



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

GEORGE ANASTAS, CHP

President

7007 Wyoming Blvd, NE: Suite F-2

Albuquerque, NM 87109

Tel: (505) 828-1003

Fax: (505) 828-1062

Email: anastas@eeg.org

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CDC/NIOSH Docket Officer
CDC/NIOSH Docket Office
Robert A. Taft Laboratories, M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

VIA e-mail: NIOCINDOCKET@CDC.GOV

Subject: Comments on the Interim Final Rule on Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act as presented in 66 FR 50978 through 50991, October 5, 2001

Dear Sir or Madam:

The Health Physics Society (the Society) is an independent non-profit scientific organization of approximately 6000 professionals who specialize in radiation safety. The Society has an interest in the implementation of the Energy Employees Occupational Illness Compensation Program Act (the Act) and the methods for dose reconstruction used to implement the Act. The Society appreciates the opportunity to participate in this rulemaking. As President of the Society, the following information is provided in response to the Federal Register Notice soliciting comments from interested organizations.

On May 2, 2001, Society President Paul Rohwer provided Mr. L. J. Elliott, Acting Director of the National Institute of Occupation Safety and Health (NIOSH) Office of Compensation Analysis and Support, extensive comments and recommendations regarding the development of guidelines and promulgation of regulations covering: (1) probability of causation; (2) dose reconstruction; and, (3) designation of Special Exposure Cohorts. I am enclosing, for reference, the recommendations and discussions of the items relating to dose reconstruction that were in the attachment to the May 2, 2001, letter. If the comments below do not refer to one of the HPS comments in the enclosure the Society considers the rule has appropriately addressed the comment or the comment is not pertinent to this rule.

This interim rule is to provide methods for determining a reasonable estimate of radiation dose to a covered employee diagnosed with cancer through a dose reconstruction. The October 5, 2001, Federal Register Notice identified three generic topics for comment. Society comments are provided within the context of these three generic topics followed by additional comments that do not directly relate to one of the generic questions.

1) Does the interim rule make appropriate use of current science for conducting dose reconstructions to be used in an occupational illness compensation program?

The interim rule provides the overall approach and structure for dose reconstruction in support of the Act. There is considerable detail in implementing provisions of the rule that is not contained in the rule itself. These implementation details, although not appropriate for inclusion in this rule, are important for evaluating the appropriateness of the use of science in conducting dose reconstructions. Therefore, the following comments are provided with the reservation that these details are not available for review and evaluation.

With regard to this general concern for the implications of the implementation details, this concern could be addressed by adopting Society recommendation I.A.3 in the enclosure. Peer review by expert organizations, such as the National Academies, would include review of the implementation details and their implication on the appropriate use of current science. As noted in the discussion for this recommendation in paragraph I.B.3 of the enclosure, the U. S. General Accounting Office concluded that “an independent review process . . . could mitigate concerns about the integrity of the [dose reconstruction program for atomic veterans].” This conclusion is also valid for the dose reconstruction program under the Act. NIOSH should institutionalize a requirement for a periodic peer review in the rule.

We note that the methodologies of the most recent recommendations of the International Commission on Radiological Protection (ICRP) will be used to estimate internal radiation doses. We recognize the current ICRP recommendations (ICRP 60 and supporting reports) are implemented essentially worldwide, with the exception of in the United States. The fact the United States has not adopted these recommendations should be accommodated in the rule. One accommodation would be by instituting the peer review by U. S. expert groups as recommended above. Another accommodation would be to be very clear the ICRP recommendations being used are only those associated with the metabolic models and radiation weighting factors for calculating equivalent organ dose to the relevant organ(s) for the specific cancer of concern. This would make it clear the organ weighting factors for calculating an effective equivalent dose will not be used, and thus any criticism or concern for the incorporation of non-fatal cancers, years of life loss, infinite hereditary risk, etc., into the determination of these organ weighting factors will be obviated.

Although the rule refers to calculating the estimated annual equivalent doses to “the relevant organ(s) or tissue(s)” [§ 82.10(j)] the report contents described in § 82.26(b)(1) only refers to “Annual dose estimates”, without specifying dose to what, and § 82.26(b)(2) follows

with a description of doses to “the primary cancer site(s).” There should be no reason to reconstruct doses other than those associated with the organ(s) or tissue(s) relevant to the specific claim. This should be clearly stated in the rule and the ambiguity of § 82.26(b)(1) and (2) should be clarified.

Society recommendation II.A.3 in the enclosure is that “Dose reconstruction should estimate a “maximum realistic” dose for use in the probability of causation calculation.” It is not clear if the “maximum realistic” dose is the same as the “highest reasonably possible value” contained in the definition of worst-case assumption in the rule [§ 82.5(r)].

The definition of worst-case assumption includes the provision that it assigns the highest reasonably possible value, based upon reliable science, documented experience and relevant data, to a radiation dose to a covered employee. In §82.2(a) the example of a worst-case assumption relates to the solubility classification of an inhaled material. If the classification cannot be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer. To be consistent with the definition of worst-case assumption, this example should include the condition that the classification chosen will be reasonable for the exposure or work place conditions. It would be helpful if other examples of worst-case assumptions are identified and evaluated against reasonable criteria. The use of worst-case assumptions should be judicious and have a strong scientific and practical basis.

2) Does the interim rule appropriately balance the potential precision of dose reconstructions and the necessary efficiency of the dose reconstruction process?

We understand that NIOSH is establishing a dose reconstruction process that limits the work effort where it is evident the outcome of the compensation claim will be unaffected because the use of worst-case assumptions does not produce a compensable level of radiation dose. We think this approach is reasonable and should result in reducing unnecessary efforts while maintaining the integrity of the process.

3) Does the interim rule implement an appropriate process for involving the claimant in the dose reconstruction?

It is unclear if the interim rule allows for the estate of a claimant to act on behalf of the claimant. We think a clarification of the potential role of the claimant’s estate would be of value.

If the claimant were ill or infirm, the ability of a claimant to identify a person to act on the claimant’s behalf would be an important provision. Accordingly, if there is not a provision addressing this issue elsewhere, the definition of claimant should be broadened to include a person or persons acting on behalf of the claimant.

4) Additional comments not directly related to the three generic topics.

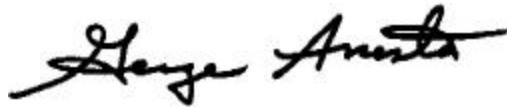
Film badge records and other records of external dose measurements will be used to assess external doses, when available, including exposures from medical screening x-rays that were required as a condition of employment. HHS may wish to evaluate the propriety of including medical radiation exposure (or an estimate of medical radiation exposure) as a result of work related injuries. In addition, medical x-ray procedures are sometimes repeated because of a variety of factors. There should be some means to accommodate the radiation dose from unsuccessful x-ray procedures associated with employment at a covered facility.

The rule should clearly state that the dose reconstruction process will only consider occupational radiation doses received at a “covered facility” and not consider occupational doses received at non-covered facilities or medical and dental x-ray exposures not related to employment at covered facilities.

The Health Physics Society understands and appreciates the societal impetus of the Energy Employees Occupational Illness Compensation Act of 2000. We trust that the information provided in this letter is of use in this important effort.

Thank you for the opportunity to comment on the interim rule.

Sincerely,

A handwritten signature in black ink, appearing to read "George Anastas", with a stylized, cursive script.

George Anastas, President
Enclosure



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

SELECTED PORTIONS RELATED TO DOSE RECONSTRUCTION FROM THE

HEALTH PHYSICS SOCIETY

Comments and Input to the
National Institute for Occupational Safety and Health

On

Fundamental Principles for the Development of Guidelines and Promulgation
of Regulations

in accordance with the

Energy Employees Occupational Illness Compensation Act (EEOICA) of 2000
And
Executive Order 13179

WHICH WAS ENCLOSED IN A LETTER FROM PAUL ROHWER TO
L. J. ELLIOTT DATED MAY 2, 2001

Offices of the Executive Secretary, 1313 Dolley Madison Blvd., Suite 402, McLean, VA, 22101

Phone: (703) 790-1745 **Fax:** (703) 790-2672 **Email:** hps@burkinc.com **Home Page:** www.hps.org

I. GENERAL PROCESS

- A. Proposed **Fundamental Principles** for the general process of developing guidelines and promulgating regulations under the EEOICA:
1. Guidelines and regulations should be founded upon, and consistent with the most current consensus scientific knowledge.
 2. The Advisory Board on Radiation and Worker Health (the Board) should establish an expert working committee for each of the technical issues under its jurisdiction (i.e., probability of causation, dose reconstruction, and Special Exposure Cohort designation) to:
 - a. advise the Board on the most current consensus scientific knowledge related to their technical area of responsibility, and
 - b. draft guidelines and regulations for Board action based on the current consensus scientific knowledge and directions from the Board.
 3. Guidelines and regulations should be subject to an established independent peer review process using expert organizations such as the National Academies.
 4. Development of guidelines and promulgation of regulations should be accomplished in an open, inclusive, and democratic process.
 5. Regulations should be established in accordance with the provisions of the Administrative Procedures Act.
 6. Guidelines and regulations should include provisions for periodic review of the current consensus scientific knowledge to evaluate if the guidelines or regulations need to be changed to reflect more current knowledge and to evaluate if previous claim decisions need to be re-addressed.
 7. Guidelines and regulations should include provisions for an appropriate appeals process by claimants.

B. Discussion:

1. With regard to proposed fundamental principle I.A.1 above, the EEOICA (Sec. 3611 (b)) establishes that the purpose of the compensation program is to provide for compensation of employees and, where applicable, survivors of employees suffering from illnesses incurred by the employees in the performance of duty for the Department of Energy and certain of its contractors and subcontractors. The likelihood that a specific illness in an individual was incurred due to the performance of their duty, as opposed to a non-occupational etiology, is a determination that must be made by scientific and medical experts based on the most current knowledge about the association of an individual's workplace exposure and the disease. Because cancer is such a prevalent disease, studies of the association of workplace exposures as a cause of cancer in a workforce are difficult to perform and are open to divergent interpretation of results. The scientific community addresses the issue of differing study results through the "peer review" process with "consensus scientific committee" determinations. Therefore, the purpose of the EEOICA can only be achieved if current consensus scientific knowledge is used as the foundation for the guidelines and regulations implementing the Act. The Health Physics Society (HPS) has a formal position statement titled "Compensation For Diseases That Might Be Caused By Radiation Must Consider The Dose." The last paragraph of the position statement titled "Compensation Programs" provides the HPS position that "If the reason [for a compensation program] is compensation for a disease or injury caused by exposure to an agent, like radiation, *then the best scientific and medical knowledge, including dose-response considerations* should support the likelihood that the compensated disease could be caused by the measured or reconstructed exposure" (emphasis added). A copy of the position statement is attached.
2. With regard to proposed fundamental principle I.A.2 above, the EEOICA (Sec. 3624 (a) (2)) directs that the composition of the Board reflect a balance of scientific, medical, and worker perspectives. This, with the fact the members are at a Presidential appointment level, will result in a Board with members of diverse levels and areas of expertise. In order for all members of the Board to have an appreciation for the details of the scientific issues involved in each of the related but different technical areas for which they have responsibility, they should have the assistance of expert technical committees to do the "drafting and ground work" for their review and subsequent "big picture" discussion and decision making. The EEOICA (Sec. 3624 (c)) provides for a staff for the Board to facilitate the work of the Board. Although staff is necessary, the expertise of those developing the proposed guidelines and regulations that are considered by the Board should be established through the appointment of expert working committees appointed by the Board.
3. With regard to proposed fundamental principle I.A.3 above, in January 2000 the U. S. General Accounting Office (GAO) reported to the Senate Committee on Veterans'

Affairs the results of their review of the validity of dose reconstruction as a tool for determining veterans' eligibility for benefits (GAO/HEHS-00-32). One of the conclusions of this report was that "an independent review process . . . could mitigate concerns about the integrity of the program." We believe this conclusion can be applied to each of the technical areas of responsibility for the Board, i.e., probability of causation, dose reconstruction, and designation of Special Exposure Cohorts. The independent review should be accomplished by expert organizations charged with scientific reviews, such as the National Academies.

4. With regard to proposed fundamental principle I.A.7 above, an appropriate appeals process incorporates provisions to accomplish two purposes. These are to: (1) accommodate consideration of information an aggrieved claimant feels was not correct, or not correctly considered; and, (2) limit the process such that, while protecting the rights and interests of all workers the administration and processing is not overly burdensome on either the claimant or the compensation system.
5. All other proposed fundamental principles above are considered to be self explanatory.

II. DOSE RECONSTRUCTION

- A. Proposed **Fundamental Principles** for developing guidelines and promulgating regulations to be used to estimate the cumulative past radiation doses incurred by individual claimants:
 1. Dose reconstruction is a standard and valid practice for estimating the amount of radiation exposure when more direct evidence is not available.
 2. Dose reconstruction need only support the information required to evaluate the probability of causation and not necessarily attempt to estimate a highly refined dose if such refinement does not make a difference in the probability of causation calculation.
 3. Dose reconstruction should estimate a "maximum realistic" dose for use in the probability of causation calculation.
 4. Dose reconstruction methods should be developed and performed by an expert committee of qualified radiation health professionals with full understanding of the areas of uncertainty.

B. Discussion:

1. With regard to proposed fundamental principle III.A.1 above, this principle reinforces the provisions of the EEOICA (Sec. 3623 (c) (3) (A)) that guidelines for determination of causation be based on radiation dose of the employee. The HPS position that dose reconstruction, either based on personnel monitoring devices or on reconstruction techniques, can provide a calculation of the dose and dose range that is adequate to support compensation decisions is contained in the attached position statement on compensation. In its report to the Senate, the GAO (GAO/HEHS-00-32) concluded "Available scientific studies indicate that dose reconstruction is a valid method for estimating veterans' exposure to decide disability claims, and we have not identified a better alternative." This conclusion is directly applicable to the cohort of energy employees subject to the EEOICA.
2. With regard to proposed fundamental principle III.A.2 above, the methodology adopted for calculating the probability of causation will determine the methods for doing dose reconstruction.

For example, each facility covered by the EEOICA should have an historical exposure assessment performed by radiation health professionals that provides information about the *potential* for exposure to personnel based on areas in the facility and/or work operations performed in the facility as a function of time. This historical exposure assessment should consider all the issues of uncertainty discussed in paragraph III.B.4 below. Such facility historical exposure assessments have been performed on many facilities and are a standard task for radiation health professionals. The results of the facility historical exposure assessment are then used as a "screening" tool for an individual claimant. "Screening" is an initial dose analysis intended to focus resources on those cases that warrant a more detailed analysis. Using the individual's work history information, a screening assessment can be performed using the facility historical exposure assessment to determine if it is reasonable that the individual claimant could have received exposure in excess of the minimum compensable dose for their specific disease. The screening calculation can be refined to be more rigorous the closer the individual's screening dose calculation is to the minimum compensable dose. If the screening dose is significantly below, or above the minimum compensable dose then the individual can be screened out, or screened in without further dose reconstruction work. If the individual is screened in with a significantly high dose such that the probability of causation calculations leave little doubt the test for "at least as likely as not" will be met, then further dose reconstruction is not warranted. Greater detail and effort in dose reconstruction only needs to be done for those individuals with a screening dose close to the minimum compensable dose, or for whom the probability of causation calculation is close to the compensation value. For these individuals, further dose reconstruction techniques, such as refinement of the work history, use of advanced technology techniques, etc., should be employed to get the "most likely" dose estimate. The screening assessment inherently requires the application of professional judgment,

and is an item appropriate for the independent review recommended in proposed fundamental principle I.A.3 and the appeals process recommended in proposed fundamental principle I.A.7.

3. With regard to proposed fundamental principle III.A.3 above, there are two major areas of uncertainty that can be factored into a calculation of the probability of causation, one associated with the individual's dose and one associated with the risk factor used in the probability of causation calculation. The EEOICA (Sec. 3623 (c)(3)(A)) has established guidance on the uncertainty associated with the risk factor, i.e., use of the upper 99 percent confidence level of the calculation. However, the uncertainty associated with a dose reconstruction is not subject to an uncertainty calculation like that for the probability of causation as provided in the radio-epidemiological tables. The uncertainty of a specific individual's dose reconstruction can only be estimated by the radiation professionals performing the dose reconstruction itself. As discussed above, the rigor with which an individual dose reconstruction is performed will be dependent on the estimated dose in relation to decision points imbedded in the probability of causation calculation. The closer an estimated dose is to a decision point, i.e., a screen in/screen out or a compensate/not compensate point, the more the effort should be made to estimate the "realistic" uncertainty of the dose estimate. A "maximum realistic" dose estimate should be estimated and used as a point estimate of dose for the remainder of the probability of causation determination. The estimation of a "maximum realistic" dose inherently requires the application of professional judgment, and is an item appropriate for the independent review recommended in proposed fundamental principle I.A.3 and the appeals process recommended in proposed fundamental principle I.A.7.

4. With regard to proposed fundamental principle III.A.4 above, guidelines for performing dose reconstruction should be developed by an expert technical committee as recommended in proposed fundamental principle I.A.2. These guidelines should address the standard methods of performing a dose estimate which include: (1) evaluation of people doing the same work who were properly monitored or who already have approved dose estimates; (2) length of exposure and dose rate or radioactive material concentrations in the area; and, (3) the application of evolving biological measurement techniques. These guidelines should also address how to handle the areas of uncertainty in performing dose reconstruction. Examples of these areas of known, or potential uncertainty are:
- a. Appropriateness of personnel monitoring techniques when monitoring records are available with considerations of monitoring device location on the body (external), sample time versus exposure time (bioassay for internal), sensitivity of monitoring techniques, appropriateness if in an accident situation, etc.
 - b. Changes in radiation protection standards, terminology, radiation monitoring practices, and radiation dosimetry methodologies over time
 - c. Collation and resolution of multiple sources of exposure data