

more cancers included in the list of specified cancers.) Co-workers of the employees who do not incur any of the cancers included by HHS would not be included as members of the class added to the Cohort. NIOSH would conduct dose reconstructions for cancer claims covering these co-workers.

C. Health Endangerment

The four labor organizations and two advocacy groups commenting on the rule, and one individual opposed the use of risk models (NIOSH-IREP) to establish whether or not the health of a class of employees petitioning to be added to the Cohort was endangered. The commenters believe health physicists could not make reliable determinations as to whether the dose to which a class may have been exposed could have exceeded the dose benchmark that was to be established using risk models. The commenters also questioned the procedure for using the risk models, which they found insufficiently detailed, and were concerned that use of risk models would set too stringent a standard for health endangerment. In place of using risk models, the commenters recommended either the use of physician opinion or the employment and monitoring criteria that Congress specified to be used for the statutorily defined members of the Cohort employed by the gaseous diffusion plants in EEOICPA (see 42 U.S.C. 7384l(14)). Alternatively, several individual commenters recommended use of epidemiological analyses, comparing the health of employees at the sites included by Congress in the Cohort to the health of groups of employees at other sites petitioning to be added to the Cohort.

The current proposed standard to be used by NIOSH for establishing sufficient accuracy in section 83.13 would allow HHS to omit the use of risk models in establishing health endangerment. Under this standard, when NIOSH is unable to estimate doses with sufficient accuracy, then, by definition, NIOSH will not be able to estimate the maximum dose that employees in the class might have incurred. Lacking a factual basis for establishing such a cap or upper bound to the possible level of radiation exposure, NIOSH cannot quantitatively evaluate health endangerment. The procedure that remains in the rule for establishing that health may have been endangered is described under section 83.13(b)(3). As recommended by several labor organizations, the advocacy groups, and individual commenters, this procedure is similar to the approach taken by Congress in 42 U.S.C.

7384l(14), but it allows NIOSH greater flexibility to make use of detailed information that might be available.

First, instead of using a general monitoring criterion to indicate which employees had radiation exposure, NIOSH will specifically identify, by job title and other employment parameters, employees with potential exposure, as provided under section 83.13. This allows NIOSH to specifically include within a class those employees with potential for radiation exposure whose doses cannot be estimated with sufficient accuracy.

Second, NIOSH might not universally apply the 250 day employment criterion that Congress specified in 42 U.S.C. § 7384l(14)(A). NIOSH will use the 250 day employment criterion only when it lacks sufficient basis to establish a lower minimum duration.

Specifically, when the exposure of concern occurred during a discrete incident likely to have involved exceptionally high level exposures, such as nuclear criticality incidents or other events involving similarly high levels of exposures resulting from the failure of radiation protection controls, the proposed rule would allow NIOSH to specify presence during the incident as sufficient employment duration for including members in the class. In these cases, it would be impossible to specify any duration of exposure that would delimit the potential for health endangerment, and the 250 day default criterion would be irrelevant.

HHS has not incorporated into the rule the recommendation of one labor organization to establish health endangerment on the basis of a physician's opinion. The commenter suggested this model would be appropriate because it is used for making determinations in workers' compensation programs. Physicians evaluate occupational causation and degree of impairment for patients seeking workers' compensation, but under this rule there is no patient to evaluate, only very limited exposure information pertaining to a class of employees. A physician could not judge health endangerment with respect to exposure to ionizing radiation without dose information on the class of employees and specification of the cancers incurred by the employees.

HHS also has not incorporated into the rule the recommendation to base determinations of health endangerment on epidemiological comparisons between the health of congressionally established classes and future classes to be designated by the Secretary, or on the basis of any other epidemiological comparisons.

Epidemiological comparisons would require health data that would not be available in reasonable time. Moreover, there would be numerous methodological difficulties in making such comparisons, as was generally recognized by the commenters making this recommendation. For example, comparisons would require populations of sufficient size for analysis, whereas the size of classes of employees may often be too small to permit valid analyses.

D. Timeliness of Dose Reconstructions and Petition Decisions

The four labor organizations, two advocacy groups, and several individuals expressed concern about the time that may be required to conduct a dose reconstruction and, if a dose reconstruction is not feasible, the additional time required to add a class of employees to the Cohort. They recommended NIOSH establish a time limit on its dose reconstructions, the tolling of which would determine the dose reconstruction to be infeasible, and they recommended time limits on actions involved in considering a petition for adding a class to the Cohort. Individual commenters were specifically concerned about the time required to add a claimant with cancer to the Cohort, if NIOSH determines that it cannot complete his dose reconstruction.

HHS agrees that it should achieve a reasonable balance between the duration of effort to obtain data for a dose reconstruction and the speed with which it can complete a dose reconstruction. The NIOSH dose reconstruction rule (42 CFR part 82) and program incorporate efficiency measures to address precisely this concern. Taking this a step further, as discussed above, NIOSH will consider establishing a time limit or time guidelines for the completion of a dose reconstruction.

In addition to these measures, section 83.14 has been added to the proposed rule to expedite the consideration of petitions by claimants for whom NIOSH has found it cannot complete dose reconstructions under 42 CFR part 82. The new section would allow NIOSH to establish for evaluation a class of employees based only on the information obtained during the attempt to conduct the dose reconstruction for the employee covered by such a claim, so that adding the employee to the Cohort, together with other employees who match the same essential characteristics, could be considered by the Board and HHS without delay. HHS would then, through collection and