DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 83

RIN 0920–AA07

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

AGENCY: Department of Health and Human Services.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This document describes how the Department of Health and Human Services (''HHS'') proposes to consider designating additional classes of employees to be added to the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000 (''EEOICPA''). Under EEOICPA, and Executive Order 13179, the Secretary of HHS is authorized to make such designations, which take effect 180 days after Congress is notified unless Congress provides otherwise. An individual member (or the survivors of a member) of a class of employees added to the Special Exposure Cohort would be entitled to compensation if the Department of Labor (''DOL'') finds that employee incurred a specified cancer and the claim meets other requirements established under EEOICPA.

DATES: HHS invites comments on this notice of proposed rulemaking from interested parties. Comments must be received by August 26, 2002.

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

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

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal. Some specific topics for comment are identified under section III, which summarizes the proposed procedures.

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

II. Background

A. Statutory Authority

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

EEOICPA instructed the President to designate one or more Federal Agencies to carry out the compensation program. Pursuant to this statutory provision, the President issued Executive Order 13179 (''Providing Compensation to America's Nuclear Weapons Workers'') which assigned primary responsibility for administering the compensation program to the Department of Labor (''DOL''). 65 FR 77487 (December 7, 2000). DOL published an interim final rule governing DOL's administration of EEOICPA on May 25, 2001 (66 FR 28948).

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

(1) HHS is to develop procedures for considering petitions to be added to the Special Exposure Cohort established under EEOICPA by classes of employees at DOE and Atomic Weapons Employer (''AWE'') facilities. HHS is also to apply these procedures in response to such petitions. Covered employees (and certain eligible survivors) included in the Special Exposure Cohort who have a specified cancer qualify for compensation under EEOICPA. The procedures HHS is proposing to use for considering Special Exposure Cohort petitions are the subject of this notice of proposed rulemaking.

(2) HHS is to develop guidelines by regulation to be used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duty at a DOE or AWE facility. HHS published a notice of proposed rulemaking proposing these ''Probability of Causation'' guidelines on October 5, 2001 (66 FR 50967) and published a final rule on May 2, 2002 (67 FR 22296).

(3) HHS is also to develop methods by regulation to estimate radiation doses (''dose reconstruction'') for certain individuals with cancer applying for benefits under the DOL program. HHS published an interim final rule promulgating these methods under 42 CFR Part 82 on October 5, 2001 (66 FR 50978) and published a final rule 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 staff the Advisory Board on Radiation and Worker Health and provide it with administrative and other necessary support services. The Board, a federal advisory committee, will advise 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). EEOICPA specifies which employees comprise the Cohort initially, including employees of DOE, DOE contractors or subcontractors, or AWEs who worked an aggregate of at least 250 days before February 1, 1992 at a gaseous diffusion plant in (1) Paducah, Kentucky, (2) Portsmouth, Ohio, or (3) Oak Ridge, Tennessee and who were or could have

been monitored in those jobs using dosimetry badges; or (4) employees of DOE or DOE contractors or subcontractors employed before January 1, 1974 on Amchitka Island, Alaska and exposed to ionizing radiation in the performance of duty related to the Long Shot, Milrow, or Cannikin underground nuclear tests. Employees included in the Cohort who incur a specified cancer [1] qualify for compensation (see DOL regulations 20 CFR 30 at 66 FR 28948 for details). Cancer claims submitted by these employees or their survivors do not require DOL to evaluate the probability that the cancer was caused by radiation doses incurred during the performance of duty for nuclear weapons programs of DOE, as is required for other cancer claims covered by EEOICPA.

C. Purpose of the Proposed Procedures

EEOICPA authorized the President to designate classes of employees to be added to the Cohort, while providing Congress with the opportunity to review these decisions and prevent their implementation. As noted previously, the President has delegated his authority in this matter to the Secretary of HHS. The purpose of this notice of proposed rulemaking is to establish procedures by which the Secretary of HHS will determine whether to add to the Cohort new classes of employees from DOE and AWE facilities. The procedures are intended to ensure that petitions for additions to the Cohort are given uniform, fair, scientific consideration, that petitioners and interested parties are provided opportunity for appropriate involvement in the process, and to comply with specific statutory requirements of EEOICPA.

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

EEOICPA includes several requirements for these procedures. The Advisory Board on Radiation and Worker Health (''the Board'') is authorized to provide advice to the President (delegated to the Secretary of HHS) concerning the designation of additional classes as members of the Cohort. The Board's advice is to be based on ''exposure assessments by radiation health professionals, information provided by DOE, and other such information as the Board considers appropriate.'' 42 U.S.C. 7384q. Section 7384q specifies that HHS obtain the advice of the Board ''after consideration of petitions by classes of employees for such advice.'' This section also mandates two broad criteria to govern HHS decisions, which are to be made after receiving the advice of the Board. Members of a class of employees at a DOE or AWE facility may be treated as members of the Cohort for purposes of the compensation program if HHS ''determines that: (1) It is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.'' Finally, 42 U.S.C. 7384l(14)(C) requires the Secretary to submit a report to Congress for each class of employees the Secretary designates to be added to the Cohort. The report must define the class of employees covered by the designation and specify the criteria used to make the designation. This section requires that the designation take effect 180 days after the date on which HHS submits the report to Congress unless Congress takes action to reverse or expedite the designation.

E. Relationship of Proposed Procedures to Rules Proposed and Promulgated by HHS To implement EEOICPA

These procedures complement the two HHS rules promulgated by HHS on May 2, 2002, to implement EEOICPA for cancer claimants who are not members of the Cohort. These are the final rule: ''Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000'' promulgated at 42 CFR Part 81 (67 FR 22296), and the final rule: ''Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000'' promulgated at 42 CFR Part 82 (67 FR 22314).

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

HHS is requiring a finding that NIOSH would be unable to complete dose reconstructions for the individual members of a class of employees to satisfy this first statutory requirement concerning ''sufficient accuracy.'' In practical terms, if NIOSH can successfully reconstruct the radiation doses of members of the class under the requirements of 42 CFR Part 82, then the doses of the class members can be estimated with ''sufficient accuracy'' for DOL to adjudicate claims.

Commenters on 42 CFR Part 82 asked HHS to define the conditions under which NIOSH would not have sufficient information to complete a dose reconstruction, with the understanding that such conditions would be relevant to petitions to add classes to the Cohort. As HHS explained in response to the comments, these conditions will vary on a case-by-case basis. In some cases, limited information about the radiation source term (type and quantity of radioactive material) and the process in which it was used, without any individual monitoring records, will be sufficient to complete a dose reconstruction, particularly when the potential level of radiation that was emitted is extremely low. In these cases, NIOSH can make use of worst case assumptions to fully account for the highest possible radiation doses that might have been incurred.

Simplifying assumptions become more difficult to apply, however, when the potential level of radiation exposure for an individual ranges greatly, particularly when they range from low levels to potentially compensable levels (levels that produce a probability of causation of 50% and above). In these circumstances, the ability of NIOSH to complete a dose reconstruction depends on the extent and quality of information available to substitute for monitoring data. This can be defined on a case-by-case basis but not by using rigid criteria; the potential circumstances are not readily foreseeable.

Some of the methods of dose reconstruction under 42 CFR Part 82 will also be applied in these procedures, to the limited extent feasible, to make the second statutorily required determination as to whether: ''there is reasonable likelihood that * * * radiation * * * may have endangered the health of members of the class.'' Although dose reconstructions would not be feasible for individual members of a petitioning class of employees, the process of determining that dose

[1] Specified cancers are a limited group of cancers that are compensable under provisions governing compensation for members of the Cohort. The list of specified cancers and the provisions governing compensation for the Cohort can be found at 20 CFR Part 30. In addition, Pub. L. 107–20 added renal cancer to the list of specified cancers, and Pub. L. 107–107 added leukemia, when initial exposure is before age 21, to the list.

reconstructions are not feasible should provide information to determine imprecisely the potential level of radiation to which the class could have been exposed. For example, the most limited information indicating the type, form, and quantities of radioactive materials present or used in a work operation would provide a basis for judging whether occupational exposures could have exceeded certain specific levels, as discussed further below.

The HHS rule 42 CFR Part 81 establishes guidelines by which DOL will estimate the probability that the cancer of an employee was caused by ionizing radiation doses incurred by the employee in the performance of duty for DOE nuclear weapons programs. The guidelines are based in substantial part on scientific work of the National Cancer Institute, which has developed an important scientific tool, the Interactive RadioEpidemiological Program (IREP) for this purpose. IREP produces statistical estimates of the probability that a specific cancer was caused by specific amounts and types of ionizing radiation. NIOSH worked with NCI on IREP and developed a special application of IREP (''NIOSH–IREP'') to serve the needs of DOL in implementing EEOICPA for cancer claimants who are not members of the Cohort.

NIOSH–IREP will be used by HHS in these procedures, in conjunction with dose estimating methods, as discussed above, in making the determination required by EEOICPA as to whether ''there is reasonable likelihood that * * * radiation * * * may have endangered the health of members of the class.'' In particular, NIOSH will use NIOSH–IREP to determine whether a radiation exposure to a class of employees was potentially high enough to cause any of the specified cancers for which members of the class could be compensated under provisions of EEOICPA and 20 CFR Part 30 concerning eligibility for compensation. Use of NIOSH–IREP for this purpose will provide a feasible degree of objectivity and consistency between the policies governing compensation for claims under provisions for the Cohort and under provisions for all other cancer claims. Additional detail on how HHS proposes using NIOSH–IREP in evaluating Cohort petitions is provided under Section III of this Supplementary Information and Section 83.12 of the procedures.

III. Summary of Proposed Rule

Congress, in enacting EEOICPA, created an Energy Employees Occupational Illness Compensation Program to ensure an efficient, uniform, and adequate compensation system for certain employees involved in nuclear weapons production and related activities. Under Executive Order 13179, the President assigned primary responsibility for administering the program to DOL. The President assigned various technical responsibilities for policymaking and assistance to HHS. Included among these is the issuance and implementation of these proposed procedures for designating classes of employees to be added to the Cohort. This proposed rule includes procedures for the submission of petitions to add classes of employees to the Cohort and procedures by which HHS will consider such petitions and determine their outcome, with the advice of the Advisory Board on Radiation and Worker Health (''the Board'').

Subtitle A—Introduction

Section 83.0 and 83.1 briefly describe how this proposal relates to DOL authorities under EEOICPA and report the assignment of responsibility for this proposal to HHS. Section 83.1 also outlines the purpose of the proposal and general principles guiding its development.

Section 83.2 describes the relevance of this proposal for cancer claimants under EEOICPA. It explains the option of petitioning for a Cohort designation by cancer claimants for whom NIOSH attempted and was unable to complete dose reconstructions. The initial claims of these individuals will be denied by DOL, because for individuals who are not a member of the Cohort, DOL must determine the probability that their cancers were caused by their radiation exposures. DOL's determination relies upon NIOSH's ability to successfully produce radiation dose estimates through its dose reconstruction program under EEOICPA. Section 83.2 also explains that individuals who would be eligible to file a claim but have yet to incur a cancer, ''potential claimants,'' can also submit petitions on behalf of a class of employees.

Section 83.3 summarizes the role of DOL in administering claims for individuals who are members of classes of employees added to the Cohort under this proposal. It identifies the principal criteria applied by DOL in reviewing each claim, and provides a reference locating the relevant regulatory requirements.

Subtitle B—Definitions

Section 83.5 defines the principal terms used in this proposal. It includes terms specifically defined in EEOICPA that, for the convenience of the reader of this proposal, are repeated in this section.

An important statutory term requiring interpretation by HHS is ''endangered the health.'' This term is interpreted by HHS to mean ''there is a reasonable likelihood that the radiation dose may have caused a specified cancer,'' since members of the Cohort cannot be compensated as Cohort members for any adverse health effects other than specified cancers. This definition and the related issue of establishing a ''reasonable likelihood'' are addressed below in the discussion of Section 83.12 under ''Procedures for Adding Classes of Employees to the Cohort.'' HHS invites comment on this definition.

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

Section 83.6 provides an overview of the procedures.

Section 83.7 describes the qualifications for a person submitting a petition. A petition can be submitted by one or more DOE, DOE contractor or subcontractor, or AWE employees, their survivors, or a labor union representing the employees. Consideration was given to allowing other potential representatives of classes of employees to submit petitions, such as persons who have performed evaluations of radiation exposures and radiation protection programs at DOE sites on a contractual basis or in the course of research. These individuals may have sufficient expertise to identify classes of employees that should be added to the Cohort under this policy. However, HHS found it reasonable to require that such experts work on behalf and with the consent of one or more members of the class, who are the interested parties. Hence, the consenting member(s) of the class can submit the petition with the aid of the expert, who would assist the petitioners to provide justification for the petition, as provided for under Section 83.9. HHS invites public comment on these proposed qualifications. In particular, HHS seeks suggestions about any additional categories of individuals who might be authorized to submit a petition on behalf of a class of employees.

Section 83.8 describes the procedure for submitting a petition. Petitioners are required to complete a form made available by NIOSH, which can be submitted in hard copy or electronically. The form is intended to enable HHS to provide clear and consistent guidance to petitioners efficiently, explaining the information required from the petitioners for HHS to evaluate the petition.

Section 83.9 summarizes the informational requirements of a petition. HHS requires a petitioner to establish a substantial basis for petitioning to be part of the Cohort. The type of information needed to establish a substantial basis differs, depending on the circumstances of the proposed class. The information is described generally in this section and specifically in the petition form to be provided to potential petitioners by NIOSH.

If the proposed class includes one or more members who have already submitted claims and for whom NIOSH was unable to complete a dose reconstruction due to insufficient information, the informational requirements of the petition are minimal. The petitioner need only include a copy of NIOSH dose reconstruction report(s), together with information required by HHS to administer the petition evaluation.

Petitions involving claims for which NIOSH has attempted unsuccessfully to complete dose reconstructions provide a substantial basis for HHS consideration. For this reason, HHS encourages potential petitioners qualified to submit claims to DOL (i.e., covered employees who have already incurred a cancer) to do so and allow NIOSH to attempt to complete individual dose reconstructions prior to submitting petitions.

If NIOSH has not yet determined whether or not it can complete dose reconstructions for a class of employees, the petition must include detailed information defining the proposed class of employees on whose behalf the petition is being submitted, and information to justify the petition. This information must include positive evidence that records required to conduct dose reconstructions do not exist. NIOSH would assist potential petitioners in requesting information from their current or former employers on the availability of such records, if the employer were unresponsive to such requests by the petitioner.

The information provided by the petitioner will help HHS and the Board make the required determinations of: (1) Whether or not the class was exposed to levels of radiation that may have endangered the health of the class; and (2) whether records and information available are adequate to estimate with sufficient accuracy the radiation doses incurred by individual members of the proposed class.

HHS invites comments on the general scheme proposed here, particularly the different requirements for potential petitioners depending upon whether or not NIOSH has already determined it is not possible to conduct dose reconstructions for members of the proposed class. HHS also invites comments on the specific informational requirements. Do they achieve a fair and reasonable balance between the level of burden placed on potential petitioners and the information HHS and the Board need to consider petitions fairly and efficiently? Are there alternative approaches that HHS should consider?

Section 83.10 describes the roles and procedures of NIOSH, HHS, and the Board in selecting petitions for evaluation and notifying the petitioners of the resulting decision. NIOSH will select petitions for evaluation that have met the requirements of this section. Petitioners who have not met the informational requirements for a petition will be notified of this finding in writing, after the opportunity to remedy any omissions. The Board will have the opportunity to review the petition and the finding of HHS and provide its recommendation before HHS makes a final decision. HHS will then notify the petitioner of the final decision to select or not select the petition for evaluation.

NIOSH will present to the board petitions that are selected together with a plan for evaluating the petition. NIOSH will initiate the evaluation as soon as possible, but will consider any advice of the Board concerning the plan, when the Board gives such advice. The Board will have already provided NIOSH advice on a generic approach to such evaluations.

Section 83.11 describes procedures that apply when HHS decides not to select a petition for evaluation. A cancer claim for a member of the class of employees proposed by the petition would continue to be adjudicated under provisions of 20 CFR Part 30 governing claims for compensation not based upon the Cohort. Under these provisions, NIOSH would attempt to conduct a dose reconstruction for the individual. HHS will reverse its decision not to evaluate the petition if NIOSH finds that dose reconstructions cannot be completed for members of the class proposed by the petition. HHS may also reconsider its decision to not select a petition at any time based on new information.

Section 83.12 describes how NIOSH will evaluate petitions to support the Board in making recommendations and the Secretary in deciding the outcome of the petition. The section specifies the potential types of information, which are the same as those used for dose reconstruction under 42 CFR Part 82, and specifies the potential sources for this information. NIOSH will evaluate this information to make two determinations required by EEOICPA: (1) Whether there was ''a reasonable likelihood that such radiation dose may have endangered the health of members of the class'' and (2) whether the level of radiation exposures to individual members of the class can be estimated with ''sufficient accuracy''—in other words, using the methods of dose reconstruction established under 42 CFR Part 82. If health was endangered and the level of radiation exposures to individuals cannot be estimated through dose reconstructions, these findings would provide the basis for the Board to advise and HHS to decide that a class of employees be added to the Cohort.

HHS interprets ''endangered the health'' to mean a finding that there was a reasonable likelihood that such radiation dose may have caused a specified cancer since, as explained above, EEOICPA restricts compensation under provisions concerning the Cohort to those members of the Cohort who have incurred a specified cancer. To determine whether the potential level of radiation exposure is sufficient to produce ''a reasonable likelihood'' of having caused a specified cancer, HHS will apply an objective but necessarily less demanding standard than was established under EEOICPA and applied under 42 CFR part 81 [2], as follows.

NIOSH would use NIOSH–IREP, a software tool which was developed under 42 CFR Part 81 for estimating the probability that specific radiation doses caused a specific type of cancer in a specific individual. Since use of NIOSH–IREP requires information about the type of cancer, the attributes of the individual, and the circumstances of the individual's exposure to radiation, information which may not be known or applicable to a class of employees, NIOSH will apply hypothetical values for these variables as necessary. The hypothetical values will reasonably represent what is known about the class of employees and its radiation exposure, while giving the benefit of the doubt to the employees with respect to what may be unknown. However, because the specified cancers differ according to the amount and type of radiation dose that will result in a probability of causation of 50% or higher calculated at the 99 percent credibility limit using NIOSH–

[2] Under EEOICPA and 42 CFR Part 81, the standard for ''at least as likely as not'' is a 50% or greater probability at the upper 99 percent credibility limit. This standard is designed to provide a large margin of error in ensuring that an employee whose cancer was likely to have been caused by radiation would not be denied compensation under EEOICPA. For a full explanation of this statistical concept and its use in NIOSH–IREP, see the explanation in the preamble to 42 CFR Part 81 (66 FR 50967, 50968–9).

IREP, NIOSH will select the type of specified cancer that is most readily caused by the radiation exposures to which the employees were potentially exposed—the ''most radiogenic'' specified cancer.[3] If leukemia is the most radiogenic cancer caused by the radiation exposures of concern to the class, however, NIOSH would select both leukemia and the most radiogenic solid tumor cancer, to reasonably account for the fact that leukemia is extremely radiogenic but also rare (it may not occur at all in the employee class). NIOSH will then use these variables and the selected type of cancer in NIOSH–IREP to determine the level of radiation dose to which a member of the proposed class of employees would have to have been exposed to reach a probability of causation of 50 percent at the 99 percent credibility limit.[4] Using this level as the benchmark, NIOSH would determine whether the actual level of radiation to which members of a class may have been exposed could have reached or exceeded this benchmark, based on the radiation source term (the type and quantity of radioactive materials), the work processes, the radiation safety procedures, or other relevant information. If so, the class would satisfy the criterion for health endangerment.

The practical result of this approach is to establish an objective measure of health endangerment with minimal use of subjective expert judgment. Subjective judgment will grant petitioning classes the benefit of the doubt with respect to all assumptions about radiation exposure levels and characteristics required to substitute for the lack of dosimetry records and information from DOE or the AWEs. Given the sparsity of records and information required to substantiate a SEC petition, these assumptions should be relatively few and simple. They should provide an easy basis for review by the Board and other experts.

By evaluating probability of causation using the most radiogenic cancer, HHS similarly gives the petitioning class a substantial benefit of the doubt with respect to the cancers that will actually be incurred by members of the class. This reasonably minimizes the level of radiation dose required to produce a probability of causation of 50 percent at the 99 percent credibility limit, and thereby helps ensure HHS would approve a petition when there is a ''reasonable likelihood'' that the health of members of the class may have been endangered.

The entire approach presented above is intended to ensure HHS makes determinations of health endangerment as fairly, transparently, and consistently as possible, and compliant with the statutory requirement that HHS establish a ''reasonable likelihood'' that the health of members of the class may have been endangered. HHS invites comment on its proposed interpretation of health endangerment and approach to evaluate it.

Based on the findings of evaluations used to make the two determinations discussed above, NIOSH may propose revisions, as appropriate, to the proposed definition of the class of employees covered by the petition. For example, NIOSH might find through such evaluations that the definition of the class of employees should be broadened to include additional workers not identified previously, or that the individuals identified in several petitions should constitute a single class of employees. NIOSH might also find that more than one class of employees is proposed by the petition, for which the two determinations discussed above differ.

The definition of the class will include a minimum duration of employment for an individual to be included in the class. Members of the gaseous diffusion plants included by statute in the Cohort must have been employed at the plants for a minimum of 250 days, as provided under EEOICPA. The same duration may be appropriate for other classes of employees added to the Cohort. NIOSH will propose a minimum duration, as appropriate, based on its findings concerning the circumstances, types, and potential levels of radiation exposure to each class of employees. In cases in which NIOSH cannot establish a substantial basis for specifying a duration of employment, NIOSH will use the 250 day duration of employment required for employees of the gaseous diffusion plants.

With the completion of this evaluation, NIOSH will provide the Board and the petitioners with an evaluation report summarizing its methods and findings. The contents of the report are specified in this section.

Section 83.13 describes how the Board will evaluate a petition. Its evaluation will be conducted in one or more public meetings that will be announced in the **Federal Register**, together with a summary of the petition and the NIOSH evaluation report. The Board will review the petition and the NIOSH report. In addition, the petitioner will have the opportunity to address the Board regarding its petition and the NIOSH evaluation report. If NIOSH subsequently conducts additional evaluation in response to the review and recommendation of the Board, NIOSH will provide a supplementary report to the petitioner(s) and the Board for further deliberation. At the conclusion of the Board's deliberation, the Board will prepare a report providing recommendations to the Secretary on whether or not to add the proposed class of employees to the Cohort, as well as on the definition of the class. The report will include the criteria and information that provide the basis for the Board's recommendations.

Section 83.14 describes how the Secretary will produce final decisions on the outcome of petitions. The Secretary will issue proposed decisions to the petitioner(s), including a definition of the class or classes of employees effected and a summary of the criteria and information supporting the decision. The petitioner(s) will have 30 days to challenge a proposed decision of the Secretary by requesting an administrative review of the record. After 30 days or resolution of a challenge, the Secretary will transmit a final decision to the petitioner(s). At this time, the Secretary will also publish in the **Federal Register** decisions to deny adding classes of employees to the Cohort. Decisions to add a class of employees to the Cohort will not be published in the **Federal Register** until expiration of the 180 day congressional review period addressed in § 83.15 and discussed below.

Section 83.15 describes the role of Congress in designating additional classes as members of the Cohort. As required by EEOICPA, the Secretary will notify Congress by report of final decisions to add classes of employees to the Cohort, including a definition of the class and the criteria and information upon which the decision was based. Congress will then have 180 days during which it may take an action to reverse or expedite the designation. Without action by Congress, the designation becomes effective automatically 180 days after the date Congress received the report of the Secretary. Within 200 days, the Secretary will transmit to DOL and publish in the **Federal Register** the definition of the class covered by the

[3] Despite selection of the most radiogenic cancer to calculate probability of causation, once a class of employees has been added to the Cohort, members would be eligible for compensation for incurring any of the specified cancers, not only the cancer used for this calculation.

[4] In a case where NIOSH uses both leukemia and the most radiogenic solid tumor cancer, NIOSH would average the two doses resulting from the NIOSH–IREP analysis to produce a single dose level to use as the benchmark discussed subsequently in this paragraph.

designation and the outcome of the designation, reflecting any action taken by Congress.

Section 83.16 describes how the Secretary would cancel a final decision to add a class to the Cohort or modify a final decision to reduce the scope of a class the Secretary had added to the Cohort. The addition of a class to the Cohort by the Secretary is premised on the lack of sufficient records and information to enable NIOSH to complete dose reconstructions for members of the class under 42 CFR Part 82. In the event that HHS subsequently obtains sufficient records and information for reconstructing the doses of some or all members of a class the Secretary has added to the Cohort (e.g., records that were deemed non-existent or missing at the time HHS decided to add the class to the Cohort), the provisions of Section 16 are intended to reverse or modify the decision. Covered employees who are no longer in the Cohort may still seek compensation by establishing that their cancer was at least as likely as not related to covered employment. Thus, their claims seeking compensation for cancers would be evaluated by DOL and forwarded to NIOSH for dose reconstructions under 42 CFR Part 82.

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 entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. This notice of proposed rulemaking is being treated as a ''significant regulatory action'' within the meaning of the executive order because it meets the criterion of Section 3(f)(4) in that it raises novel or legal policy issues arising out of the legal mandate established by EEOICPA. It proposes to establish practical procedures, grounded in current science, by which the Secretary of HHS can fairly consider petitions to add classes of employees to the Cohort. The financial cost to the federal government of responding to these petitions is likely to vary from several thousand dollars to as much as tens of thousands of dollars, depending on the availability of information and scope of the petition.

The notice of proposed rulemaking carefully explains the manner in which the procedures are consistent with the mandate of 42 U.S.C. 7384q and implements the detailed requirements of that section. The proposal does not interfere with State, local, and tribal governments in the exercise of their governmental functions.

The proposal is not considered economically significant, as defined in 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 proposal for consistency with the President's priorities and the principles set forth in E.O. 12866.

B. Regulatory Flexibility Act

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

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

Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The Paperwork Reduction Act is applicable to the data collection aspects of these proposed procedures.

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of projects. To request more information on this project or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer at (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 45 days of this notice.

Under the proposed rule, NIOSH will provide an ''SEC Petition Form'' petitioners must use to submit a petition. The form and accompanying instructions will assist the claimants in meeting the informational requirements of these procedures for petitions to be selected for evaluation by HHS and the Board. The completed form can be submitted in hard copy or electronically over the internet.

There will be no cost to respondents for this data collection. This is a new data collection. The estimated annual burden of this data collection is described in the table below.

Respondents	Number of respondents	Number of responses	Avg. burden per response (hrs.)	Total hours
SEC Petition Form	90	1	68/60	103

D. Small Business Regulatory Enforcement Fairness Act

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

E. Unfunded Mandates Reform Act of 1995

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

F. Executive Order 12988 (Civil Justice)

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

G. Executive Order 13132 (Federalism)

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

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

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

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

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

List of Subjects in 42 CFR Part 83

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

Text of the Proposed Rule

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 42 CFR to add 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.

Subpart B—Definitions

Subpart C—Procedures for Adding Classes 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 (''EEOICPA''), 42 U.S.C. 7384–7385 [1994, supp. 2001], provides for the payment of compensation benefits to

covered employees and, where applicable, survivors of such employees, of the United States Department of Energy (''DOE''), its predecessor agencies and certain of its contractors and subcontractors. Among the types of illnesses for which compensation may be provided are cancers. There are two methods set forth in the statute for claimants to establish that a cancer incurred by a covered worker is covered by the 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 other method to establish that a cancer incurred by a covered worker is covered by EEOICPA is to establish that the worker was a member of the Special Exposure Cohort (''Cohort'') who suffered a specified cancer after beginning employment at a DOE or AWE facility. Section 7384l(14) of the EEOICPA includes certain classes of employees in the Cohort. Section 7384q of the Act 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 authorized the President to designate additional classes of employees to be added to the Cohort, while providing Congress with the opportunity to review and affect these decisions. The President has delegated authority to consider and make such designations to the Secretary. The purpose of this part is to specify the procedures by which HHS determines whether to add new classes of employees from DOE and AWE facilities to the Cohort. HHS will consider adding new classes of employees only in response to petitions by or on behalf of such classes of employees, as authorized under EEOICPA and described in these procedures. The procedures are intended to ensure petitions for additions to the Cohort are given uniform, fair, scientific consideration, that petitioners and interested parties are provided opportunity for appropriate involvement in the process, and that the process is consistent with statutory requirements specified in EEOICPA.

§ 83.2 How would cancer claimants be affected by the procedures in this part?

This part implements provisions of EEOICPA intended to serve potential and current cancer claimants whose radiation doses (incurred by a covered employee in the case of a survivor claimant) cannot be estimated by the completion of a NIOSH dose reconstruction.

(a) A current cancer claimant can petition on behalf of a class of employees to be added to the Cohort upon determination by NIOSH that it cannot complete a dose reconstruction for the claimant. The initial claim of the claimant must be denied by DOL, since compensation for a cancer claim not based on the Cohort provision requires the completion of NIOSH dose reconstruction. However, if a petition by the claimant is successful, the claimant could reapply and obtain compensation as a Cohort member (or survivor of a Cohort member), if the claim qualifies under requirements governing compensation to members of the Cohort.

(b) A potential cancer claimant, a qualified DOE, DOE contractor or subcontractor, or AWE employee who has not incurred cancer, can also petition on behalf of a class of employees to be added to the Cohort. A successful petition would entitle the claimant, upon incurring a specified cancer, to submit a claim for compensation under provisions of the Cohort.

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

DOL will adjudicate claims for compensation 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. In summary, this review by 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 for 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 proposal, a group of employees who work or worked at the same DOE or AWE facility, who may have experienced similar types and levels of exposure to radiation, and for whom the availability of information and recorded data on such 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 an employee of DOE, a DOE contractor or subcontractor, or an atomic weapons employer, as further defined in EEOICPA.

(h) *Endangered the health* is a statutory term from EEOICPA which means, for the purposes of these procedures, ''there is reasonable likelihood that the radiation dose may have caused a specified cancer,'' determined according to these procedures using NIOSH-IREP.

(i) *Interactive RadioEpidemiological Program (''IREP'')* is a computer software program that uses information on the dose-response relationship and specified factors such as a claimant's radiation exposure, gender, age at diagnosis, and age at exposure to calculate the probability of causation for a given pattern and level of radiation exposure.

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

(k) *Probability of causation* means, for the purposes of these procedures, the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure. This concept is further explained under 42 CFR Part 81, which provides guidelines by which DOL will determine probability of causation under EEOICPA.

(l) *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.

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

(n) *Specified cancer* (as defined in section 4(b) of the Radiation Exposure Compensation Act Amendments of 2000 (42 U.S.C. 2210 note) and section 7384l(17) of EEOICPA means:

(1) Leukemia (other than chronic lymphocytic leukemia) if onset occurred more than two years after first exposure;

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

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

(i) Multiple myeloma;

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

(4) Primary cancer of the:

(i) Thyroid;

(ii) Male or female breast;

(iii) Esophagus;

(iv) Stomach;

(v) Pharynx;

(vi) Small intestine;

(vii) Pancreas;

(viii) Bile ducts;

(ix) Gall bladder;

(x) Salivary gland;

(xi) Urinary bladder;

(xii) Brain;

(xiii) Colon;

(xiv) Ovary;

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

(5) Primary or secondary bone cancer.

(6) Primary or secondary renal cancers.

(o) The specified diseases designated in paragraph (n) of 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.

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 by which NIOSH, the Board, and the Secretary will operate in considering a petition, leading to the Secretary's final decision to accept or deny the petition. The petition requirements differ for classes of employees including members who have submitted cancer claims already, for whom NIOSH attempted and was unable to complete individual dose reconstructions as specified under 42 CFR 82.12. As required by EEOICPA, the procedures include formal notice to Congress of any decision by the Secretary to add a class to the Cohort, and the opportunity for Congress to change the outcome of the decision.

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

Petitioners must be one of the following:

(a) One or more DOE, DOE contractor or subcontractor, or AWE employees or their survivors (as defined under EEOICPA and 20 CFR Part 30); and/or

(b) A labor union representing or formerly having represented DOE, DOE contractor or subcontractor, or AWE employees who would be included in the proposed class of employees.

§ 83.8 How is a petition submitted?

(a) The petitioner(s) must send a completed ''SEC Petition Form'' to NIOSH/OCAS addressed as follows: SEC Petition, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–R45, Cincinnati, OH 45226.

(b) The SEC petition form is available from NIOSH by calling the NIOSH toll-free phone service at 1–800–35–NIOSH. The form is also available from the NIOSH homepage at: *www.cdc.gov/niosh.* The form can be completed and submitted electronically following instructions provided on the NIOSH homepage.

§ 83.9 What information must a petition include?

The petition must include complete information according to the instructions on the SEC petition form. As explained by these instructions, in addition to identifying and contact information, the petitioner(s) must provide the substantive information described under paragraph (a) or (b) of this section before the petition is considered. These informational requirements are also summarized in Table 1 of this section.

(a) The petition must transmit a copy of a report produced by NIOSH under 42 CFR 82.12 notifying the petitioner(s) that NIOSH attempted and could not complete a dose reconstruction for the individual(s) due to insufficient records and information; [1] or, alternatively,

(b) The petition must provide the following:

(1) A proposed class definition [2] specifying:

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

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

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

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

(2) A description of the petitioners' basis for believing the class was exposed to levels of radiation at the facility that may have ''endangered the health of members of the class.'' [3] An adequate basis must include the following:

(i) A description of short-term radiation-related health effects or health care interventions that demonstrate special efforts to respond to a hazardous radiation exposure, such as a depressed white blood cell count associated with radiation exposure or the application of chelation therapy among members of the class; and/or

(ii) The following two requirements:

(A) An identification of radioactive materials and emissions; contaminated tools, equipment, or areas; and/or any other relevant information suggesting the class was potentially exposed; and

(B) A description of shortcomings of radiation protection measures, including the deficiencies of particular measures used or the omission of measures that should have been used to

[1] A Cohort petition by an individual for whom NIOSH was unable to complete an individual dose reconstruction under 42 CFR Part 82 will be selected for evaluation without requiring further information or documentation from the petitioner to justify consideration of the petition. NIOSH will have already collected related information from the claimant through a structured interview during the dose reconstruction process. NIOSH will establish an initial class definition based on records and information NIOSH obtained during the attempted dose reconstruction, which NIOSH would supplement with additional data collection, as necessary. HHS will establish a final class definition with the advice of the Board.

[2] HHS will determine the final class definition for each petition (see § 83.14 of these procedures).

[3] HHS interprets the statutory language ''endangered the health'' [see 42 U.S.C. § 7384q(b)(2)] to mean ''there is a reasonable likelihood that the radiation dose may have caused a specified cancer,'' since claimants cannot be compensated as members of the Cohort for any adverse health effects other than certain cancers under the relevant provisions of EEOICPA [see 42 U.S.C. § 7384l(9) and (17)].

prevent hazardous radiation exposures at the facility; and

(3) A description of the petitioner's basis for believing records and information available are inadequate to estimate the radiation doses incurred by any members of the proposed class of employees. An adequate basis must include at least one of the following elements:

(i) Documentation indicating the petitioner(s) sought records on radiation exposures at the facility and relevant to the petition and that DOE or the AWE responded indicating the records do not exist; or

(ii) 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 and relevant to the petition and specifying the basis for finding these documented limitations would prevent the completion of dose reconstructions for individual members of the class under 42 CFR Part 82 and related NIOSH technical implementation guidelines.

TABLE 1.—INFORMATIONAL REQUIREMENTS FOR PETITIONS

Petitioner identifying and contact information and either (a) or (b):	
(a)	(b)
Copy of NIOSH dose reconstruction report indicating that NIOSH was unable to reconstruct the radiation dose of a worker included in the proposed class.	(1) Proposed class definition identifying: (i) Facility, (ii) Job titles/duties, (iii) Period of employment, and if relevant, (iv) Exposure incident. (2) Basis for health endangerment; either: (i) Health effects or health care or (ii)(A) Identification of potential exposures, and (B) Shortcoming of radiation protection. (3) Basis for infeasibility of dose reconstruction; either: (i) Demonstrated lack of records or (ii) Expert report.

§ 83.10 How will HHS select petitions for evaluation?

(a) Where HHS finds the petition meets the requirements specified in §§ 83.7 through 83.9, HHS will transmit a written report notifying the petitioner(s) that it has selected the petition for evaluation. The HHS report will also provide the petitioner(s) with information on the steps and expected duration of the evaluation and deliberative processes required pursuant to these procedures.

(b) Where HHS finds the petition does not meet the requirements specified in §§ 83.7 through 83.9,

(1) HHS will notify the petitioner(s) of any requirements that are not met by the petition, and provide 30 days for the petitioner(s) to revise the petition accordingly.

(2) After 30 days, for petitions that continue to fail to meet one or more requirements, HHS will transmit a written report notifying the petitioner(s) of the recommended finding to not select the petition for evaluation and the basis for this recommended finding. The report will also inform the petitioner(s) that this recommended finding will be reviewed by the Board.

(3) HHS will report the recommended finding and its basis to the Board at its next meeting. HHS will consider the recommendations of the Board before producing a final decision on whether or not to select the petition for evaluation.

(4) HHS will report the final decision to the petitioner, including the basis for the decision and the recommendation of the Board.

(c) NIOSH will present petitions selected for evaluation to the Board with plans specific to evaluating each petition.[4] Each specific evaluation plan will be based on a general plan for evaluating petitions which NIOSH will develop in consultation with the Board. Each specific evaluation plan will include the following elements:

(1) An initial proposed definition for the class being evaluated, subject to revision as warranted by evaluation conducted under § 83.12; and

(2) A schedule 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 selected petitions and associated evaluation plans to the Board.

(e) NIOSH will publish a notice in the **Federal Register** notifying the public of its plans to evaluate a petition and soliciting information relevant to the evaluation.

§ 83.11 What happens to petitions that HHS does not select for evaluation?

(a) Qualified cancer claims by members of the class of employees proposed in the petition will be subject to NIOSH dose reconstructions under 42 CFR part 82. [5] If NIOSH is unable to complete such dose reconstructions, a petitioner on behalf of the class can submit a new petition on this basis, as provided under § 83.9(a).

(b) Based on new information, HHS may, at its discretion, reconsider a petition that was not selected for evaluation.

§ 83.12 How will NIOSH evaluate a petition?

(a) NIOSH will collect information on the types and levels of radiation exposures that potential members of the class may have incurred, as specified under 42 CFR 82.14, from the following potential sources, as necessary:

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

(2) DOE;

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

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

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

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

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

(8) Information obtained from any public meetings NIOSH convenes; and

(9) Other sources.

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

[5] Only claims which DOL determines involve a covered employee who has cancer can be adjudicated by DOL to receive dose reconstructions by NIOSH under the DOL and HHS rules cited.

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

(1) Is there a ''reasonable likelihood that such radiation dose may have endangered the health of members of the class?'

(i) To make this determination, NIOSH will interpret the statutory term ''endangered the health'' [see 42 U.S.C. 7384q(b)(2)] to mean there is a reasonable likelihood that the radiation dose may have caused a specified cancer, since the Cohort claims based on provisions of the Act can only be approved for specified cancers under the relevant provisions of EEOICPA, [see 42 U.S.C. 7384l(9) and (17)].

(ii) To determine whether radiation levels could have caused a specified cancer, NIOSH will determine the minimum level of radiation dose at which NIOSH–IREP will produce a probability of causation of 50% at the upper 99 percent credibility limit for the most radiogenic [6] specified cancer or cancers that could have resulted from the types of radiation exposures potentially incurred by potential members of the class. NIOSH will use reasonable values that confer the benefit of the doubt to the class for demographic factors used by NIOSH–IREP cancer models, such as gender and age at time of radiation exposure, except when actual values are known for the class in general; when the actual values are known, NIOSH will use these values to the extent possible. Similarly, NIOSH will use reasonable values conferring the benefit of the doubt to the class in selecting any radiation exposure parameters that are unknown and that affect the probability of causation estimate. Using this procedure to establish a minimum radiation dose level, NIOSH will determine whether potential members of the class could have incurred at least this threshold dose.

(2) Can the level of radiation exposures to individual members of the class be estimated, using the methods of dose reconstruction established under 42 CFR Part 82?

(3) How should the class be defined, to be consistent with the findings of paragraphs (b)(1) and (2) of this section?

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

(1) An identification of the relevant petitions;

(2) A proposed definition of the class or classes of employees to which the evaluation applies, and a summary of the basis for this definition, including any justification that may be needed for the inclusion of individuals who were not identified in the original petition(s), the identification of any individuals who were identified in the original petition(s) who should constitute a separate class of employees, and the merging of multiple petitions that represent a single class of employees; the proposed class definition(s) will address the following parameters:

(i) The DOE or 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, an identification of an unmonitored or unrecorded exposure incident or incidents, when such an incident(s) comprises the basis of the petition; and

(v) A minimum duration of employment for inclusion in the class; [7] and

(vi) Any other parameters that serve to define the membership of the class.

(3) a summary of the findings evaluating the potential for the health of members of the class to have been endangered by radiation exposures incurred in the performance of duty, and a description of the evaluation methods and information upon which these findings are based; and

(4) a summary of the findings evaluating the adequacy of existing records and information to allow for the successful reconstruction of 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.

§ 83.13 How will the Board evaluate a petition?

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

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

(c) NIOSH may decide to conduct additional evaluation addressing a petition(s), upon the request of the Board. If NIOSH conducts further evaluation, it will report new findings of this evaluation to the Board and the petitioner(s).

(d) Upon the completion of NIOSH evaluation and deliberations of the Board concerning a petition, the Board will develop and transmit to the Secretary a consensus [8] report containing its recommendations. The Board's report will include the following:

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

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

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

(4) The criteria and information upon which the recommendation is based, including NIOSH evaluation reports, information presented by petitioners, and the deliberation of the Board.

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

(a) The Secretary will propose, and transmit to all affected petitioners, a decision to add or deny adding classes of employees to the Cohort.

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

[6] The ''most radiogenic'' specified cancer will be the type of specified cancer that is most readily caused by the radiation exposures to which the employees were potentially exposed. In more technical terms, it will be the type of specified cancer which requires the lowest dose of the radiation types to which the employees were potentially exposed to produce a probability of causation of 50 percent at the upper 99 percent confidence limit using NIOSH–IREP. In a case in which the most radiogenic specified cancer is leukemia, NIOSH would select both leukemia and the most radiogenic solid tumor cancer and apply them separately in the NIOSH–IREP analysis discussed in this section, and then average the two resulting threshold doses to establish the threshold dose to be applied in evaluating health endangerment for the class.

[7] NIOSH will define the minimum duration of employment as 250 days for classes for which NIOSH lacks a substantial basis to support establishment of a different minimum duration.

[8] The term ''consensus'' as used with respect to the decisions of federal advisory committees established under the Federal Advisory Committee Act (FACA) does not necessarily mean ''unanimity.'' These committees have broad parameters under which they can define the extent of agreement among members of the committee that will constitute consensus and allow a decision to be adopted as a decision of the committee.

decisions of the Secretary under these procedures must be submitted in writing, with accompanying documentation supporting the assertions.

(c) HHS will issue a final decision on the designation and definition of the class, and transmit a report of the decision and the criteria and information upon which the decision is based to the petitioner(s).

(d) HHS will publish in the **Federal Register** at this time decisions to deny adding a class of employees to the Cohort, including a definition of the class and a summary of the criteria and information upon which the decision is based. HHS will not publish in the **Federal Register** affirmative decisions to add a class to the Cohort until expiration of the 180 day congressional review period, as specified under § 83.15.

(e) As a matter of discretion, the Secretary may consider other factors or employ other procedures not set forth in this part when he deems it necessary to do so to address the circumstances of a particular petition.

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

(a) If the Secretary designates a class of employees to be added to the Cohort, the Secretary will transmit to Congress a report providing the designation, the definition of the class of employees covered by the designation, and the criteria and information upon which the designation was based. [9]

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

(c) Within 200 days after transmittal of the report to Congress, the Secretary will transmit to DOL and publish in the **Federal Register** 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.

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

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

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

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

(2) An analysis by NIOSH of the utility of the new information for conducting dose reconstructions under 42 CFR Part 82; the analysis will be performed consistently with the analysis of a petition by NIOSH under §§ 83.12(b)(2), 83.12(b)(3), 83.12(c)(2), and 83.12(c)(4);

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

(4) Any additional procedures that the Secretary may deem appropriate, as specified in the notification provided for under paragraph (b)(1) of this section.

Dated: June 12, 2002.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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