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Subject: Comments Regarding Designating Classes of Employees as Members of the Special Exposure Cohort
Importance: High

Comments Regarding Designating Classes of Employees as Members of the Special Exposure Cohort Attached.

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Comments Regarding the HHS Notice of Proposed Rulemaking for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 Federal Register Vol. 68, No. 45, pp.11294-11310 (March 7, 2003)

FROM

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Scientific Questions and Concerns Regarding the Proposed Rule

I. Section 83.13(b)(1)(i) states that NIOSH will determine that "radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class"

QUESTIONS

1. How will NIOSH evaluate whether or not there is sufficient information to estimate the maximum dose to an individual?
2. What is the scope of information and minimum amount of information needed to estimate the maximum dose to an individual?
3. What methods of retrospective dose assessment will be allowed in assessing the maximum dose to an individual?

COMMENTS

1. In order to have consistency between dose assessments for individuals, a detailed *a priori* methodology needs to be established prior to any formal dose reconstruction.
2. Minimum data requirements needed to assess whether or not a valid dose reconstruction is possible needs to be placed in the public record prior to any dose reconstruction efforts.

II. Section § 83.13 (a) states (a) NIOSH will collect information on the types and levels of radiation exposures that potential members of the class may have incurred, as specified under 42 CFR 82.14, from various sources as necessary. Subpart (ii) states that in general, to establish a positive finding under paragraph (b)(1)(i) of this section would require, at a minimum, that NIOSH have access to reliable information on the identity or set of possible identities and maximum quantity of each radioisotope.

QUESTION

1. What is meant by reliable information?

COMMENTS - THE NEED FOR RELIABLE EXTERRNAL DOSIMETRY

1. For reliable dose assessment, dosimetry must accurately reflect actual personal exposure (dose). However, studies of film badges, performed under controlled and ideal conditions, as recent as 1981 indicated that the film dosimetry, commonly used prior to the 1980s lacked both precision and accuracy and yielded underestimates of true neutron exposure approaching 80% in some instances (Sims et al. 1982). The radiation dosimetry film in the 1950s through the mid 1970s produced even less accurate and precise estimates of the true personal exposure. For example, a study (Larson et al. 1967) of film detector performance performed by Pacific Northwest Laboratories for the Atomic Energy Commission as late as the mid 1960s documented that the relative error of the film badge for common types of x-ray and neutron exposure exceeded 500%.

2. Reliable assessment of neutron exposure is particularly problematic. As Griffith et al. pointed out in 1979, "Care must be taken when using dosimeter data to infer the dose or dose-equivalent to the whole body or individual organs. The data must be augmented by instrumental survey information if it is to provide a complete picture of personnel exposure." It is extremely problematic to get either reliable or valid retrospective exposure estimates 30 to 50 years after the fact when the instrumental survey information is no longer available. It is well documented in the scientific literature the limited energies that neutron dosimetry can record. Even in cases where the neutron film badge can theoretically record the neutron activity for a specific energy, historic neutron dosimeters worn for a month will not produce reliable (accurate) results because of fading. Nonetheless, AEC/DOE employees often retained the same neutron film dosimetry for a

month, even though researchers knew in the 1960's (Zelac R.E. 1968) that because of neutron fading, dosimeters should not be worn for more than 2 weeks.

3. Additional information is needed in the rule to establish and assess the basic requirements for reliable dosimetry.

Examples of the type of information needed to assess reliability follow:

a. Control dosimeter information and control charts to assess accuracy and precision of detector
b. Logs of temperature and resulting effects on dose recording during the exposure process and how temperature effects adjustments were performed.
c. Information on chemicals in the work area and their effect on the film
d. Information on the variations in the latency period between film exposures and film processing (image degradation)
e. The variations in the chemical composition of mixtures used to develop and fix the film
f. Calibration comparisons between real time instrumentation and control films
g. Information on the film treatment and storage duration prior to usage
h. Duration of detector exposure period (neutron fading, etc.)
i. Documentation of the ability of dosimetry to detect the type and spectrum of radiation encountered in the workplace
j. Complete documentation of external exposures including extremity exposure information
k. etc.

COMMENT - THE NEED FOR RELIABLE INTERNAL DOSIMETRY

For internal dosimetry to be reliable, detailed QA/QC records are also indispensable including other information such as sensitivity of measurement, sampling frequency, etc. In most cases, these records are non existent in many facilities prior to the 1980s. While workplace monitoring data may be helpful, this data is also subject to reliability concerns and may have no correlation with actual exposures.

III. Section 83.13 (b)(1) (ii) states in general, to establish a positive finding under paragraph (b)(1)(i) of this section would require, at a minimum, that NIOSH have access to reliable information on the identity or set of possible identities and maximum quantity of each radioisotope (the radioactive source material) to which members of the class were potentially exposed without adequate protection.

QUESTIONS

1. How will the range of possible exposures be determined?
2. What methods will be used to assess reliability and validity of maximum quantities of radioisotopes used 30 to 50 years ago and the chemical form of the radioisotope?
3. How will the adequate worker protection be documented?

COMMENTS

1. Detailed information is needed to assess exposure such as shielding, chemical form of the radioisotope, distance between worker and source, geometry of source material, presence of other materials (for example, Be) that may alter the form and total activity of the radiation, etc. In my opinion, it is a fatal flaw in the proposed rule to assume that an investigator 30 to 50 years after the fact can validly reconstruct work conditions and processes that led to maximal exposures at the time of employment. For example, even a small cut on an unprotected hand can allow the introduction of lethal quantities of certain types of radioisotopes commonly handled by AEC workers. In addition, because of the secrecy of the much of the former AEC/DOE work especially on bomb construction and dismantlement, much of the work process information has been intentionally suppressed or destroyed.

IV. In preamble to the proposed Special Exposure Cohort rule, a statement is made, "The Health Physics Society further recommended that determinations of the feasibility of estimating doses with sufficient accuracy be limited to relevant cancers. This comment reflects the fact that the feasibility of a dose reconstruction can be specific to certain cancer sites in the body and hence to the type of cancer an employee incurs. For example, internal doses of radiation resulting from inhalation, ingestion, or absorption of internal emitters, such as radon progeny or uranium, only concentrate and significantly irradiate certain organs and tissues. Hence, it may be appropriate to limit the finding that it is not feasible to estimate radiation doses with sufficient accuracy to certain tissue-specific cancer sites relevant to individuals with specific types of cancers."

Further, Mr. Katz stated during the March 7, 2003 Radiation Advisory Board meeting - "It's feasible if we can -- if we have access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class. If we can put an upper bound on the dose to the class, then we can do the dose reconstructions. An example of radon gas. If we can estimate all the radiation doses for an individual except for their exposure to radon, radon daughters, then the tissue -- the organ that is exposed to radiation is the lung. And for practical purposes, other tissues, other organs are not exposed. And we can do a -- in effect, cap the dose for those individuals with cancers other than lung cancer. We can't do it for lung cancer. And in that case, you would establish a class that included anyone who has or incurs in the future lung cancer and was exposed -- was at the site, et cetera."

COMMENT:

1. Further limitation of cancer types based on the currently known health effects of a certain type of exposures should proceed very cautiously. Mr. Katz's assertion that for all practical purposes other tissues other than the lung are not exposed is misleading. The lung receives the largest dose from radon progeny, but radon gas is lipophilic and can expose bone marrow, brain, testis, breast, etc. Most of our existing knowledge about the adverse effects of radon exposure comes from radon-exposed underground miners. It is interesting to note that in many studies of laboratory radon-exposed animals; there was a higher rate of mammary tumors than lung tumors. A causal link between radon exposure and breast cancer would obviously not be elucidated in male dominated miner studies. Some researchers also think the doses to the basal cells, particularly where the skin is thin like the face, are also not negligible. In addition to lung dose reconstruction, the dose from radon gas and decay products to <u>other organs</u> should be included within the overall dose reconstruction process.

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