>
<td>C15(M), C16, C18, C25, C33, C50(F), C61(M).</td>
</tr>
<tr>
<td>Other urinary organs (C79.1)</td>
<td>C18, C33, C34, C49(M), C43, C44(M), C50(F), C64(M), C65(F), C66(F), C68(F).</td>
</tr>
<tr>
<td>Skin (C79.2)</td>
<td>C18, C33, C34, C49(M), C43, C44(M), C50(F), C64(M), C65(F), C66(F), C68(F).</td>
</tr>
<tr>
<td>Brain and spinal cord (C79.3)</td>
<td>C33, C34, C43(M), C50(F), D03(M).</td>
</tr>
</tbody>
</table>

§ 81.5 Use of personal and medical information.

(b) Cancer diagnosis (by ICD–10–CM code) for primary and secondary cancers.

4. Revise § 81.21 to read as follows:

§ 81.21 Cancers requiring the use of NIOSH–IREP.

(a) DOL will calculate probability of causation using NIOSH–IREP.

(b) Carcinoma in situ (ICD–10–CM code) for primary and secondary cancers.


5. Amend § 81.23 by revising paragraph (a) to read as follows:

§ 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 of this paragraph (a) indicates the primary cancer site(s) DOL will use in NIOSH–IREP when the primary cancer site is unknown.

Table 1 to Paragraph (a)

Primary cancers (ICD–10–CM codes) 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.
and C92.A).

leukemia’’ (ICD–10–CM codes C92.6
lymphocytic leukemia’’ (ICD–10–CM
CM codes C91–C95), ‘’acute
NIOSH–IREP Operating Guide. These
up to three of the four alternate
probability of causation estimates from

7. Amend § 81.25 by redesignating
footnote 4 as footnote 3.

§ 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’’ (ICD–10–
CM codes C91–C95), ‘’acute
lymphocytic leukemia’’ (ICD–10–CM
code C91.0), and ‘’acute myelogenous
leukemia’’ (ICD–10–CM codes C92.6
and C92.A).

§ 81.25 [Amended]
§ 7. Amend § 81.25 by redesignating
footnote 4 as footnote 3.

Dated: July 25, 2019.
Alex M. Azar II,
Secretary, Department of Health and Human
Services.
[FR Doc. 2019–16347 Filed 7–31–19; 8:45 am]
BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS
COMMISSION

47 CFR Part 20
[WT Docket No. 17–228, FCC 18–167]

Revisions to Reporting Requirements
Governing Hearing Aid-Compatible
Handsets

AGENCY: Federal Communications
Commission.

ACTION: Final rule; announcement of
compliance dates.

SUMMARY: The Wireless
Telecommunications Bureau (WTB or
the Bureau) announces that the Office of
Management and Budget (OMB) has
approved the information-collection and
recordkeeping requirements associated with
the recently amended hearing aid
compatibility provisions addressing
wireless service provider record
retention, website posting, and
certification filing requirements and
announces the date by which service providers
must be in compliance with these provisions.

DATES: Effective August 1, 2019.

Compliance Dates: Compliance with
47 CFR 20.19(e), (h) and (i) is required
as of September 3, 2019. The § 20.19(i)
service provider certification filing
requirement must be completed
between the compliance date and no
later than 30 days after the compliance
date.

FOR FURTHER INFORMATION CONTACT:
Susannah Larson, Wireless
Telecommunications Bureau, at (202)
418–1883 or via email:
susannah.larson@fcc.gov. For additional
information concerning the Paperwork
Reduction Act information collection
requirements contact Cathy Williams at
(202) 418–2918 or via email:
cathy.williams@fcc.gov.

SUPPLEMENTARY INFORMATION: This
document announces that OMB
approved the information collection
requirements in revised §§ 20.19(e), (h),
and (i) on June 25, 2019. Revised
§ 20.19(e) addresses the reporting and
certification requirements applicable to
de minimis wireless service providers.
Revised § 20.19(h) sets forth service
provider website posting and record
retention obligations and revised
§ 20.19(i) sets forth service provider
annual certification requirements. The
Commission adopted these revised rules in
the following Report and Order

Revisions to Reporting Requirements
Governing Hearing Aid-Compatible
Mobile Handsets, FCC 18–167,
published at 83 FR 63098 on December
7, 2018 (Report and Order).
The Report and Order provides that the
Bureau will publish a document in the
Federal Register announcing
compliance dates for revised §§ 20.19(e),
(h), and (i) once OMB approval is
obtained for the paperwork burden
associated with these sections. Further,
the Report and Order states that the
Bureau will revise § 20.19(m) once OMB
approval is obtained for §§ 20.19(e),
h, and (i) and a compliance date for these
sections is established. Section 20.19(m)
states that compliance with the
paperwork obligations of §§ 20.19(e),
h, and (i) is not required until OMB
approval is obtained and a compliance
date is established. The other rule
amendments that the Commission
adopted in the Report and Order did not
require OMB approval and compliance
with those rule sections was required as
of January 7, 2019. See Report and

With respect to §§ 20.19(e) and (h),
service providers must be in compliance
with these sections by the compliance
date set out above, except to the extent
that these sections reference the
§ 20.19(i) certification requirement.
With respect to the § 20.19(i)
certification requirement, service
providers may begin filing their
certifications on the compliance date
announced above and must have their
certifications filed with the Commission
within 30 days of that date. Service
providers will be using new electronic
FCC Form 855 to make their
certifications. The OMB approved
instructions for how to fill out and file
the electronic FCC Form 855
certification will be available on the
hearing aid compatibility section of the
FCC website starting on the compliance
date listed above. We remind service
providers that the initial certifications

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<th>Secondary cancer (ICD–10–CM code)</th>
<th>ICD–10–CM code of likely primary cancers</th>
</tr>
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<tr>
<td>Other parts of nervous system (C79.4)</td>
<td>C33, C34, C43(M), C50(F), C61(M), C82, C84 (excluding C84.6, C84.7), C85, C86 (excluding C86.5, C86.6), C91.4, C96, D03(M). C33, C34, C50(F), C61(M).</td>
</tr>
<tr>
<td>Bone and bone marrow (C79.5)</td>
<td>C18(F), C50(F), C56(F), C57(F).</td>
</tr>
<tr>
<td>Ovary (C79.6)</td>
<td>C18(F), C33, C34, C50(F).</td>
</tr>
<tr>
<td>Adrenal gland (C79.7)</td>
<td>C18, C33, C34, C43(M), C50(F), C56(F), C57(F), C61(M), C67(M), D03(M).</td>
</tr>
<tr>
<td>Other specified sites (C79.8)</td>
<td>C18, C33, C34, C43(M), C50(F), C56(F), C57(F), C61(M), C67(M), D03(M).</td>
</tr>
<tr>
<td>Unspecified sites (C79.9)</td>
<td>C15(M), C16, C18, C33, C34, C43, C50(F), C61(M), D03(M).</td>
</tr>
<tr>
<td>Carcinoid tumor of distant lymph nodes (C7B.01)</td>
<td>C16(M), C18, C19(M), C20(M), C21(M), C25, C33, C34, C50(F).</td>
</tr>
<tr>
<td>Carcinoid tumor of bone (C7B.03)</td>
<td>C33, C34, C50(F), C61(M).</td>
</tr>
<tr>
<td>Carcinoid tumor of peritoneum (C7B.04)</td>
<td>C16, C18, C19(M), C20(M), C21(M), C25, C33, C34(M), C49, C50(F), C54(F), C56(F), C57(F).</td>
</tr>
<tr>
<td>Merkel cell carcinoma (C7B.1)</td>
<td>C18, C33, C34, C49(M), C43, C44(M), C50(F), C64(M), C65(M), C66(M), C68(M), D03.</td>
</tr>
</tbody>
</table>