

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

G. Recommendations for Section 83.9

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

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

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

H. Recommendation for Section 83.10

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

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

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

comment, however, on whether petitioners should have the option to seek an administrative review of adverse final decisions.

I. Recommendation on Section 83.13

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

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

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

J. Recommendation on Section 83.14

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

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

V. Publication of a Second Notice of Proposed Rulemaking

HHS is publishing this second notice of proposed rulemaking to provide opportunity for public comment on the changes to the initial proposal discussed above. Some of these changes are substantial and were not discussed as options in the initial notice, nor were they otherwise foreseeable extensions, abbreviations, or variations of the initial proposal. These substantial changes include: a more qualified definition of

sufficient accuracy; revised procedures for establishing health endangerment, which eliminate the use of cancer risk models and of subjective judgments to quantify potential radiation doses; the potential for defining a class to be added to the Cohort by type of cancer in addition to previously specified employment parameters; and expedited procedures for evaluating petitions by claimants for whom NIOSH lacked sufficient information to complete dose reconstructions.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

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

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