

DRAFT COMMENTS ON PROPOSED AMENDEMENTS TO 42 CFR PART 83

SPECIAL EXPOSURE COHORT RULE

The Advisory Board on Radiation and Worker Health submits the following comments on the proposed changes to the Special Exposure Cohort Regulations at 42 CFR Part 83 which were included in the Interim Final Rule (IFR) published on December 22, 2005. The purpose of this rulemaking is to harmonize the HHS rule with the new time limits included in the Conference Report for the FY 05 Defense Authorization Act (P.L. 108-375) which were set forth to ensure that evaluations of Special Exposure Cohort petitions are completed in a timely fashion by NIOSH and the Advisory Board, and that Special Exposure Cohort determinations will be decided by the Secretary of HHS within 30 days of receipt of a recommendation from the Advisory Board.

The Conference Report States:

“To ensure that applications to be a SEC member are processed promptly, new timelines have been included. Within 180 days of receipt of a petition for designation as members of a SEC, the Director of NIOSH must submit to the Advisory Board a recommendation on that petition, including all supporting documentation. During the 180 period when NIOSH is preparing the petition for review by the Advisory Board, NIOSH should identify all deficiencies in the petition within the first 30 days. When the President receives an affirmative recommendation from the Advisory Board to designate a class to the SEC, the President shall have a period of 30 days in which to accept or reject the recommendation and notify Congress. If the President does not send a determination notice within 30 days, and if there is an affirmative Board recommendation, the class recommended to be a SEC will automatically become a SEC, subject to a 30 day notification period in Congress.”

We have a number of questions and comments about the proposed amendments:

1. We do not believe that the proposed seven day time period in the IFR is adequate for petitioners to appeal the disqualification of an SEC petition. Given the limited resources of most petitioners and the potential need for them to gather more technical information to address the reasons for their disqualification, the 30 days in the existing CFR Part 83.11 is a more reasonable time period for such appeals.
2. The text of the rule does not specify the 180 day time period required in P.L. 108-375. The 180 day time period is only mentioned in the Preamble of the rule, a part of the rule that is explanatory not binding. This is confusing and needs to be clarified. In addition, the current proposal includes a new definition of petition that appears to initiate the 180 day time period only after

the petition has qualified and ends it with the presentation of just the evaluation report (but not necessarily a recommendation). This leaves no specified time period for petition qualification or for the development and presentation of a NIOSH recommendation based on the SEC petition evaluation. We notes that the conference report also indicates that during the 180 day time period for SEC petition evaluation, NIOSH should “identify all deficiencies” within 30 days of receipt of that petition. Appropriate changes should be made to the rule address these problems with the IFR and to make the Final Rule consistent with the Conference Report.

3. The Board is supportive of the need for the SEC petition process to proceed in a timely fashion, consistent with the Conference Report. Petitioners and interested parties should know how long each step will take in order to better understand how the evaluation of their petition will progress. Having this information will help avoid concerns that their petitions are being inappropriately delayed. This information should include expected time periods for initial petition qualification, the NIOSH evaluation of qualified petitions including recommendations, the Board’s review of the NIOSH evaluation, the development of the Board’s recommendation to the Secretary of HHS, the submission of the Board’s recommendation to the Secretary of HHS (usually 21 days), and finally the Secretary’s decision and transmission of that decision to Congress (30 days in the amended regulations).

The Board believes that providing expected time periods in the regulation and some additional published guidelines would be useful. Such guidelines and regulations should recognize the need for timely responses to petitions. Therefore, the Board recommends that NIOSH develop guidelines for the entire SEC petition process including regulations covering at least the portions required by the new law.