

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 81

[Docket Number NIOSH–209]

RIN 0920–AA39

Guidelines for Determining Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Revision of Guidelines on Non-Radiogenic Cancers

AGENCY: National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, DHHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) is proposing to treat chronic lymphocytic leukemia (CLL) as a radiogenic cancer under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). Under current guidelines HHS promulgated as regulations in 2002, all types of cancers except for CLL are treated as being potentially caused by radiation and hence as potentially compensable under EEOICPA. HHS proposes to reverse its decision to exclude CLL from such treatment.

DATES: The Department invites written comments on this Notice of Proposed Rulemaking from interested parties. Comments must be received by June 20, 2011.

ADDRESSES: You may submit comments, identified by “RIN 0920–AA39,” by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* NIOSH Docket Officer, nioshdocket@cdc.gov. Include “RIN 0920–AA39” and “42 CFR 81.30” in the subject line of the message.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be posted without change to <http://www.regulations.gov> and <http://www.cdc.gov/niosh/docket/archive/docket209.html>, including any personal information provided. 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> or <http://www.cdc.gov/niosh/docket/archive/docket209.html>.

FOR FURTHER INFORMATION CONTACT: Stuart Hinnefeld, Director, Division of Compensation Analysis and Support,¹ National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS–C46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to dcas@cdc.gov.

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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 proposal. In addition, HHS invites comments specifically on the following questions related to this rulemaking:

(1) Does epidemiological and other scientific research support finding that CLL is caused by radiation, and what are the major limitations of the determination (whether affirmative or negative)?

(2) If CLL were to be covered under EEOICPA, does the risk model proposed

by the National Institute for Occupational Safety and Health (NIOSH) use the best available science and methodological approaches to express the dose-response relationship between radiation exposure and CLL? Does the approach NIOSH is taking in this package appropriately account for the uncertainty associated with the limited evidence of radiogenicity? In this context, did NIOSH make use of appropriate biological and epidemiological information in the development of its proposed model? If not, please cite specific research studies that NIOSH should have considered as well as alternative modeling approaches that could also be considered.

Comments submitted by e-mail or mail should be addressed to the NIOSH Docket Officer, titled “NIOSH Docket #209,” and should identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to: nioshdocket@cdc.gov. E-mail comments may be provided as e-mail text or as a file attachment. Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by HHS.

All comments submitted will be available for examination in the rule docket (a publicly available repository of the documents associated with the rulemaking) both before and after the closing date for comments. A complete electronic docket containing all comments submitted will be available at <http://www.cdc.gov/niosh/docket/archive/docket209.html> and <http://www.regulations.gov>, or comments will be available in hard-copy by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

II. Background

A. Introduction

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384–7385, established a compensation program to provide a lump-sum payment of \$150,000 and prospective medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to radiation, beryllium, or silica 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 lump-sum payments for certain survivors of these covered employees.

¹The name of the NIOSH Office of Compensation Analysis and Support (OCAS) was changed to the Division of Compensation Analysis and Support (DCAS) in March 2010.

Under Executive Order 13179 (“Providing Compensation to America’s Nuclear Weapons Workers”), the Department of Labor (DOL) has primary responsibility for administering the compensation program. HHS performs several technical and policymaking roles in support of the DOL program. One of these is to develop guidelines, by regulation, 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 duty at a DOE facility or an atomic weapons employer facility. HHS published a final rule establishing these “probability of causation” guidelines on May 2, 2002 (67 FR 22296) under 42 CFR part 81.

The HHS probability of causation guidelines comprise a set of policies and procedures by which DOL determines whether it is “at least as likely as not” that the cancer of a nuclear weapons employee was caused by radiation doses the employee incurred while employed at a facility both involved in the production of nuclear weapons and covered under EEOICPA. These procedures direct DOL to use one or more appropriate quantitative risk assessment models to calculate the probability that a cancer was caused by the relevant radiation doses. The risk models, originally developed by the National Cancer Institute (NCI) and again revised by an expert work group, chaired by NCI, in 2002 for use under EEOICPA, are contained within a computer program called the NIOSH Interactive RadioEpidemiological Program (NIOSH–IREP).² NIOSH–IREP contains a risk model for every type of cancer covered by an EEOICPA claim, except for CLL. The guidelines designate CLL as non-radiogenic, and hence require DOL to assign a probability of causation value of “zero.”

There were two related scientific reasons for designating CLL as non-radiogenic at the time the HHS guidelines were promulgated in 2002. The first was that the epidemiological studies did not demonstrate radiation as the cause of CLL, a conclusion reached by a number of expert scientific committees, as well as by NIOSH.³ This evidence included studies of a variety of designs on populations with a variety of high radiation exposures, including British ankylosing spondylitis patients treated with x-rays;⁴ U.S., Canadian,

and European women exposed to radiation during treatment for uterine cancer;⁵ nuclear workers in the United Kingdom and internationally;⁶ and Japanese atomic bomb survivors from World War II.⁷ No major epidemiological study as of that date had found a statistically significant increase in the risk of CLL associated with radiation exposure, let alone a dose-response relationship.⁸

The second reason was that, even if NIOSH had determined that CLL should be treated as radiogenic, NIOSH scientists judged it would not have been feasible to develop a quantitative risk model, specifying a dose-response relationship between radiation and CLL, given the existing scientific evidence at that time. Hence, it was not feasible to include CLL as a radiogenic cancer under the guidelines.

B. NIOSH Reconsideration of CLL

Basis for Reconsideration

In the original technical documentation for NIOSH–IREP, the discussion of the rationale for excluding CLL from consideration under EEOICPA stated that this decision would be revisited as new scientific information became available. Although HHS received little comment on the designation of CLL as non-radiogenic during the rulemaking that established the probability of causation guidelines under EEOICPA, NIOSH has steadily since heard concerns about this policy decision from EEOICPA claimants, their representatives, and others.

In response to stakeholder input, the Congressional appropriations language for fiscal year 2004 directed NIOSH to

in patients treated for ankylosing spondylitis. *Br. J. Cancer*. 1987;55:179–190.

⁵ Curtis RE, Boice JD, Stovall M, *et al.* Relationship of leukemia risk to radiation dose following cancer of the uterine corpus. *J. Natl. Cancer Inst.* 1994;86:1315–1324.

⁶ Muirhead CR, Goodill AA, Haylock RGE, *et al.* Occupational radiation exposure and mortality: second analysis of the National Registry for Radiation Workers. *J. Radiol. Prot.* 1999;19:3–26.

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.* 1995;142:117–132.

⁷ Preston DL, Kusumi S, Tomonaga M, *et al.* Cancer incidence in atomic bomb survivors. Part III: Leukemia, lymphoma and multiple myeloma, 1950–1987. *Radiat. Res.* 1994;137:S68–S97.

⁸ A dose-response relationship between radiation and CLL would be a finding that the incidence of CLL among populations increases with increases in the amount of radiation dose. With such a relationship, populations with a moderate amount of radiation dose would be found to have a moderate frequency of CLL, populations with a high amount of radiation dose would be found to have a high frequency of CLL, and populations with a very high amount of radiation dose would be found to have a very high frequency of CLL.

conduct epidemiological research and other activities to “establish the scientific link between radiation exposure and the occurrence of chronic lymphocytic leukemia.”⁹ To this end, a focus on the radiogenicity of CLL was added to existing research conducted under the NIOSH Occupational Energy Research Program (OERP). On July 21, 2004, OERP convened a public meeting, during which a panel of six experts in epidemiologic and molecular CLL research, unaffiliated with NIOSH, met to: (1) Discuss available research strategies for investigating the potential relationship between the incidence of CLL and worker exposures to ionizing radiation; and (2) identify gaps in current research.¹⁰ The consensus among the panelists was that the current scientific evidence was inconclusive with respect to CLL’s association with ionizing radiation and additional research was required to definitively answer this question.

Subsequent to the July meeting, five additional subject matter experts unaffiliated with NIOSH were asked by NIOSH’s Division of Compensation Analysis and Support to provide their individual judgments as to whether the evidence of an association, or lack thereof, between radiation exposure and the risk of developing CLL [is] sufficient to continue to regard CLL as a non-radiogenic cancer and to continue to exclude it, *a priori*, from eligibility for compensation under EEOICPA.¹¹

This second round of review was undertaken because the purpose of the July 2004 expert panel convened by OERP was focused on how to definitively address the question of radiogenicity, rather than on the narrower context of the continued exclusion of CLL from consideration under the unique conditions prescribed under EEOICPA. That is, EEOICPA requires that consideration be given to the uncertainty associated with risk models and, in fact, requires that probability of causation (and hence, the compensation decision) be evaluated at the upper 99th percentile of the credibility level of the distribution of

⁹ NIOSH publication 2006–100. *Report of the public meeting to seek input on gaps in chronic lymphocytic leukemia (CLL) radiogenicity research, held July 21, 2004.*

¹⁰ A summary of the proceedings of this meeting can be found in: NIOSH Publication 2006–100. *Report of the public meeting to seek input on gaps in chronic lymphocytic leukemia (CLL) radiogenicity research, held July 21, 2004.*

¹¹ NIOSH, Office of Compensation Analysis and Support (OCAS). *Chronic lymphocytic leukemia (CLL): reconsideration of exclusion from eligibility for compensation under EEOICPA*. 2005. This document is included in the docket for this rulemaking.

² An interactive version of NIOSH–IREP is available on the Internet at: https://www.niosh-irep.com/irep_niosh/.

³ 67 FR 22296, 22302 (May 2, 2002) (codified at 42 CFR part 81).

⁴ Darby SC, Doll R, Gill SK, *et al.* Long-term mortality after a single treatment course with X-rays

possible outcomes. Because of this, the IREP program was designed to include cancers whose central estimate of the risk coefficient, while not statistically significant, may be significantly greater than 1 at the upper uncertainty limit and thus produce a probability of causation greater than or equal to 50 percent (*i.e.*, be compensable).

The experts chosen for this review were selected by NIOSH based on their past experience in the area of radiation epidemiology, with the goal of obtaining a diverse range of perspectives on the matter. Each of the five experts consulted posited a scientific opinion about the weight of the evidence. The full text of these opinions is available in the docket for this rulemaking.

One reviewer concluded that “the available evidence is insufficient to rule out an association between ionizing radiation and CLL.”¹²

A second reviewer found no evidence on epidemiologic grounds to support the contention that CLL is induced by radiation, stating that:

From the scientific point of view, this evidence could be interpreted as the absence of a convincing association between radiation exposure and subsequent CLL. If risks are present, but, are not identified in epidemiological studies, then they are certainly much smaller than the risks estimated for other types of leukemia.¹³ The reviewer did comment, however, that CLL remains one of the most controversial issues in radiation epidemiology:

Though in the past it was thought to be definitely non-radiogenic, recent discoveries, particularly from genetic and molecular studies, provide evidence that lymphatic cancers may differ to a great degree from other types of leukemia. If risks are present, they are probably so small as to render them virtually undetectable in individual studies under currently available scientific epidemiological methods.¹⁴

This reviewer refrained from offering an opinion on whether CLL should be included in the list of cancers that are potentially compensable under EEOICPA and concluded “from an epidemiological point of view it is not possible to prove that there is no risk of

CLL due to occupational radiation exposure. It is only possible to say that currently we do not have solid scientific evidence to say that CLL is radiogenic.”¹⁵

A third reviewer concluded that

In fact, the scientific evidence pertaining to the molecular mechanisms of CLL induction weighs heavily towards the conclusion that CLL is similar to other hematological malignancies whose etiology involves structural changes on the chromosomal level that cause mutational changes on the molecular level, altering important cellular functions, and, ultimately, leading to malignant transformation of a cell. The weight of this scientific evidence is in support of the conclusion that the somatic mutations that contribute to the genesis of CLL can be produced by ionizing radiation exposure.¹⁶

He concluded by stating:

Available scientific evidence suggests that CLL incidence will be increased by exposure to ionizing radiation. Scientific evidence does not provide a sufficient basis for regarding CLL as non-radiogenic.¹⁷

A fourth reviewer concluded his review by stating “my expert opinion supports including CLL as a radiogenic cancer and against the continuing, and it seems to me, arbitrary practice of exclusion.”¹⁸

A fifth reviewer found that “[t]he body of scientific evidence indicates that chronic lymphocytic leukemia (CLL) is not caused by exposure to ionizing radiation at any level of dose.”¹⁹ He concluded that,

based on epidemiologic studies of radiation finding no evidence for an association with CLL, coupled with the etiologic and clinical differences between CLL and the other forms of leukemia that are caused by radiation, CLL should not be considered a radiation-inducible cancer.²⁰

This reviewer also provided a counterargument to Reviewer #3’s position that the type of genetic damage that may be involved in the carcinogenesis of CLL, namely deletions of chromosomal material, can be caused by radiation, which is a known clastogen (an agent that breaks

chromosomes). According to Reviewer #5, other carcinogenic clastogens besides radiation (*e.g.*, benzene and tobacco smoke) found by epidemiological studies to cause myeloid leukemia, have also been found not to cause CLL, and hence proposes that another, unspecified carcinogenic mechanism must operate for CLL.²¹

In sum, of the five reviewers, three offered their support for the consideration of CLL as radiogenic for the purposes of potential compensation. Three reviewers, Reviewer #1, Reviewer #2, and Reviewer #3, offered the opinion that, while the evidence presented by the epidemiology studies reviewed in 2002 might not have provided conclusive proof that CLL is caused by ionizing radiation, genetic studies offer a perspective much different from that demonstrated by epidemiology studies and should be considered. The only stated opposition to including CLL came from Reviewer #5, who recognized that the conclusions reached by NIOSH with regard to other cancers deemed potentially compensable were based on NIOSH’s stated policy to “err on the side of the claimant when the state of scientific knowledge is lacking.”²²

Finally, NIOSH asked four subject matter experts to review a 2009 draft report of the CLL risk model. Of those reviewers, two also provided reviews in 2004 (Reviewers #2 and #3). The 2009 reviewers were not charged specifically with reviewing the evidence of radiogenicity and were asked to evaluate the proposed risk model (discussed below) based on the premise that CLL has a probability of causation greater than zero. According to the NIOSH summary of the 2009 reviews,

[t]he reviewers did not disagree with our basic conclusion, namely that CLL could be radiogenic, and that, from an epidemiological perspective, we can only conclude that we currently do not have solid scientific evidence of a well-defined dose-response from the LSS [Life Span Study of Japanese atomic bomb survivors] data, but not that there is no risk of CLL due to occupational radiation exposure.²³

Of these reviewers, only one premised his opinion about CLL radiogenicity on the compensation program’s inclusion of other cancers with similarly weak

¹² Crowther, MA. *Letter to Centers for Disease Control and Prevention*. Report submitted to NIOSH, November 17, 2004. A copy of this report is available in the docket for this rulemaking.

¹³ Zablotska, L. *Comments on the arguments for covering chronic lymphocytic leukemia under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) advanced by its stakeholders in “Chronic Lymphocytic Leukemia: Reconsideration of Exclusion from Eligibility for Compensation under EEOICPA.”* Report submitted to NIOSH, December 16, 2004. A copy of this report is available in the docket for this rulemaking.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Richardson DB. *Chronic lymphocytic leukemia: Reconsideration of exclusion from eligibility for compensation under EEOICPA*. Report submitted to NIOSH, November 2004. A copy of this report is available in the docket for this rulemaking.

¹⁷ *Id.*

¹⁸ Ozonoff, D. *Letter to Russell Henshaw, NIOSH, regarding Reconsideration of CLL*. Report submitted to NIOSH, December 1, 2004. A copy of this report is available in the docket for this rulemaking.

¹⁹ Boice, JD. *Reconsideration of chronic lymphocytic leukemia for purposes of compensation*. Report submitted to NIOSH, January 7, 2005. A copy of this report is available in the docket for this rulemaking.

²⁰ *Id.*

²¹ *Id.*

²² NIOSH. *Charge to reviewers: Chronic lymphocytic leukemia: reconsideration of exclusion from eligibility for compensation under EEOICPA*. Undated. This document is available in the docket for this rulemaking.

²³ NIOSH, Office of Compensation Analysis and Support (OCAS). *Response to review comments on draft report: development of a CLL risk model for NIOSH-IREP*. December 1, 2009. This document is available in the docket for this rulemaking.

evidence of radiogenicity; the other 2009 reviewers addressed only the science. One of those individuals, Reviewer #2 in the 2004 review, reversed her prior opinion that epidemiological evidence in support of CLL's radiogenicity is lacking and stated that

new evidence that came into light in the year since the report has been issued, provides evidence for the hypothesis advocated by [the report's authors] that CLL may be radiogenic and that its risk profile may be similar to that previously observed for other types of leukemia and/or [non-Hodgkin's lymphoma]. These studies are of particular importance because they provide evidence from the low-dose studies, a dose range of primary interest for occupationally exposed workers in the U.S.²⁴

These reviews²⁵ have led NIOSH to better appreciate some of the possible limitations of the epidemiological evidence, and particularly the substantial reliance on mortality studies for a disease that may not always be recorded as the primary cause of death, being principally a slowly developing cancer of old age. An examination of the long latency period between initial radiation exposure and CLL diagnosis has led some researchers to conclude that many epidemiology studies fail to "appropriately account for a protracted induction latency, and morbidity period between radiation exposure and CLL mortality."²⁶ Another limitation stems from the low incidence of CLL, resulting in studies limited by low statistical power.²⁷ NIOSH's review of both epidemiological and biological research has demonstrated that evidence for the radiogenicity of CLL is growing, and that "[i]rradiation may have been given a clean bill of health with respect to CLL with less than adequate evidence."²⁸

Under EEOICPA, NIOSH is required to develop guidelines using the 1985 radioepidemiological tables (or its successor) in computing probability of causation. The Act further requires that the probability of causation decision be made at the upper 99 percent credibility level.²⁹ When the original 1985 radioepidemiological tables were

revised in 2002, the expert working group (chaired by NCI) included additional cancers that did not have statistically significant excess relative risk coefficients. The logic for doing so is based on the fact that, if one accounts for uncertainty, it is possible for the upper limit for the risk coefficient to be greater than 1, even if the central estimate of risk is not statistically significant. The technical basis behind the revised radioepidemiological tables,³⁰ including the provision for including cancers with non-statistically significant central estimates of risk, was documented in a report reviewed by the National Academy of Sciences (NAS). NAS supported the inclusion of cancers without demonstrated radiogenicity, but proposed an approach for calculating the Assigned Share for those cancers that differed from the approach used for cancers with demonstrated radiogenicity in the 1990 draft report of the working group to revise the radioepidemiological tables. NIOSH-IREP includes models and calculates probability of causation for all cancers except CLL. It does so by considering the uncertainty associated with the excess relative risk (ERR) values and using the 99th percentile of that probability distribution in the probability of causation calculation. Given that the law requires the use of the upper 99 percent credibility level in making compensation decisions,³¹ the inclusion of CLL despite the limited evidence of radiogenicity, is considered appropriate by NIOSH. In short, the NIOSH-IREP risk models for those cancers lacking statistically significant central estimates of risk account for the uncertainty inherent in epidemiological studies of the association between ionizing radiation exposure and cancer.

NIOSH also considered the classification of CLL in relation to other lymphomas (although CLL is designated a leukemia, clinically and etiologically it appears to be a lymphoma³²) of

primary importance to this effort. CLL is now classified as a form of non-Hodgkin's lymphoma (NHL) by both NCI and the World Health Organization.³³ Under contemporary classification schemes, NHL comprises CLL and small lymphocytic lymphoma (SLL); SLL and NHL are both compensable under EEOICPA.

Finally, in the Agency's judgment, including CLL as a potentially compensable cancer would be in keeping with already-established Federal policy. The U.S. Department of Veterans Affairs (VA) recognizes CLL as a form of non-Hodgkin's lymphoma, and thus a radiogenic cancer, for the purpose of compensation under the Nuclear Test Personnel Review Program.³⁴

With respect to the radiogenicity of CLL, the Agency finds the evidence of radiogenicity offered by epidemiology studies to be non-determinative, but no longer believes that it is possible to state that the probability of causation equals zero. NIOSH has weighed the non-determinative epidemiology evidence, the mechanistic argument for CLL causation, similarities between CLL and other compensated cancers, the classification of CLL, and the treatment of CLL as a potentially-compensable radiogenic cancer by the VA, and finds sufficient evidence to include CLL as a compensable cancer under EEOICPA, and thus allow claimants with CLL to be eligible for dose reconstruction. The remaining issue NIOSH had to address to pursue such a policy was the practical matter of developing a model with a quantitative dose-response relationship for CLL.

Risk Model

The NIOSH efforts to develop a quantitative radiation risk model for CLL began with a review of key papers on the epidemiological, molecular, and clinical bases of CLL, including but not limited to those cited by Richardson *et*

²⁴ Zablotska LB. *Evaluation of a prototype CLL risk model for potential inclusion in the computer program NIOS-IREP*. Report submitted to NIOSH, September 2009. A copy of this report is available in the docket for this rulemaking.

²⁵ A timeline of the various reviews initiated by NIOSH is available in Appendix A.

²⁶ Richardson DB, Wing S, Schroeder J, *et al*. Ionizing radiation and chronic lymphocytic leukemia. *Environ. Health Persp.* 113:1-5. 2005.

²⁷ Id.

²⁸ Hamblin TJ. Have we been wrong about ionizing radiation and chronic lymphocytic leukemia? *Leuk. Res.* 2008;32:523-525.

²⁹ 42 U.S.C. 7348n(c)(3)(A).

³⁰ National Academy of Sciences. *A Review of the Draft Report of the NCI-CDC Working Group to Revise the 1985 Radioepidemiological Tables*. National Academies Press. 2000.

³¹ 42 U.S.C. 7348n(c)(3)(A).

³² Harris NL, Jaffe ES, Diebold J, Flandrin G, Muller-Hermelink HK, Vardiman J, Lister TA, and Bloomfield CD. World Health Organization classification of neoplastic diseases of the hematopoietic and lymphoid tissues: Report of the clinical advisory committee meeting—Airlie House, Virginia, November 1997. *J. Clin. Oncol.* 17:3835-3849.

Boice JD. *Reconsideration of chronic lymphocytic leukemia for purposes of compensation*. January 7, 2005.

National Cancer Institute. *Adult non-Hodgkin lymphoma treatment (PDQ®): health professional version*. Modified July 8, 2010. [http://www.cancer.gov/cancertopics/pdq/treatment/adult-](http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional/allpages)

[non-hodgkins/healthprofessional/allpages](http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional/allpages). Accessed July 15, 2010.

³³ National Cancer Institute. *Adult non-Hodgkin lymphoma treatment (PDQ®): health professional version*. Modified July 8, 2010. <http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional/allpages>. Accessed July 15, 2010.

Harris NL, Jaffe ES, Diebold J, *et al*. World Health Organization classification of neoplastic diseases of the hematopoietic and lymphoid tissues: Report of the clinical advisory committee meeting—Airlie House, Virginia, November 1997. *J. Clin. Oncol.* 1999;17:3835-3849.

³⁴ Kocher DC and Apostoaei JA. *Screening doses for induction of cancers calculated with the Interactive RadioEpidemiologic Program (IREP)*. Fort Belvoir, VA: U.S. Department of Defense, Defense Threat Reduction Agency, March 2007. Technical Report DTRA-TR-07-4.

al.³⁵ and by Boice;³⁶ the NIOSH Annotated Bibliography for CLL;³⁷ the CLL special issue of the *British Journal of Haematology*;³⁸ and the Biological Effects of Ionizing Radiation (BEIR) VII committee.³⁹ NIOSH also compiled information pertinent to developing the new model: Sex and age-specific background incidence rates for CLL from the NCI's Surveillance, Epidemiology, and End Results (SEER) registry for the U.S. population⁴⁰ and from the International Agency for Research on Cancer (IARC) databases for the Japanese population.⁴¹

NIOSH also evaluated epidemiology study data potentially bearing on the issue of latency of CLL,⁴² and created a risk model for CLL by modifying the existing NIOSH-IREP risk model for lymphoma and multiple myeloma⁴³ to include an extended latency period. Use of the lymphoma and multiple myeloma risk models as a starting point was considered appropriate, given the classification of CLL as a form of non-Hodgkin's lymphoma.

The extended latency period for CLL was examined in some detail. After reviewing a number of studies, the midpoint of the latency period for CLL within the draft risk model was set at 15 years, with an uncertainty band of ± 5 years. As with other cancers in the NIOSH-IREP model, the risk of developing CLL is considered to be very low for short times after exposure with

the magnitude of the risk increasing by an adjustment factor that confers the maximum risk value at 20 years post-exposure.

A draft report entitled "Development of a Risk Model for Chronic Lymphocytic Leukemia," which includes NIOSH's analysis of the literature along with the justification for the proposed model, was provided to four subject matter experts for review in 2009.⁴⁴ Two of the four individuals previously were asked to provide their judgment regarding the evidence of radiogenicity of CLL in 2004. NIOSH received comments on many substantive issues with regard to CLL, including the potential radiogenicity of CLL; implications of reclassification as an NHL; the appropriateness of using the NIOSH-IREP lymphoma and multiple myeloma model for CLL; the appropriateness of extended latency for CLL; and a number of additional issues pertinent to this rulemaking. NIOSH addressed these comments in a report available in the regulatory docket for this rulemaking. The comments resulted in one major modification to the proposed risk model: The shortening of the midpoint of the latency period for CLL from 15 to 10 years, while maintaining the uncertainty in the midpoint at ± 5 years.⁴⁵

The CLL risk model was quantitatively tested by calculating probability of causation results for males between 20 and 40 years of age hypothetically exposed to 1 Sievert (Sv) of high-energy gamma radiation. Although the evaluations were restricted to exposures to males, the results for women are very similar, because the same risk coefficient is used and the age-specific incidence patterns in Japanese women and U.S. women are similar. The results of these evaluations indicate that the probability of causation exceeds 50 percent only at the 99th percentile, and then only for times since exposure greater than 15 years for men initially exposed at age 20. Doses higher than 1 Sv will be required to produce 99th percentile values of probability of causation that equal or exceed a value of 50 percent for older ages at time of exposure or at time of diagnosis.

CLL is considered a disease that originates from a population of antigen-selected, mature B lymphocytes. As such, these cells could potentially

undergo transformation to CLL clones anywhere within the hematopoietic or lymphatic system, thus complicating the reconstruction of the radiation dose to the target organ. This is particularly problematic for reconstructing doses due to internally deposited radionuclides, because the radiation dose in this case is most often not homogeneously distributed within the body. To resolve this issue, NIOSH proposes to use a probabilistic approach to dose reconstruction where the radiation dose to the B lymphocytes is a weighted average, based on the dose to a given site and the probability that a B cell precursor for CLL will occupy that site. A document that provides the scientific basis for this approach to reconstruction of dose has been prepared by NIOSH and is included in the NIOSH Docket for this rulemaking.

C. Purpose of the Rule

The purpose of this rule is to provide for coverage of CLL under part B of EEOICPA. Presently, the probability of causation guidelines at 42 CFR part 81 designate CLL as non-radiogenic and require DOL to assign a probability of causation to CLL of zero, when presented in a claim for compensation under part B of EEOICPA. This proposed revision would remove the designation of CLL under § 81.30 of the guidelines. In concert with this change, NIOSH would add a CLL risk model to NIOSH-IREP and DOL would refer CLL claims under part B of EEOICPA to NIOSH for dose reconstructions, to be followed by determinations of probability of causation by DOL under these revised guidelines.

D. Technical Review by the Advisory Board on Radiation and Worker Health

EEOICPA required that HHS obtain a technical review by the Advisory Board on Radiation and Worker Health (the Board) prior to establishing the probability of causation guidelines to be amended through this rulemaking.⁴⁶ HHS interprets this requirement also to apply to any revisions HHS would make to these guidelines. Hence, HHS will obtain a technical review by the Board and consider the findings of this review in promulgating the final regulation.

III. Summary of Proposed Rule

The proposed rule would remove § 81.30 of 42 CFR part 81 thus rescind the designation of CLL as a non-radiogenic cancer under this part. The effect of this rescission would be that a qualified claim for CLL under part B of EEOICPA would be referred by DOL to

³⁵ Richardson DB, Wing S, Schroeder, J, et al. Ionizing radiation and chronic lymphocytic leukemia. *Environ. Health Persp.* 2005;113:1-5.

³⁶ Boice, JD. *Reconsideration of chronic lymphocytic leukemia for purposes of compensation.* Report submitted to NIOSH, January 7, 2005.

³⁷ Silver SR, Hiratzka SL, Schubauer-Berigan MK, Daniels RD. Chronic lymphocytic leukemia: A systematic review. *Cancer Causes Control.* 2007;18:1077-1093.

³⁸ CLL special issue of *British Journal of Haematology.* December 2007;135:629-848.

³⁹ National Research Council, Board on Radiation Effects Research. *Health risks from exposure to low levels of ionizing radiation: BEIR VII Phase 2.* The National Academies Press, Washington, DC, 2006.

⁴⁰ National Cancer Institute. *Surveillance Epidemiology and End Results (SEER) Program.* <http://seer.cancer.gov>. Accessed July 15, 2010.

⁴¹ Parkin DM, Whelan SL, Ferlay J, Raymond L, Young J (eds.). *Cancer incidence in five continents, Volume VII.* Lyon, France: World Health Organization, International Agency for Research on Cancer, 1997. IARC Scientific Publication No. 143.

⁴² See Appendix C, Assessment of potential latency for incidence of CLL, lymphomas, and multiple myeloma, in *Development of a risk model for chronic lymphocytic leukemia for NIOSH-IREP.* January 5, 2010. A copy of this report is available in the docket for this rulemaking.

⁴³ Land CE, Gilbert ES, Smith JM, et al. *Report of the NCI-DC Working Group to revise the 1985 NIH radioepidemiological tables.* Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, 2003. NIH Publication No. 03-5387.

⁴⁴ The names of experts whose opinions were solicited, the request, and the responses from these experts are included in the NIOSH Docket for this rulemaking.

⁴⁵ NIOSH, Office of Compensation Analysis and Support (OCAS). *Response to review comments on draft report: Development of a CLL risk model for NIOSH-IREP.* December 1, 2009.

⁴⁶ 42 U.S.C. 7384n(c).

NIOSH for radiation dose reconstruction and, upon completion of the dose reconstruction, DOL would determine the probability of causation and complete the adjudication of the claim on that basis. Presently, such claims are not referred to NIOSH for dose reconstruction, since under the current language of § 81.30(a), DOL is required to assign a probability of zero to CLL.

Upon promulgation of the final regulation, DOL would identify open and closed cases (NIOSH estimates the number of closed cases to be about 363) under part B of EEOICPA involving CLL claims and attempt to notify the claimants of the new provision. In addition, NIOSH would assist DOL in identifying active and closed cases involving multiple primary cancers including CLL, to identify those whose outcome might be affected by the new provision. For all cases involving CLL, NIOSH would revise the dose reconstruction to take into account radiation doses relevant to CLL, and DOL would recalculate the probability of causation accordingly.

IV. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The rule is consistent with the requirements of 42 U.S.C. 7384n(c). The rule does not interfere with State, local, or Tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in § 3(f)(1) of E.O. 12866. CLL is a rare cancer, with a lifetime risk of 0.48 percent; according to data provided by NCI, an estimated 1.1 percent of all cancers will be CLL.⁴⁷ This low risk

among the U.S. population, coupled with the weak evidence for CLL's radiogenicity, indicates DOL is unlikely to receive a substantial volume of claims for CLL, thus limiting the administrative expenses associated with such claims and the potential compensation costs. Since 2001, NIOSH has received approximately 33,000 cases⁴⁸ that included all cancers currently covered under EEOICPA; given that an estimated 1.1 percent of all cancers occurring among adults are CLL, NIOSH estimates that approximately 363 of those cases would have sought compensation for CLL. NIOSH also receives an average of 200 new cases per month from DOL, and therefore estimates an expected total of 12,000 cases over the next 5 years; based on the 1.1 percent incidence rate, NIOSH estimates that approximately 132 of those cases will seek compensation for CLL. The Agency expects to review the 363 reopened cases plus 132 new CLL cases in the first 5 years after promulgation of this rule—a total of approximately 99 CLL cases per year for the first 5 years. The estimated cost to NIOSH of conducting dose reconstructions is \$12,000 per reconstructed case (\$1,188,000 per year); DOL estimates its direct cost per adjudicated case to be about \$8,000 (\$792,000 per year); and DOE estimates its cost per case to be \$198 per each DOL request for employment verification, and \$372 for responding to each NIOSH request for exposure data (\$56,430 per year). In sum, NIOSH estimates the administrative costs to the three Federal agencies associated with CLL cases to be \$2,036,430 per year.

Based on our knowledge of the exposure potential for the claimant population and the probability of causation guidelines discussed above, NIOSH expects that approximately 30 percent of CLL cases—30 cases per year—will result in compensation. Compensated claimants receive \$150,000 plus medical expenses, which are estimated to cost about \$20,000 per year (costs tend to be higher in the first year of treatment, but benefits are payable only from the date of filing a claim, and most claimants have already begun treatment by that time). The financial award granted to successful claimants comes directly from the U.S. Treasury's Energy Employees Occupational Illness Compensation Fund (42 U.S.C. 7384f); NIOSH estimates that annual compensation will

risk (percent) of being diagnosed with cancer by site and race/ethnicity: both sexes, 17 SEER areas, 2005–2007.

⁴⁸ This figure represents the number of individual cases requiring dose reconstruction that have been forwarded to NIOSH by DOL.

amount to \$5,100,000. In total, this rule is estimated to cost the Federal government (the three Federal agencies plus the U.S. Treasury) \$7,136,430 per year, or just over 7 percent of the established \$100 million annual threshold for economic significance.⁴⁹

There are no feasible alternatives to this regulatory action. OMB has reviewed this probability of causation rule for consistency with the President's priorities and the principles set forth in E.O. 12866 and E.O. 13563.

B. 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, small governmental units, and small not-for-profit organizations. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The rule affects only DOL, DOE, HHS, and certain individuals covered by EEOICPA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

C. 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 10 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 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 at 20 CFR part 30. Thus, HHS has determined that the PRA does not apply to this rule.

⁴⁹ NIOSH further estimates the upper bounds of potential costs associated with CLL compensation. To address any potential uncertainty in the incidence estimate, multiplying by a factor of 2 will increase the CLL incidence rate from 1.1 percent to 2.2 percent. Doing so will result in a total of 990 cases, or 198 CLL cases per year for the first 5 years. Reconstructing 198 cases per year will likely cost NIOSH \$2,376,000 per year, DOL \$1,584,000 per year, and DOE \$112,860 per year for an estimated total cost to the 3 Federal agencies of \$4,072,860. With an incidence rate of 2.2 percent, NIOSH predicts that 30 percent, or 60 cases, will be compensated. Given an award of \$150,000 per case plus medical expenses, NIOSH estimates that the rule will result in compensation of \$10,200,000. In total, NIOSH estimates that this rulemaking will cost the Federal government no more than \$14,272,860 annually.

⁴⁷ National Cancer Institute. SEER Cancer Statistics Review 1975–2007; Table 1.14. *Lifetime*

D. 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.

E. 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, adjusted annually for inflation. For 2010, the inflation adjusted threshold is \$135 million.

F. 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.

G. 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.”

H. 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.

I. 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.

J. 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 proposed rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 81

Cancer, Government employees, Occupational safety and health, Nuclear materials, Radiation protection, Radioactive materials, Workers’ compensation.

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

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

Subpart E—Guidelines To Estimate Probability of Causation

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

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

§ 81.30 [Removed]

2. Remove § 81.30.

Dated: December 9, 2010.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix A

CHRONOLOGY OF CLL-RELATED ACTIVITIES INITIATED BY NIOSH

Date	Description
May 2002	NIOSH publishes Probability of Causation Rule (42 CFR part 81), excluding CLL for eligibility under EEOICPA. CLL is the only type of cancer granted an <i>a priori</i> probability of causation of 0%.
July 2004	Based on direction from the U.S. Congress, the NIOSH Occupational Energy Research Program convenes a public meeting in Washington, DC to: (1) discuss available research strategies for investigating the potential relationship between the incidence of CLL and worker exposures to ionizing radiation and (2) identify gaps in the current research.
September–October 2004	The NIOSH Office of Compensation Analysis and Support (now the Division of Compensation Analysis and Support (DCAS)) recruits five outside experts, not affiliated with NIOSH, to evaluate if: the evidence of an association, or lack thereof, between radiation exposure and the risk of developing CLL [is] sufficient to continue to regard CLL as a non-radiogenic cancer and to continue to exclude it, <i>a priori</i> , from eligibility for compensation under EEOICPA.
November 2004–January 2005	NIOSH receives opinions on the radiogenicity of CLL from outside experts regarding and prepares summaries.
July 2005	Because the opinion of a majority of subject experts is that CLL should not continue to be excluded from eligibility of compensation under EEOICPA, NIOSH begins the development of a model capable of quantifying the risk of developing CLL as a consequence of exposure to ionizing radiation.

CHRONOLOGY OF CLL-RELATED ACTIVITIES INITIATED BY NIOSH—Continued

Date	Description
August 2005–June 2009	NIOSH conducts research into an appropriate risk model for CLL, including selection of the appropriate target organ and methodology for reconstructing dose.
July 2009	NIOSH completes draft report that describes the CLL risk model (and the scientific rationale behind it) and recruits four subject matter experts to review the draft model.
September–August 2009	NIOSH receives subject matter expert comments on the draft CLL risk model.
January 2010	NIOSH addresses subject matter expert comments on the CLL risk model and finalizes the risk model.

[FR Doc. 2011–6329 Filed 3–18–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 110218148–1169–01]

RIN 0648–BA83

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Golden Crab Fishery Off the Southern Atlantic States; Control Date

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Advanced notice of proposed rulemaking; consideration of a control date.

SUMMARY: NMFS announces that it is establishing a control date of December 7, 2010, to control future access to the golden crab fishery operating in the exclusive economic zone (EEZ) of the South Atlantic. If changes to the management regime are developed and implemented under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), a control date could be used to limit the number of participants in the fishery. This announcement is intended, in part, to promote awareness of the potential eligibility criteria for future access so as to discourage speculative entry into the fishery while the South Atlantic Fishery Management Council (Council) and NMFS consider whether and how access to the golden crab fishery should be controlled.

DATES: Written comments must be received on or before 5 p.m., local time, April 20, 2011.

ADDRESSES: You may submit comments, identified by 0648–BA83, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the

Federal eRulemaking Portal <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* Attn: Karla Gore 727–824–5305.
- *Mail:* Karla Gore, NMFS Southeast Regional Office, Sustainable Fisheries Division, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, *etc.*) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

To submit comments through the Federal e-rulemaking portal <http://www.regulations.gov>, enter “NOAA–NMFS–2011–0044” in the keyword search, then check the box labeled “Select to find documents accepting comments or submissions”, then select “Send a comment or submission”. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council; toll free 1–866–SAFMC–10 or 843–571–4366; kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: At their December 2010 meeting, the Council recommended a control date of December 7, 2010, for the golden crab fishery. The Council manages golden crab under the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region. The control date would apply to persons who are contemplating entering the golden crab fishery in the EEZ of the South Atlantic region. If adopted, a control date would be established for the golden crab fishery. The Council requested that this control date be published in the **Federal Register** to notify fishermen that if they

enter such a fishery after December 7, 2010, they may not be assured of future access if the Council and/or NMFS decide to limit entry or impose other measures to manage these fisheries.

Establishment of the control date would allow the Council to evaluate the level of participation in the subject fishery and address any level of overcapacity. Control dates are intended to discourage speculative entry into a fishery, as new entrants entering the fishery after the control date are forewarned that they are not guaranteed future participation in the fishery.

Establishment of this control date does not commit the Council or NMFS to any particular management regime or criteria for entry into the golden crab fishery. Fishermen are not guaranteed future participation in the fishery regardless of their level of participation before or after the control date. The Council may recommend a different control date or it may recommend a management regime that does not involve a control date. Other criteria, such as documentation of landings or fishing effort, may be used to determine eligibility for participation in a limited access fishery. The Council and/or NMFS also may choose to take no further action to control entry or access to the fisheries, in which case the control date may be rescinded. Any action by the Council will be taken pursuant to the requirements for fishery management plan and amendment development established under the Magnuson-Stevens Act.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their participation in the golden crab fishery in the South Atlantic EEZ.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 16, 2011.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2011–6583 Filed 3–18–11; 8:45 am]

BILLING CODE 3510–22–P