DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 83

RIN 0920–AA07

Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Notice of Proposed Rulemaking

AGENCY: Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document describes how the Department of Health and Human Services (''HHS'') proposes to consider designating classes of employees to be added to the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA''). Under EEOICPA, and Executive Order 13179, the Secretary of HHS is authorized to make such designations, which take effect 180 days after Congress is notified unless Congress provides otherwise. An individual member (or the survivors of a member) of a class of employees added to the Special Exposure Cohort would be entitled to compensation if the Department of Labor (''DOL'') finds that employee incurred a specified cancer and the claim meets other requirements established under EEOICPA. HHS previously published a proposal for these procedures on June 25, 2002 (67 FR 42962). Public comment on the original proposal has led HHS to make substantial changes to the procedures that require issuance of this second notice of proposed rulemaking.

DATES: HHS invites comments on this notice of proposed rulemaking from interested parties. Comments must be received by April 7, 2003.

ADDRESSES: Address written comments on the notice of proposed rulemaking to the NIOSH Docket Officer electronically by e-mail to *NIOCINDOCKET@CDC.GOV. See* **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing. Alternatively, submit printed comments to NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS-R45, Cincinnati, OH 45226, Telephone (513) 841–4498 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal.

Comments should identify the author(s), return address, and phone number, in case clarification is needed. Comments can be submitted by e-mail to: *NIOCINDOCKET@CDC.GOV.* If submitting comments by e-mail, they may be provided as e-mail text or as a Word or Word Perfect file attachment. Printed comments can also be submitted to the address above. All communications received on or before the closing date for comments will be fully considered by the Secretary. An electronic docket containing all comments submitted will be available over the Internet on the National Institute for Occupational Safety and Health (''NIOSH''), Office of Compensation Analysis and Support Web page at *www.cdc.gov/niosh/ocas,* or comments will be available in writing by request.

II. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act, 42 U.S.C. 7384–7385 [1994, supp. 2001], EEOICPA, established a compensation program to provide a lump sum payment of $150,000 and prospective medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy (''DOE'') and certain of its vendors, contractors and subcontractors. This legislation also provided for payment of compensation for certain survivors of these covered employees.

EEOICPA instructed the President to designate one or more Federal Agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179 (''Providing Compensation to America's Nuclear Weapons Workers''), which assigned primary responsibility for administering the compensation program to the Department of Labor (''DOL''). 65 FR 77487 (December 7, 2000). DOL published a final rule governing DOL's administration of EEOICPA on December 26, 2002 (67 FR 78874).

The executive order directed the HHS to perform several technical and policymaking roles in support of the DOL program:

(1) HHS is to develop procedures for considering petitions to be added to the Special Exposure Cohort established under EEOICPA by classes of employees at DOE and Atomic Weapons Employer (''AWE'') facilities. HHS is also to apply these procedures in response to such petitions. Covered employees included in the Special Exposure Cohort who have a specified cancer, and eligible survivors of these employees, qualify for compensation under EEOICPA. The procedures HHS is proposing to use for considering Special Exposure Cohort petitions were initially proposed as a notice of proposed rulemaking on June 25, 2002 (67 FR 42962) under 42 CFR Part 83 and are the subject of this second notice of proposed rulemaking.

(2) HHS is to develop guidelines by regulation to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duty at a DOE or AWE facility. HHS published a final rule establishing these ''Probability of Causation'' guidelines on May 2, 2002 (67 FR 22296) under 42 CFR Part 81.

(3) HHS is also to develop methods by regulation to estimate radiation doses (''dose reconstruction'') for certain individuals with cancer applying for benefits under the DOL program. HHS published a final rule promulgating these methods under 42 CFR Part 82 on May 2, 2002 (67 FR 22314). HHS is applying these methods to conduct the program of dose reconstruction required by EEOICPA.

(4) Finally, HHS is to provide the Advisory Board on Radiation and Worker Health with administrative and other necessary support services. The Board, a federal advisory committee whose members are appointed by the President, is advising HHS in implementing its roles under EEOICPA described here.

42 U.S.C. 7384p requires HHS to implement its responsibilities with the assistance of the National Institute for Occupational Safety and Health (NIOSH), an Institute of the Centers for Disease Control and Prevention, HHS.

B. What Is the Special Exposure Cohort?

The Special Exposure Cohort (''the Cohort'') is a category of employees defined under 42 U.S.C. 7384l(14). In this definition, Congress specified which employees comprise the Cohort initially, including employees of DOE,

DOE contractors or subcontractors, or AWEs who worked an aggregate of at least 250 days before February 1, 1992 at a gaseous diffusion plant in (1) Paducah, Kentucky, (2) Portsmouth, Ohio, or (3) Oak Ridge, Tennessee and who were monitored using dosimetry badges or worked in a job that had exposures comparable to a job that is or was monitored using dosimetry badges; or (4) employees of DOE or DOE contractors or subcontractors employed before January 1, 1974 on Amchitka Island, Alaska and exposed to ionizing radiation in the performance of duty related to the Long Shot, Milrow, or Cannikin underground nuclear tests. Employees included in the Cohort who incur a specified cancer [1] qualify for compensation (*see* DOL regulations 20 CFR part 30 for details). Cancer claims submitted by these employees or their survivors do not require DOL to evaluate the probability that the cancer was caused by radiation doses incurred during the performance of duty for nuclear weapons programs of DOE, as is required for other cancer claims covered by EEOICPA.

C. Purpose of the Proposed Procedures

EEOICPA authorized the President to designate classes of employees to be added to the Cohort, while providing Congress with the opportunity to review these decisions and expedite or reverse them. As noted previously, the President has delegated his authority in this matter to the Secretary of HHS. The purpose of this notice of proposed rulemaking is to establish procedures by which the Secretary of HHS will determine whether to add to the Cohort new classes of employees from DOE and AWE facilities. The procedures are intended to ensure that petitions for additions to the Cohort are given uniform, fair, scientific consideration, that petitioners and interested parties are provided the opportunity for appropriate involvement in the process, and to comply with specific statutory requirements of EEOICPA. The procedures also address, within their relevant scope, the stated congressional purpose of the compensation program to provide timely compensation to covered employees or their survivors for covered illnesses incurred by such employees in the performance of duty.

[1] Specified cancers are a limited group of cancers that are compensable under provisions governing compensation for members of the Cohort. The list of specified cancers can be found in this rule under section 83.5.

D. Statutory Requirements for Designating Classes of Employees as Members of the Cohort

EEOICPA includes several requirements for these procedures. The Advisory Board on Radiation and Worker Health (''the Board'') is authorized to provide advice to the President (delegated to the Secretary of HHS) concerning the designation of additional classes as members of the Cohort. The Board's advice is to be based on ''exposure assessments by radiation health professionals, information provided by the Department of Energy, and such other information as the Advisory Board considers appropriate.'' 42 U.S.C. 7384q. Section 7384q specifies that HHS obtain the advice of the Board ''after consideration of petitions by classes of employees * * * for such advice.'' This section also mandates two broad criteria to govern HHS decisions, which are to be made after receiving the advice of the Board. Members of a class of employees at a DOE or AWE facility may be treated as members of the Cohort for purposes of the compensation program if HHS ''determines that: (1) It is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.''

Finally, 42 U.S.C. 7384l(14)(C) requires the Secretary to submit a report to Congress for each class of employees the Secretary designates to be added to the Cohort. The report must define the class of employees covered by the designation and specify the criteria used to make the designation. This section requires that the designation take effect 180 days after the date on which HHS submits the report to Congress ''unless Congress otherwise provides.''

E. Relationship of Proposed Procedures to Existing Rule Promulgated by HHS To Implement EEOICPA

These procedures complement the HHS final rule: ''Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000'' promulgated by HHS on May 2, 2002 at 42 CFR Part 82 (67 FR 22314).

The rule 42 CFR part 82 provides the methods by which NIOSH is conducting dose reconstructions to estimate the radiation doses incurred by individual covered employees who have incurred cancer. These estimates are required by EEOICPA to adjudicate a cancer claim for an employee who is not a member of the Cohort or whose claim is not covered by provisions of EEOICPA for compensating members of the Cohort. The methods to arrive at these estimates, however, will be directly considered by HHS in reviewing petitions to add classes of employees to the Cohort. In particular, HHS will consider these methods in determining for a petitioning class of employees, as required by EEOICPA, whether ''it is not feasible to estimate with sufficient accuracy the radiation dose that the [individual members of] the class received.''

III. Summary of Public Comments

On June 25, 2002, HHS promulgated a notice of proposed rulemaking specifying procedures for adding classes of employees to the Cohort (42 CFR part 83; *see* 67 FR 42962). Public comments were solicited from June 25, 2002 to August 26, 2002. During this period, comments were also submitted by the Advisory Board on Radiation and Worker Health.

HHS received comments from nine organizations and 36 individuals. Organizations commenting included several labor organizations representing DOE workers, the Defense Threat Reduction Agency (which conducts radiation dose reconstructions for a compensation program serving U.S. Atomic Veterans), the Health Physics Society, and two advocacy groups. A summary of these comments and HHS responses is provided below. These are organized by general topical area. The HHS responses in this section also serve to explain changes made to the original proposal and the intent of the new rule provisions.

A. Feasibility of Dose Reconstructions

As noted above, EEOICPA requires HHS to find that it is ''not feasible to estimate with sufficient accuracy the radiation dose that the class received'' as a condition for adding the class to the Cohort. HHS received comments from several labor organizations and an advocacy group recommending that the rule establish one or more clear tests defining when dose reconstructions would not be feasible, some commenters distinguishing this requirement as separate and apart from the requirement for ''sufficient accuracy.'' One specific recommendation is that HHS establish a time limit for completing dose reconstructions, the expiration of which would determine the dose reconstruction to be not feasible. HHS has consistently heard concern about the duration of processes for adjudicating cancer claims and its impact on claimants in failing health and their families. These concerns were

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.

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

analysis of additional information, separately evaluate the possibility that there might be additional groups of employees whose circumstances are similar and would hence constitute a broader class of employees at the facility that should be added to the Cohort, under the procedures specified in section 83.13. This system should effectively ensure that classes of employees including a cancer claimant for whom NIOSH could not complete a dose reconstruction are considered for addition to the Cohort as quickly as possible.

HHS has not adopted the recommendation to apply regulatory time limits to the evaluation of petitions, the tolling of which would, without other consideration, result in the addition of such petitioning classes to the Cohort. Such a policy would conflict with the requirements under EEOICPA that Cohort additions be limited to classes of employees for whom it is not feasible to estimate radiation doses with sufficient accuracy and whose health may have been endangered by radiation doses. It could also broadly undermine the intent under EEOICPA to adjudicate cancer claims, whenever feasible, consistently with the requirements cited above: on the basis of whether it is ''at least as likely as not'' that such cancers were caused by radiation doses incurred in the performance of duty for nuclear weapons programs.

The establishment of regulatory time limits for petitions would be imprudent as well, since HHS cannot control the scope or volume of petitions it receives. A single petition could cover thousands of employees involved in hundreds of different occupations and activities over many years of operations at a facility. HHS could also receive hundreds of petitions simultaneously. In either of these circumstances, the resources of HHS and the Board to evaluate the petitions within a fixed deadline could readily be overwhelmed. HHS would then be required by regulation to add these classes of employees to the Cohort automatically.

HHS also received recommendations from individuals, employees, survivors, and a labor organization, to achieve timeliness by streamlining processes as much as possible, and in particular, again, for claimants for whom NIOSH has already established the infeasibility of completing their dose reconstruction.

As discussed above, HHS has added special procedures to streamline the petition decision process for claimants. In addition, based on a recommendation by the Board, HHS has eliminated a requirement that the Board review NIOSH decisions to deny evaluations of petitions that do not meet minimal petition requirements. Under section 83.11 of the rule, the Board now has the option, rather than the duty, to advise NIOSH concerning such decisions.

One labor organization recommended against the use of notices in the **Federal Register** to notify the public about relevant actions with respect to a petition. The commenter expressed concern that such notices would prolong the time required to consider petitions. An advocacy group, however, specifically commended the use of such notices and recommended another opportunity within the procedures to provide such notice.

The notices proposed have been retained. These notices can be issued by HHS without delaying the evaluation of petitions. The notices serve the intended purpose of officially informing the public of HHS actions of consequence. They also serve as a basis for further disseminating this information through the NIOSH and other federal agency communications, public media, and other information outlets serving interested parties.

One labor organization recommended that the Board meet frequently to minimize delays with respect to its role in advising the Secretary on Cohort decisions.

HHS intends to convene the Board as frequently as necessary and possible for this purpose.

E. Defining a ''Class'' and Its Membership

Several individual commenters questioned the meaning of a ''class'' of employees. Relevant to this, one commenter wanted to know what would happen if a class included some members for whom dose reconstruction is feasible and others for whom it is not feasible. Another commenter wanted to know whether a petition could cover all the employees of an entire facility, as a single class. Finally, the two advocacy groups recommended the definition of a class allow for the possibility that a class of employees was employed at multiple facilities. Such classes might include certain crews of construction or maintenance workers that might have been assigned to work at several facilities.

The concept of a class is defined generically in section 83.5 of the rule. To summarize, a class is a group of employees whose members must have two factors in common: they must have worked at the same facility; and the availability of records and information must be comparable with respect to the feasibility of estimating their radiation doses with sufficient accuracy. Petitioners will be encouraged to define a class as specifically as possible and appropriate with respect to other parameters, such as dates of employment, occupations, specific locations of work, specific operations of concern, etc.

One result of the process of evaluating a petition will be to establish the final definition of the class, which may differ from the class definition as it was proposed initially by the petitioner(s). The class might be redefined because the proposed definition mixed employees whose doses can be estimated with others whose doses cannot be estimated, as commented above. Classes will be very specifically defined, as described under provisions of section 83.13, with respect to a variety of employment parameters, such as dates of employment or job titles, to precisely identify the group of employees included in the decision by the Secretary to add or denying adding the class to the Cohort.

It is allowable under section 83.9 of this proposed rule to submit a petition defining the class as all the employees at the facility or any subset thereof, insofar as the petition provides adequate justification for being broadly inclusive. This section of the rule is intended, however, to require as much specificity as is consistent with the justification. It is in the interest of the petitioners to specify the class as narrowly as warranted. In general, the broader the petitioner(s) defines the class, the more time will be required to evaluate the petition, since HHS will have to determine whether the proposed class includes heterogeneous groups of employees with respect to the requirements of this rule. For example, if a petition defines a class as all employees who worked in a certain building without specifying the relevant time period or relevant occupations, HHS would have to determine whether all occupations were potentially exposed to radiation doses that cannot be estimated. It is possible that monitoring or records might be deficient only for employees working during a certain period of time, or for certain occupations employed in the building.

By defining the class more broadly than warranted, the petitioner(s) also risks HHS's determining against the petition in its entirety, despite the possibility that some subgroups covered by the class definition might qualify. HHS will be diligent in evaluating major subgroups of employees that HHS discerns under a broad class definition, but the more broadly the class is

defined, the less likely HHS is to identify all possible subgroups.

HHS has not revised the definition of class to allow for a class of employees defined as having been employed at multiple facilities, as proposed by commenters. The statutory language used by Congress in the section of EEOICPA describing the procedure for designating additional members of the Cohort (42 U.S.C. 7384q) does not allow HHS to define a class as a group of employees from multiple facilities. Congress refers to ''facility'' in the singular form in each place it is used in this section (''class of employees at *any* Department of Energy *facility* who likely were exposed to radiation at *that facility*'' in 42 U.S.C. 7384q(a)(1); ''*a* Department of Energy facility or at *an* atomic weapons employer *facility*'' in 42 U.S.C. 7384q(b); (emphasis added in both sections)). This limitation would not, however, prevent a petitioner(s) from submitting petitions separately for employees at each facility at which the class was employed, defining separate, facility-specific classes.

F. Modifications and Cancellations of Cohort Additions

Two labor organizations, the two advocacy groups, and several individuals commented on the provisions under section 83.18 of the current proposal allowing the Secretary to cancel or modify a class once it is established. The commenters recommended such a decision by the Secretary should only apply prospectively, for the adjudication of future claims. In other words, they recommended such a decision should not affect claimants who have already been compensated as a member of the Cohort, by potentially requiring the cessation of medical benefits or the return of the lump sum cash benefit.

DOL will determine the relevance of such decisions by HHS with respect to claims that DOL has already decided and claimants who have already received compensation.

G. Submission of Petitions to the Board

The two advocacy groups and one labor organization recommended that all petitions evaluated by NIOSH be submitted to the Board as well. This comment appears to refer to the Board's recommendation that it not have a role in deciding whether or not a petition meets the minimal requirements to be evaluated by NIOSH, the Board, and HHS (see Board recommendations in the following section). The Board considered its role to be limited to the evaluation of qualified petitions and recommended that NIOSH or HHS have the exclusive administrative role to ensure that petitions meet basic requirements.

HHS has revised the rule consistently with the view of the Board. Under section 83.12, the Board will receive all petitions that NIOSH ultimately finds meet the requirements for evaluation. Under section 83.10, however, the Board will not review petitions that NIOSH finds do not meet the requirements for evaluation. It should be noted that before making such a final decision, NIOSH will first provide petitioners with guidance and time to remedy petitions that initially do not meet the requirements. In light of this provision, HHS seeks comment on whether HHS should provide an option for petitioners to seek an administrative review of adverse final decisions.

H. Petitions by Claimants

Several individuals recommended against requiring claimants to petition when NIOSH has found that it cannot complete their dose reconstructions. They suggested NIOSH should initiate action to evaluate such classes automatically, upon establishing such a finding.

HHS interprets EEOICPA as requiring the submission of a petition to initiate consideration for adding a class of employees to the Cohort. However, as specified under the dose reconstruction rule (42 CFR part 82.12), NIOSH will encourage claimants in these circumstances to file a petition. In addition, HHS has designed the requirements and procedures to minimize the burden on these claimants as petitioners. As provided under section 83.9, the claimant is required only to authorize a petition. No other documentation or information is required.

I. Use of Information by the Board for Evaluating a Petition

Two labor organizations commented that the statute allows the Board to provide advice concerning a petition using information other than exposure assessments by radiation health professionals and information from DOE. This provision of EEOICPA is specifically quoted under the ''statutory requirements. . .'' sections of this and the previous notices (see section II.D above).

The initial proposal did not limit the information the Board could obtain and consider. However, in response to the comment, under section 83.15 of the current proposal, HHS has specifically authorized the Board to obtain and consider such information as it considers appropriate.

J. Use of Federal Register Notices by HHS in the Petition Process

Two advocacy groups recommended that HHS issue a **Federal Register** notice, in addition to those already proposed, to inform the public that HHS has sent a report to Congress designating a class for addition to the Cohort, for review by Congress.

HHS omitted such a notice from the original proposal out of concern that notifying the public of affirmative decisions prior to their review by Congress might be confusing, particularly if Congress were to reverse such a decision. It is probably more important, however, that interested parties are informed to ensure they have the opportunity to make their views known to Congress. Hence, HHS agrees with the recommendation and has added such a notice.

K. Publicizing HHS Decisions

One labor organization recommended that HHS use other announcement procedures, in addition to publication in the **Federal Register**, to notify classes of their addition to the Cohort or of modifications of an added class.

HHS intends to work with DOE, DOL, AWEs, public media, labor organizations, and others to publicize decisions. Such activities, however, do not require specification in the rule.

L. Transmission of Designations of New Classes to DOL

Two advocacy groups and one labor organization recommended that HHS transmit designations adding classes to the Cohort to DOL on the first business day following expiration of the 180 day congressional review period.

HHS has committed in the current proposal to transmit designations within five days of either expiration of the congressional review period or final congressional action, whichever occurs first. The five day period is a maximum, not a minimum, and allows for the potential for delay in communications between Congress and HHS and for administrative processes within HHS.

M. Eligible Petitioners

The initial proposal defined eligible petitioners to include employees, survivors, and labor organizations. One individual recommended adding to the list of eligible petitioners the [management] staff of DOE field offices and sites, on the basis that they may have expertise on employee classes with radiation exposure for whom dose reconstructions may not be feasible. The two advocacy groups recommended that non-union worker advocacy groups be added to the list.

In section 83.7(c) of the proposal, HHS has allowed for a worker or survivor to authorize any individual or entity, such as a worker advocacy group, to petition on behalf of a class. HHS has not specifically added the management staff of DOE field offices and sites. Employees of DOE sites and field offices with work experience at DOE sites are generally included among those eligible to submit petitions under section 83.7(a) (if they would themselves be included among the proposed class of employees) and (c) (if, in the proper discharge of their official duties, they are petitioning on behalf of other employees who would be included in the proposed class).

One individual raised concerns about one of the introductory sections of the rule (section 83.2), as it was initially proposed. The commenter believed it could be interpreted to require employees or survivors to submit a claim for compensation to DOL as a prerequisite to petitioning for addition to the Cohort.

The text of concern, which was explanatory and not procedural, has been deleted from the rule to streamline the rule as much as possible. Employees and their survivors are not required to submit a claim as a prerequisite to petitioning for a class. On the other hand, HHS and DOL encourage any employee who has incurred a cancer and hence is eligible to submit a claim to do so immediately. Medical benefits for a cancer claim awarded under EEOICPA are established based on the date on which the claim is submitted to DOL. Any medical costs for the cancer incurred before the date the claim is submitted would not be covered. For this reason, employees with cancer should submit claims to DOL without delay.

N. Petition Informational Requirements

Labor organizations and the two advocacy groups submitted a variety of comments concerning the informational requirements of a petition, and recommended not requiring the use of a form for petitioning. In general, these comments argued for less burden on petitioners.

Under section 83.9, HHS has reduced the informational requirements substantially to comprise a minimal basis for justifying a petition. HHS has eliminated the requirement that petitioners have sought records from DOE or AWEs to demonstrate a basis for concern about the feasibility of estimating radiation doses for the class. HHS recognizes that such efforts could be of little practical value to the evaluation of a petition. HHS has also eliminated the requirement that petitioners demonstrate a basis for suspecting the health of the class may have been endangered, since the basis for establishing health endangerment under the proposal (a finding that doses cannot be estimated with sufficient accuracy and a determination as to whether this finding applies to radiation exposure during a discrete exposure incident or during routine operations) does not require information available to the petitioners.

The procedures continue to require petitioners to justify their concern that it may not be feasible to estimate the radiation dose incurred by employees of the class with sufficient accuracy. HHS has attempted to specify clear and minimal requirements for this justification. The procedures also may require petitioners to substantiate the occurrence of discrete exposure incidents potentially involving high level exposures, when such an incident comprises the basis of the petition and if NIOSH is otherwise unable to verify the occurrence of incident through other sources. The evidence that may be required in these cases, however, is similar to informational requirements that were included in the initial proposed rule.

Finally, HHS has made optional the use of a petition form for the submission of petitions, although its use should assist, rather than burden, petitioners.

O. Technical Assistance for Petitioners

One labor organization and the two advocacy groups recommended HHS sponsor technical assistance or training for petitioners to address informational requirements. The commenters suggested some petitioners are unlikely to have sufficient expertise to address these requirements without assistance.

Although NIOSH will provide guidance to petitioners, HHS does not intend to sponsor independent technical experts to assist petitioners in developing the basis for a petition. The purpose of a petition, as discussed in the rule, is to identify classes of employees that should be considered for addition to the Cohort. In other words, it is to bring to the attention of the Board, NIOSH, and HHS, classes of employees who were exposed to radiation at a DOE or AWE facility but for whom there are reasonable grounds to suspect radiation doses cannot be estimated with sufficient accuracy. If a petitioner lacks reasonable grounds for identifying such a class, as defined in the rule, they should not file a petition. In addition, in cases where members of the class submit claims and NIOSH determines that it cannot complete dose reconstructions for them, this finding can serve as the basis for a Cohort petition.

P. Basis for Petitioning

One labor organization recommended that petitioners should be permitted to petition on the basis of qualitative or quantitative information, and any such information as the Board deems appropriate. The commenter further recommended that the petitioner should not be required to prove that doses cannot be estimated or that health was endangered.

In this rule, HHS has identified minimal requirements for a petition. A petition that does not meet these minimal requirements would not present a substantial likelihood of identifying a class that should be added to the Cohort, according to the statutory requirements for making such additions.

Meeting these petition requirements does not prove, however, that the statutory requirements will be met; the petitioner is not proving that it is not feasible to estimate doses with sufficient accuracy and that doses may have endangered the health of members of the class. These statutory requirements will be determined in the course of evaluating the petition.

The Board has had the opportunity to recommend alternatives to the petition requirements in the initial proposal. The Board's recommendations on requirements for petitions are reflected in the current proposal without exception, as discussed in Section IV below. The Board will have the opportunity again to recommend requirements during the public comment period on this second notice. HHS will consider any such alternatives for use in the final rule. In addition, section 83.11(c) of the current proposal would allow the Board to advise NIOSH concerning a petition after NIOSH has preliminarily found the petition does not meet the requirements specified in the rule.

Q. Deciding Whether To Petition

Several individuals sought guidance concerning how one should decide whether or not to petition to be added to the Cohort. One commenter noted that he had a claim awaiting dose reconstruction and wanted to know whether he should petition immediately or await the outcome of the dose reconstruction. Another commenter noted more generally that an employee may want to consider whether he has a better chance of being compensated as a member of the Cohort or through dose reconstruction. The commenter recommended that HHS provide in the

rule as much guidance as possible concerning these decisions.

The rule provides clear requirements explaining who is eligible to petition and identifying the information required of the petitioners. In terms of helping individuals decide whether to petition, as discussed in the HHS rule on dose reconstruction (42 CFR part 82.12), NIOSH will directly encourage any claimant for whom it cannot complete a dose reconstruction to petition. As discussed above, HHS and DOL also encourage any employee who has incurred a cancer to submit a claim to DOL immediately, whether or not they submit a petition to HHS, since medical benefits only cover medical costs incurred for the cancer beginning on the date a claim is submitted. Otherwise, HHS generally encourages petitions whenever there is justification, as specified in the rule; in other words, whenever it is known that a class of employees was exposed to radiation that was not monitored, either by personal dosimetry such as radiation badges and biological tests, or by monitoring of the area in which the class of employees worked. Knowledge that the records of such monitoring were destroyed, lost, or falsified would also justify submitting a petition. The rule also specifies expert sources that may justify a petition.

Petitioners should understand, however, that having justification to petition does not mean that the petition will be successful. For example, in some cases NIOSH may be able to conduct dose reconstructions even when no radiation monitoring information is available, using knowledge of health physics and with sufficient information on the radiation source, quantity, and the relevant work processes that might involve radiation exposures.

It also may be useful for potential petitioners to understand how HHS plans to prioritize petitions for evaluation. The highest priority petitions will be those based on NIOSH finding that it is unable to complete a dose reconstruction for a claimant. These petitions will be evaluated first because in these cases, HHS already knows there is a class of employees for whom dose reconstructions are infeasible and among whom one or more individuals have incurred cancer, for which a claimant is awaiting a decision on a claim. The second highest priority will be petitions for a class of employees that does not include current claimants awaiting dose reconstructions. The lowest priority will be petitions including current claimants awaiting dose reconstructions, since the dose reconstruction process will determine whether or not it is feasible to estimate doses with sufficient accuracy for these claimants. If NIOSH finds the dose reconstructions cannot be completed for these claimants, then their petition process will be expedited, as described above.

R. Use of Unspecified Procedures by HHS

One labor organization recommended that HHS strike provisions in the initially proposed rule (section 83.14(e)) that would have allowed the Secretary to make Cohort determinations based on factors and procedures other than those specified in the rule.

HHS has omitted this provision from the current proposed rule. The provision was intended to permit the Secretary flexibility in responding to novel, unforseen issues that might arise in the course of considering the addition of a particular class of employees. Upon further consideration, HHS believes the specified procedures of this rule will fully and expeditiously serve its purpose.

S. Decisionmaking Authority

HHS received several comments concerning its authority to determine whether or not to add a class of employees to the Cohort. One labor organization recommended HHS be required to comply with the recommendation of the Board. Another labor organization and an advocacy group recommended the Secretary delegate authority for such determinations to the Director of NIOSH to expedite the determinations.

Section 3626 of EEOICPA (42 U.S.C. 7384q) specifically authorizes the President (delegated to the Secretary of HHS) to determine whether or not to add a class of employees to the Cohort and specifically limits the role of the Board to providing advice related to such determinations. Hence, this rule cannot make the recommendations of the Board binding on the Secretary. Moreover, the Federal Advisory Committee Act, under which the Board is established, specifies the following: ''Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.'' (5 U.S.C.A. App. 2 § 9(b)).

The Secretary can delegate authority to the Director of NIOSH to determine the designation of classes of employees. The Secretary may consider such a delegation of authority for the designation of certain classes of employees if, upon experience, the Secretary finds this is likely to improve the effectiveness and efficiency of the program.

T. Regulatory Approach

HHS received several comments concerning the regulatory approach to establishing these procedures. One labor organization and the two advocacy groups recommended this rule be issued as an interim final rule to allow HHS and petitioners to obtain experience with certain elements of the rule before rulemaking is completed. Three other labor organizations recommended that these procedures be issued as a general statement of policy rather than a rule, asserting that more flexibility is required in such procedures than could be encompassed in a rule. The commenters did not specify, however, the provisions that require greater flexibility.

As discussed below, HHS has determined that the rule, as initially proposed, required changes that were not discussed in the initial notice of proposed rulemaking and that could not reasonably have been anticipated based on a reading of the initial notice. For this reason, HHS is issuing this second notice of proposed rulemaking and obtaining public comment on this revised proposal.

For the same reason, HHS does not find sufficient justification to publish these procedures as an interim final rule with a request for comments. If HHS were to issue the current proposal as an interim final rule, the rule and determinations the Secretary would make under the rule could be legally contested on the basis of HHS not having provided sufficient notice and opportunity for public comment in advance of issuing the rule. Such a contest could delay implementation of these procedures more substantially than issuance of this second notice.

HHS considered the issuance of a statement of policy, versus a rule, before issuing the initial proposed rule in June 2002. HHS found then, and continues to find, that these procedures are regulatory in nature, comprising requirements that are binding on petitioners and on HHS.

U. Congressional Review Period

One individual commented that the 180 day congressional review period should be eliminated or shortened to 60 days or less.

HHS must allow for the full 180 day review period as required by law under

section 3621(14)(C)(ii) of EEOICPA (42 U.S.C. 7384l(14)(C)(ii)). Under section 3621(14)(C)(ii), however, Congress can reduce this review period to expedite the addition of a class to the Cohort. This is acknowledged under section 83.17 of this rule.

V. Non-regulatory Comment: Dose Reconstructions for Cohort Members With Non-Specified Cancers

HHS received several comments on matters extraneous to the rule, but relevant to the Cohort.

The two advocacy groups and a labor organization questioned how NIOSH would handle cancer claims for individuals in the Cohort who have a cancer that is not one of the specified cancers.

DOL refers claims for individuals in the Cohort who have a cancer that is not one of the specified cancers to NIOSH for dose reconstruction. NIOSH will conduct these dose reconstructions if sufficient information is available. The situation becomes complicated, however, if the individual may have incurred radiation doses that NIOSH cannot estimate, because the necessary information is not available. This will be true for classes of employees added to the Cohort by the Secretary.

NIOSH will develop dose reconstruction procedures with the advice of the Board to address these circumstances. The procedures will have to resolve the issue of whether or not to assign a radiation dose covering a potential exposure that cannot be estimated with sufficient accuracy, and if so, how to determine the characteristics and quantity of dose to be assigned. This issue is further discussed under section IV in response to a recommendation by the Board.

W. Non-Regulatory Comment: Giving Claimants the Benefit of the Doubt in Dose Reconstructions

One labor organization commented that NIOSH dose reconstructions should give the benefit of the doubt to the claimants when making assumptions concerning potentially unknown factors, such as the solubility of a radioactive material.

NIOSH gives the benefit of the doubt to claimants when making assumptions concerning unknown factors, except when the claim involves recorded doses sufficiently high to qualify for compensation without full development of the dose estimate. The NIOSH implementation guides for dose reconstructions, which are available from NIOSH, consistently illustrate this policy.

X. Non-Regulatory Comment: Basis for Including Employees of the Gaseous Diffusion Plants in the Cohort

Several individuals questioned the basis for the decision by Congress to include employees of the gaseous diffusion plants in the Cohort. The commenters believe the potential for health endangering radiation exposure was as great or greater at other DOE facilities. For this reason, the commenters indicated that Congress should have included other DOE facilities in the Cohort.

This is a matter that was decided by Congress and is beyond the control of HHS. Therefore, HHS has not responded to the comment.

Y. Non-Regulatory Comment: Basis for Limiting Cohort Provisions to the 22 Specified Cancers

Several individuals questioned the decision by Congress to limit the diseases covered by EEOICPA for the compensation of employees as members of the Cohort to 22 specified cancers. Commenters questioned why other cancers are not included, as well as other illnesses such as acute health effects from high levels of radiation and diseases related to exposure to asbestos and heavy metals.

This is a matter that was decided by Congress and is beyond the control of HHS. Therefore, HHS has not responded to the comment.

HHS notes that Congress also established Part D of EEOICPA to assist DOE contractor employees in seeking compensation through the appropriate state workers' compensation systems for occupational illnesses related to toxic exposures at DOE facilities.

Z. Non-Regulatory Comment: Recommendations for Adding Specific Classes to the Cohort

A labor organization, an advocacy group, and several individuals recommended the addition of specific employee classes to the Cohort.

This rule must be promulgated through the issuance of a final rule before petitions can be evaluated. NIOSH will notify individuals and organizations who have indicated an interest in petitioning at that time.

IV. Recommendations of the Advisory Board on Radiation and Worker Health

HHS requested the Board to consider issues related to making additions to the Cohort. As discussed above, the Board has an integral role in the evaluation of petitions to add classes of employees to the Cohort.

The Board reviewed issues related to the Cohort during its public meeting on May 2–3, and reviewed the initial notice of proposed rulemaking during its public meetings on July 1–2, August 14–15, and August 22, 2002. In preparation for the July meeting, the Board members individually reviewed the initial notice of proposed rulemaking, which was published on June 25, 2002. The members also considered public comments on these rules provided during public meetings of the Board and at four regional meetings held in July and August 2002. In addition, NIOSH staff members gave formal presentations on the proposed rule and related issues during the Board meetings. The transcripts and minutes of these meetings are included in the NIOSH docket for this rule and are available to the public.

All of the Board members participated in the review of these guidelines and the members present at the August 22 meeting concurred in establishing the Board findings and recommendations. The Board provided recommendations on general issues related to the rule, as well as recommendations for text and other changes to specific sections of the rule. The recommendations, which are available to the public from the NIOSH Docket, are summarized below, together with responses by HHS to the recommendations.

A. Dose Reconstruction for Members of the Cohort

Claims for cancers that are not included among the specified cancers cannot be compensated under provisions of EEOICPA covering members of the Cohort. These claims will require a NIOSH dose reconstruction and a probability of causation determination by DOL, despite the fact that the employee is a member of the Cohort. The Board recommended that NIOSH review the proposed rule to ensure it does not preclude appropriate handling of these dose reconstructions. Relatedly, the Board also recommended that NIOSH develop procedures [for dose reconstructions] for claims for which the employee's dose history is partially but not completely covered in the employment parameters that define a Cohort class.

As discussed in response to similar public comments, this proposed rule would not affect claims that require dose reconstructions. The determination by the Secretary to add a class of employees to the Cohort does, however, have implications for the conduct of dose reconstructions for these members of the Cohort. When HHS adds members to the Cohort, HHS will have determined that radiation doses for

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

comprised all individuals who performed a certain task or manned a certain type of operation at a facility.

G. Recommendations for Section 83.9

The Board recommended HHS eliminate the proposed requirement that petitioners obtain from DOE or an AWE a response to a request for records, indicating that dosimetry records are unavailable pertaining to radiation exposures incurred by employees. The Board noted that it may not be possible for petitioners to obtain such a response from AWEs and from DOE for certain DOE employees. The Board suggested HHS consider requiring a ''good faith effort'' to obtain records instead.

As discussed in response to this comment from the public, HHS agrees and has eliminated this proposed requirement. HHS has decided not to propose any requirement with respect to the procurement of records, even for a good faith effort, since this would be burdensome to petitioners and often without value to the evaluation of the petition.

The Board also recommended that HHS add an element to this section allowing petitioners to submit a government report or published scientific report concerning a deficiency of dosimetry records as a basis for petitioning. HHS agrees and has added this option.

H. Recommendation for Section 83.10

Section 83.10 of the initially proposed rule (now section 83.11) included the Board in the process for selecting petitions for evaluation. The Board would review each petition that HHS proposes to deny an evaluation (because the petition does not meet requirements specified in section 83.9) prior to HHS's making a decision.

The Board recommended HHS independently select petitions for evaluation, without the involvement of the Board. The Board was particularly concerned about its ability to handle this work load and did not consider as crucial its judgment on the qualifications of a petition to receive an evaluation.

HHS has revised the petition selection process in response to the concerns of the Board. Accordingly, the Board will not review petitions that NIOSH finds do not meet the requirements for a petition. This change should also be considered in light of the clarified and simplified petition requirements specified in this current proposal, and the process by which NIOSH will assist petitioners whose petitioners do not initially meet the requirements, before making a final decision. HHS seeks comment, however, on whether petitioners should have the option to seek an administrative review of adverse final decisions.

I. Recommendation on Section 83.13

Section 83.13 of the initially proposed rule (now section 83.15) specifies the process by which the Board will review petitions. This section includes a provision for inviting petitioners to present directly to the Board concerning their petition and NIOSH evaluation findings addressing their petition.

The Board recommended changes to this section to emphasize that the Board's role is advisory, not adjudicatory; and to clarify that the recommendations of the Board are only part of the information to be considered by the Secretary in making a decision with respect to a petition.

HHS has revised section 83.15 and 83.16 to address the concerns of the Board. As recommended by the Board, the term ''evidence'' is omitted from section 83.15, and section 83.16 clearly specifies that the Board recommendations are only part of the information to be considered by the Secretary in reaching a decision.

J. Recommendation on Section 83.14

Section 83.14 of the initially proposed rule provided the Secretary with flexibility to make use of unspecified procedures and information to address novel, unforeseen circumstances in the evaluation of a petition. The Board was concerned about the broad latitude that this authority would provide the Secretary, and recommended that the rule require that such unspecified procedures as might be applied under this broad authority would not conflict with procedures specified in the rule.

As discussed in response to similar public comments, HHS has omitted from the current rule authority for the Secretary to make use of unspecified procedures under this rule. Upon further consideration, HHS believes the specified procedures of this rule will fully and expeditiously serve its purpose.

V. Publication of a Second Notice of Proposed Rulemaking

HHS is publishing this second notice of proposed rulemaking to provide opportunity for public comment on the changes to the initial proposal discussed above. Some of these changes are substantial and were not discussed as options in the initial notice, nor were they otherwise foreseeable extensions, abbreviations, or variations of the initial proposal. These substantial changes include: a more qualified definition of sufficient accuracy; revised procedures for establishing health endangerment, which eliminate the use of cancer risk models and of subjective judgments to quantify potential radiation doses; the potential for defining a class to be added to the Cohort by type of cancer in addition to previously specified employment parameters; and expedited procedures for evaluating petitions by claimants for whom NIOSH lacked sufficient information to complete dose reconstructions.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under executive order (E.O) 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the executive order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. This notice of proposed rulemaking is being treated as a ''significant regulatory action'' within the meaning of the executive order because it meets the criterion of section 3(f)(4) in that it raises novel or legal policy issues arising out of the legal mandate established by EEOICPA. It proposes to establish practical procedures, grounded in current science, by which the Secretary of HHS can fairly consider petitions to add classes of employees to the Cohort. The financial cost to the federal government of responding to these petitions is likely to vary from several thousand dollars to as much as tens of thousands of dollars, depending on the availability of information and scope of the petition.

The notice of proposed rulemaking carefully explains the manner in which the procedures are consistent with the

mandate of 42 U.S.C. 7384q and implements the detailed requirements of that section. The proposal does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The proposal is not considered economically significant, as defined in § 3(f)(1) of the E.O. 12866. It has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR parts 1 and 30. DOL has determined that its rule fulfills the requirements of E.O. 12866 and provides estimates of the aggregate cost of benefits and administrative expenses of implementing EEOICPA under its rule (*see* 66 FR 28948, May 25, 2001). OMB has reviewed this proposal for consistency with the President's priorities and the principles set forth in E.O. 12866.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. We certify that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. This proposal affects only DOL, DOE, HHS, and certain individuals covered by EEOICPA. Therefore, a regulatory flexibility analysis as provided for under RFA is not required.

C. What Are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under This Proposed Rule, and How Are Comments Submitted?

Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The Paperwork Reduction Act is applicable to the data collection aspects of these proposed procedures. The Centers for Disease Control and Prevention will publish a separate notice in the **Federal Register** announcing its intent to collect this data and seek OMB approval of the data collection instrument.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the Department will report to Congress promulgation of this proposed rule prior to its effective date. The report will state that the Department has concluded that this proposed rule is not a ''major rule'' because it is not likely to result in an annual effect on the economy of $100 million or more. However, this proposed rule has a subordinate role in the adjudication of claims under EEOICPA, serving as one element of an adjudication process administered by DOL under 20 CFR parts 1 and 30. DOL has determined that its rule is a ''major rule'' because it will likely result in an annual effect on the economy of $100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local or tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the Federal court system. HHS adverse decisions may be reviewed in United States District Courts pursuant to the Administrative Procedure Act. HHS has attempted to minimize that burden by providing petitioners an opportunity to seek administrative review of adverse decisions. HHS has provided a clear legal standard it will apply in considering petitions. This proposed rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The proposed rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

H. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this proposed rule on children. HHS has determined that the proposed rule would have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this proposed rule on energy supply, distribution or use, and has determined that the proposed rule will not have a significant adverse effect on them.

List of Subjects in 42 CFR Part 83

Government employees, Occupational safety and health, Nuclear materials, Radiation protection, Radioactive materials, Workers' compensation.

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 42 CFR Chapter I by adding Part 83 to read as follows:

PART 83—PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

Subpart A—Introduction

Sec.
83.0 Background information on the procedures in this part.
83.1 What is the purpose of the procedures in this part?
83.2 How will DOL use the designations established under the procedures in this part?

Subpart B—Definitions

83.5 Definitions of terms used in the procedures in this part.

Subpart C—Procedures for Adding Classes of Employees to the Cohort

83.6 Overview of the procedures in this part.

83.7 Who can submit a petition on behalf of a class of employees?
83.8 How is a petition submitted?
83.9 What information must a petition include?
83.10 If a petition satisfies all relevant requirements under § 83.9, does this mean the class will be added to the Cohort?
83.11 What happens to petitions that do not satisfy all relevant requirements under §§ 83.7 through 83.9?
83.12 How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?
83.13 How will NIOSH evaluate petitions, other than petitions by claimants covered under § 83.14?
83.14 How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR Part 82?
83.15 How will the Board consider and advise the Secretary on a petition?
83.16 How will the Secretary decide the outcome of a petition?
83.17 What is the role of Congress in acting upon the final decision of the Secretary to add a class of employees to the Cohort?
83.18 How can the Secretary cancel or modify a final decision to add a class of employees to the Cohort?

Authority: 42 U.S.C. 7384q; E.O. 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321.

Subpart A—Introduction

§ 83.0 Background information on the procedures in this part.

The Energy Employees Occupational Illness Compensation Program Act, as amended (''EEOICPA'' or ''the Act''), 42 U.S.C. 7384 *et seq.*, provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of the United States Department of Energy (''DOE''), its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two methods set forth in the statute for claimants to establish that a cancer incurred by a covered worker is compensable under EEOICPA. The first is to establish that the cancer is at least as likely as not related to covered employment at a DOE or Atomic Weapons Employer (''AWE'') facility pursuant to guidelines issued by the Department of Health and Human Services (''HHS''), which are found at 42 CFR part 81. The second method to establish that a cancer incurred by a covered worker is compensable under EEOICPA is to establish that the worker is a member of the Special Exposure Cohort (''the Cohort'') and suffered a specified cancer after beginning employment at a DOE or AWE facility. Section 3621(14) of EEOICPA (42 U.S.C. 7384l(14)) includes certain classes of employees in the Cohort. Section 3626 of the Act (42 U.S.C. 7384q) authorizes the addition to the Cohort of other classes of employees. This authority has been delegated to the Secretary of HHS by Executive Order 13179.

§ 83.1 What is the purpose of the procedures in this part?

EEOICPA authorizes the President to add classes of employees to the Cohort, while providing Congress with the opportunity to review and expedite or reverse these decisions. The President delegated his authority to the Secretary of HHS. This part specifies the procedures by which HHS will determine whether to add new classes of employees from DOE and AWE facilities to the Cohort. HHS will consider adding new classes of employees in response to petitions by or on behalf of such classes of employees. The procedures specify requirements for petitions and for their consideration. These requirements are intended to ensure that petitions are submitted by authorized parties, are justified, and receive uniform, fair, scientific consideration. The procedures are also designed to give petitioners and interested parties opportunity for appropriate involvement in the process, and to ensure that the process is timely and consistent with requirements specified in EEOICPA. The procedures are not intended to provide a second opportunity to qualify a claim for compensation, once HHS has completed the dose reconstruction and DOL has determined that the cancer subject to the claim was not ''at least as likely as not'' caused by the estimated radiation doses. DOL has established procedures separate from those covered by this rule, under 20 CFR part 30, for cancer claimants who want to contest the factual determinations or how NIOSH conducted their dose reconstructions.

§ 83.2 How will DOL use the designations established under the procedures in this part?

DOL will adjudicate compensation claims for members of classes of employees added to the Cohort according to the same general procedures that apply to the statutorily defined classes of employees in the Cohort. Specifically, DOL will determine whether the claim is for a qualified member of the Cohort with a specified cancer, pursuant to the procedures set forth in 20 CFR Part 30.

Subpart B—Definitions

§ 83.5 Definitions of Terms Used in the Procedures in this part.

(a) *Advisory Board on Radiation and Worker Health (''the Board'')* is a federal advisory committee established under EEOICPA and appointed by the President to advise HHS in implementing its responsibilities under EEOICPA.

(b) *Atomic Weapons Employer (''AWE'')* is a statutory term of EEOICPA which means any entity, other than the United States, that:

(1) Processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and

(2) Is designated by the Secretary of Energy as an atomic weapons employer for purposes of EEOICPA.

(c) *Class of employees* means, for the purposes of this rule, a group of employees who work or worked at the same DOE or AWE facility, and for whom the availability of information and recorded data on radiation exposures is comparable with respect to the informational needs of dose reconstructions conducted under 42 CFR part 82.

(d) *HHS* is the U.S. Department of Health and Human Services.

(e) *DOE* is the U.S. Department of Energy, which includes predecessor agencies of DOE, including the Manhattan Engineering District.

(f) *DOL* is the U.S. Department of Labor.

(g) *Employee,* for the purposes of these procedures, means a person who is or was, for the purposes of EEOICPA, an employee of DOE, a DOE contractor or subcontractor, or an Atomic Weapons Employer.

(h) *NIOSH* is the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(i) *Radiation* means ionizing radiation, including alpha particles, beta particles, gamma rays, x rays, neutrons, protons and other particles capable of producing ions in the body. For the purposes of the proposed procedures, radiation does not include sources of non-ionizing radiation such as radio-frequency radiation, microwaves, visible light, and infrared or ultraviolet light radiation.

(j) *Secretary* is the Secretary of Health and Human Services.

(k) *Specified cancer* as defined in § 3621 of EEOICPA (42 U.S.C. 7384l(17)) and the DOL regulation implementing EEOICPA (20 CFR 30.5(dd)) means:

(1) Leukemia (other than chronic lymphocytic leukemia) provided that onset of the disease was at least two years after initial occupational exposure;

(2) Lung cancer (other than in situ lung cancer that is discovered during or after a post-mortem exam);

(3) Bone cancer;

(4) Renal cancers;

(5) The following diseases, provided onset was at least 5 years after first exposure:

(i) Multiple myeloma;

(ii) Lymphomas (other than Hodgkin's disease);

(iii) Primary cancer of the:

(A) Thyroid;

(B) Male or female breast;

(C) Esophagus;

(D) Stomach;

(E) Pharynx;

(F) Small intestine;

(G) Pancreas;

(H) Bile ducts;

(I) Gall bladder;

(J) Salivary gland;

(K) Urinary bladder;

(L) Brain;

(M) Colon;

(N) Ovary;

(O) Liver (except if cirrhosis or hepatitis B is indicated).

(6) The specified diseases designated in this section mean the physiological condition or conditions that are recognized by the National Cancer Institute under those names or nomenclature, or under any previously accepted or commonly used names or nomenclature.

(l) Survivor means a surviving spouse, child, parent, grandchild and grandparent of a deceased covered employee as defined in EEOICPA.

Subpart C—Procedures for Adding Classes of Employees to the Cohort

§ 83.6 Overview of the procedures in this part.

The procedures in this part specify who may petition to add a class of employees to the Cohort, the requirements for such a petition, how a petition will be selected for evaluation by NIOSH and for the advice of the Board, and the process NIOSH, the Board, and the Secretary will use to consider a petition, leading to the Secretary's final determination to accept or deny adding a class to the Cohort. Special procedures are included for considering the addition of a class of employees to the Cohort when NIOSH finds, through the process of attempting a dose reconstruction for an employee under 42 CFR 82.12, that available information is insufficient to complete the dose reconstruction. As required by EEOICPA, the procedures in this part include formal notice to Congress of any decision by the Secretary to add a class to the Cohort, and the opportunity for Congress to expedite or change the outcome of the decision.

§ 83.7 Who can submit a petition on behalf of a class of employees?

A petitioner or petitioners must be one or more of the following:

(a) One or more DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees, or their survivors; or

(b) One or more labor organizations representing or formerly having represented DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees; or

(c) One or more individuals or entities authorized in writing by one or more DOE, DOE contractor or subcontractor, or AWE employees, who would be included in the proposed class of employees, or their survivors.

§ 83.8 How is a petition submitted?

The petitioner(s) must send a petition in writing to NIOSH. A petition must provide identifying and contact information on the petitioner(s) and information to justify the petition, as specified under § 83.9. Detailed instructions for preparing and submitting a petition, including an optional petition form, are available from NIOSH through direct request (1–800–35–NIOSH) or on the Internet at *www.cdc.gov/niosh/ocas.*

§ 83.9 What information must a petition include?

(a) All petitions must provide identifying and contact information on the petitioner(s). The information required to justify a petition differs, depending on the basis of the petition. If the petition is by a claimant in response to a finding by NIOSH that the dose reconstruction for the claimant cannot be completed, then the petition must provide only the justification specified under paragraph (b) of this section. All other petitions must provide only the information specified under paragraph (c) of this section. The informational requirements for petitions are also summarized in Table 1 at the end of this section.

(b) The petition must notify NIOSH that the claimant is petitioning on the basis that NIOSH found, under 42 CFR 82.12, that the dose reconstruction for the claimant could not be completed due to insufficient records and information.

(c) The petition must include the following:

(1) A proposed class definition [1] specifying:

(i) The DOE or AWE facility at which the class worked;

(ii) The location or locations at the facility covered by the petition (*e.g.*, building, technical area);

(iii) The job titles and/or job duties of the class members;

(iv) The period of employment relevant to the petition;

(v) Identification of any exposure incident that was unmonitored, unrecorded, or inadequately monitored or recorded, if such incident comprises the basis of the petition; and

(2) A description of the petitioner's (petitioners') basis for believing records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class of employees with sufficient accuracy. This description must include one of the following elements:

(i) Documentation or statements provided by affidavit indicating that radiation exposures and doses to members of the proposed class were not monitored, either through personal or area monitoring; or

(ii) Documentation or statements provided by affidavit indicating that radiation monitoring records for members of the proposed class have been lost, falsified, or destroyed; or

(iii) A report from a health physicist or other individual with expertise in dose reconstruction documenting the limitations of existing DOE or AWE records on radiation exposures at the facility, as relevant to the petition, and specifying the basis for finding these documented limitations might prevent the completion of dose reconstructions for members of the class under 42 CFR part 82 and related NIOSH technical implementation guidelines; or

(iv) A report published by a scientific government agency or published in a peer-reviewed scientific journal that identifies dosimetry and related information that are unavailable (due to either a lack of monitoring or the destruction or loss of records) for estimating the radiation doses of employees covered by the petition and also finds that such information might be essential to produce such estimates.

(3) If the petition is based on an exposure incident as described under paragraph (c)(1)(v) of this section, the petitioner(s) may be required to provide evidence that the incident occurred, if

[1] HHS will determine the final class definition for each petition (*see* § 83.16 of these procedures).

NIOSH is unable to obtain records or confirmation of the occurrence of such an incident from sources independent of the petitioner(s). In such cases, either of the following may qualify as evidence:

(i) Medical evidence that one or more members of the class may have incurred a high level radiation dose from the incident, such as a depressed white blood cell count associated with radiation exposure or the application of chelation therapy; or

(ii) Confirmation by affidavit from two employees who witnessed the incident, providing this evidence is consistent with other information available to HHS.

TABLE 1 FOR § 83.9.—SUMMARY OF INFORMATIONAL REQUIREMENTS FOR PETITIONS

[Petitioner(s) must submit identifying and contact information and either A. or B. of this table]

A. The claimant's authorization of the petition, based on NIOSH having found it could not complete a dose reconstruction for the claimant submitting the petition; or	B. (1) Proposed class definition identifying: (i) Facility, (ii) relevant locations at the facility; (iii) job titles/duties, (iv) period of employment, and if relevant, (v) exposure incident. (2) Basis for infeasibility of dose reconstruction; either: (i) Lack of monitoring; or (ii) destruction, falsification, or loss of records; or (iii) expert report; or (iv) published scientific report.

§ 83.10 If a petition satisfies all relevant requirements under § 83.9, does this mean the class will be added to the Cohort?

Satisfying the informational requirements for a petition does not mean the class will be added to the Cohort. It means the petition will receive a full evaluation by NIOSH, the Board, and HHS, as described under §§ 83.13 through 83.16. The role of the petitioner(s) is to identify classes of employees that should be considered for addition to the Cohort.

§ 83.11 What happens to petitions that do not satisfy all relevant requirements under §§ 83.7 through 83.9?

(a) NIOSH will notify the petitioner(s) of any requirements that are not met by the petition, assist the petitioner(s) with guidance in developing relevant information, and provide 30 calendar days for the petitioner(s) to revise the petition accordingly.

(b) After 30 calendar days from the date of notification under paragraph (a) of this section, NIOSH will notify the petitioner(s) of its decision to evaluate the petition, or its final decision that the petition has failed to meet the requirements for evaluation and the basis for this decision.

(c) Based on new information, NIOSH may, at its discretion, reconsider a decision not to select a petition for evaluation.

§ 83.12 How will NIOSH notify petitioners, the Board, and the public of petitions that have been selected for evaluation?

(a) NIOSH will notify the petitioner(s) in writing that it has selected the petition for evaluation. NIOSH will also provide the petitioner(s) with information on the steps of the evaluation and other processes required pursuant to these procedures.

(b) NIOSH will combine separate petitions and evaluate them as a single petition if, at this or at any point in the evaluation process, NIOSH finds such petitions represent the same class of employees.

(c) NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition. Each evaluation plan will include the following elements:

(1) An initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation conducted under § 83.13; and

(2) A list of activities for evaluating the radiation exposure potential of the class and the adequacy of existing records and information needed to conduct dose reconstructions for all class members under 42 CFR part 82.

(d) NIOSH may initiate work to evaluate a petition immediately, prior to presenting the petition and evaluation plan to the Board.

(e) NIOSH will publish a notice in the **Federal Register** notifying the public of its decision to evaluate a petition.

§ 83.13 How will NIOSH evaluate petitions, other than petitions by claimants covered under § 83.14?

(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 the following potential sources, as necessary:

(1) The petition or petitions submitted on behalf of the class;

(2) DOE and AWE facility records and information;

(3) Potential members of the class and their survivors;

(4) Labor organizations who represent or represented employees at the facility during the relevant period of employment;

(5) Managers, radiation safety officials, and other witnesses present during the relevant period of employment at the DOE or AWE facility;

(6) NIOSH records from epidemiological research on DOE populations and records from dose reconstructions conducted under 42 CFR part 82;

(7) Records from research, dose reconstructions, medical screening programs, and other related activities conducted to evaluate the health and/or radiation exposures of employees of DOE, DOE contractors or subcontractors, and the AWEs; and

(8) Other sources.

(b) NIOSH will evaluate records and information collected to make the following determinations:

(1) *Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?* (i) 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.

(ii) 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. Alternatively, if members of the class were potentially exposed without adequate protection to unmonitored radiation from radiation generating equipment (*e.g.*, particle accelerator, industrial x-ray equipment), in general, NIOSH would require relevant equipment design and performance specifications or information on maximum emissions.

(iii) In general, access to personal dosimetry data and area monitoring data are not necessary to estimate the maximum radiation doses that could

have been incurred by any member of the class.

(iv) If NIOSH determines that it is not feasible to estimate radiation doses with sufficient accuracy, NIOSH will also determine whether such finding is limited to radiation doses incurred at certain tissue-specific cancer sites, and hence limited to specific types of cancers (whether or not such cancer(s) is a specified cancer under § 83.5(k)).

(2) *How should the class be defined, consistent with the findings of the analysis discussed under paragraph (b)(1) of this section?* NIOSH will define the following characteristics of a class, taking into account the class definition proposed by the petition and modified as necessary to reflect the results of the evaluation under paragraph (b)(1) of this section:

(i) Any of the following employment parameters, as necessary to identify members included in the class: facility, job titles, duties, and/or specific work locations within the facility or site, the relevant time period, and any additional identifying characteristics of employment;

(ii) If applicable, the identification of a exposure incident, when unmonitored radiation exposure during such an incident comprises the basis of the petition or the class definition;

(iii) If applicable, the identification of a set of one or more types of cancers to which NIOSH's finding that it was not feasible to estimate radiation doses with sufficient accuracy is limited.

(3) If it is not feasible to estimate with sufficient accuracy radiation doses for members of the class, as provided under paragraph (b)(1) of this section, then NIOSH must also make the following determination as required by statute [*see* 42 U.S.C. 7384q(b)(2)]: Is there a ''reasonable likelihood that such radiation dose may have endangered the health of members of the class?''

(i) For classes of employees that may have been exposed to radiation during discrete incidents 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, NIOSH will assume for the purposes of this section that any duration of unprotected exposure could cause a specified cancer, and hence may have endangered the health of members of the class. Presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, will satisfy the health endangerment criterion.

(ii) For health endangerment not established on the basis of a discrete incident, as described under paragraph (b)(3)(i) of this section, NIOSH will specify a minimum duration of employment to satisfy the health endangerment criterion as having been employed for a number of work days aggregating at least 250 work days within the employment parameters established for the class.

(c) NIOSH will submit a report of its evaluation findings to the Board and to the petitioner(s). The report will include the following elements:

(1) An identification of the relevant petitions;

(2) A proposed definition of the class or classes of employees to which the evaluation applies, and a summary of the basis for this definition, including, as necessary:

(i) Any justification that may be needed for the inclusion of groups of employees who were not specified in the original petition(s);

(ii) The identification of any groups of employees who were identified in the original petition(s) who should constitute a separate class of employees; or

(iii) The merging of multiple petitions that represent a single class of employees.

(3) The proposed class definition will address the following employment parameters:

(i) The DOE facility or the AWE facility that employed the class;

(ii) The job titles and/or job duties and/or work locations of class members;

(iii) The period of employment within which a class member must have been employed at the facility under the job titles and/or performing the job duties and/or working in the locations specified in this class definition;

(iv) If applicable, identification of an exposure incident, when potential radiation exposure during such an incident comprises the basis of the class definition;

(v) If necessary, any other parameters that serve to define the membership of the class; and

(vi) For a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a minimum duration of employment within the employment parameters of the class for inclusion in the class, as defined under § 83.13(b)(3).

(4) The proposed class definition may also specify that members of the class are limited to employees who incur a cancer from a set of one or more types of cancers specified by NIOSH. This provision applies to classes of employees for which the finding that it is not feasible to estimate radiation doses with sufficient accuracy is limited to certain tissue-specific cancer sites, relevant to individuals with specific types of cancers.

(5) a summary of the findings concerning the adequacy of existing records and information for reconstructing doses for individual members of the class under the methods of 42 CFR part 82; and a description of the evaluation methods and information upon which these findings are based.

(6) for a class for which it is not feasible to estimate radiation doses with sufficient accuracy, a summary of the basis for establishing the duration of employment requirement with respect to health endangerment.

§ 83.14 How will NIOSH evaluate a petition by a claimant whose dose reconstruction NIOSH could not complete under 42 CFR part 82?

(a) NIOSH may establish two classes for evaluation, to permit the timely adjudication of the existing cancer claim:

(1) A class of employees defined using the research and analyses already completed in attempting the dose reconstruction for the employee identified in the claimant's petition; and

(2) A class of co-workers similar to the class defined under paragraph (a)(1) of this section, to be defined by NIOSH on the basis of further research and analyses, using the procedures outlined under § 83.13.

(b) NIOSH will determine the health endangerment criteria for adding the class under paragraph (a)(1) of this section to the Cohort, using the procedures outlined under § 83.13. NIOSH will report to the Board the results of this determination, together with its finding under 42 CFR part 82 that there was insufficient information to complete the dose reconstruction.

(c) NIOSH will evaluate the petition as it may concern a class of co-workers, as described under paragraph (a)(2) of this section, according to the procedures under § 83.13.

§ 83.15 How will the Board consider and advise the Secretary on a petition?

(a) NIOSH will publish a notice in the **Federal Register** providing notice of a Board meeting at which a petition will be considered, and summarizing the petition to be considered by the Board at the meeting and the findings of NIOSH from evaluating the petition.

(b) The Board will consider the petition and the NIOSH evaluation report at the meeting, to which the petitioner(s) will be invited to present views and information on the petition and the NIOSH evaluation findings.

(c) In considering the petition, the Board may obtain and consider

additional information not addressed in the petition or the initial NIOSH evaluation report.

(d) NIOSH may decide to further evaluate a petition, upon the request of the Board. If NIOSH conducts further evaluation, it will report new findings to the Board and the petitioner(s).

(e) Upon the completion of NIOSH evaluations and deliberations of the Board concerning a petition, the Board will develop and transmit to the Secretary a report containing its recommendations. The Board's report will include the following:

(1) The identification and inclusion of the relevant petition(s);

(2) The definition of the class of employees covered by the recommendation;

(3) A recommendation as to whether or not the Secretary should designate the class as an addition to the Cohort;

(4) The criteria and information upon which the recommendation is based, including NIOSH evaluation reports, information provided by the petitioners, any other information considered by the Board, and the deliberations of the Board.

§ 83.16 How will the Secretary decide the outcome of a petition?

(a) The Secretary will propose, and transmit to all affected petitioners, a decision to add or deny adding classes of employees to the Cohort. This decision will take into consideration the evaluations of NIOSH and the recommendations of the Board, and may also take into consideration information presented to the Board and its deliberations.

(b) HHS will provide the petitioner(s) 30 calendar days to contest the proposed decision of the Secretary. If the petitioner(s) submits to HHS a challenge that includes substantial evidence that the proposed decision relies on a record of either factual or procedural errors in the implementation of these procedures, then HHS will consider the evidence submitted by the petitioner(s) prior to issuing a final decision. Challenges to decisions of the Secretary under these procedures must be submitted in writing, with accompanying documentation supporting the assertions of the challenge.

(c) HHS will issue a final decision on the designation and definition of the class, and transmit a report of the decision and the criteria and information upon which the decision is based to the petitioner(s). HHS will also publish notice of the decision in the **Federal Register**, including a definition of the class and a summary of the criteria and information upon which the decision is based.

§ 83.17 What is the role of Congress in acting upon the final decision of the Secretary to add a class of employees to the Cohort?

(a) If the Secretary designates a class of employees to be added to the Cohort, the Secretary will transmit to Congress a report providing the designation, the definition of the class of employees covered by the designation, and the criteria and information upon which the designation was based.[2]

(b) A designation of the Secretary will take effect 180 calendar days after the date on which the report of the Secretary is submitted to Congress, unless Congress takes an action that reverses or expedites the designation.

(c) Within five work days of either expiration of the congressional review period or final congressional action, whichever comes first, the Secretary will transmit to DOL a report providing the definition of the class and one of the following outcomes:

(1) The addition of the class to the Cohort; or

(2) The result of any action by Congress to reverse or expedite the decision of the Secretary to add the class to the Cohort.

(d) The report specified under paragraph (c) of this section will be published on the Internet at *www.cdc.gov/niosh/ocas* and in the **Federal Register**.

§ 83.18 How can the Secretary cancel or modify a final decision to add a class of employees to the Cohort?

(a) The Secretary can cancel a final decision to add a class to the Cohort, or can modify a final decision to reduce the scope of a class added by the Secretary, if HHS obtains records relevant to radiation exposures of members of the class that enable NIOSH to estimate the radiation doses incurred by individual members of the class through dose reconstructions conducted under the requirements of 42 CFR part 82.

(b) Before cancelling a final decision to add a class or modifying a final decision to reduce the scope of a class, the Secretary intends to follow evaluation procedures that are substantially similar to those described in this part for adding a class of employees to the Cohort. The procedures will include the following:

(1) Publication of a notice in the **Federal Register** informing the public of the intent of the Secretary to review the final decision on the basis of new information and describing procedures for this review;

(2) An analysis by NIOSH of the utility of the new information for conducting dose reconstructions under 42 CFR part 82; the analysis will be performed consistently with the requirements for analysis of a petition by NIOSH under §§ 83.13(b)(1)and(2), and 83.13(c)(2)and(3);

(3) A recommendation by the Board to the Secretary as to whether or not the Secretary should cancel or modify its final decision that added the class to the Cohort, based upon a review by the Board of the NIOSH analysis and any other relevant information considered by the Board;

(4) An opportunity for members of the class to contest a proposed decision by the Secretary to cancel or modify the prior final decision that added the class to the Cohort, including a reasonable and timely effort by the Secretary to notify members of the class of this opportunity; and

(5) Publication in the **Federal Register** of a final decision to cancel or modify the prior final decision that added the class to the Cohort.

Dated: March 5, 2003.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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[2] *See* 42 U.S.C. 7384l(14)(C)(ii).