GOVERNMENT ACCOUNTABILITY PROJECT
NATIONAL OFFICE
1612 K STREET, NW SUITE #1100 • WASHINGTON, D.C. 20006
202.408.0034 • WWW.WHISTLEBLOWER.ORG

March 20, 2006

Via Fax and E-mail to NIOCINDOCKET@cdc.gov

John Howard, MD
Director
National Institute for Occupational Safety and Health
200 Independence Ave, SW
Washington, DC 20201

NIOSH Docket Office
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226

RE: Comments on HHS Interim Final Rule--Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (RIN 920-AA13)

Dear Dr. Howard:

The Government Accountability Project ("GAP") appreciates the opportunity to comment on the Department of Health and Human Services ("HHS") Interim Final Rule "Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000" which was published in the Federal Register on December 22, 2005 (70 FR 75949).[1] The Interim Final Rule ("IFR") amends 42 CFR Part 83 (published on May 28, 2004), and purports to incorporate the amendments to the Energy Employees Occupational Illness Compensation Program Act ("EEOICPA"), which were enacted into law on October 28, 2004 as part of the FY 05 Defense Authorization Act (P. L.108-375).

With respect to deadlines governing the designation of Special Exposure Cohort ("SEC") petitions, the 2004 amendments state:

[1] Amongst its programs activities, GAP oversees the implementation of EEOICPA, and worked on the enactment of the Special Exposure Cohort amendments to EEOICPA that were included in the FY 05 Defense Authorization Act. GAP also provided oral comment on this Interim Final Rule at the ABRWH Meeting on January 24-26, 2006 in Oak Ridge, TN

> *"DEADLINES—(1) Not later than 180 days after the date on which the President receives a petition for designation as members of the Special Exposure Cohort, the Director of the National Institute for Occupational Safety and Health shall submit to the Advisory Board on Radiation and Worker Health a recommendation on that petition, including all supporting documentation."*

The Conference Report to the FY 05 Defense Authorization Act (H. Rep.108-767) provided additional legally binding guidance regarding what must take place within this 180 day time period:

> *"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."* (emphasis added)

GAP provides the following comments, identifies key weaknesses and provides suggestions on additions to the rule:

1. **The Interim Final Rule (IFR) in §83.5 and §83.11 never once mentions the 180-day deadline** for making a recommendation to the Advisory Board on Radiation and Worker health ("ABRWH") upon receipt of the petition. Although the Preamble to the rule states that the statutory deadlines are the reason for the rulemaking, there is no reason why the 180-day deadline is left out. Setting forth the 180-day time limit within the body of the rule is not "superfluous" simply because the deadline was included in the law, as was suggested by CDC staff. If CDC were consistent in its argument, why is it including the 30-day statutory deadline for Secretarial action upon receiving an ABRWH recommendation? Why is this 30-day deadline included in the IFR, but the 180-day requirement is not? One possible explanation for the inconsistency is that CDC has a tactical reason to build-in ambiguity on exactly when the 180-day clock begins and ends, and wants to have room to hedge on the specific obligations it is prepared to honor. From a claimant perspective, this ambiguity appears to be designed to make it harder to hold the agency to the requirements of the law. It also will invite Congress, we suspect, to be

even more prescriptive in drafting deadlines. We urge HHS to include the 180 day deadline for processing petitions in Sections 83.5 and 83.11.

2. **The IFR sets forth no consequences for missing the 180-day deadline.** We note that NIOSH has already missed the 180-day deadline for issuing recommendations on several SEC Petitions that were filed after enactment of P.L. 108-375, including Rocky Flats and Oak Ridge Y-12. NIOSH admits that it has not complied with the law. We urge HHS to include a provision which requires NIOSH to submit its petition to the Advisory Board, or on before the 180th day, and if it fails to meet this deadline to have the Secretary of HHS send a letter to the petitioner and the impacted Congressional delegation and the Committees of Jurisdiction that NIOSH is missing its statutory deadline, the reason for missing the deadline, and the expected date of compliance. Further, to the extent the reason is driven by NIOSH's contractor failing to comply with deadlines or not meeting required deliverables, then the contractor's costs associated with non performance should be disallowed in their entirety.

3. **The newly minted definition of a "petition" allows NIOSH to evade Congressional direction to process the SEC petitions within 180 days.** The IFR establishes a definition for the term SEC "petition" in § 83.5 which was not previously defined in the SEC rule at 42 CFR Part 83. The IFR Preamble states that "only submissions by qualified petitioners that meet the informational and procedural requirements of a petition under the rule will be considered to be 'petitions' and hence will be covered by the 180-day deadline." Receipt of a SEC petition will be treated as a mere "submission," and until it is "qualified" as meeting the informational and procedural requirements under 42 CFR Part 83, it will not be deemed a "petition" subject to the 180-day time limits.

   This part of the IFR is completely at odds with the Conference Report which states that "During the 180-day 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."[2] This language directs NIOSH to resolve both petition qualification and evaluation within the 180-day time frame, and does not authorize NIOSH to qualify petitions outside of the 180-day time period. HHS's IFR conveniently ignored the Conference Report language, and never reconciled the conflict between the IFR and the plain language of the Conference Report.

   The HHS definition of "petition" is inconsistent with the 180-day time limits set forth in the Conference Report (H. Rep. 108-767) for both the qualification and evaluation of the SEC Petition. NIOSH needs to amend the rule to require the 180- day clock to commence upon receipt of the SEC petition in the mail and avoid the linguistic redefinition of an SEC petition as a mere "submission" when it is received in the mail. The definition of "petition" should be deleted or defined as the document received by NIOSH that is

[2]The IFR makes no reference to qualifying petitions outside the 180 day deadline in Conference Report language.

initially submitted by the petitioner.

Further we note that the IFR sets no time limits on how long it will take to "qualify" a petition. The Preamble says it can take "months," but qualifying a petition is, in general, a simple matter of helping petitioners file a technically adequate petition. Some qualifying SEC petitions have justifications as short as 1 sentence. Creating an extralegal concept of "submission" is nothing more than a transparent effort to weasel additional time, and evades the 180-day time limit on an SEC review set forth in Congressional Report Language. It is remarkable that 5+ years after enactment of EEOICPA, when more than adequate time has elapsed for NIOSH to secure records, that NIOSH is trying to get out of deadlines to process SEC petitions in a timely manner.

In sum, the IFR is in violation of the Conference Report. The term petition should be deleted, or modified so as to ensure that the entire SEC review is encompassed within 180 days.

4. **The IFR unfairly reduces the time for a petitioner to file an appeal regarding the "qualification" of an SEC petition to 7 days from the 30 days** now contained in 42 CFR Part 83.11(c). Seven days is far too short of a time period to file an appeal. We strongly urge HHS to establish a 30-day time period for petitioners to file an appeal from the receipt of a letter disqualifying a petition, and extend all related deadlines should an appeal be granted. In the Board Conference call on March 15, 2006, OCAS Director Larry Elliott suggested that 7days was not a hardship for petitioners, because all that is required is a letter notifying NIOSH that a petitioner desires an appeal. That is not what the IFR states. Section 83.11(c) requires that petitioners must "specify why the proposed findings should be reversed based on the petition requirements and on the information that the petitioners had already submitted." This requires a full exposition of issues, not a mere notification. Mr. Elliott did not retract his misstatement when his interpretation was questioned by the ABRWH. Further, the IFR should be clarified to make clear that a petitioner may refile a new petition, without prejudice, if new information materializes at a later date.

5. **The IFR should define the term "recommendation."** The term "recommendation" should be defined as "yes" or "no" on all classes and subclasses covered in a SEC petition. The OCAS Director, Larry Elliott, implied on a January 9, 2006-ABRWH conference call that a "recommendation" is not necessarily an up-or-down recommendation on a petition, but may include a notification that additional time is needed to process a part of the SEC petition. He suggested that the term "recommendation" is open to legal interpretation, and indicated that this legal interpretation was being applied to the pending Oak Ridge Y-12 SEC petition where NIOSH established two subclasses within the Y-12 petition. The transcript reflects a NIOSH view that staff may exceed the 180-day time limit for making a recommendation on a subclass covering the 1948-1957 time period, if it had previously made a "recommendation" to approve an earlier time period covering 1942-1947. This SEC

petition for Y-12 plumbers and pipefitters was filed on 2/15/05 and qualified on 4/29/05. The transcript states (pp. 65-67):

> **MR. GRIFFON:** Paul, before we move on to that, can I just ask Lew or Larry a question about the Y-12 petition?
>
> **DR. ZIEMER:** Sure.
>
> **MR. GRIFFON:** Is there a calendar issue here? When did the clock start ticking, and when is the deadline for this evaluation report? Are we –
>
> **MR. ELLIOTT:** Well, the clock started ticking when the petition became qualified, and we met the 180 day deadline and provided an evaluation report to the Board that spoke to the early years of Y-12. And we are still pursuing the remainder years for that one petition.
>
> **MR. GRIFFON:** The clock for the rest of the remaining years? I don't understand it, but it's not an issue any more or...
>
> **MR. ELLIOTT:** Well, I don't believe we see it as an issue, that we met the 180-day mark by providing a recommendation to the Board, an evaluation report on the early years, and we have provided a recommendation essentially to the Board that we're continuing our evaluation on the remainder of that petition pending the resolution of the site profile issues.
>
> **DR. ZIEMER:** We've also, those initial deadlines have been met. Now action is with the Board and there's, the clock doesn't really run for now. Is that correct?
>
> **MR. ELLIOTT:** I believe that's the way we would see it. Mark, does that answer your question?
>
> **MR. GRIFFON:** Well, it's an answer, yeah. I just, I thought that the entire, that an SEC petition had to have an evaluation report for all members of a class by that given deadline. I know this is a little different because it's been sort of merged, it merges three different petitions, but I'm a little unclear, but --
>
> **MR. ELLIOTT:** I think it's a matter of how one interprets the amendment language,…

Mr Elliot's legal interpretation evades the plain language of the law. It also evades the legislative purposes which are to promote prompt processing and provide a **complete** recommendation after 180 days. The law states: *the Director of the National Institute for Occupational Safety and Health shall submit to the Advisory Board on Radiation and Worker Health a recommendation on that petition, <u>including all supporting</u>*

documentation (emphasis added).

It is more than a stretch to construe the term "recommendation" to authorize additional time, and there is nothing in the law to support that notion. If a "recommendation" can include a NIOSH statement that more than 180 days will be taken to process the petition, then time limits set forth by Congress are effectively nullified by bureaucratic fiat. "Recommendations" are just that—a recommendation to approve or deny a petition with supporting documentation. The fact that NIOSH chooses to administratively subdivide the petition into different time periods does not grant NIOSH permission to evade the 180 day deadline. Indifference to Congressional intent is an invitation for more prescriptive legislation. Please define the term "recommendation."

6. **NIOSH should clarify that SEC Evaluation Reports will contain a "recommendation."** NIOSH has suggested it may submit "SEC Evaluation Reports" without "recommendations" to satisfy the 180-day deadline. NIOSH has separately stated that SEC Evaluation Reports will include a "recommendation." Given these contradictory statements, the rule should clarify that SEC Evaluation Reports provided to the ABRWH must include a "recommendation."

7. **NIOSH should set 21 day time limit for transmitting ABRWH Recommendations to the Secretary of HHS.** The time to transmit an ABRWH recommendation to the Secretary has been a source of delay in one very prominent SEC case (IAAP). In response, the ABRWH has requested that NIOSH transmit the recommendation and administrative record to the Secretary within 21 days. Experience has demonstrated this is adequate time to secure transcripts of the ABRWH deliberations, formalize the ABRWH's letter to the Secretary and transmit. This time period should not be left open ended if the goal of "prompt" processing is to be honored. Thus, we urge that the rule include 21 days for the Advisory Board recommendation to be transmitted to the HHS Secretary.

8. **Rule should clarify legal significance of the HHS Review Panel.** §83.18 of the IFR provides for an administrative review of a "final" Secretarial decision to deny a SEC petition by a 3-person HHS Review Panel. However, the HHS Review Panel findings and recommendations in §83.18 are not binding on the Secretary. Their findings are purely advisory in the IFR. Please clarify whether a petitioner's exhaustion of remedies occurs upon issuance of a final Secretarial determination, or whether appeal to this Review Panel is necessary prior to a petitioner seeking judicial review of a Secretarial determination. Please explain how the HHS Review Panel is considered an appeals body, if the Secretary can freely ignore the HHS Review Panel findings?

9. **The identity and contact information of SEC petitioners under Section 83.13 should be disclosed in the interest of transparency. If necessary, 42 CFR Part 83 should be amended accordingly.** The HHS rule presently states at 42 CFR Part 83:

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

NIOSH has interpreted “information of a personal nature” to include the names and contact information of the SEC petitioners in Y-12, ORINS, Chapman Valve, and several others locations. Is it appropriate for Section 83.13 SEC petitioners to be afforded complete anonymity when they are the public's representative in the SEC proceedings under Section 83.13 which will affect hundreds if not thousands of potential claimants? Is it an “unwarranted invasion of personal privacy” for NIOSH to provide limited information—such as petitioners’ names and contact information--to members of the affected SEC class?

A balancing test needs to be undertaken which weighs anonymity against the fact that SEC petitioners are (self-selected) representatives of the public, and there is a necessity for interested SEC class members or others to communicate relevant information to the petitioners representing a class. It is not an “unwarranted” invasion of personal privacy to disclose the names and contact information (while excluding protected information, such as Social Security Numbers or medical information) given the public role that is assumed when individuals purport to speak (or not) on behalf of an entire SEC class.

NIOSH OCAS Director Larry Elliott revealed on the January 9, 2006 ABRWH conference call, for example, that he has spoken with the two Y-12 petitioners, and he claims they have acceded to his various requests and legal interpretations of the 180-day rule. These two Y-12 SEC petitioners are representing a large class of individuals—perhaps in excess of 1000--whose interests are directly affected by actions they take or fail to take.

It is noteworthy that the Y-12 petitioners have apparently not participated in the Working Group sessions or Board calls. They did not identify themselves at the ABRWH meeting in Oak Ridge, TN. They are petitioners in absentia, and equity suggests that others impacted by this SEC Petition should be permitted to make contact with the Petitioners and determine their reasons for non participation, or make appropriate arrangements for additional or substitute participation on behalf of the class in Working Groups, Board meetings and other communications. History has demonstrated the imperative of informed participation by SEC petitioners in the process. Needless secrecy forecloses this possibility. I hope this is not NIOSH’s intent.

The rule should be modified to advise the Section 83.13 petitioners that their identity and contact information will be disclosed. Should such limited disclosure be deemed unpalatable, nothing requires such individuals to become SEC petitioners under 83.13. Individuals do not have an expectation of anonymity when they file a comment on a site profile or in this rulemaking, nor should they when it involves matters of applicability affecting an entire class under Section 83.13.

Thank you for consideration of these comments. Please contact Richard Miller at 202-408-0034, x 127, or e-mail at rickudana@aol.com if you have any questions.

Sincerely,

Richard Miller
Senior Policy Analyst