Miller, Diane M.

From: Keith Dinger [keith.dinger@verizon.net]
Sent: Monday, August 26, 2002 1:09 PM
To: NIOCINDOCKET@CDC.GOV
Subject: HPS Comments on 42CFR83

Dear Sir or Madam:

I am forwarding, on behalf of the Health Physics Society's President, Dr. John R. Frazier, comments on the Notice of Proposed Rulemaking for Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the EEOICPA of 2000 as published in the Federal Register, Vol. 67, No. 122, Pages 42962 to 42973 of June 25, 2002.

The comments are contained in the attached letter, HPScomments.42CFR83.doc, with two enclosures, HPScomments.42CFR83.enclosure1 and HPScomments.42CFR83.enclosure2.

Please to do not hesitate to contact Dr. Frazier or myself if you have any questions about these comments. Please contact me if you have any problems receiving the documents.

Sincerely,

Keith H. Dinger, CHP
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HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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August 26, 2002

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

Subject: Comments on the Notice of Proposed Rulemaking on Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 as presented in 67 FR 42962 through 42973, June 25, 2002

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, in its role as the professional radiation safety organization, has specialized expertise in issues related to the implementation of the Energy Employees Occupational Illness Compensation Program Act (the Act). As the current President of the Society, I am pleased to provide comments on the proposed procedures, as contained in the referenced Federal Register, for designating classes of employees as members of the Special Exposure Cohort (SEC) under the Act. The Society appreciates the opportunity to participate in this rulemaking.

The Health Physics Society has issued a position statement titled "Compensation for Diseases That Might Be Caused by Radiation Must Consider the Dose." The Society position statement has been provided to the National Institute of Occupational Safety and Health (NIOSH) in previous communications and is enclosed with this response for further reference. Additionally, on May 2, 2001, Society President Paul S. Rohwer provided Mr. L. J. Elliott, Acting Director of the NIOSH Office of Compensation Analysis and Support, the enclosed comments and recommendations regarding the development of guidelines and regulations covering the major issues involved in implementing the Act, including the issue of designating employees as members of the SEC. The following additional comments are based on the Society's position statement and Dr. Rohwer's letter of May 2, 2001.

One of the proposed fundamental principles contained in Dr. Rohwer's letter for designating a SEC was that "The conditions for designation of a class of workers as a Special Exposure Cohort must be extraordinary enough to justify disregarding [the scientific fact that the likelihood a specific cancer is associated with an individual's exposure is dependent on the individual's dose]." The proposed rule establishes a process for designating an SEC that is dependent on the determination that a dose reconstruction cannot be completed by NIOSH in accordance with 42CFR82. This process establishes that the "extraordinary" condition justifying the designation of an SEC is a condition in which NIOSH cannot complete a dose reconstruction for the purposes of determining compensation for an individual.

The Health Physics Society cannot conceive of a situation in which a dose reconstruction, including the establishment of an "upper bound" dose, cannot be performed, thus permitting the determination of compensation on an individual basis in accordance with 42CFR81 and 42CFR82.

Determination of an upper bound, or "worst-case scenario" dose is a standard health physics practice. An upper bound dose can be calculated with minimal information about the source of radiation exposure and potential exposure conditions of the individual. Although an upper bound dose has the potential for being very different from the actual dose an individual received, it does represent an upper limit to the possible dose and is more accurate than an assessment that no "reconstruction of the dose is possible."

The dose reconstruction rule, 42CFR82, recognizes there are potential situations in which the dose cannot be reconstructed with "sufficient accuracy" to permit the determination of a dose for use in determining compensation. The dose reconstruction rule provides for the use of worst-case scenario doses only to determine that an individual's claim does not warrant further research because the worst-case dose excludes the possibility of a compensable level of exposure. In responding to comments on 42CFR82, HHS explained that the conditions under which NIOSH would not have sufficient information to complete a dose reconstruction will vary on a case-by-case basis and that the definition could not use rigid criteria because the potential circumstance are not readily foreseeable.

Although the Society agrees that not all potential circumstances can be readily foreseeable, we believe that the possibility of not being able to reconstruct an upper bound dose on an individual is small and that the use of an individual upper bound dose for determination of compensation is based in science, unlike the designation of SECs for which individual doses are not considered. The Society believes that these concepts should be clearly explained in the proposed rule because the conditions under which a finding of not being able to determine dose have not been clearly stated in 42CFR82.

The Society requests the proposed rule clarify that, through the use of standard dose reconstruction techniques such as worst-case scenarios, it will only be in extraordinary circumstances that the procedures of 42CFR83 will be required to designate SECs.

The Department of Health and Human Services (HHS) invited comments on "its proposed interpretation of health endangerment and approach to evaluate it."

Dr. Rohwer's letter of May 2, 2001, proposed that a fundamental principle for developing guidelines and regulations under the Act be that "Guidelines and regulations [be] founded upon, and consistent with the most current consensus scientific knowledge." Additionally, he proposed that a fundamental principle for designating additional classes of Special Exposure Cohorts be that "Special Cohorts [be] designated for specific diseases."

The proposed procedures for adding classes of employees to the Special Exposure Cohort do not adopt either of these recommended fundamental principles.

Paragraph III. *Subtitle C – Procedures for adding Classes of Employees to the Cohort*, describes the procedure to implement the requirement that there be "a reasonable likelihood that such radiation dose may have endangered the health of members of the class." The procedure involves using the software tool NIOSH-IREP to determine the threshold dose for the "most radiogenic specified cancer" for the exposure conditions to which the employees were potentially exposed. Exposure conditions involving the intake of radioactive materials may result in widely varying doses to individual organs. In addition, it is known that the radio-sensitivity of individual organs varies widely. Footnote 3, page 42966, states that "Despite selection of the most radiogenic cancer to calculate probability of causation, once a class of employees has been added to the Cohort, members would be eligible for compensation for incurring any of the specified cancers, not only the cancer used for this calculation." This explanation is not included in the proposed rule itself, and 42CFR83.12(c)(2) does not specifically include specified cancers as one of the parameters used to define the SEC.

The proposal to include <u>all</u> specified cancers in an SEC if the cohort has a potential to receive a compensable exposure for any <u>one</u> cancer does not use current scientific knowledge about the differing radio-sensitivities of various organs or the possibility of widely varying organ doses under certain exposure conditions.

It is possible under the proposed 42CFR83 that an SEC could be established based on one of the more radio-sensitive organs, one of the rare cancers with a large uncertainty, or one of the higher dosed organs from the exposure

conditions. However, if a 42CFR83.12(b)(1)(ii) evaluation were performed for all specified cancers, it could demonstrate that other organs do not have "a reasonable likelihood" of causation by the exposure.

Compensating persons with occurrences of these specified cancers that do not meet the "likelihood" test is neither fair nor scientific.

Unfairness can occur if persons with exposures meeting the dose reconstruction criteria of 42CFR82, which disqualifies them for consideration as an SEC, have doses and diseases that are not compensable because the probability of causation does not establish "likelihood" while similarly exposed and diseased persons in an SEC are compensated. Additionally, this procedure could result in an SEC being established due to a large uncertainty associated with a rare cancer that then results in frequent payments to the SEC claimants that develop commonly occurring cancers that do not otherwise meet the "likelihood" test. Additionally, payment of compensation for specified cancers that cannot meet the "likelihood" test of a 50% probability of causation is not consistent with consensus science.

I note that the proposed procedures do appropriately provide for the definition of an SEC to include specification of things such as the period of employment, job titles, job duties, job locations, and the existence of an unmonitored exposure incident. For consistency, the procedures should also provide for the inclusion of these and other important factors, such as specified cancers that meet the "likelihood" test, leading to the SEC classification. Inclusion of the specified cancers applicable to a particular SEC also eliminates the need to have a special dose averaging procedure, as explained in footnote 6 of §83.12(b)(1)(ii), if the most radiogenic cancer is leukemia. Since the threshold dose for the most radiogenic solid tumor will be higher than that for leukemia, this averaging procedure could be unfair if potential exposures to members of the SEC were as high as the leukemia threshold but not as high as the "averaged" threshold.

The Health Physics Society recommends that the definition of a Special Exposure Cohort be specific to the types of specified cancer that meet the "likelihood" test for the potential exposures incurred by the cohort.

The rule should make it clear that a determination by NIOSH that a dose reconstruction could not be completed for an individual includes the determination that a worst-case scenario could not be constructed to demonstrate the employee did not incur a compensable level of radiation dose.

A key element to the procedure for designating additional members as an SEC is a report produced by NIOSH under 42CFR82.12 notifying the petitioner(s) that NIOSH attempted and could not complete a dose reconstruction for the individual. An expected reason for not being able to complete a dose reconstruction is the lack of dosimetry, work, and exposure records, which can

appear to meet the provision in the Act that allows designation of an SEC if "it is not feasible to estimate with sufficient accuracy the radiation dose that the [individual members of] the class received." However, it is a common health physics practice to make worst-case scenario assumptions to estimate a "bounding dose" in the absence of records. This practice is recognized and incorporated into the 42CFR82 procedures in 42CFR82.10(k). However, someone that is reading 42CFR83 may not know 42CFR82 incorporates this practice and may mistakenly assume the absence of records will automatically qualify as a determination that NIOSH could not complete a dose reconstruction for the individual.

The Health Physics Society recommends 42CFR83.5 or 42CFR83.9 include clarification that a dose reconstruction is considered completed in accordance with 42CFR82 if "worst-case" assumptions, which do not underestimate the dose to the employee, demonstrate the employee could not have incurred a compensable level of radiation dose.

The Health Physics Society understands and appreciates the societal impetus for the Energy Employees Occupational Illness Compensation Act of 2000 and strives to support the Act while maintaining sound science in public policy. We hope that the information provided in this letter is of use in this important effort.

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

Sincerely,

John R. Frazier

John R. Frazier, Ph.D., CHP
President

Enclosures

HEALTH PHYSICS SOCIETY

COMPENSATION FOR DISEASES THAT MIGHT BE CAUSED BY RADIATION MUST CONSIDER THE DOSE

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: March 2000
Reaffirmed: March 2001

Contact: Richard J. Burk, Jr.
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EXECUTIVE SUMMARY

Based on the extensive knowledge of radiation health effects, the Health Physics Society believes that a person's radiation dose must be considered in determining whether to provide compensation for a disease that could have been caused by radiation. Further, there should be no compensation for persons whose lifetime doses are less than approximately 0.1 Sv (10 rem).

INTRODUCTION

Many workers and members of the general public who have actually, or possibly, been exposed to radiation since the widespread introduction of technologies using radiation or radioactivity are now at the age where they will be more likely to experience a variety of diseases. We know that some diseases may be caused by high doses of radiation. The most reliable studies of the effects of radiation exposure at the low levels received by occupational workers and members of the public have not been able to detect adverse health effects associated with their radiation exposure except at the higher doses, i.e., greater than approximately 0.1 Sv. Even at the higher doses, the studies are not all consistent. However, inherent limitations of these studies leave open the possibility there are small undetected risks at the low levels of exposure experienced in the workplace and in the environment.

Social values and conscience have evolved with the changing of national priorities since the 1940s and 1950s, resulting in the examination of yesterday's practices for radiation safety in light of today's political environment and knowledge. This has led to proposals for disease-compensation programs based on the presumption of causation of disease by low levels of radiation exposure. Presumption of causation means that a person with a disease could be compensated on the pure assumption that the disease was caused by radiation without evidence of receiving any radiation exposure or for receiving radiation exposure at levels not known to cause the disease.

RADIATION AND DISEASE

Our knowledge about the potential health effects of ionizing radiation is extensive. It is known that radiation cannot cause all types of disease. It is also known that for those diseases observed to be caused by radiation, the likelihood that radiation will cause the disease increases as the dose increases. In other words, any particular disease's likelihood to have been caused by radiation is dependent on the dose to the individual. This relationship of increasing likelihood of disease with increasing dose has only been observed for doses greater than approximately 0.1 Sv. The likelihood of radiation-induced disease below this level, if it exists at all, is so small that it is not measurable, it is not a matter of scientific fact, and it can only be estimated utilizing hypothetical mathematical dose-response models.

Presumption of causation has no scientific or medical basis without consideration of dose. That is, the simple fact that some radiation exposure occurred is not a measure of hazard. The amount of exposure (i.e., the dose) is the only measure of the hazard and the only measure of the likelihood a disease or injury has been caused by radiation. In addition, everyone is exposed to natural sources of ionizing radiation every day without any observable effects. Therefore, exposures that are potentially hazardous, justifying consideration of compensation, must significantly exceed exposures from normal life activities.

DOSE DETERMINATION

Given the scientific knowledge that the relationship between ionizing radiation exposure and disease depends on the dose, the issue of disease causation often concentrates on the adequacy of knowing the actual, or possible dose to the populations of interest.

Personnel dosimetry by use of film badges, and other detection devices, was well established by the early 1950s. When available, the results of personnel dosimetry devices provide an excellent basis for establishing doses to individuals. When personnel dosimetry results are not available, reconstruction of a dose, and in particular a range of doses, can reasonably be done. The dose to an individual from a specified source is a matter of physical and physiological parameters based on the radiation source and exposure mode. Given the identification of the radiation source and the exposure mode, dose reconstruction can provide a calculation of the dose and dose range that is adequate to support decisions on whether a selected population, or an individual having a disease or injury, may have been affected by that particular radiation exposure.

COMPENSATION PROGRAMS

The Health Physics Society strongly supports compensation for individuals who are injured, or wronged, by practices which have clearly caused them harm. However, the reason for allocating public funds to provide compensation to selected individuals should be clearly stated. If the reason 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.

* The Health Physics Society is a non profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at: 1313 Dolley Madison Blvd,. Suite 402, McLean, VA 22101; phone: 703-790-1745; FAX: 703-790-2672; email: HPS@BurkInc.com.

HEALTH PHYSICS SOCIETY

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May 2, 2001

Mr. L. J. Elliott (R-45)
Acting Director, Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health
4676 Columbia Parkway
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Dear Mr. Elliott:

As President of the Health Physics Society (HPS), I am pleased to provide the enclosed comments and input to the National Institute for Occupational Safety and Health (NIOSH) on responsibilities delegated to NIOSH by the Energy Employee's Occupational Illness Compensation Act (EEOICA) of 2000, and Executive Order 13179. These comments and input are provided in response to your invitation for such contained in your letter to our Congressional Liaison, Keith H. Dinger, dated April 6, 2001.

Thank you very much for the opportunity to provide these comments and input. NIOSH has been given a number of important tasks in the process of establishing and implementing a program to provide fair compensation to deserving workers within the Department of Energy nuclear weapons complex. The HPS is appreciative of the opportunity to offer its expertise in the field of radiation sciences to assist you with these tasks.

Your letter requested comments and input on three areas of responsibility. These areas deal with the development of guidelines and promulgation of regulations on: (1) probability of causation; (2) dose reconstruction; and, (3) designation of Special Exposure Cohorts. The enclosed HPS comments and input are organized into these three areas with additional comments and input addressing the general process of developing and implementing a fair and equitable compensation program.

The scope of the three tasks covered by your request is extensive and the time to develop the comments and input, relatively short. In developing our comments and input, we felt it essential to relay to you some fundamental principles we feel are important to be incorporated into the guidelines and regulations as they are developed. The enclosure lists proposed fundamental principles in each area with some discussion as appropriate. We hope you find this approach to be helpful at this stage of the process.

The comments and input contained in this letter and enclosed material are based on approved positions of the HPS, which are referenced where appropriate. In addition, these comments and input have been approved by the HPS Board of Directors and, as such, can be considered representative of the general membership of the Society, but not necessarily representative of any one member's thoughts or opinions.

Once again, thank you for this opportunity. The HPS has one interest in this process, i.e., the use of sound science in the formulation of public policy. I hope NIOSH and you will continue to see and use the HPS as a resource for assistance in this important initiative.

Sincerely,

Paul S. Rohwer

Paul S. Rohwer, Ph.D., CHP

Enclosures

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 (EEPICA) of 2000
And
Executive Order 13179

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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. PROBABILITY OF CAUSATION

A. Proposed **Fundamental Principles** for developing guidelines and promulgating regulations to be used to assess the probability that a claimant's cancer was caused by his or her occupational exposure to radiation:

1. The probability that a claimant's cancer was caused by his or her occupational exposure to radiation must consider the person's radiation dose.

2. Probability of causation determinations should only be made where the person's occupational exposure exceeds some minimum value below which there is no known risk of cancer causation in

populations exposed below this value. This value should be approximately 0.1 Sv (10 rem).

B. **Discussion**:

1. With regard to proposed fundamental principle II.A.1 above, the attached HPS position statement "Compensation For Diseases That Might Be Caused By Radiation Must Consider The Dose" sufficiently discusses this principle. This principle is incorporated into the requirements in the EEOICA (Sec. 3623 (c) (3) (A)) which states the "guidelines [for making the determination an individual sustained a cancer in the performance of duty] shall be based on the radiation dose received by the employee (or a group of employees performing similar work) at such facility. . ." It should be noted that the HPS position statement does not specifically state how an individual's dose should be used in consideration of determining if a cancer is occupationally related (i.e., how to calculate or use a probability of causation) with the exception of the establishment of a minimum value for calculating a probability, which is our second fundamental principle.

2. With regard to proposed fundamental principle II.A.2 above, the HPS position statement on compensation states "there should be no compensation for persons whose lifetime doses are less than approximately 0.1 Sv (10 rem)." This position is explained in the following, which is taken from the position statement. "This relationship of increasing likelihood of disease with increasing dose has only been observed for doses greater than approximately 0.1 Sv. The likelihood of radiation-induced disease below this level, if it exists at all, is so small that it is not measurable, it is not a matter of scientific fact, and it can only be estimated utilizing hypothetical mathematical dose-response models."

   The HPS position regarding a value below which compensation should not be paid is based on its position statement titled "Radiation Risk In Perspective." A copy of this position statement is attached. This statement contains the HPS position that "In accordance with current knowledge of radiation health risks, the Health Physics Society recommends against quantitative estimation of health risks below an individual dose of 5 rem in one year or a lifetime dose of 10 rem in addition to background radiation." The position statement sufficiently discusses the rational for this position.

   The EEOICA (Sec. 3623 (c) (3) (A)) refers to the use of the radio-epidemiological tables published under the Orphan Drug Act in determining the likelihood an individual's cancer is related to their

employment. These radio-epidemiological tables use the scientific knowledge regarding the relationship of cancer induction and radiation exposure obtained from studies where this relationship is observable, i.e., at doses greater than approximately 10 rem. They then *extrapolate* that relationship to doses below 10 rem where the relationship can not be observed, but where it can only be estimated using hypothetical mathematical dose-response models. This extrapolation is an example of a quantitative estimation of health risks below 10 rem with which the HPS does not agree.

3. In summary, incorporation of fundamental principles I.A.1, II.A.1, and II.A.2 results in a proposal that the probability of causation use the current scientific knowledge of radiation health effects to calculate an individual's probability of causation using the individual's dose, provided that dose is above an established value below which compensation should not be provided. The establishment of the minimum value for which compensation should be provided could be refined using our scientific knowledge to establish an organ dose value for each type of cancer, in lieu of a general "whole body equivalent" dose. When an individual's dose is greater than the minimum value for compensation, the HPS does not have a position on the specific method of calculating a probability of causation, or how to use this calculation to determine if the dose was "at least as likely as not" to have caused the cancer (EEOICA Sec. 3623 (b)). This should be the subject of study and recommendation by an expert technical committee formed as recommended by proposed fundamental principle I.A.2.

III. 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 judgement, 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 judgement, 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

IV. DESIGNATION OF SPECIAL EXPOSURE COHORTS

A. Proposed **Fundamental Principles** for establishing a process to consider and decide whether to designate additional classes of workers to be included in the Special Exposure Cohort:

1. The conditions for designation of a class of workers as a Special Exposure Cohort must be extraordinary enough to justify disregarding scientific fact.

2. The only doses needed to be determined with "sufficient accuracy" are those doses which are in the range of the minimum compensable dose and the compensable probability of causation value for the designated disease.

3. Special Exposure Cohorts can be designated for specific diseases and sub-populations of a given facility.

4. The currently designated Special Exposure Cohorts in the EEOICA do not provide any precedence for establishment of guidelines for designation of Special Exposure Cohorts in the future.

B. **Discussion:**

1. With regard to proposed fundamental principle IV.A.1 above, it is a matter of scientific fact that the likelihood a specific cancer is associated with an individual's exposure is dependent on the individual's dose. This fact is discussed in some detail in the attached HPS position statement on compensation. Therefore, the conditions existent for an entire class of individuals to be designated as a Special Exposure Cohort, such that the dose to none of the individuals in the class is considered in the determination of their qualification for compensation, requires those conditions to be extraordinary.

2. With regard to proposed fundamental principle IV.A.2 above, the EEOICA (Sec. 3626 (b) (1)) establishes that a condition that can justify designation of a Special Exposure Cohort is if it is determined that "it is not feasible to estimate with sufficient accuracy the radiation dose that the class received." Doses that are in a range that can not affect the decision to compensate for a disease do not need to be known with any accuracy. That is, if a screening dose reconstruction concludes the dose to a class of workers is unlikely to be able to be estimated accurately, but that it is not likely the doses could approach a level that would be compensable, the class should not be eligible for designation as a Special Exposure Cohort under this provision of the EEOICA. Therefore, the only conditions that should be considered as qualifying for this provision are those doses for which the inability to provide an estimate with a realistic dose range could possibly be in the range of compensable doses.

3. With regard to proposed fundamental principle IV.A.3, since most Department of Energy facilities covered by the EEOICA are relatively large facilities with processes and work assignments varying in complexity and type, it is not expected that the two conditions given in the EEOICA (Sec. 3626 (b)) would exist for all employees at one facility. For example, an historical exposure assessment may reveal a work assignment such as cleaning out radioactive dust collection bags without respirators could be expected to result in a compensable dose to all that did that assignment over some determined amount of time. However, it is not logical to think other work assignments, such as clerical personnel, would also be appropriate to include in the class of workers.

   Similarly, since each type of cancer has a different radio-sensitivity, or dose response, the compensable dose under a probability of causation calculation will differ. Therefore, the criteria that the doses for the entire class are likely to be compensable will be expected to differ by disease.

Therefore, designation of Special Exposure Cohorts should not be applied to entire facilities or entire classes of disease, i.e., all cancers.

4. With regard to proposed fundamental principle IV.A.4 above, the Special Exposure Cohorts established in the EEOICA (Sec. 3621 (14)) were defined by legislative edict without benefit of the guidelines and regulations that will be established for designation of additional classes of workers in the future. Therefore, these Special Exposure Cohorts should not be considered as providing precedence for establishing guidelines and regulations for future designations.

   The HPS recommends that once the Special Exposure Cohort guidelines and regulations are established by the Board, the EEOICA designated Special Exposure Cohorts be re-evaluated to determine if their designation should be changed in some way to provide consistency with potential future designations.