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

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; Final Rule

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This document describes how the Department of Health and Human Services (''HHS'') will 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 eligible 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.

DATES: *Effective Date:* This final rule is effective May 28, 2004.

Compliance Date: Affected parties are required to comply with the information collection requirements in § 82.9 effective May 28, 2004.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. 7384–7385, 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 lump sum payments 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, on December 7, 2000, 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 11, 2000). DOL published a final rule governing DOL's administration of EEOICPA on December 26, 2002 (67 FR 78874).

Executive Order 13179 directed HHS to perform several technical and policymaking roles in support of the DOL program:

(1) HHS was to develop procedures for considering petitions by classes of employees at DOE and Atomic Weapons Employer (''AWE'') facilities to be added to the Special Exposure Cohort established under EEOICPA. These procedures are the subject of this rule. 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.

(2) HHS was 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 facility 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 was 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 (''the Board'') 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 classes of employees to comprise the Cohort initially, including DOE employees, DOE contractor or subcontractor employees, who were (1) employed an aggregate of at least 250 work days before February 1, 1992 at a gaseous diffusion plant in Paducah, Kentucky, Portsmouth, Ohio, or 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 (2) 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. As provided in 42 U.S.C. 7384l(9)(A), 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 Rule

EEOICPA authorized the President to designate additional classes of employees to be included in 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 rule 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

[1] Specified cancers are a limited group of cancers that EEOICPA specifies are compensable under provisions governing compensation for members of the Cohort. Although the list of specified cancers is determined by statute, the list can also be found in this rule under § 83.5.

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.

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

EEOICPA includes several requirements for these procedures. The Board shall provide advice to the President (delegated by Executive Order 13179 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 facility 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)(ii) 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 Procedures to an 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).

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 for DOL 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 class received.''

II. Summary of Public Comments

HHS published a first notice of proposed rulemaking (''NPRM'') specifying procedures for adding classes of employees to the Cohort on June 25, 2002 (67 FR 42962). Public and Board comments on this first NPRM led HHS to make substantial changes in the proposal, which resulted in the publication of a second NPRM on March 7, 2003 (68 FR 11294). HHS solicited public comments on this second NPRM from March 7, 2003 to May 6, 2003.[2] During this period, comments were also submitted by the Board.

HHS received comments on the second NPRM from 11 organizations and 19 individuals, including 14 Members of Congress. Organizations commenting included six national or local labor organizations representing DOE workers, the Health Physics Society, and four 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 proposed rule and to supplement explanations from both NPRMs concerning the intent of the final rule.

A. Feasibility of Dose Reconstructions: Timeliness, Cost, and Availability of Records

As discussed 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. The NPRM proposed the criterion that this condition would be met if NIOSH were not able to establish ''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'' (68 FR 11308).

HHS received comments from several labor organizations, an advocacy group, and Members of Congress recommending that the rule establish additional criteria defining when dose reconstructions would not be feasible. Some commenters recommended distinguishing this requirement as separate and apart from the requirement for ''sufficient accuracy.'' The most common recommendation was for HHS to establish a time limit for completing dose reconstructions, after which the dose reconstruction would be determined to be not feasible. Commenters recommended time limits ranging from 180 days to 24 months.

HHS does not agree that a regulatory time limit on dose reconstructions would be appropriate in this rule, which establishes procedures for determining whether to add a class of employees to the Cohort. Some of the factors that could protract a dose reconstruction, such as a poorly defined employment history or work history, would be specific to the case of an individual employee, and would not be germane to a class of employees.

HHS does not believe a time limit on the duration of a dose reconstruction to be an appropriate addition to the dose reconstruction rule, either. Such a limit would eliminate the flexibility to address special circumstances and could effectively nullify the statutory requirements for dose reconstruction and the determination of probability of causation in their entirety by deeming all DOE and AWE employees to be members of classes of employees for whom dose reconstruction is not feasible.

In addition, a regulatory time limit could delay compensation for claimants whose dose reconstructions might exceed a regulatory deadline but would still be completed prior to the time at which a class of employees could be added to the Cohort. As this rule describes, Congress has 180 days to review any HHS decision to add a class to the Cohort, before such a decision could become effective.

One of the most important factors presently affecting the timeliness of dose reconstructions is the current

[2] HHS extended the public comment period from 30 to 60 days at the request of the Board and members of the public.

backlog of dose reconstructions, which is a result of the extensive development requirements of the dose reconstruction program. NIOSH began receiving cases requiring dose reconstructions in October of 2001, long before the dose reconstruction program could establish even minimal capacity for completing dose reconstructions. HHS completed final rules establishing the methods of dose reconstruction in May of 2002. NIOSH awarded a contract to build external capacity for conducting dose reconstructions in September of 2002.

NIOSH and its contractor for dose reconstructions are now employing more than 300 staff (including more than 100 health physicists) and are working to complete tasks necessary to eliminate the backlog. These tasks include the completion of ''site profiles,'' which summarize site-specific exposure conditions, dosimetry, and other relevant information. In parallel with this necessary developmental work, NIOSH is completing dose reconstructions at an increasing pace for cases involving sites for which NIOSH has already issued site profiles and for which site profiles are not needed. It took NIOSH 26 months to complete the first 1000 dose reconstructions. NIOSH completed the second 1000 in 14 weeks. This rate is continuing to improve.

An advocacy group and some Members of Congress also recommended HHS consider the cost of dose reconstructions as a criterion for feasibility, to avoid incurring ''prohibitive expense'' in conducting a dose reconstruction.

HHS has not included a cost criterion in the rule. The NIOSH dose reconstruction program is designed with procedures specifically intended to minimize the time and financial resources required for dose reconstructions. Individual dose reconstructions are presently costing an average of less than $10,000 each. A regulatory cost criterion would require HHS to incur unproductive expenses and might delay the consideration of petitions substantially, since HHS would have to estimate dose reconstruction costs related to each Cohort petition.

Some Members of Congress also recommended that HHS consider the deficiency or complete absence of records as a criterion for feasibility.

HHS included such provisions in the NPRM and in the final rule, as discussed in the following section discussing comments on ''sufficient accuracy.'' NIOSH internal procedures for evaluating petitions, available upon request from NIOSH (1–800–356–4674) or from the NIOSH Web page (*www.cdc.gov/niosh/ocas*), provide step-by-step practical information on how NIOSH will evaluate the availability of information needed to estimate the radiation doses of a class of employees with sufficient accuracy. These recommended internal procedures do not create any substantive rights on the behalf of petitioners. Comments may be provided at any time about these procedures to OCAS at ocas@cdc.gov. Any subsequent revision of the internal procedures will be posted on the NIOSH Web site at *www.cdc.gov/niosh/ocas*. If there are any substantial revisions to these procedures, NIOSH will publish a **Federal Register** Notice including an indication that there have been substantial revisions, a paragraph summarizing the changes, and that the revised procedures can be found on the NIOSH Web site at *www.cdc.gov/niosh/ocas*. Comments regarding these internal procedures or any revisions thereto are invited.

In addition, HHS has added a provision to section 83.13(c)(1)(i) of the rule, as part of the feasibility determination by NIOSH under this section, to require that NIOSH determine whether it has information regarding monitoring, source, source term, or process information from the site where the employees worked to serve as the basis for a dose reconstruction. EEOICPA requires that determinations of probability of causation for claimants under EEOICPA be based on the radiation dose received by the employee (or a group of employees performing similar work) at the facility where the employee(s) worked. 42 U.S.C. 7384n(c)(3)(A). Consequently, for NIOSH to determine that dose reconstruction is feasible, dose reconstruction must, as a starting point, be based on some information from the site where the employee worked. This basis requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but it requires the use of some information from the site.

HHS has also added a new § 83.13(b) which authorizes the Director of the Office of Compensation Analysis and Support (OCAS) within NIOSH to determine that records and/or information requested from DOE, an AWE, or another source to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available. This will facilitate the efforts of NIOSH to evaluate petitions within a reasonable amount of time in relation to the records and/or information required to evaluate the petition and any other relevant factors.

Some Members of Congress also recommended that the rule clarify that EEOICPA does not require a demonstration that no ''worst case estimate'' can be reached for inclusion in the Cohort.

HHS has clearly and completely specified the statutory requirements of EEOICPA relating to the addition of classes of employees to the Cohort, under section I(D) above. The rule itself provides procedures by which HHS will implement these statutory requirements. Related specifically to the comment, to add a class of employees to the Cohort, EEOICPA requires that HHS find that ''it is not feasible to estimate with sufficient accuracy the radiation dose that the class received;* * *;'' 42 U.S.C. 7384q(b). Subsection 83.13(c)(1) of this rule specifies clearly the approach HHS will use to evaluate feasibility. This approach, as it relates to the statutory requirement regarding feasibility, is discussed above, in sections B and C below, and in the second NPRM (68 FR 11296). The ability to estimate the maximum radiation dose received by members of a class is technically a critical distinction between circumstances in which it is feasible to estimate radiation doses through dose reconstruction and those in which it is not feasible to do so.

B. Feasibility of Dose Reconstructions: Relevance of Type of Cancer to Feasibility Determinations

The NPRM included provisions that would have allowed NIOSH to define a class of employees that it would recommend be added to the Cohort according to the specific cancers for which dose reconstruction is not feasible and hence demonstrate a reasonable likelihood of a dose that may have endangered the health of members of the class. Several commenters questioned the scientific proposition that it could be feasible to estimate radiation doses for individuals with certain cancers, but not feasible to estimate doses for individuals with other cancers. The statutory provisions of EEOICPA neither require nor prohibit HHS from establishing cancer-specific classes.

The Board, which specifically reviewed this issue, recognized that this situation ''may be scientifically and theoretically possible.'' Two theoretical examples of this situation, involving external radiation exposures (originating from outside of the body), were identified and considered during meetings of the Board and were not

contested by members of the Board (*see* Transcript of the Advisory Board on Radiation and Worker Health, March 7, 2003, page 17; Transcript of the Advisory Board on Radiation and Worker Health, March 28, 2003, pages 46–48).

On the other hand, some members of the Board did contest the proposition that it could be feasible to estimate radiation doses from internal exposures (originating from radioactive materials that are taken into the body) for certain cancer sites and not others. This discussion clarified that all tissues and organs could be irradiated to some degree in cases involving internal exposures (*see* Transcript of the Advisory Board on Radiation and Worker Health, March 7, pages 36–37; Transcript of the Advisory Board on Radiation and Worker Health, March 31, 2003, pages 42–66). As a result, a scientific finding concerning the feasibility of estimating doses in cases involving internal exposures would have to apply to all cancers. This reduces the practical applicability of a policy for establishing cancer-specific classes on the basis of the feasibility of dose reconstruction, since additions to the Cohort are likely to involve internal radiation exposures.

A second scientific issue related to the issue of adding cancer-specific classes to the Cohort but not related to the HHS proposal, is whether or not certain cancers should be excluded from a class because the radiation exposure of concern is unlikely to have caused those cancers. The Health Physics Society advocated such a policy, providing an example of situations in which one might reasonably conclude the probability of causation would be very low for certain cancers. An advocacy group and several labor organizations recommended against such a policy. HHS did not propose and has not established such a policy, which relates to health endangerment rather than the feasibility of dose reconstruction.

The most prevalent comment HHS received on this rule did not concern the scientific justification for establishing cancer-specific classes, but argued that such a policy conflicted with EEOICPA and with congressional intent. These commenters included the 14 Members of Congress, advocacy groups, and labor organizations. Although the courts generally give little weight to statements by individual legislators when determining congressional intent, many of these commenters referenced an October 12, 2000 statement by Senator Jeff Bingaman to the full Senate. In this statement, Senator Bingaman said that groups of workers added to the Cohort ''would be eligible for compensation for a fixed list of radiation related cancers,'' meaning the list of 22 ''specified cancers'' established under EEOICPA and listed in section 83.5(m) of this rule. S10377, *Congressional Record,* October 12, 2000.

Many commenters also expressed the view that it would be unfair and contrary to EEOICPA for HHS to exclude from classes of employees to be added to the Cohort employees who incur certain specified cancers, since all specified cancers are compensable for members of the classes included in the Cohort by statute. The relevant portion of the statutory provision of EEOICPA reads as follows: ''The term 'covered employee with cancer' means any of the following: [a]n individual with a specified cancer who is a member of the Special Exposure Cohort, * * *'' 42 U.S.C. 7384l(9)(A).

In addition, while the Board indicated that it might be scientifically and theoretically possible for the situations addressed by the NPRM to exist, the Board recommended against the establishment of cancer-specific classes, as discussed below, stating that it was concerned about ''providing some level of equity between the definition of new SEC classes and those already defined in the legislation.''

The provisions of EEOICPA that directly govern which classes of employees can be added to the Cohort are the feasibility and health endangerment provisions addressed under the ''statutory requirements'' section above. These provisions can be interpreted in different ways to either support or oppose the establishment of cancer-specific classes. They neither require nor prohibit HHS from establishing cancer-specific classes.

As discussed above, in support of cancer-specific classes, HHS has identified possible situations in which the feasibility of estimating doses would differ by type of cancer. In addition, the Health Physics Society and a member of the Board identified possible situations in which a determination of health endangerment might differ by type of cancer.

In opposition to including provisions for cancer-specific classes, one could interpret ''it is not feasible to estimate with sufficient accuracy the radiation dose that the class received'' to mean: it is not feasible to estimate with sufficient accuracy the radiation dose to any cancer site rather than the dose relevant to the cancer incurred by any particular employee. Similarly, health endangerment could be interpreted to mean an employee having been put at risk of certain types of cancers, regardless of whether the employee actually incurred one of the cancers for which the employee was at risk. Such interpretations would allow one to define a class without qualification, even when it would be feasible to estimate radiation doses for employees with all but one type of cancer, and even if most types of cancers were unlikely to have been caused by the radiation exposure of concern.

In light of the ambiguity of the statute, the limited practical applications of the option to establish cancer-specific classes, the nearly unanimous public opposition, and the opposition of the Board, HHS has omitted from the final rule the provisions in the NPRM that would have allowed the addition to the Cohort by HHS of cancer-specific classes of employees. Furthermore, HHS has revised section 83.13(c)(1) of the rule to state explicitly that NIOSH will make determinations of feasibility based on whether or not NIOSH is able to reconstruct doses for every type of cancer for which radiation doses are reconstructed.

The practical consequence of these changes is that HHS might designate classes of employees to be added to the Cohort under this rule despite the possibility that it might be feasible to estimate radiation doses with sufficient accuracy for some members of the class; specifically, that it might be feasible to estimate radiation doses with sufficient accuracy for a member of the class who incurs one of a subset cancer types for which there might be adequate dose-related information, as discussed above.

C. Accuracy of Dose Reconstructions

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

The most frequent of these comments requested HHS provide additional detail, either in the rule or in guidelines, to define how NIOSH would establish, under § 83.13(c)(1), ''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* * *'' HHS was asked to provide the methods by which maximum radiation doses would be estimated, and to define ''sufficient information.'' The Board requested that NIOSH issue guidelines to provide additional clarification concerning sufficient accuracy, after promulgation of this final rule.

As discussed above, NIOSH is issuing internal procedures concurrently with the promulgation of this rule that provide more detailed procedures for how it will evaluate petitions. While these procedures do not establish any substantive rights, they specify how NIOSH will identify available information and the general methods for determining whether such information will be sufficient to estimate maximum radiation doses for employees in the class, when such estimates are necessary. The internal procedures supplement the guidelines already provided in this final rule under section 83.13(c)(1). The internal procedures also provide limited generic information on how maximum radiation doses can be estimated when necessary. More specific detail outlining how available information would be used to conduct dose reconstructions would be provided within each NIOSH evaluation of a petition that finds that it is feasible to estimate radiation doses with sufficient accuracy for the class.

One individual commented that the rule puts excessive emphasis on estimating the maximum possible doses of radiation.

This emphasis was unintended. The proposed rule defined only the limits of dose reconstruction. The public should realize, however, that HHS may receive petitions for classes of employees for whom there is sufficient information to conduct dose reconstructions that provide more precise estimates than maximum doses, using, for example, personal or area monitoring records. For these petitions, methods for estimating maximum radiation doses would not be addressed in the NIOSH evaluation because they would not be relevant, since more precise dose reconstructions would be feasible. HHS has clarified the rule on this point, adding the following provision (identified below in italics) to section 83.13(c)(1):

> 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, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class*, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose*.

HHS has also supplemented the guidelines previously included in the rule regarding the feasibility of estimating the radiation dose of a class of employees with sufficient accuracy. A new § 83.13(c)(1)(iii) specifies the following additional guidelines:

> In many circumstances, to establish a positive finding under paragraph (b)(1)(i) of this section would also require information describing the process through which the radiation exposures of concern may have occurred and the physical environment in which the exposures may have occurred.

One labor organization interpreted the NPRM as indicating that NIOSH would use analytic models, presumably to estimate maximum doses when necessary, at the expense of the timely completion of dose reconstructions.

The use of analytic models in such instances is efficient, not delaying. Dose reconstructions that rely more extensively on analytic exposure models can be completed far more quickly than dose reconstructions that require the collection and evaluation of extensive monitoring data, which may still involve the use of analytic exposure models as well.

An individual commented that this rule should define how NIOSH determines the reliability of dosimetry information for use in dose reconstructions. The commenter correctly noted that the accuracy of dosimetry results is affected by a variety of factors, some of which the commenter enumerated. The commenter also asserted that it was a ''fatal flaw'' of the NPRM to assume that maximum doses can be estimated 30 to 50 years after the fact.

The HHS dose reconstruction rule (42 CFR Part 82) and related dose reconstruction guidelines specify how doses are reconstructed and explain how NIOSH takes into account various factors that affect the interpretation of dosimetry information, particularly the limitations of dosimetry programs from the early decades of nuclear weapons production. The types of studies the commenter cited, that have evaluated the shortcomings of dosimetry programs, are used by NIOSH to interpret the records of such dosimetry programs.

The NPRM and this final rule, however, do not reflect an assumption that it will be feasible to estimate maximum doses or to more precisely estimate doses. The determination by NIOSH, the Board, and the Secretary of HHS as to whether dose reconstruction is feasible for a particular class of employees is a central element of this rule.

Related to this latter point, an advocacy group and a labor organization questioned whether petitioning is ''futile'' under the provisions of this rule concerning feasibility, because, in the view of the commenters, NIOSH ''raised the bar'' for evaluating whether doses can be estimated with sufficient accuracy from the first NPRM to the second NPRM, from when a dose reconstruction cannot be completed to when maximum doses (nor more precise doses) cannot be estimated.

The provisions of the second NPRM discussed in the comment are no more exclusive than those of the first NPRM, only more specific. The specificity was requested by the Board and sought by other public commenters as well.

There is, however, a substantial difference between the minimal requirements for submitting a petition, when such a petition is not based on NIOSH having already found that a claimant's dose reconstruction cannot be completed, and the requirements for adding a class of employees to the Cohort. Such petitions provide NIOSH with basic information necessary to begin the determination process, but NIOSH is likely to have more extensive access to information for dose reconstructions than petitioners. NIOSH will consider all information as necessary, not only information provided by the petitioner, to determine whether or not the radiation doses of the class of employees can be estimated with sufficient accuracy.

One labor organization commented that NIOSH had failed to address limitations of the NPRM. In explanation, the commenter asserted that the estimation of maximum doses would not be sufficient to estimate lifetime exposure and would not be valid in circumstances involving a mixture of radionuclides.

If NIOSH can estimate the maximum quantity of a radionuclide that could have been inhaled, ingested, or absorbed by an employee, then the maximum doses resulting from such internal exposure can be estimated for the entire period between exposure and the occurrence of cancer, as is necessary for NIOSH dose reconstructions.

With respect to mixtures of radionuclides, the critical issue is the extent of information about the mixture (e.g., quantities and identities). The involvement of multiple radionuclides is not inherently an obstacle to dose reconstruction. On the other hand, in situations involving exposure of a class of employees to a mixture of radionuclides of uncertain identity and quantity, NIOSH may not be able to estimate radiation doses and the class may be added to the Cohort, as provided for under this rule.

Two labor organizations questioned how NIOSH could estimate radiation doses for workers who move between buildings or facilities and who may not, themselves, have any knowledge of radiation sources.

If doses can be estimated for employees who worked steadily within a building or facility, then typically they could be estimated for employees who were in the building or facility episodically. A major difference in some such dose reconstructions, in cases in which the worker was not monitored at some or any of the locations, would be the need to allocate the worker's time among various locations. It is relatively straightforward to do so, using assumptions that give the benefit of the doubt to the worker when information concerning the duration of the worker's activities at different locations is insufficient.

An advocacy group, a labor organization, and some Members of Congress asserted that the provision of the NPRM requiring that NIOSH have sufficient information to be able to estimate maximum radiation doses, at a minimum, is incompatible with a provision of the dose reconstruction rule (42 CFR 82.10(k)(2)). Some of these commenters interpret the provision of the dose reconstruction rule as limiting the use of worst-case assumptions, which must be used in estimating maximum radiation doses, to non-compensable cancer claims (i.e., claims for which the probability of causation is below 50 percent). Furthermore, the commenters conclude that this perceived incompatibility could result in a situation in which NIOSH might find that it could not complete a dose reconstruction for a claimant and yet NIOSH could find, under this rule, that the claimants' doses can be estimated, preventing HHS from adding a class of employees including the claimant to the Cohort. For this reason, the commenters recommended that HHS amend the dose reconstruction rule to be compatible with this rule.

The dose reconstruction rule (42 CFR Part 82) does not require any revision with respect to this concern. It is not possible for NIOSH to determine that it cannot complete a dose reconstruction for a claimant under the dose reconstruction rule and simultaneously find the same dose reconstruction to be feasible under this rule (42 CFR Part 83).

The dose reconstruction rule very specifically restricted the condition on the use of worst-case assumptions to the case when they are used as an efficiency measure to limit time-consuming and resource-consuming additional research and analysis. This narrow restriction is stated in the dose reconstruction rule as follows (emphasis added):

> At any point during steps of dose reconstruction described [above], NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met: * * * (2) Dose is determined using worst-case assumptions related to radiation exposure and intake, *to substitute for further research and analysis*; * * *
>
> * * * Worst-case assumptions will be employed *under condition 2 to limit further research and analysis* only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose.'' 42 CFR Part 82.10(k)

In contrast, this Cohort rule implies the use of worst-case assumptions for dose reconstructions in essentially the opposite situation, to estimate maximum radiation doses in cases in which NIOSH lacks extensive information that could be used to conduct ''further research and analysis,'' rather than as an efficient substitute for such further research and analysis.

The dose reconstruction rule does not assert or imply any restriction in circumstances in which the total information available is limited. In fact, the rule generally anticipates such circumstances in describing the hierarchy of information that might be used in a dose reconstruction, depending on availability. In the introductory section of the rule, it describes the dose reconstruction practice of using assumptions to substitute for a lack of data:

> ''For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent worst-case conditions.'' 42 CFR Part 82.2(a).

Furthermore, the Cohort rule provides that whenever NIOSH finds under the dose reconstruction rule that it cannot complete a dose reconstruction, this finding will suffice, without exception or further consideration, to support a determination that it is not feasible to estimate the radiation doses of individual members of the class with sufficient accuracy. This was implicit in § 83.14 of the NPRM but has been made explicit, to eliminate any uncertainty in interpretation, with the following inserted text (in italics):

> (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. *HHS will consider this finding under 42 CFR Part 82 sufficient, without further consideration, to determine that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy.*

Two labor organizations asserted, in contrast with the comments discussed immediately above, that the NPRM and the dose reconstruction rule (42 CFR Part 82) were inappropriately linked through their implicit use of common criteria for determining the feasibility of dose reconstructions. EEOICPA required HHS to establish, by regulation, methods for arriving at reasonable estimates' of radiation doses incurred by individuals (42 U.S.C. 7384n(d)). As discussed above, EEOICPA requires HHS to determine that it is not ''feasible'' to estimate with ''sufficient accuracy'' the radiation dose that a class received, for HHS to add a class of employees to the Cohort (42 U.S.C. 7384q(b)(1)). The commenters believe the use of different terms in these two sections of EEOICPA (reasonable estimates of doses versus doses that are not feasible to estimate with sufficient accuracy) signals different intentions of Congress for determining the feasibility of dose reconstruction as it arises through the dose reconstruction program versus through a petition for adding a class to the Cohort. Accordingly, the commenters recommend that HHS establish different criteria for these two situations.

The statutory provisions concerning the development of dose reconstruction methods (42 U.S.C. 7384n(d)) are concerned with how dose reconstructions are to be done, not a determination as to whether or not they can be done. It is implicit, nonetheless, that these dose reconstructions must be ''feasible to estimate with sufficient accuracy.'' It appears to HHS that the use of this phrase under provisions for considering the addition of classes of employees to the Cohort, and the omission of this phrase under provisions concerning dose reconstruction, simply reflects the fact that these two separate provisions of EEOICPA address different but complementary circumstances.

An advocacy group and several labor organizations questioned whether or not an estimate of the maximum radiation dose produced by a dose reconstruction would be represented by a single value (point estimate) or by a distribution of values (that take uncertainty into account).

When NIOSH is limited to estimating maximum doses in a dose reconstruction based on source term and process information, the dose reconstruction is likely to rely substantially on one or more worst-case

assumptions that contribute to defining the level or levels of exposure and the characteristics of the exposure. It is unknown, however, how often such dose reconstructions would produce a point estimate of dose, versus a distribution of dose values that estimates dose. There are various circumstances that could result in the estimation of a distribution of dose values, such as when factors affecting the dose estimate have known and documented variability and/or uncertainties. NIOSH might use a distribution of values, for example, to characterize the particulate sizes of a radioactive material that has been ground or cut, when this factor had been studied and documented at comparable operations. In such a case, the distribution of values for particulate size would result in a distribution of dose values rather than a single, point estimate of dose.

One advocacy group and labor organization requested the rule or guidelines define ''plausible circumstances,'' asserting that use of this term was simply substituting for the term ''sufficient accuracy.'' In context, HHS uses the term as follows: ''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* * * *'' (emphasis added). 42 CFR 83.13(c)(1)(i).

In this case, ''plausible circumstances'' is not substituting for ''sufficient accuracy'' as suggested, since the operative concept here is the ability to estimate the maximum radiation dose. The identification of plausible circumstances qualifies how such doses would be estimated. It means that NIOSH is not required to utilize unlikely, unreasonable, or illogical scenarios to estimate radiation doses. Furthermore, it is not reasonable to construct a ''litmus test'' for defining plausibility. It involves expert judgment, which will be applied by NIOSH and the Board in determining what are plausible circumstances consistent with the known information relevant to the evaluation of the petition. Dose reconstruction routinely uses expert judgment to address unknown and uncertain information. The important matter with respect to such judgments is that the NIOSH dose reconstruction program provides the benefit of the doubt to the claimant in identifying plausible scenarios, to ensure that dose reconstructions do not underestimate doses.

One advocacy group and one labor organization also recommended that NIOSH consider applying a statistical concept such as ''the size of the standard error'' in guidelines for defining sufficient accuracy. The general idea of this comment is that NIOSH would define quantitatively the degree to which the range and likelihood of all possible dose estimates supported by the facts could diverge from the central tendency of these estimates.

There is not a good scientific or logical basis for establishing a statistical measure of precision, which is not equivalent to accuracy, as a requirement for NIOSH dose reconstructions under EEOICPA. Any claimant for whom a less precise but more accurate estimate would support compensation might challenge such a requirement as arbitrary. For example, NIOSH might estimate that an employee incurred a radiation dose to the prostate of between 20 and 100 rem, with a central tendency of 60 rem. This dose distribution is not as precise as an estimate of between 50 and 70 rem, for example, but it could be more accurate to the degree that it appropriately accounts for the variability and uncertainty in the available data and hence better characterizes what we know and do not know about the level of dose received by the employee.

HHS interprets ''sufficient accuracy'' in practical terms as sufficiently accurate to assure the fair adjudication of claims. NIOSH dose reconstructions provide this assurance by using methods that build on the factual and scientific bases using two principal measures that are designed to overestimate every employee's dose.

First, as discussed above, the expert judgments (assumptions) used in NIOSH dose reconstructions give claimants the benefit of the doubt, when possible. When information is missing or questionable, the claimant is generally favored by NIOSH assuming the occurrence of the more harmful of plausible exposure scenarios.

Second, NIOSH accounts quantitatively for the factual and scientific uncertainties involved in each dose reconstruction and includes this measure of uncertainty in the probability of causation calculation performed by DOL. In practical terms, this favors the claimant because, pursuant to 42 U.S.C. 7384n(c)(3)(A), DOL calculates the probability of causation at the upper 99 percent credibility limit; in other words, any uncertainty in the dose used to adjudicate the claim will contribute to DOL overestimating the likelihood that the employee's cancer was caused by radiation.

These two measures taken together, claimant-favorable assumptions and the estimation of probability of causation at the upper 99 percent credibility limit, produce a doubly upper-bounded estimate of the employee's radiation dose. By these measures, whenever it is feasible for NIOSH to estimate radiation doses for a cancer claimant, NIOSH is almost certain to be overestimating the actual radiation doses.

D. Health Endangerment

In addition to the condition that HHS find that it is not feasible to estimate the radiation doses of a class of employees with sufficient accuracy, a second requirement of EEOICPA for adding a class to the Cohort is that HHS find that there is ''a reasonable likelihood that such radiation dose may have endangered the health of members of the class.'' Under section 83.13(b)(3) of the NPRM, HHS proposed a standard based on the duration of employment within the employment conditions under which radiation doses cannot be estimated. As a default, this standard would be 250 work days, the same standard required by EEOICPA for employees of the gaseous diffusion plants included in the Cohort by Congress. 42 U.S.C. 7384l(14)(A). In addition, for classes of employees that may have been exposed to radiation during discrete incidents that were likely to have involved exceptionally high level exposures, such as nuclear criticality incidents, HHS provided that an employee's presence with potential exposure during the discrete incident, rather than a quantified duration of potential exposure, would satisfy the health endangerment criterion.

HHS received relatively few comments concerning the health endangerment provisions of the rule and these were generally supportive. A few commenters recommended changes.

An advocacy group and a labor organization recommended that employees should be able to accumulate the 250 work days required to qualify as members of a class added to the Cohort on the basis of their employment at multiple facilities, if the class includes employment at the multiple facilities. The central concern behind this comment is that some nuclear weapons workers are likely to have been employed at more than one facility, potentially conducting similar work (such as construction or maintenance) and incurring similar exposures for which dose reconstruction might not be feasible. The commenters are aware that DOL qualifies employees of the gaseous

diffusion plants to be included in the Cohort by aggregating their employment across all three of the plants, and hence believe classes added to the Cohort should be treated similarly.

DOL is interpreting a section of EEOICPA that establishes a single, multi-facility class (42 U.S.C. 7384l(14)(A)), while HHS is interpreting a different section of EEOICPA (42 U.S.C. 7483q), which does not allow HHS to define a class as a group of employees from multiple facilities. However, HHS agrees with the principle of aggregating employment within separate classes of the Cohort for the purpose of determining health endangerment. There is no compelling health reason to distinguish between employment within one class of the Cohort and employment distributed among several classes of the Cohort, nor to distinguish whether such classes were employed at the same facility or at separate facilities. In any case, the employee would have accumulated 250 work days of employment involving exposure to radiation that either cannot be estimated by dose reconstruction under the provisions of this rule or for which Congress determined there was not a need for dose reconstruction when Congress included the various groups of employees in the Cohort.

Accordingly, HHS has added a provision to the rule to implement this principle of aggregating employment. Whenever HHS adds a class of employees to the Cohort for which the 250 work days requirement is applicable, HHS will define class eligibility such that DOL can aggregate the work days of an employee from among all other classes in the Cohort for which the employee meets all of the other requirements for membership, except for the work days requirement. For this purpose, section 83.13(c)(3)(ii) of the rule includes the following additional text (in italics):

> (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 parameters established for the class *or in combination with work days within the parameters established for one or more other classes of employees in the Cohort.*

An advocacy group and two labor organizations recommended that the rule allow for the health endangerment test to be met in fewer than 250 work days for work operations lasting fewer than 250 days. The commenters indicated that certain short-term operations may have involved high level exposures. The comments also reflected the assumption that high level exposures could have occurred through the omission of radiation protection controls, versus their failure, only the latter of which was identified in the NPRM.

HHS has not established a separate criterion that would waive the 250 work days employment requirement for any short-term operation, since exceptionally high level exposures are not inherent to such operations. Section 83.13(c)(3)(i) of the HHS rule already provides for waiving the 250 work days employment requirement whenever classes of employees may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures, including any such incidents that may have occurred during projects of short duration. HHS has revised the text of this section to allow for the possibility that exceptionally high exposures could result from circumstances involving the omission of radiation protection controls, as well as their failure. With respect to this change, however, HHS advises potential petitioners that the omission of radiation protection controls, in and of itself, is not substantial evidence that exceptionally high level radiation exposures were likely. The provision of the rule allowing HHS to waive the 250 work days requirement is intended to address exposure scenarios distinctly more certain and severe than would be represented by exposure conditions generally at the gaseous diffusion plants, for which Congress established the precedent of setting an employment duration requirement at 250 work days.

An advocacy group recommended HHS incorporate into the rule a text excerpt of the NPRM preamble that explained that HHS will use the 250 work days employment requirement ''only when it lacks sufficient basis to establish a lower minimum standard.''

HHS has not incorporated this text into the rule for two reasons. First, the term ''only'' may be misleading. HHS has no basis to predict that the 250 work days employment requirement would be waived for the majority of classes of employees that may be added to the Cohort. Moreover, the text is not appropriate for the rule, since it could be interpreted to require HHS to demonstrate that it lacks sufficient basis to waive the 250 work days requirement, versus demonstrating that there is sufficient basis to waive the requirement. This would amount to requiring HHS to ''prove the negative,'' that it lacks certain information.

One labor organization commented that EEOICPA provides no basis for considering the effects of radiation in isolation when considering health endangerment.

EEOICPA specifically requires that HHS consider whether ''* * * such *radiation dose* may have endangered the health of members of the class'' (emphasis added) 42 U.S.C. 7384q(b)(2). This might allow HHS to take into account a synergistic or risk-potentiating relationship between a chemical and a radiation exposure, if such a relationship were known. Otherwise, EEOICPA does not authorize HHS to consider health risks other than exposure to radiation.

Two individuals commented that HHS should use epidemiological data to compare the cancer risks of classes of employees petitioning for addition to the Cohort with those of the groups included in the Cohort by statute. The commenters recommended that classes with cancer risks that are roughly comparable be added to the Cohort.

HHS cannot add classes to the Cohort on the basis of health endangerment alone. As discussed above, pursuant to 42 U.S.C. 7384q(b)(1), HHS must also find that dose reconstruction is not feasible. Moreover, as discussed in the second NPRM in response to this comment, there is no practical and scientifically defensible method for making such epidemiological comparisons for a variety of reasons, including limitations concerning timeliness, statistical power, and other matters (68 FR 11297).

One labor organization asserted that Congress intended for HHS to use the same criteria for considering whether to add classes of employees to the Cohort as were used by Congress itself to include groups in the Cohort by statute.

As discussed above, Congress specified in EEOICPA, 42 U.S.C. 7384q(b), the criteria that it intended HHS to use.

E. Eligibility To Petition

Section 83.7 of the NPRM specified parties that would be eligible to submit a petition on behalf of a class of employees. This included: ''(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.''

HHS received conflicting comments concerning this provision. One labor organization recommended that HHS narrow the above provision specifically, and implied HHS would have to narrow another provision of § 83.7 that would

allow employees and survivors to petition (paragraph (a)), ''to recognize the exclusive right of a labor union to represent the collective interests of employees in represented bargaining units who might petition for inclusion in the SEC.'' The commenter asserted: ''Any NIOSH procedures inconsistent with this bedrock principle are incompatible with the National Labor Relations Act.'' The commenter further speculated that NIOSH would conserve resources by limiting the right to petition to the certified labor organization whenever the class includes members of an existing bargaining unit of a labor organization. The commenter explained that such a limitation ''will avoid the potential problem of several competing representatives filing overlapping or inconsistent petitions on behalf of common employees.''

Two other labor organizations (one being a local unit of the commenter discussed above) and three advocacy groups expressed unqualified support for the eligibility requirements proposed in the NPRM and specifically opposed the recommendations and rationale of the commenter discussed above. One of these commenters asserted that the National Labor Relations Act (NLRA) provision regarding the exclusive right of a labor union to represent collective interests of employees in union-represented bargaining units does not apply to petitions for Cohort status under the EEOICPA. Some members of this group of commenters further argued that the limitation proposed by the first commenter above would be unworkable given the large number of unions representing employees at a single site.

On its face, the NLRA, which in pertinent part at 29 U.S.C. 159(a) establishes the exclusive right of a labor union to represent employees in union-represented bargaining units for the purpose of ''collective bargaining in respect to rates of pay, wages, hours of employment, or other conditions of employment,'' does not apply to petitions for Cohort status under EEOICPA, as these do not involve ''collective bargaining in respect to rates of pay, wages, hours of employment, or other conditions of employment.'' None of the items potentially addressed by collective bargaining are determined by HHS in considering a petition to add a class of employees to the Cohort.

HHS discussed the issue of potentially overlapping petitions, which concerned the first commenter above, in the first NPRM (67 FR 42966). This situation is unavoidable and HHS does not expect it to present major difficulties. HHS will consider concurrent petitions jointly, to the extent that they identify a class in common. With respect to the commenter's concern about potential conflicts between petitions, decisions by HHS on petitions will not govern decisions on subsequent petitions for the same class, or any part thereof, so long as substantial new information, germane to the criteria for adding a class to the Cohort, is provided by a subsequent petition.

For the reasons discussed above, HHS has retained in the rule the relevant provisions of § 83.7 from the NPRM, without change.

HHS revised § 83.7 to limit the number of petitioners that can submit a single petition to a maximum of three individuals and/or organizations. This limitation, which limits the number of petitioners but does not limit the number of members of a class of employees, is intended to facilitate the timely consideration of petitions by NIOSH, the Board, and the Secretary, since each petitioner for a petition has procedural rights under the rule that, if applicable to a large number of petitioners, could prolong the consideration of a petition substantially. HHS has also added a definition of the term ''petitioner'' under § 83.5(j) of the rule to reflect this change.

F. Petition Requirements

Section 83.9 of the NPRM specifies informational requirements that must be fulfilled by petitioners in order for HHS to consider the petition. An advocacy group and two labor organizations commented generally that they support the reduced requirements of this second NPRM, compared to the first NPRM. Commenters had several specific recommendations.

Subsection (b) requires claimants to petition when NIOSH has found that it cannot complete their dose reconstructions. The information to be provided by the petitioner in such cases is minimal, in effect simply notifying NIOSH formally that the claimant wishes to petition. Nonetheless, one labor organization recommended against this requirement, asserting that it is unnecessarily burdensome. The organization recommended that HHS automatically consider the addition of a class in these cases.

HHS interprets EEOICPA, 42 U.S.C. 7384q(a)(3), to require the submission of a petition to initiate consideration for adding a class of employees to the Cohort. As specified under the dose reconstruction rule (42 CFR 82.12), NIOSH will encourage and assist these claimants to file a petition and has minimized the requirements for their petitions.

Subsection (c)(1)(i) specifies that petitioners, other than the claimant-petitioners covered under subsection (b), must propose a definition of the class of employees for whom the petition would apply, including identifying, among other items: ''The DOE or AWE *facility* at which the class worked* * *'' (emphasis added). Three advocacy groups and three unions commented on this provision.

The commenters recommended that petitions be allowed to cover multiple facilities. Commenters explained that certain occupational groups, such as construction and maintenance workers, had work tasks that spanned separate sites, or had occupational histories that commonly involved work at more than one site, and that there may be similar deficiencies in radiation monitoring for these particular occupational groups across such sites. Furthermore, in response to the finding of HHS in the NPRM stating that EEOICPA does not allow for classes to be defined to encompass employees at more than one facility (68 FR 11298–11299), some of the commenters asserted that HHS is not properly interpreting the statute. Specifically, the commenters assert that it is proper in this case to interpret ''the singular [facility] to include the plural [facilities].''

The very first section of the United States Code, 1 U.S.C. 1, says: ''In determining the meaning of any act of Congress, *unless the context indicates otherwise*—words importing the singular include and apply to several persons, parties, or things * * *'' (emphasis added). In the case of 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), the context indicates Congress did not define a class as a group of employees from multiple facilities. In particular, the context of the reference to a ''class of employees at *any* Department of Energy facility who likely were exposed to radiation at *that* facility'' in 42 U.S.C. 7384(q)(a)(1) cannot be interpreted as a class covering more than one facility (emphasis added). HHS therefore believes that the concept of considering and adding multi-facility classes was not anticipated nor provided for in EEOICPA.

As a result, HHS has not revised this section, nor the definition of the class under 83.5, to allow for classes spanning employment at multiple facilities. This limitation would not, however, prevent a petitioner from

submitting petitions separately for employees at each facility at which a group was employed, defining individual, facility-specific classes. Furthermore, changes in this rule eliminate the potential value of defining classes to include employment at multiple facilities. Under this rule (83.13(c)(3)(ii)), a claimant will be able to qualify as a member of a class added to the Cohort by HHS by combining the duration of his or her period of employment within the class with other periods of employment among other classes in the Cohort. Hence, for example, if classes of construction workers involved in certain operations were separately added to the Cohort from Hanford and from Los Alamos, then a construction worker who was employed for 100 work days in the specified operations at Hanford and for 150 work days in the specified operations at Los Alamos would meet a 250 work days employment requirement that might be established for such classes and he or she would qualify as a member of the Cohort.

Subsection 83.9(c)(2) specified various options available to petitioners to support a petitioner's belief that records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class of employees with sufficient accuracy. Two advocacy groups and two labor organizations recommended changes to paragraph (iv) to allow petitioners to use in support the report of any government agency, rather than only reports by agencies that conduct scientific work. The commenters suggested any government agency should be considered a potentially credible source of information. The commenters also recommended against requiring that such reports specifically address the need for any dosimetry information identified in the report, with respect to dose reconstruction. The Board provided a similar recommendation (discussed in the following section).

HHS agrees that this provision should be clarified and improved, consistent with these comments. The paragraph now reads as follows:

(iv) A scientific or technical report, published or issued by an agency of the Executive branch of government, the General Accounting Office, the Nuclear Regulatory Commission, or the Defense Nuclear Facilities Safety Board, or published in a peer-reviewed 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.

Subsection 83.9(c)(3) of the NPRM specified evidence that would be required only when a petition is based on an exposure incident (versus routine operations) and NIOSH is unable to obtain records or confirmation of the occurrence of such an incident from sources independent of the petitioner(s). One option specified for such evidence was confirmation by affidavit from two employees who witnessed the incident.

One labor organization commented that a total of two witnesses should be sufficient and that secondhand accounts should be sufficient when eyewitnesses are deceased. The Board made similar recommendations (discussed in the following section).

HHS has revised this subsection in response to the comments from the public and the Board. HHS has omitted the requirement for a specific number of witnesses, and has provided that the witnesses can be or include individuals who were informed by eyewitnesses, when the eyewitnesses are deceased, are incapable of providing an affidavit for reasons of poor health or impairment, or could not be located. HHS has also clarified that the provision of affidavits, in and of itself, would not constitute adequate evidence to verify the occurrence of an exposure incident. As with any other evidence used to evaluate petitions, NIOSH would have to consider the credibility and adequacy of the evidence provided in the affidavits.

One labor organization commented that the NPRM required petitioners to know the source terms (the identities and quantities of the radioactive materials) to which employees were exposed.

Neither the NPRM nor the final rule includes such a requirement.

HHS has added a new § 83.9(c)(5) necessary to provide that NIOSH would only be required to reconsider its initial evaluation or any subsequent evaluations concerning the addition of a particular class of employees to the Cohort (a class that has already been considered by NIOSH as the result of one or more previously submitted petitions) when a new petition for such a class provides substantially new information regarding the feasibility of estimating radiation doses with sufficient accuracy. This change will ensure that the Board and HHS can consider in a timely fashion the addition to the Cohort of as many classes as possible. The change preserves the ability of NIOSH, the Board, and HHS to reconsider the addition of a class when petitioners identify information not considered by NIOSH that might lead NIOSH and/or the Board to new findings and recommendations concerning a class previously considered.

G. Administrative Review of Decisions To Not Evaluate a Petition

Section 83.11 of the NPRM proposed procedures by which NIOSH would assist petitioners on petitions that NIOSH finds do not meet the relevant requirements for a petition. A petition that fails to meet such requirements despite such assistance would not be further considered by HHS. HHS solicited comments from the public as to whether HHS should offer the petitioner an administrative review of such final decisions.

Two advocacy groups and three labor organizations recommended the rule include the option of an administrative review. The commenters recommended that HHS specify the procedure for such reviews and that they be conducted independently. One commenter recommended that such reviews be conducted by NIOSH internally.

In response to the public comments, HHS has included an option for prospective petitioners to request an administrative review. Paragraphs (b) through (e) of section 83.11 have been revised and added for this purpose. The review would be conducted by three HHS personnel, appointed by the Director of NIOSH, who were not involved in the initial consideration of the petition. The rule provides for a simple and timely process, with minimal requirements imposed on the petitioner. When appropriate, NIOSH would notify a petitioner of the right to seek an administrative review and of the associated procedures.

H. Decisions by the Secretary

Section 83.16 of the NPRM described procedures by which the Secretary would decide the outcome of a petition.

An advocacy group, four labor organizations, and some Members of Congress requested additional detail or provided other comment on these procedures. The advocacy group recommended the Secretary delegate his authority to the Director of NIOSH and questioned the extent of the discretion of the Secretary and the ''weight'' that would be assigned to the advice of the Board. A labor organization recommended the rule limit the circumstances under which the Secretary may reject a recommendation of the Board to add a class to the Cohort, and should require explanation of such decisions. Another labor organization asserted that the rule does not specify the criteria by which the Secretary will make decisions. Several commenters

recommended the rule require the Secretary to make decisions within 21 days of receiving recommendations from NIOSH and the Board.

The advocacy group, a labor union, and some Members of Congress also sought additional information about the procedure for administrative review of proposed decisions. The advocacy group and a labor organization specifically questioned whether such reviews would include the opportunity for oral presentations by petitioners and experts, and the availability of the administrative record of the NIOSH evaluation(s).

HHS has specified procedures under § 83.16 in greater detail in response to these comments. The procedures now specify that the Director of NIOSH will propose decisions on behalf of HHS. The authority to issue final decisions, however, has not been delegated to the Director of NIOSH. As discussed in the preamble of the NPRM, the Secretary may consider such a delegation on the basis of experience.

The criteria for making proposed and final decisions were implicit in the NPRM but have been specified explicitly in the rule; these are the criteria to be applied by NIOSH in evaluating a petition under § 83.13(c), implementing the two criteria specified in EEOICPA (42 U.S.C. 7384q(b)(1) and (2)).

HHS has revised the procedures for issuing proposed decisions to clarify that NIOSH would issue multiple proposed decisions in response to a single petition, when NIOSH determines that the petition encompasses more than one class of employees. As defined under § 83.5(c), a class of employees means, for the purposes of this rule, a group of employees who work or worked at the same DOE facility 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. Based upon NIOSH's evaluation of a petition, NIOSH may find that records are sufficient to conduct dose reconstructions for part of a proposed class, as defined by the petitioner, and insufficient to conduct dose reconstructions for another part of the proposed class. In such a case, NIOSH would define two or more separate classes of employees, distinguished by the difference in the sufficiency of the information available to conduct dose reconstructions.

Related to this clarification, HHS has also revised the procedures to authorize petitioners to contest only those proposed decisions that would deny the addition of a class to the Cohort and to contest a health endangerment determination under § 83.13(c)(3)(ii) for a decision that would add a class to the Cohort. This limitation will expedite the process of completing the consideration by HHS of classes that NIOSH has proposed adding to the Cohort by omitting a 30-day period, specified under the NPRM, during which HHS would have been required to await a challenge. It also will ensure that consideration by HHS of such classes would not have to further await, beyond the 30-day period, the outcome of a challenge in which a petitioner asserts that the proposed scope of the class is overly restrictive. This limitation will not prevent a petitioner from contesting any proposed decision or aspect of a proposed decision regarding his or her petition that would deny the addition to the Cohort of individuals covered by the petition or a resultant NIOSH proposed decision.

The section newly specifies the independence with which proposed decisions will be reviewed in response to challenges and provides clarification concerning the requirements of such challenges and the nature of such reviews. These will be records-based reviews conducted by a panel of three HHS personnel, appointed by the Secretary, rather than hearings involving witnesses and presided over by an administrative law judge. The reviews will not involve oral presentations or the introduction of new information that had not previously been presented or submitted to NIOSH or the Board prior to the Board completing its report of recommendations to the Secretary under § 83.15. Petitioners will have received all NIOSH evaluations concerning their petitions, and will have access to the administrative record for such evaluations, all publicly available information considered by the Board, as well as to the final report of the Board; petitioners will not have access to information protected by the Privacy Act and information classified for purposes of national security. Complete instructions for contesting proposed decisions will be provided to each petitioner.

The rule does not specify any particular weight that HHS will accord the advice of the Board in making proposed and final decisions. The Board recommendations are advisory. HHS would not prejudge such advice and will consider it according to its merits. Section 83.16 specifies the sources and scope of information that HHS will consider in making its decisions, and provides that HHS will explain the basis for the decisions.

The rule does not require that HHS make final decisions within 21 days or any specified period. Decisions will be made as expeditiously as possible, but HHS is providing petitioners 30 days to contest proposed decisions and such challenges would then have to be considered. The volume and scope of petitions, factors not controlled by HHS and impossible to predict, also might affect the speed of such decisions.

I. Cancelling or Modifying a Final Decision

One labor organization commented on the provisions under § 83.18 of the NPRM allowing the Secretary to cancel or modify a class that the Secretary had added to the Cohort. The commenter recommended such a decision by the Secretary be applied prospectively, for the adjudication of future claims; in other words, 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, pending the results of a re-adjudication of the claim.

Since DOL makes final compensation eligibility determinations for claimants, DOL will determine the application of such decisions by HHS to claims that DOL has already decided and claimants who have already received compensation.

J. Definitions of Terms Used in the Rule

Section 83.5 provided definitions of terms used in the NPRM.

Three advocacy groups and four labor organizations commented on several of the definitions. The Board also commented on definitions.

The advocacy groups and two labor organizations recommended that the definition for a ''class of employees'' (§ 83.5(c)) in the NPRM be revised to allow for a class that would span multiple facilities. One advocacy group and one labor organization also recommended that this definition be revised to define a class in terms of information that is not available.

The multi-facility issue is fully discussed above, under the section addressing comments on petition requirements. HHS does not interpret EEOICPA to allow for petitioners to define multi-facility classes of employees. Hence, HHS has not changed the definition as recommended by the commenters. This limitation would not, however, prevent a petitioner from submitting petitions separately for employees at each facility at which a group was employed,

defining individual, facility-specific classes. Furthermore, as discussed above under the section on health endangerment, changes in this rule eliminate any potential value of defining classes to include employment at multiple facilities.

The terminology of the definition in the NPRM, in specifying that a class is defined in part by ''the availability of information,'' was appropriate and has not been changed in the final rule. The term ''availability'' covers the possibility that information is available or is not available, with respect to the informational needs of dose reconstructions conducted under 42 CFR Part 82. Both of these possibilities need to be covered, since HHS might define classes of employees for whom information is sufficient for the needs of dose reconstructions and other classes for whom information is insufficient, as provided under this part.

The NPRM did not include a definition of the term ''facility,'' which is used in the rule. Two advocacy groups and three labor organizations recommended the rule include a definition of facility, and that the definition be defined as broadly as possible. Some specific suggestions for wording were provided.

HHS has not included a definition of the term ''facility'' in the rule since ''atomic weapons employer facility'' and ''Department of Energy facility'' are already defined in EEOICPA (42 U.S.C. 7384l(5) and (12)). These statutory definitions are complex. As a necessary consequence, DOE facility or AWE facility definitions must be considered on a case-by-case basis. To provide guidance on the types of facilities that would fall within the statutory definitions, and in particular, whether the term ''facility'' is limited to a single building or can also include multiple buildings, HHS has included a footnote to § 83.9(c)(1)(i) in the final rule which provides:

> Depending on the factual circumstances present, a facility that meets the definition of an AWE facility or DOE facility covered under EEOICPA (42 U.S.C. 7384l(5) and (12)) could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing numerous buildings or structures, including the grounds upon which it is located.

While a petition for a class of employees must be limited to one facility, a facility can constitute a site encompassing numerous buildings or structure, including the grounds upon which it is located. This has no effect, however, on the prospects for a class being added to the Cohort or the prospects for an individual employee being included as a member of a class added to the Cohort. These depend on the criteria specified in this rule, regardless of the scope of the petition. As discussed above, the latter also can depend on whether an employee meets a 250 work days employment criterion, when applicable, but § 83.13(c)(3)(ii) of the rule allows this criterion to be met through employment within the parameters of separate classes included in the Cohort.

HHS received two comments on the definition of ''specified cancers'' (§ 83.5(k)) provided in the NPRM. An advocacy group recommended the definition be amended to allow for other cancers specified by DOL. A labor organization recommended that the definition include rectal cancers, which have been determined by DOL, after consultation with the National Cancer Institute, to be a subset of cancer of the colon for the purposes of compensation for members of the Cohort.

The statutory definition of ''specified cancer'' can be found in EEOICPA at 42 U.S.C. 7384l(17). This definition cannot be changed by HHS; it can only be changed by Congress. The definition of ''specified cancer'' in the NPRM and in this final rule at § 83.5(m)(6) explains, however, that the specified cancers identified in the definition mean the physiological condition or conditions that are recognized by the National Cancer Institute, the scientific body with which DOL consults if there are questions regarding the proposed classification of a particular cancer.

HHS has added a definition of petitioner under § 83.5(j). The definition limits the number of petitioners that can submit a single petition to a maximum of three individuals and/or organizations. This limitation, which limits the number of petitioners but does not limit the number of members of a class of employees, is intended to facilitate the timely consideration of petitions by NIOSH, the Board, and the Secretary, since each petitioner for a petition has procedural rights under the rule that, if applicable to a large number of petitioners, could prolong the consideration of a petition substantially. HHS has also revised § 83.7 of the rule to reflect this change.

K. Miscellaneous Comments

The rule provides for petitions in two distinct circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant, under 42 CFR Part 82, and finds that the dose reconstruction cannot be completed, because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer.

An advocacy group recommended that the rule explain these two circumstances that have been provided for under the rule. The commenter recommended specifically that the rule clarify that petitioners or potential class members are not required, as a prerequisite for petitioning, already to have incurred a cancer or to have filed a claim for a cancer.

HHS agrees with the comment and has added explanation to the overview of the rule under § 83.6 to summarize the two distinct circumstances for petitions.

A labor organization commented that the rule is unduly vague about the types of information used to evaluate petitions, citing § 83.14(a)(8) of the NPRM, which reads: ''Other sources.''

Section 83.13(a) provides a list of seven specific sources prior to the provision of concern to the commenter. It may not be possible for HHS to specify every possible source of information that might assist NIOSH in evaluating a petition. The purpose of specifying the limited list is to give the public a sense of the range of sources that might provide useful information. The purpose of including a non-specified ''other'' category is to clearly communicate that NIOSH will not be limited to using the sources it has identified in the rule.

L. Non-Regulatory Comment: Dose Reconstructions for Cohort Members With Non-Specified Cancers

Two advocacy groups questioned how NIOSH would handle dose reconstructions for individuals in the Cohort who have a cancer that is not one of the specified cancers or for individuals not included in the Cohort because they do not meet the health endangerment criterion of having been employed for 250 work days, when this criterion is applicable. In both situations, part or all of an employee's work experience may include potential radiation exposures that cannot be estimated. For the latter situation, one of the commenters suggested a scheme for assigning radiation doses to some cases.

Under current dose reconstruction procedures, NIOSH would estimate all of the radiation doses of such employees that can be estimated. Some of these employees may have sufficient radiation

doses that can be estimated to support compensation without taking into account any potential radiation exposures that cannot be estimated. NIOSH may be able to estimate all radiation doses of certain employees, depending on the type of cancer they incurred. NIOSH may also be able to estimate radiation doses for some current members of the Cohort, who were included in the Cohort by statute but have a cancer that is not one of the specified cancers for which an individual can be compensated as a member of the Cohort. However, NIOSH is not authorized under EEOICPA to administratively assign radiation doses to employees for whom radiation doses cannot be estimated using methods of dose reconstruction. For any claimant referred to NIOSH who is a member of the Cohort and has a cancer not defined as a ''specified cancer'' under EEOICPA (and so is not eligible for compensation under EEOICPA without a dose reconstruction), NIOSH will continue to attempt to complete a dose reconstruction, using whatever information is available about that member's entire work history.

M. Non-Regulatory Comment: Reporting Estimated Completion Dates for Petition Evaluations

One advocacy group and two labor organizations suggested that NIOSH report to Congress an estimated completion date for petitions whose evaluations by NIOSH will not be completed within 180 days.

An automatic reporting procedure would divert HHS resources from reviewing Cohort petitions and completing dose reconstructions. Moreover, a ''one-size-fits-all'' reporting procedure of the type proposed would be inappropriate, considering the wide variability that is likely in the scope and volume of petitions, and in the duration of Board evaluations and proceedings involving the petitioner(s) associated with each petition.

Two advocacy groups and two labor organizations recommended that NIOSH provide grants to fund health physicists and other experts to assist petitioners, as well as training workshops to address the informational requirements of a petition.

Petitioners should not need the assistance of health physicists to address the requirements for a petition under § 83.9. Most petitioners should find the petition instructions and petition form provided by NIOSH will be sufficient guidance. NIOSH, in coordination with the DOL/DOE resource centers, will assist petitioners on an individual basis as well. Section 83.11 of the rule commits NIOSH to providing further assistance to petitioners whose petitions have not met the basic requirements for evaluation.

N. Non-Regulatory Comment: Reporting on the Rate of Success of Petitions and Claimants

Two individual commenters recommended HHS report on the success rate of petitions for the addition of classes of employees to the Cohort. The commenters also recommended that DOL report on the success rates of cancer claimants seeking compensation under EEOICPA, providing individual rates by class of employees in the Cohort and a separate rate for claimants who are not members of the Cohort.

NIOSH provides extensive public information through its OCAS internet homepage (*www.cdc.gov/niosh/ocas*) on the status of its dose reconstruction activities and plans to be informative concerning petitions as well. The homepage will provide information on the status and the outcomes of petitions. The commenters should contact DOL if they wish to recommend specific types of reports on claims adjudication outcomes that might be useful to the public.

O. Non-Regulatory Comment: Recommendations To Add Specific Classes to the Cohort

Three labor organizations and one individual commented that various employee groups might or should qualify to become members of the Cohort.

NIOSH will send notices including this final rule and related information to all individuals or organizations who have indicated to NIOSH their intent to petition.

P. Non-Regulatory Comment: Completion of Dose Reconstructions for Mallinckrodt Chemical Company Employees

One individual reports that NIOSH has access to complete dosimetry data on employees of Mallinckrodt Chemical Company and that minimal dose reconstruction is required for these workers. On this basis, the commenter recommends that NIOSH be required to complete these dose reconstructions within 180 days.

The commenter assumes that if extensive radiation monitoring information is available, then dose reconstructions require ''minimal'' work. This is generally true for claims for which the monitoring data alone, prior to dose reconstruction, indicate high level exposures. In such cases, NIOSH would only conduct dose reconstruction to the extent sufficient to document dose levels that meet the threshold for compensation. In most settings, however, the majority of workers are unlikely to have records indicating high level radiation exposures. For these workers, NIOSH needs to carefully evaluate the adequacy of monitoring and monitoring records and to account for any deficiencies that might otherwise lead NIOSH to underestimate radiation doses.

The full process for dose reconstructions is outlined in 42 CFR Part 82 and described in greater detail in technical documents available from NIOSH. These procedures were designed to be as efficient as possible.

Q. Non-Regulatory Comment: Inclusion of Transcripts of Board Meetings in the Administrative Record of the Rulemaking

One advocacy group recommended that HHS include the transcripts of Board meetings for March 7, 14, and 28, 2003, and May 1, 2003 in the administrative record of this rulemaking. These Board meetings included discussions and decisions by the Board concerning its advice on this rulemaking, as well as public comment on issues considered by the Board.

HHS has included the transcripts of the referenced Board meetings in the NIOSH docket for this rule.

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

HHS requested the Board to provide advice concerning these procedures for 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 meeting on May 2–3, 2002, and reviewed the initial NPRM, which was published on June 25, 2002, during its meetings on July 1–2, August 14–15, and August 22, 2002. After making substantial changes based on public comment and Board recommendations, NIOSH issued a second NPRM on March 7, 2003. The Board reviewed the second NPRM during meetings on March 7, 14, and 28, 2003, and May 1, 2003. The members also considered public comments on the two NPRMs provided during 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 two NPRMs and related issues during the Board meetings. The transcripts and minutes of these meetings are available to the

public and are included in the NIOSH docket for this rule.

All of the Board members participated in the review of the second NPRM and concurred in establishing the Board findings and recommendations, with the exception of an abstention by one Board member concerning one finding and recommendation. The Board provided several recommendations on substantial issues addressed in the NPRM, as well as recommendations for clarifying specific sections of the NPRM. The recommendations, which are available to the public from the NIOSH docket for this rule, are summarized below, together with responses by HHS to the recommendations.

A. Removing Cancer-Specific Provisions Concerning Determinations of the Feasibility of Dose Reconstruction

The Board recommended that HHS remove provisions of the NPRM in section 83.13 that would allow HHS to limit the employees included in a class to be added to the Cohort to those who incur specific types of cancers. The Board acknowledged that it may be possible in certain cases to determine that radiation doses are limited to certain specific sites in the body, which would provide a scientific basis for excluding employees who incur certain other types of cancer from certain classes that HHS might add to the Cohort. This finding notwithstanding, the Board was concerned that provisions accounting for such a possibility might conflict with the intent of Congress and, furthermore, the Board was concerned about providing ''some level of equity'' between the definition of classes added to the Cohort by HHS and those already defined by Congress in EEOICPA, which are not limited by type of cancer.

As discussed above in response to similar public comments, HHS has omitted all provisions for establishing cancer-specific classes from the final rule, in response to the recommendations of the Board and to public comments. HHS agrees with the Board that the perception of the public that such provisions would constitute unfair treatment under EEOICPA should be an overriding consideration for this decision.

B. Developing Guidelines Addressing the Feasibility of Estimating Doses With Sufficient Accuracy

The Board recommended that NIOSH develop guidelines, within a reasonable time period after promulgation of the final rule, to provide additional clarification on how NIOSH would determine whether it is feasible to estimate doses with sufficient accuracy, as specified under § 83.13(b) of the NPRM and § 83.13(c) of the rule. The Board recommended that it have the opportunity to review such guidelines. The Board also recommended that HHS make changes to the dose reconstruction rule (42 CFR Part 82), if any are needed, to resolve any potential conflict between these two rules that could leave claimants unable to obtain either a dose reconstruction or status as a member of the Cohort.

As discussed in response to public comments, NIOSH is issuing concurrently with this rule procedures to implement the guidelines specified under section 83.13 of this rule by which NIOSH will evaluate a petition, including the determination addressed in this recommendation by the Board. The Board will have the opportunity to provide recommendations to NIOSH on these procedures, although NIOSH will not delay its evaluation of petitions to obtain recommendations of the Board, or make revisions to the procedures. The rule provides under § 83.15 for the Board to consider each evaluation of a petition NIOSH completes and to request NIOSH to conduct additional analyses. Therefore, the Board will always have the opportunity to discuss with NIOSH any concerns the Board might have with the procedures and methods of a NIOSH evaluation.

As discussed in response to public comments, the dose reconstruction rule and this rule do not conflict with respect to determining the feasibility of dose reconstruction. No revision of the dose reconstruction rule is necessary for this purpose.

The consistency between the two rules does not, however, guarantee that all claimants will either receive a dose reconstruction or be included as members of the Cohort, as expressed by the Board. It is possible for a claimant to be excluded from the Cohort on the basis that the employee was not employed for a minimum of 250 work days within the parameters of a class of employees. This is specified under EEOICPA (42 U.S.C. 7384l(14)(A)), which provides statutory requirements defining the groups from the gaseous diffusion plants that Congress included in the Cohort, and under § 83.13(c)(3)(ii) of this rule, which addresses the statutory requirement for HHS to find that the health of members of a class may have been endangered, for such a class to be added to the Cohort.

C. Combining Employment Within Separate Cohort Classes for Meeting Health Endangerment Requirements

The Board recommended that employees be credited for days of employment within separate classes added to the Cohort, if necessary, to meet a 250 work days employment requirement that might be applicable to qualify as a member of a class added to the Cohort. As discussed above in response to similar public comments, HHS agrees with the Board and has added a provision to the rule for this purpose. Section 83.13(c)(3)(ii) provides that whenever HHS adds a class to the Cohort for which a 250 work days employment requirement is applicable, employees will be able to meet this requirement by combining their employment within the added class with employment within other classes in the Cohort.

D. Adding a Definition for the Term ''Facility''

The Board recommended HHS add to the rule a definition for the term ''facility'' to more clearly specify the limit of the scope of a petition. The Board further recommended that HHS define facility broadly to encompass entire nuclear weapons production sites, such as Los Alamos and Rocky Flats. The Board was particularly concerned that facility not be defined as limited to individual buildings, structures, etc., which the Board was concerned could cause difficulties in considering petitions that relate to operations spanning more than one building or other type of facility.

As discussed above in response to similar public comments, HHS has included in the final rule a footnote to § 83.9(c)(1)(i) that explains that an AWE facility or DOE facility covered under EEOICPA (42 U.S.C. 7384l(5) and (12)) could constitute a single building or structure, including the grounds upon which it is located, or a site encompassing numerous buildings or structures, including the grounds upon which it is located.

E. Evidence Confirming the Occurrence of Unrecorded Exposure Incidents

Under § 83.9(c)(3), the NPRM provided that for petitions based on exposure incidents, versus routine operations, petitioners would be required to provide evidence confirming the occurrence of the incident in cases that cannot be confirmed independently by NIOSH. One of the options for such evidence was the provision of affidavits from two employees who witnessed the incident.

The Board recommended that HHS clarify that affidavits from only two witnesses would be required, since the rule could be interpreted as requiring two witnesses in addition to the petitioner in a case in which the petitioner was also a witness. The Board further recommended that in cases in which eyewitnesses may no longer be living or might be difficult to locate, the rule should allow NIOSH to accept the accounts of other parties who were informed of the incident but were not witnesses to the incident.

As discussed above in response to similar public comments, HHS has revised this section of the rule to omit the requirement for a specific number of witnesses, to make the accommodation recommended by the Board with respect to situations in which eyewitnesses are not available, and to clarify that the provision of one or more affidavits would not, in and of itself, be sufficient to confirm the occurrence of an incident; NIOSH would have to consider the adequacy and credibility of the evidence provided in the affidavits.

F. Reviews of Findings That a Petition Does Not Satisfy the Requirements for a Petition

In the NPRM, HHS requested comment on whether or not the rule should provide an opportunity for petitioners to obtain a review of NIOSH findings that a petition does not meet the requirements specified under § 83.9. The first NPRM had provided for the Board to conduct such reviews, but the Board objected to such a role, which it viewed as an administrative function.

The Board was concerned about the lack of an administrative appeals process for such decisions and recommended HHS consider how such reviews could be conducted.

As discussed above in response to public comments, HHS has added provisions to § 83.11 to give petitioners the option of an administrative review of proposed NIOSH decisions.

G. Recommendations for Section 83.9

The Board recommended revisions to clarify the descriptions of two types of reports that a petitioner could use to support a petitioner's belief that records and information available are inadequate to estimate the radiation doses incurred by members of a class of employees. The first type is an unpublished report by a health physicist or expert in dose reconstruction that might be commissioned by petitioners. The second is a scientific report published in a peer reviewed journal or issued by a government agency.

HHS clarified these provisions consistently with the recommendations of the Board, with one exception. With respect to the first type of report described above, the revisions suggested by the Board would omit the requirement that the expert document his or her findings with respect to the limitations of records on radiation exposures. HHS has retained this requirement. HHS believes it is reasonable to require experts to support their assertions on factual matters with factual evidence.

The Board also recommended HHS consider whether placement of subsection (c)(3) is appropriate within this section, since the subsection addresses information requirements that only come into effect for certain petitions, in cases in which NIOSH requires additional information. The Board was concerned that this might be confusing to petitioners.

HHS has retained the placement of this subsection because it specifies informational requirements for a petition, even though they are conditional requirements. The introductory paragraph of the subsection has been revised to clarify that NIOSH would not require a petitioner to provide the information discussed in the subsection when the petition is submitted, but only upon request. In addition, petitioners will have information from NIOSH in addition to this rule, such as petition instructions and an optional petition form, to guide them through the petition process.

H. Recommendations for Section 83.13

The Board recommended a revision of § 83.13(b)(1)(iii) of the NPRM, which informed the public that NIOSH may often be able to estimate maximum radiation doses without personal dosimetry data and area monitoring data. The Board appeared to be concerned that readers might interpret the statement as being dismissive of the value of such information for dose reconstructions. HHS has revised this subsection (83.13(c)(1)(iv) of the final rule) to remedy this concern, as follows (in italics):

> (iv) In many circumstances, access to personal dosimetry data and area monitoring data is not necessary to estimate the maximum radiation doses that could have been incurred by any member of the class, *although radiation doses can be estimated more precisely with such data.*

I. Recommendations for the Preamble

The Board also made several editorial recommendations for clarifying the preamble of the NPRM. The preamble to this final rule, however, does not include any of the text addressed by the Board's recommendations.

IV. 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 rule 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 establishes 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 thousands of dollars to as much as hundreds of thousands of dollars, depending on the availability of information and the scope of the petition.

The rule 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 rule does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The rule is not considered economically significant, as defined in section 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 Special Exposure Cohort rule 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 rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The rule 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 Rule?

The Paperwork Reduction Act is applicable to the data collection aspects of this rule. 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.

NIOSH has obtained approval from OMB to collect data as specified under this rule under OMB Control No. 0920–0639.

The rule requires classes of employees seeking to be added to the Special Exposure Cohort to submit written petitions for such consideration to NIOSH. HHS has specified the information that petitioners are required to include in their petitions. All petitioners will be required to include identifying and contact information. Other informational requirements will depend on the circumstances of the petition. Petitioners who are claimants for whom NIOSH has attempted to complete a dose reconstruction under 42 CFR Part 82 and has concluded that the dose reconstruction is not feasible are only required to acknowledge their intent to petition; no other information is required. All other petitioners will have to provide more extensive information that comprises the justification for their petition.

NIOSH will make available to petitioners a petition form and instructions to assist petitioners. As appropriate, NIOSH will also provide an authorization form that would be required by individuals who seek to authorize others to serve as petitioners. The authorization form is mandatory but the petition form is not mandatory.

The only cost to respondents is their time to complete and submit the petition.

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 rule prior to its taking effect. The report will state that the Department has concluded that this 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 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 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 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 rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The 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 rule on children. HHS has determined that the 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 rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect on them.

J. Effective Date and Information Collection Approval

The Secretary has determined, pursuant to 5 U.S.C. 553(d)(3), that there is good cause for this rule to be effective immediately to avoid undue hardship on and facilitate payment to eligible claimants.

The Office of Management and Budget (OMB) approved these information collection requirements on [****INSERT DATE****] and assigned control number [****INSERT NUMBER****].

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 amends 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 How will the Secretary report a final decision to add a class of employees to the Cohort and any action of Congress concerning the effect of the final decision?
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. 7384–7385, provides for the payment of compensation benefits to covered employees and, where applicable, survivors of such employees, of 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 facility or AWE facility. In Section 3621(14) of EEOICPA (42 U.S.C. 7384l(14)) Congress included 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 part, 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 part, a group of employees who work or worked at the same DOE facility 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) *OCAS* is the Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(j) *Petitioner* means an individual or organization that submits a petition on behalf of a class of employees and qualifies as a petitioner under § 83.7. A single petition shall only include up to three petitioners.

(k) *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.

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

(m) *Specified cancer,* as is defined in Section 3621(17) 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.

(n) 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. The rule provides for petitions in two distinct circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant, under 42 CFR Part 82, and finds that the dose reconstruction cannot be completed, because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer. As required by EEOICPA (42 U.S.C. 7384l(14)(c)(ii)), 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 within 180 days.

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

A petitioner or petitioners for a petition must be one or more, up to a maximum of three, 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:

[1] HHS will determine the final class definition(s) for each petition (see § 83.16).

(i) The DOE facility or AWE facility [2] 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. This report should specify the basis for believing 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 scientific or technical report, published or issued by a government agency of the Executive Branch of government or the General Accounting Office, the Nuclear Regulatory Commission, or the Defense Nuclear Facilities Safety Board, or published in a peer-reviewed 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.

(3) If the petition is based on an exposure incident as described under paragraph (c)(1)(v) of this section, the petitioner(s) might be required to provide evidence that the incident occurred, but only if NIOSH is unable to obtain records or confirmation of the occurrence of such an incident from sources independent of the petitioner(s). Such evidence would not be required at the time the petition is submitted and the petitioner(s) would be directly informed of the need for this supplemental information. 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) NIOSH will consider evidence provided by affidavit from one or more employees who witnessed the incident. If the petitioner cannot provide such affidavits because such employees are deceased, prevented by reasons of poor health or impairment, or cannot be identified or located, then the requirement for evidence provided by affidavit can be met by providing such an affidavit from one or more individuals who did not witness the incident, provided the individual was directly informed by one or more employees who witnessed the incident.[3]

(4) The provision of any evidence under this section or other provisions of this part, including one or more affidavits, would not, in and of itself, be sufficient to confirm the facts presented by that evidence. NIOSH will consider the adequacy and credibility of any evidence provided.

(5) If, under § 83.15(a), NIOSH has already issued a **Federal Register** notice scheduling a Board meeting to consider a petition concerning a class of employees, then any petitions for such a class of employees submitted following this notice must, under paragraph (c)(2) of this section, present substantially new information that has not already been considered by NIOSH. For this purpose, NIOSH would find that information has been already considered by NIOSH if it were included in the petition(s) that were already considered by NIOSH or if it were addressed either in the report(s) by NIOSH evaluating such a petition or petitions under § 83.13(c) or in a proposed decision by NIOSH responding to such a petition or petitions under § 83.16(a).

TABLE 1 FOR § 83.9: SUMMARY OF INFORMATIONAL REQUIREMENTS FOR ALL 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 reconstrucitn for the claimant submitting the petition; or.	B. (1) A 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) The 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) scientific or technical 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

[2] Depending on the factual circumstances present, a facility that meets the definition of an AWE facility or DOE facility covered under EEOICPA (42 U.S.C. 7384l(5) and (12)) could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing numerous buildings or structures, including the grounds upon which it is located.

[3] An affidavit may be from a petitioner but HHS does not require that an affidavit be from a petitioner.

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 any petitioner(s) whose petition remains unsatisfactory of the proposed finding of NIOSH that the petition fails to meet the specified requirements and the basis for this finding.

(c) A petitioner may request in writing a review of a proposed finding within 30 calendar days of notification under paragraph (b) of this section. Petitioners must specify why the proposed finding should be reversed, based on the petition requirements and on the information that the petitioners had already submitted. The request may not include any new information or documentation that was not included in the completed petition. If the petitioner obtains new information within this 30 day period, the petitioner should provide it to NIOSH. NIOSH will consider this new information as a revision of the petition under paragraph (a) of this section.

(d) Three HHS personnel, appointed by the Director of NIOSH, who were not involved in developing the proposed finding will complete reviews within 30 work days of the request for such a review. The Director of NIOSH will consider the results of the review and then make a final decision as to whether the petition satisfies the requirements for evaluation.

(e) Proposed findings established by NIOSH under paragraph (b) of this section will become final decisions in 31 calendar days if not reviewed under paragraph (d) of this section.

(f) 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 under §§ 83.13 and 83.14, 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 or § 83.14; 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 83.14, 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 facility 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 DOE employees, DOE contractor or subcontractor employees, and/or AWE employees; and

(8) Other sources.

(b) The Director of OCAS may determine that records and/or information requested from DOE, an AWE, or another source to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.

(1) Before the Director of OCAS makes such a determination, the source(s) potentially in possession of such records and/or information will be allowed a reasonable amount of time, as determined by the Director of OCAS, to provide the records and/or information.

(2) Such a determination may take into account the types and quantity of records and/or information requested from the source, as well as any other factors that might be relevant to the judgment under paragraph (b)(1) of this this section of the amount of time that is reasonable to provide the records and/or information, which would be decided on a case-by-case basis by the Director of OCAS.

(c) 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, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose. NIOSH must also determine that it has information regarding monitoring, source, source term, or process from the site where the employees worked to serve as the basis for a dose reconstruction. This basis requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked.

(ii) In many circumstances, to establish a positive finding under paragraph (c)(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 radionuclide (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 many circumstances, NIOSH would require relevant equipment design and performance specifications or information on maximum emissions.

(iii) In many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would

also require information describing the process through which the radiation exposures of concern may have occurred and the physical environment in which the exposures may have occurred.

(iv) In many circumstances, access to personal dosimetry data and area monitoring data is not necessary to estimate the maximum radiation doses that could have been incurred by any member of the class, although radiation doses can be estimated more precisely with such data.

(2) *How should the class be defined, consistent with the findings of the analysis discussed under paragraph (c)(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 (c)(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 at the facility, the relevant time period, and any additional identifying characteristics of employment; and

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

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

(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 (c)(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 parameters established for the class or in combination with work days within the parameters established for one or more other classes of employees in the Cohort.

(d) 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 parameters of the class for inclusion in the class, as defined under paragraph (c)(3) of this section;

(4) 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; and

(5) 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 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 under § 83.13. NIOSH will report to the Board and to petitioner(s) the results of this determination, together with its finding under 42 CFR Part 82 that there was insufficient information to complete the dose reconstruction. HHS will consider this finding under 42 CFR Part 82 sufficient, without further consideration, to determine that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy.

(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. In

considering the petition, both NIOSH and the members of the Board will take all steps necessary to prevent the disclosure of information of a personal nature, concerning the petitioners or others, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

(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 relevant criteria under § 83.13(c) and findings 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(s) of a petition?

(a) The Director of NIOSH will propose, and transmit to all affected petitioners, a decision to add or deny adding classes of employees to the Cohort, including an iteration of the relevant criteria, as specified under § 83.13(c), and a summary of the information and findings on which the proposed decision is based. This proposed decision will take into consideration the evaluations of NIOSH and the report and recommendations of the Board, and may also take into consideration information presented or submitted to the Board and the deliberations of the Board. In the case of a petition that NIOSH has determined encompasses more than one class of employees, the Director of NIOSH will issue a separate proposed decision for each separate class of employees.

(b) HHS will only allow the petitioner(s) to contest a proposed decision to deny adding a class to the Cohort or to contest a health endangerment determination under § 83.13(c)(3)(ii). Such challenges must be submitted in writing within 30 calendar days and must include evidence that the proposed decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures of this part. Challenges may not introduce new information or documentation concerning the petition or the NIOSH or Board evaluation(s) that was not submitted or presented by the petitioner(s) or others to NIOSH or to the Board prior to the Board's issuing its recommendations under § 83.15.

(c) A panel of three HHS personnel, independent of NIOSH and appointed by the Secretary, will conduct an administrative review based on a challenge submitted under paragraph (b) of this section and provide recommendations of the panel to the Secretary concerning its merits and the resolution of issues contested by the challenge. Reviews by the panel will consider, in addition to the views and information submitted by the petitioner(s) in the challenge, the proposed decision, the NIOSH evaluation report(s), and the report containing the recommendations of the Board issued prior to the proposed decision under § 83.15. The reviews may also consider information presented or submitted to the Board and the deliberations of the Board prior to the issuance of the recommendations of the Board under § 83.15. The panel shall consider whether HHS substantially complied with the procedures of this part, the factual accuracy of the information supporting the proposed decision, and the principal findings and recommendations of NIOSH and those of the Board issued under § 83.15.

(d) The Secretary will make the final decision to add or deny adding a class to the Cohort, including the definition of the class, after considering information and recommendations provided to the Secretary by NIOSH, the Board, and from an HHS administrative review when such a review is conducted under paragraph (c) of this section. HHS will transmit a report of the decision to the petitioner(s), including an iteration of the relevant criteria, as specified under § 83.13(c), and a summary of the information and findings on which the decision is based. HHS will also publish a notice summarizing the decision in the **Federal Register**.

§ 83.17 How will the Secretary report a final decision to add a class of employees to the Cohort and any action of Congress concerning the effect of the final decision?

(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 findings upon which the designation was based.[4]

(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) After either the expiration of the congressional review period or notification of final congressional action, whichever comes first, the Secretary will transmit to DOL and to the petitioner(s) 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 canceling 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;

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

(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(c)(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 his final decision that added the class to the Cohort, based upon a review by the Board of the NIOSH analysis under paragraph (b)(2) of this section and any other relevant information considered by the Board;

(4) An opportunity for members of the class to contest a proposed decision 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: February 23, 2004.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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