

duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution. Respondent agreed to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Changes to the NIOSH-IREP Lung Cancer Risk Model Under the Energy Employees Occupational Illness Compensation Program Act of 2000

Authority: 42 CFR 81.12, 67 FR 22311-22312.

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice for public comment; change to a scientific element underlying the determination of probability of causation under the Energy Employees Occupational Illness Compensation Program Act of 2000.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) has changed a guideline for determining the probability of causation under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) for energy employees with cancers of the lung, trachea, or bronchus. The change affects only the NIOSH-Interactive RadioEpidemiological Program (IREP) cancer risk model termed "Lung (162)." The new guideline, which became effective on February 28, 2006, with the introduction of NIOSH-IREP Version 5.5, requires the use of both a National Institutes of Health (NIH)-IREP lung model implemented by NIH in 2003 and the original NIOSH-IREP lung model implemented by NIOSH in 2002. NIOSH-IREP Version 5.5 calculates separately the probability of causation

produced under each model for each cancer of the lung, trachea, or bronchus. The result from the model that produces the higher probability of causation at the upper 99th percentile credibility limit is reported as the probability of causation result of record for the claim. NIOSH-IREP Version 5.5 also incorporates a bias correction factor for random errors in dosimetry for those energy workers who had not smoked cigarettes ("never smokers") and who were exposed to radon. This correction was previously applied to smokers, but had been inadvertently omitted for never smokers. These changes may result in the Department of Labor (DOL) calculating higher probability of causation determinations for select cases of cancer of the lung, trachea, or bronchus among previously decided and current EEOICPA cancer claims. The changes cannot result in any lower probability of causation determinations. Although this change to the NIOSH-IREP lung cancer risk model took effect February 28, 2006, NIOSH will fully consider all comments received regarding this change and may reconsider this change or consider further revisions to the lung cancer risk model based on public comment.

DATES: NIOSH must receive public comments on this change on or before May 23, 2006.

ADDRESSES: Comments may be submitted by mail or e-mail. Mail comments concerning this change to Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, Mailstop C-46, Cincinnati, OH 45226. Submit electronic comments, titled "NIOSH-IREP Lung Cancer Model", to OCAS@CDC.GOV.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, Mailstop C-46, Cincinnati, OH 45226, Telephone: (513) 533-6800 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Solicitation of Public Comments

NIOSH invites public comments on this change to the NIOSH-IREP lung cancer risk model. NIOSH will fully consider comments received regarding this change and, based on such comments, may reconsider this change or consider further revisions to the lung cancer risk model, as appropriate. Additional details regarding this change to NIOSH-IREP, including PDF copies of all relevant documents provided to

the Advisory Board on Radiation and Worker Health, can be accessed via the NIOSH/OCAS "Probability of Causation—NIOSH-IREP" Web page at <http://www.cdc.gov/niosh/ocas/ocasirep.html>.

II. Summary of Changes to the Guidelines for Determining Probability of Causation for Cancers of the Lung, Trachea, or Bronchus as Effected in the February 28, 2006, Implementation of NIOSH-IREP Version 5.5

Under HHS regulations at 42 CFR part 81, NIOSH developed and maintains NIOSH-IREP. This computerized set of cancer risk models is used by DOL to calculate the statistical probability that the cancer or cancers of an energy employee covered under EEOICPA were at least as likely as not caused by exposure to ionizing radiation incurred by the employee while in the performance of duty for U.S. nuclear weapons programs.

HHS regulations also provide for NIOSH to add, modify, or replace cancer risk models as necessary on the basis of new evidence and/or improved scientific understanding. Accordingly, on February 28, 2006, NIOSH modified its cancer risk model "Lung (162)" to incorporate new evidence concerning the radiogenicity of lung cancer and its relationship with cigarette smoking and to make a minor technical correction concerning radon exposure.

NIOSH evaluated new interpretations of the interaction between cigarette smoking and ionizing radiation and the effects of age at exposure and age at diagnosis with respect to the development of cancers of the lung, trachea, or bronchus. In conjunction with this evaluation, NIOSH also reviewed a new lung cancer risk model implemented in 2003 by the National Cancer Institute for use in a separate version of IREP known as "NIH-IREP" and compared it to the model in NIOSH-IREP.

The NIH lung cancer risk model relies less on a multiplicative interaction than does the NIOSH model to account for the interaction between cigarette smoking and ionizing radiation in the development of lung cancer. The NIH model also adjusts risk for age at exposure and age at diagnosis, whereas the NIOSH model does not take into account these age-dependent factors. In terms of probability of causation, the NIH model is generally more favorable to smokers for some exposure profiles than the NIOSH model, whereas the NIOSH model is generally more favorable to nonsmokers for some exposure profiles. Other probability of causation calculation differences

between the models vary with the circumstances of each individual claim and are more difficult to generalize. In summary, however, the same inputs entered into NIH-IREP and the previous version of NIOSH-IREP for a cancer of the lung, trachea, or bronchus could produce different probabilities of causation for some exposure profiles.

The NIOSH review also included consideration of recommendations submitted by four internationally-recognized outside experts. The experts recruited by NIOSH were: David J. Brenner, PhD, Professor of Radiation Oncology and Public Health, Columbia University School of Public Health; Faith G. Davis, PhD, Professor of Epidemiology and Biostatistics, University of Illinois at Chicago, School of Public Health; David B. Richardson, PhD, Assistant Professor of Epidemiology, University of North Carolina School of Public Health; and Jonathan M. Samet, MD, MS, Professor and Chairman, Department of Epidemiology, Johns Hopkins University School of Public Health. Each expert reviewed the issue independently, considering the appropriateness of the NIOSH and NIH models and any alternatives to the use of these models. The only general consensus among all four reviewers was that none recommended the exclusive retention of the NIOSH lung model. Beyond this, there was a diversity of opinion as to how to properly characterize and model the interaction between cigarette smoking and ionizing radiation.

In accordance with the experts' opinions, NIOSH concluded that the current state of scientific knowledge does not support the exclusive use of either of the two IREP lung cancer risk models, and that the most reasonable option within the context of compensation was to reprogram NIOSH-IREP to run both the NIOSH and the NIH lung cancer risk models separately for each relevant EEOICPA case, and then to select the model that produces the higher probability of causation result for application to the case. The programming was accomplished and implemented on February 28, 2006, with the installation of NIOSH-IREP Version 5.5, which replaced NIOSH-IREP Version 5.4.

NIOSH-IREP Version 5.5 also incorporates a bias correction factor in the NIOSH lung model for random errors in dosimetry for "never smokers" who were exposed to radon. Due to a programming oversight, this correction had been inadvertently omitted for never smokers and was applied only to smokers in earlier versions of NIOSH-

IREP. NIOSH-IREP Version 5.5 corrects this error.

The changes introduced in NIOSH-IREP Version 5.5 on February 28, 2006, pertain only to the NIOSH-IREP cancer risk model termed "Lung (162)" and apply only to cancers of the lung, trachea, or bronchus. NIOSH will review all relevant previously completed claims that have not been compensated to identify those for which the new guidelines are applicable, and will re-evaluate the claims using the new guidelines. NIOSH will also apply the new guidelines to all currently active claims and any future cases. Application of these new guidelines may result in DOL calculating higher probability of causation determinations for select lung, trachea, or bronchus cases among previously decided and current EEOICPA cancer claims. As noted above, the changes cannot result in any lower probability of causation determinations.

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

Under 42 CFR 81.12, NIOSH is required to obtain the review of the Board before making changes to NIOSH-IREP that would have a substantial effect on probability of causation calculations. NIOSH notified the Advisory Board on Radiation and Worker Health (ABRWH) of its intent to re-evaluate the NIOSH-IREP lung cancer risk model and to review the NIH-IREP lung cancer risk model as a possible alternative model during a meeting of the Board on December 15, 2004. After the NIOSH review and evaluation was completed, NIOSH presented information describing and proposing the current NIOSH-IREP change to the Board, including a summary of the NIOSH evaluation and the expert reviews discussed above. The Board considered the change and voted unanimously to support it during the October 19, 2005, meeting of the Board in Knoxville, Tennessee. The motion to support the change included a provision that NIOSH should revisit the issue in approximately one year to determine if new evidence might warrant consideration of a single lung cancer risk model.

The Director, National Institute for Occupational Safety and Health (NIOSH), has been delegated the authority to sign **Federal Register** notices for CDC that pertain to NIOSH programmatic matters.

Dated: March 17, 2006.

John Howard,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control; Special Emphasis Panel: Centers for Agricultural Disease and Injury Research, Education and Prevention, Program Announcement Number 06-057

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Centers for Agricultural Disease and Injury Research, Education and Prevention, Program Announcement Number 06-057.

Times and Dates: 8 a.m.-5 p.m., May 1, 2006 (Closed).

8 a.m.-5 p.m., May 2, 2006 (Closed).

8 a.m.-5 p.m., May 3, 2006 (Closed).

8 a.m.-5 p.m., May 4, 2006 (Closed).

8 a.m.-5 p.m., May 5, 2006 (Closed).

Place: Residence Inn, 1456 Duke Street, Alexandria, VA 22314 telephone 703-548-5474.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Centers for Agricultural Disease and Injury Research, Education and Prevention, Program Announcement Number 06-057.

For Further Information Contact: Steve Olenchock, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, MS 1119, Morgantown, WV 26505, Telephone 304-285-6271.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.