

those members cannot be estimated with sufficient accuracy. Hence, NIOSH may not be able to complete dose reconstructions for these members.

The ability of NIOSH to conduct such dose reconstructions may depend on whether the claim is for an employee who had radiation exposures that were not considered in designating his class of employees as part of the Cohort. If the employee had sufficient radiation exposure outside of his work experience as a member of the Cohort to qualify for compensation, then his dose reconstruction could be completed on the basis of this extraneous work history. In addition, the ability to complete such dose reconstructions may depend on whether NIOSH determines it could assign doses that cannot be estimated, and on the procedures that would be established for such claims. NIOSH will discuss with the Board this option to assign doses. Of particular importance, NIOSH cannot establish a procedure that conflicts with provisions of EEOICPA. EEOICPA strictly limits the list of specified cancers that can presumptively qualify members of the Cohort for compensation.

B. Procedures for Determining Health Endangerment

HHS initially proposed that health endangerment would be evaluated using cancer risk models (NIOSH-IREP) to determine a level of dose that would constitute health endangerment and then by determining, subjectively if necessary, whether a class of employees could have incurred such a dose level or higher. The Board considered these procedures to be inadequately justified and potentially unfair. It recommended, without specificity, that NIOSH consider other procedures.

HHS finds these comments from the Board and similar public comments to be persuasive and is thus proposing substantially different procedures for determining health endangerment that do not make use of cancer risk models. Instead, HHS is proposing to define the class members who have potential exposures that cannot be estimated with sufficient accuracy and will use a duration of employment criterion. The specific 250 day criterion applied by Congress in defining which employees of the gaseous diffusion plants are included in the Cohort under 42 U.S.C. 7384l(14) will serve as a default value, when a shorter duration cannot be justified.

C. Dose Reconstructions Guidelines

The Board recommended HHS clarify in the preamble of this rule the criteria for determining when it is not possible

to complete an individual dose reconstruction with sufficient accuracy. This would assist potential petitioners to understand the criteria that will be used to evaluate a petition. The Board also recommended NIOSH develop guidelines outlining the criteria for determining that the available data are not adequate for conducting dose reconstructions, and recommended HHS consider the use of time limits. The Board recommended the Board serve as a reviewer of these guidelines.

As discussed in response to similar comments from the public, HHS has included in the proposed rule a criterion and guidance for how it would determine under this rule that it is not feasible to estimate radiation doses with sufficient accuracy. This guidance for the public will be supplemented by NIOSH reports summarizing conditions in which it finds it is unable to complete a dose reconstruction, as such cases arise. In addition, NIOSH will consider the use of a time limit or time guidelines for individual dose reconstructions under 42 CFR part 82, once the program has reached full operating capacity.

NIOSH will also consult with the Board to supplement the criterion and guidance provided in the rule in the form of dose reconstruction guidelines. It is possible, however, that the basis for these determinations will not be definable by additional, broadly applicable criteria, beyond the criterion and guidance provided in the rule. If so, case-specific summaries of circumstances when NIOSH could not complete dose reconstructions, as discussed above, might provide the best possible guidance on this issue.

D. Regulatory Approach

The Board recommended that HHS consider issuing these regulations as an interim final rule rather than a final rule. The Board was concerned that certain aspects of the final rule, if similar to the rule initially proposed in June 2002, might prove through implementation to require additional changes. If this were to occur, consideration of petitions would be substantially delayed while HHS conducted another rulemaking with a new proposal for notice and public comment.

As discussed above in response to public comments, HHS has made substantial changes to the proposed rule that require issuing another notice of proposed rulemaking. In addition, as discussed previously, HHS believes this is likely to be the most expeditious approach to establishing procedures

under which petitions can be considered.

E. Recommendations for Section 83.1 and 83.2

The Board recommended that HHS add text to this introductory section of the rule to specify that NIOSH would take an active role in identifying classes that should consider petitioning and in assisting employees in such classes to petition.

The dose reconstruction rule (42 CFR part 82.12) specifies the active role NIOSH will take to encourage and assist claimants to petition for the addition of a class, on the basis that their dose reconstructions could not be completed. In addition, this proposed rule specifies the assistance NIOSH will provide to petitioners who have not initially provided sufficient information for their petition.

HHS does not agree that the proposed rule should also include a commitment for NIOSH to identify employees for whom it has not conducted dose reconstructions, to encourage and assist them in petitioning. However, if, in the course of its work in obtaining information for dose reconstructions, NIOSH learns of other classes of employees that have a basis for petitioning, NIOSH would attempt to assist them.

The Board also recommended HHS revise section 83.1 or 83.2 to clarify that the purpose of petitions is not to serve as an appeal for claimants whose dose reconstructions did not lead to compensation. DOL has established procedures under 20 CFR part 30 for claimants who want to contest the factual determinations or how NIOSH conducted their dose reconstructions.

HHS has added text to section 83.1 to make this clarification.

F. Recommendation for Section 83.5

The Board recommended the definition of "class" include the stipulation that the members of a class have worked during a common time period.

Section 83.13 allows NIOSH to define class membership in terms of the time period as well as other potentially relevant employment parameters. In contrast, the generic definition of class provided in section 83.5 is intended to describe briefly only the invariable characteristics of a class, to aid readers of the rule. Time period may not always be a defining characteristic. It is possible there will be classes comprising workers from several distinct time periods relating to intermittent operations. Also, the time period could be irrelevant if a class