these states in the final Transport Rule with respect to the 1997 ozone season NAAQS or finalize ozone season NO_X budgets for these states, but instead published a supplemental notice of proposed rulemaking (SNPR) (76 FR 40662) to provide the public with an opportunity to comment on the conclusion that these states significantly contribute to nonattainment or interfere with maintenance of the 1997 ozone NAAQS in downwind states. EPA finalized the supplemental notice of proposed rulemaking on December 15, 2011, which was published in the **Federal Register** on December 27, 2011 (SNFR) (76 FR 80761). The SNFR found that emissions of NO_X from sources in Iowa, Kansas, Michigan, Missouri, Oklahoma, and Wisconsin either significantly contributed to nonattainment or interfered with maintenance in downwind states. The SNFR also finalized FIPs for Iowa, Michigan, Missouri, Oklahoma, and Wisconsin that required sources within the states to comply with the Transport Rule.[3]

After publication of the final Transport Rule, various parties filed petitions for review of EPA's action in the U.S. Court of Appeals for the District of Columbia Circuit (*EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302 and consolidated cases). On December 30, 2011, upon the motions of various petitioners, the Court ordered the Transport Rule stayed pending the completion of its review.

II. This Notice of Intent

The Court did not explicitly address the effect of its order on the SNFR affecting Iowa, Kansas, Michigan, Missouri, Oklahoma, and Wisconsin. Because the underlying programs of the Transport Rule have been stayed by the Court, there is no practical way for covered sources under the SNFR to comply with those programs. The SNFR employs the same methodology, modeling, and analysis as the final Transport Rule and extends the programs established in the Transport Rule to additional states. The agency will therefore treat the new rule in the same manner as the underlying Transport Rule, which has been stayed. EPA does not expect covered sources under the SNFR to comply with the provisions of that rule for the duration of the Court's stay.

[3] EPA did not finalize a FIP for Kansas. See supra footnote 2.

Dated: January 26, 2012.

Gina McCarthy,

Assistant Administrator.

[FR Doc. 2012–2328 Filed 2–3–12; 8:45 am]

BILLING CODE 6560–50–P

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: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: In a notice of proposed rulemaking published in the **Federal Register** on March 21, 2011, the Department of Health and Human Services (HHS) proposed to treat chronic lymphocytic leukemia (CLL) as a radiogenic cancer under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) (76 FR 15268). Under this final rule, CLL will be treated as being potentially caused by radiation and hence as potentially compensable under EEOICPA. HHS reverses its decision to exclude CLL from such treatment.

DATES: This final rule is effective March 7, 2012.

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 email to *dcas@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

[1] The 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.

I. Public Participation and Technical Review by the Advisory Board on Radiation and Worker Health

On March 21, 2011, HHS published a notice of proposed rulemaking (76 FR 15268), proposing to treat CLL as a radiogenic cancer. HHS initially solicited public comments from March 21, 2011, to June 20, 2011. Upon request, HHS extended the comment period to July 20, 2011 (76 FR 36891, June 23, 2011).

HHS received comments from seven stakeholders, including the Advisory Board on Radiation and Worker Health, which was required by EEOICPA to provide a technical review of a proposed amendment to the probability of causation guidelines.[2] All of the comments offered support for the inclusion of CLL under the coverage provided by EEOICPA. Specifically, the Advisory Board concurred with the NIOSH position that ''given that the law requires the use of the upper 99 percent credibility level in making compensation decisions, the inclusion of CLL despite the limited evidence of radiogenicity, is considered appropriate by NIOSH.'' Furthermore, the Advisory Board agreed that the risk model proposed by NIOSH is based on the best available science and methodological approaches to express the dose-response relationship between radiation exposure and CLL. In addition to the technical review submitted by the Advisory Board, three of the seven comments were personal stories submitted by family members of deceased energy employees who developed CLL, and the remaining three comments argued that to be fair to claimants, CLL should be included as a radiogenic cancer under Part B of EEOIPCA. There were no comments opposing this change.

II. Background

A. Introduction

The Energy Employees Occupational Illness Compensation Program Act of

[2] 42 U.S.C. 7384n(c)(2), 7384o(b)(1).

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.

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. The guidelines are published in 42 CFR part 81, and 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. The guidelines being amended by this final rule designate CLL as non-radiogenic, and hence had required 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.

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

In the March 21, 2011, notice of proposed rulemaking, NIOSH discussed the results of a panel convened in 2005 to provide judgment on evidence of an association between exposure to ionizing radiation and the risk of developing CLL, and whether CLL should continue to be excluded from eligibility for compensation under EEOICPA (76 FR 15268, 15269–70). NIOSH also discussed four subject matter expert reviews, conducted in 2009, of a draft report of the CLL risk model (76 FR 15268, 15270–71).

NIOSH's recent review found the evidence of radiogenicity offered by epidemiology studies to be non-determinative. NIOSH weighed the non-determinative epidemiologic evidence, along with other factors that included: (1) The mechanistic argument for CLL causation; (2) the similarities between CLL and other compensated cancers; (3) the classification of CLL by the World Health Organization and the National Cancer Institute as a form of non-Hodgkin's lymphoma; and (4) the treatment of CLL as a potentially-compensable radiogenic cancer by the U.S. Department of Veterans Affairs. Upon review of these facts, the Agency no longer believes that it is possible to state that the probability of causation for CLL equals zero. Because NIOSH finds sufficient evidence to include CLL as a compensable cancer under EEOICPA, claimants with CLL will be eligible for dose reconstruction under EEOICPA.

The notice of proposed rulemaking also discussed NIOSH's efforts to develop a quantitative radiation risk model for CLL.

C. Purpose of the Rule

The purpose of this rule is to provide for coverage of CLL under part B of EEOICPA. This revision removes sec. 81.30 from the probability of causation guidelines. CLL is considered radiogenic for the purposes of this compensation program; DOL will no longer be required to assign a probability of causation for CLL of zero, when presented with a claim for dose reconstruction under part B of EEOICPA. In concert with this change, NIOSH adds a CLL risk model to NIOSH–IREP and DOL will 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.

III. Summary of Final Rule

This final rule removes 42 CFR 81.30 from part 81, thus rescinding the designation of CLL as a non-radiogenic cancer under this part. The effect of this rescission will be that a qualified claim for CLL under part B of EEOICPA will be referred by DOL to NIOSH for radiation dose reconstruction and, upon completion of the dose reconstruction, DOL will 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 language of sec. 81.30, DOL was required to assign a probability of zero to CLL.

Upon promulgation of this final regulation, DOL will 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 will 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 will revise the dose reconstruction to take into account radiation doses relevant to CLL, and DOL will 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 sec. 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 sec. 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.[3] This low risk

[3] National Cancer Institute. SEER Cancer Statistics Review 1975–2007; Table 1.14. Lifetime risk (percent) of being diagnosed with cancer by site and race/ethnicity: both sexes, 17 SEER areas, 2005–2007.

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 cases [4] 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 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.[5]

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.

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.''

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

[5] 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 98 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.

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 final 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 amends 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: October 21, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–2527 Filed 2–3–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF AGRICULTURE

48 CFR Part 422

RIN 0599–AA19

Office of Procurement and Property Management; Agriculture Acquisition Regulation, Labor Law Violations; Withdrawal

AGENCY: Office of Procurement and Property Management, Departmental Management, Department of Agriculture.

ACTION: Direct Final rule; withdrawal.

SUMMARY: Due to the receipt of an adverse comment, the Office of Procurement and Property Management (OPPM) of the Department of Agriculture (USDA) is withdrawing the December 1, 2011, (76 FR 74722) direct final rule adding a new clause to the Agriculture Acquisition Regulation at subpart 422.70 entitled ''Labor Law Violations'' that would have a contractor certify upon accepting a contract that it is in compliance with all applicable labor laws and that, to the best of its knowledge, its subcontractors of any tier, and suppliers, are also in compliance with all applicable labor laws. The Department stated that in the event of an adverse comment being received by January 30, 2012, the direct final rule would be withdrawn in part or in whole. On January 27, 2012, USDA received a comment. USDA interprets this comment as adverse and, therefore, USDA is withdrawing the direct final rule.

DATES: As of February 6, 2012, the direct final rule published on December 1, 2011, at 76 FR 74722, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Donna Calacone, Office of Procurement and Property Management, at (202) 205–4036 or by mail at OPPM, Mail Stop 9306, U.S. Department of Agriculture, 300 Seventh Street SW., Washington, DC 20024–9306. Please cite ''48 CFR 422 Direct Final Rule'' in all correspondence.

SUPPLEMENTARY INFORMATION: USDA is withdrawing its direct final rule published on December 1, 2011 (76 FR 74722), entitled ''Agriculture Acquisition Regulation, Labor Law Violations,'' as USDA received an adverse comment. This document officially withdraws the direct final rule.

List of Subjects in 48 CFR Part 422

Classified information, Computer technology, Government procurement, Reporting and recordkeeping requirements.

Signed in Washington, DC, on February 1, 2012.

Jodey Barnes-Edwards,

Acting Director, Office of Procurement and Property Management.

[FR Doc. 2012–2638 Filed 2–1–12; 4:15 pm]

BILLING CODE 3410–98–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 29

[Docket No. FWS–R9–NWRS–2011–0108; FVRS84510900000U2–12X–FF09R50000]

RIN 1018–AU89

Change of Addresses for Regional Offices, Addition of One New Address, and Correction of Names of House and Senate Committees We Must Notify

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Final rule; technical amendment.

SUMMARY: We, the U.S. Fish and Wildlife Service (we, or the Service), are revising our rights-of-way (ROW) general regulations, to update or add addresses of several Service Regional Offices, and to correct the names of the House and Senate Committees we must notify upon receipt of an application for a right-of-way for an oil and gas pipeline that is 24 inches or more in diameter and again before granting a right-of-way.

DATES: This rule is effective on February 6, 2012.

ADDRESSES: Chief, Division of Realty, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 622, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Janet Bruner, (703) 358–2287.

SUPPLEMENTARY INFORMATION: We are revising our ROW general regulations at 50 CFR part 29, which prescribe the procedures for filing applications for ROWs over and across Service-administered lands and the terms and conditions under which we grant these ROWs, to update or add addresses of several Service Regional Offices and to correct the names of the House and Senate Committees we must notify upon receipt of an application for a right-of-way for an oil and gas pipeline that is 24 inches or more in diameter and again before granting a right-of-way.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable,