

presented by DOE and AWE employees and their survivors during four public meetings convened to present the proposed rule during the comment period in July and August, 2002.

HHS has not established in the proposed rule a feasibility test as to whether dose reconstructions for the class could be completed within a time limit. The factors that might delay a dose reconstruction would typically be specific to an individual employee, versus a class of employees, since the informational demands of a dose reconstruction are cancer specific and employee specific. HHS also notes that the development of the NIOSH dose reconstruction program has delayed all dose reconstructions required to date, but that this is an inevitable consequence of establishing a technical program of this unprecedented scale and complexity, and of DOE's development of a commensurately large records identification and retrieval system to support the NIOSH dose reconstruction program.

Nevertheless, the development of the most efficient processes possible to assist DOL in achieving timely adjudication of cancer claims is a high priority for HHS. For this purpose, NIOSH will consider the establishment of a time limit or guidelines concerning the duration of individual dose reconstructions conducted under 42 CFR part 82, once the dose reconstruction program reaches its full operating capacity.

B. Accuracy of Dose Reconstructions

NIOSH received various comments and recommendations that relate to the determination, discussed above, as to whether it is feasible to estimate doses to members of a class of employees with "sufficient accuracy."

Four labor organizations, an advocacy group, and several individuals questioned the ability of NIOSH to reconstruct doses with sufficient accuracy when DOE records are incomplete, lacking personal monitoring records, alleged to be fraudulent, limited to co-worker data, or lacking energy-specific dosimetry.

Most of these limitations are standard for a radiation dose reconstruction program. The purpose of dose reconstructions is specifically to estimate doses when records are incomplete or otherwise inadequate. EEOICPA explicitly recognizes this fact and requires that dose reconstructions be performed under precisely such circumstances. Moreover, as discussed in the first notice of proposed rulemaking, sufficient accuracy of estimates for a compensation program,

in contrast to estimates used for epidemiological research, is defined by the extent that it assures the fair adjudication of claims, rather than any arbitrary degree of precision. Hence, for the purposes of a compensation program, a dose estimate is sufficiently accurate if it is reasonably certain to be at least as high as the highest dose that could plausibly have been received.

The labor organizations and advocacy group commenting on this rule also requested that HHS provide one or more clear tests for when a dose estimate would be sufficiently accurate.

NIOSH has established the use of maximum doses based on worst-case assumptions in its dose reconstruction program whenever sufficient information is available to support this approach and the additional information needed for a more precise estimate is unavailable. Accordingly, the more limited the dose information available for a claim, the more likely it is a dose reconstruction will overestimate the level of radiation dose, and the greater the degree of overestimation, to achieve the objective of minimizing the possibility of ever underestimating the radiation doses used to adjudicate a claim.

This dose reconstruction approach allows HHS to establish a more qualified standard for sufficient accuracy than provided under the initial notice of proposed rulemaking. Under section 83.13 of the current proposal, 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 by any member of the class, based on the information available and using "worst-case" assumptions. As discussed above, such a maximum dose estimate would be used in dose reconstructions, if available information is inadequate to establish more precise estimates. This standard for sufficient accuracy is supported in comments on this rule by the Health Physics Society and the Defense Threat Reduction Agency. HHS believes this represents a fair standard for sufficient accuracy under EEOICPA, since it provides that dose reconstructions will be restricted to claims for which information is sufficient to prevent the underestimation of an employee's dose.

The proposed rule also specifies some general guidance for potential petitioners to consider with respect to whether there is sufficient information for NIOSH to estimate doses. In addition, NIOSH will publicize summaries of specific circumstances in

which NIOSH is unable to complete dose reconstructions with sufficient accuracy, as such cases arise through the NIOSH dose reconstruction program. These findings will be made available to the public on the Internet at <http://www.cdc.gov/niosh/ocas> or by request. Finally, NIOSH will work with the Board to develop other generic guidance, to the extent additional generic guidance is possible, concerning the feasibility of dose reconstructions.

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.

HHS has added provisions under sections 83.13 (b)(1)(iv), 83.13(b)(2)(iii), and 83.13(c)(4) of this rule to allow HHS to limit the definition of a class to those individuals who incur one or more of a limited set of types of cancers, when appropriate, as discussed above. These provisions will allow HHS to adhere fully to the statutory requirement that HHS find that "it is not feasible to estimate with sufficient accuracy the radiation dose that the class received." It will mean that in certain cases, HHS might add to the Cohort a class of employees whose membership is limited to employees who have incurred a cancer from a set of one or more types of cancers specified in the definition of the class established by HHS. (The cancer type or types HHS would specify in such cases could include one or more cancer types that are not included in the list of specified cancers established under EEOICPA and defined in section 83.5(k) of this rule,² as well as one or

² Readers should note that while HHS could define a class of employees by a type of cancer that is not in the list of specified cancers, DOL can only award compensation to members of such a class as a member of the Cohort if they incur one or more of the specified cancers, as required by EEOICPA (42 U.S.C. 7384l(9)(A)). Hence, members included in the class because they have a type of cancer that is not in the specified cancer list must also have or develop a type of cancer that is in the specified cancer list to receive compensation as a member of the Cohort.