

Dated: January 17, 2006.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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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 Dose Reconstruction Target Organ Selection for Lymphoma Under the Energy Employees Occupational Illness Compensation Program Act of 2000

Authority: 42 CFR 82.32, 67 FR 22335-22336.

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of a Change to a Scientific Element Underlying Radiation Dose Reconstructions under the Energy Employees Occupational Illness Compensation Program Act of 2000.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) has changed the selection of target organs used in dose reconstructions NIOSH produces under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) for energy employees with lymphoma cancers. This change responds to an evaluation by NIOSH of current scientific data on lymphoma, which revealed that the site of the radiation injury can differ from the site of the tumor or cancer origin documented in the medical files of a lymphoma cancer patient. The new process for selecting dose reconstruction target organs for energy employees with lymphoma cancers includes selecting the target organ that would have received the highest radiation dose from among relevant, possibly irradiated organs, as determined through the dose reconstruction process, when the identity of the target organ is in question. This change may result in the Department of Labor calculating higher probability of causation determinations for select lymphoma cases among previously decided and current EEOICPA cancer claims.

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. Summary of Public Comments

NIOSH accepted public comments on this proposed change to NIOSH dose reconstruction methods from January 19, 2006, through February 3, 2006. NIOSH received 15 comments from individuals.

Nine comments expressed support for the new lymphoma procedure, predicated on the condition that it improves chances of compensation being granted.

One comment objected to the different treatment of "structural" lymphomas (i.e., Hodgkin's disease, lymphosarcoma, reticulosarcoma, etc.) versus non-Hodgkin's and other lymphomas. A NIOSH scientist contacted the commenter and explained the technical basis for these distinctions, which in summary is that tumor location is informative of the site of radiation injury for such structural lymphomas. Upon this explanation, the commenter concurred with the procedure as proposed by NIOSH.

Five comments concerned individual claims for compensation rather than the new lymphoma procedure.

II. Summary of Recommendations of the ABRWH

The Advisory Board on Radiation and Worker Health (ABRWH) discussed the change and voted unanimously to support it during a teleconference meeting of the Board on January 9, 2006.

III. Summary of the Changes to the Dose Reconstruction Target Organ Selection for Lymphoma

NIOSH conducts radiation dose reconstructions under EEOICPA in compliance with the dose reconstruction methods specified in HHS regulations at 42 CFR part 82. These regulations provide for NIOSH to update its dose reconstruction methods as necessary on the basis of improved scientific understanding and specify a process for deciding and implementing such updates. 42 CFR 82.30-82.33. Accordingly, NIOSH has updated its method for reconstructing radiation doses in cases involving certain lymphoma cancers. Specifically, NIOSH has changed its method for identifying the target organ for which radiation doses will be reconstructed in these cases, for the reasons described below. As required for certain updates in dose reconstruction methods, NIOSH presented the proposed change to the ABRWH prior to implementation. NIOSH has also considered all public

comments concerning this change that were received prior to the comment deadline, as specified above.

NIOSH has re-examined the appropriateness of the current method of selecting dosimetry target organs for lymphoma cases in light of the current scientific knowledge on the diagnosis and etiology of the various forms of lymphoma.¹ This re-examination has revealed that for many non-Hodgkin's lymphomas, there were two problems with NIOSH's previous target organ selection method. First, the site of occurrence of the tumor is not necessarily the site of the original radiation injury. Second, the site listed in the diagnosis may not actually be the site of primary involvement. Rather, it is common to list the site of the biopsy, which may be selected on the basis of medical considerations in terms of the clinical symptoms and condition of the patient and the ease of surgical access. Both of these problems contributed to the possibility that under the previous method for select lymphoma cases, NIOSH could not be certain its dose reconstruction was based on the biologically plausible organ with the highest radiation dose.

As a result of this re-evaluation, NIOSH has modified the selection of target organs in select lymphoma cases so that the organ that would have received the highest radiation dose from among relevant, possibly irradiated organs, as determined through the dose reconstruction process, is used in the dose reconstruction. For the subset of lymphomas where tumor location is informative about the probable site of original radiation injury (e.g. Hodgkin's disease, lymphosarcoma, etc.), the information related to the site of diagnosis will be considered in target organ selection.

This change pertains only to the selection of the appropriate target organ as the site of radiation injury (i.e., for calculation of effective radiation dose during the dose reconstruction process). It has no bearing on the selection of the appropriate Interactive Radiological Epidemiology Program (IREP) cancer risk model for determining probability

¹ Crowther, M. Consultant's Report, Dose Reconstruction Project. Prepared for the National Institute for Occupational Safety and Health Office of Compensation Analysis and Support. 2005; Eckerman, K.F. Target Organs for Lymphatic and Hematopoietic Cancers Comments/Suggestions. Prepared for the National Institute for Occupational Safety and Health Office of Compensation Analysis and Support. 2005. Available online at: <http://www.cdc.gov/niosh/ocas/ocasdose.html> (1). Evaluation of Target Organ for Lymphomas; note, this information can be found under the "Miscellaneous Items" section on this page).

of causation, nor does it impact the cancer risk models themselves.

This change in NIOSH dose reconstruction methods is likely to have a substantial effect on certain EEOICPA cancer cases involving lymphomas. NIOSH will review all relevant previously completed dose reconstructions for cases that have not been compensated to identify those for which this new method is applicable, and will re-complete these dose reconstructions using this new method. NIOSH will also apply this new method in dose reconstructions for all currently active lymphoma claims and any future cases. Application of this new method may result in the Department of Labor calculating higher probability of causation determinations for select lymphoma cases among previously decided and current EEOICPA cancer claims.

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: February 8, 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 Panels (SEP): Developing Methodologies To Determine the Prevalence of Autism Spectrum Disorders in Early Childhood and Young Adult Populations, RFA DD-06-001

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): Developing Methodologies to Determine the Prevalence of Autism Spectrum Disorders in Early Childhood and Young Adult Populations, RFA DD-06-001.

Time and Date: 8 a.m.-5 p.m., March 15, 2006 (Closed).

Place: Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Building 19, Room 254/255, Atlanta, GA 30333, Telephone Number 404-639-3138.

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: Developing Methodologies to Determine the Prevalence of Autism Spectrum Disorders in Early Childhood and Young Adult Populations, RFA DD-06-001.

For More Information Contact: M. Chris Langub, Ph.D., Scientific Review Administrator, Office of Public Health Research, CDC, 1600 Clifton Road, NE., Mailstop D-72, Atlanta, GA 30333, Telephone 404-639-4640.

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.

Dated: February 9, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: National Child Abuse and Neglect Data System.

OMB No.: 6980-0229.

Description: The Administration on Children, Youth and Families established the National Child Abuse and Neglect Data System (NCANDS) to respond to the 1988 and 1992 amendments (Pub. L. 100-294 and Pub. L. 102-295) to the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 *et seq.*), as amended, which called for the creation of a coordinated national data collection and analysis program, both universal and case-

specific in scope, to examine standardized data on false, unfounded, or unsubstantiated reports. In 1988, ACYF embarked on a collaborative effort with the States to develop a voluntary national data collection and analysis program to collect, compile, and make available State child abuse and neglect reporting information from Child Protective Services agencies in the 50 States, the District of Columbia, and the territories. The first request for annual data was in July 1991. Data collection has continued on an annual basis. The Children's Bureau is currently preparing the 15th annual report based on the NCANDS date.

In 1996, the Child Abuse Prevention and Treatment Act was amended by Public Law 104-235 to require that any State receiving the Basic State Grant work with the Secretary of the Department of Health and Human Services (HHS) to provide specific data on child maltreatment to the extent practicable. The legislation specified the following data elements:

- (1) The number of children who were reported to the State during the year as abused or neglected.
- (2) Of the number of children described in paragraph (1), the number with respect to whom such reports were—
 - (A) Substantiated;
 - (B) Unsubstantiated; or
 - (C) Determined to be false.
- (3) Of the number of children described in paragraph (2)—
 - (A) The number who did not receive services during the year under the State program funded under this section or an equivalent State program;
 - (B) The number who received services during the year under the State program funded under this section or an equivalent State program; and
 - (C) The number who were removed from their families during the year by disposition of the case.
- (4) The number of families who received preventive services from the State during the year.
- (5) The number of deaths in the State during the year resulting from child abuse or neglect.
- (6) Of the number of children described in paragraph (5), the number of such children who were in foster care.
- (7) The number of Child Protective Services workers responsible for the intake and screening of reports filed in the previous year.
- (8) The agency response time with respect to each such report with respect to initial investigation of reports of child abuse or neglect.
- (9) The response time with respect to the provision of services to families and children where an allegation of abuse or neglect has been made.
- (10) The number of Child Protective Services workers responsible for intake, assessment, and investigation of child abuse