THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 1 6 2009

Rocky Flats United Steelworkers of America, Local 8031
2280 E. 139th Avenue
Brighton, CO 80602

Re: SEC Petition 00030

Dear

Thank you for your letter requesting an administrative review of my determination regarding Special Exposure Cohort (SEC) status for Rocky Flats workers who were exposed to radiation dose from 1967 to 2005 and to radiation dose other than neutron dose from 1952 to 1966.

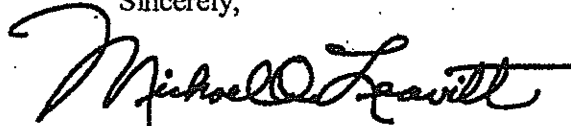
Pursuant to 42 CFR § 83.18(b), and because you filed a challenge on behalf of a class of workers from the Rocky Flats Plant in Golden, Colorado, who I had determined should not be added to the SEC, I appointed a panel of three HHS personnel, independent of the National Institute for Occupational Safety and Health (NIOSH), to conduct an administrative review. The panel has now completed its review of the challenge.

In evaluating your points of appeal, the panel came to three categories of conclusions. In most instances, the panel found no merit to the issues raised in the points of appeal, and recommended no further action. In one instance, the panel found some merit to the issues raised in the point of appeal, but did not recommend further action. In two instances, the panel could not determine conclusively whether there was merit to the issues raised in the points of appeal and recommended further inquiry of NIOSH. Subsequently, NIOSH was asked to provide responses to the two outstanding issues.

After review of the administrative review panel's thorough report and of NIOSH's additional response, I have decided not to revise my August 6, 2007, final decision. Please note that, in line with the administrative review panel's report, NIOSH recognizes the need to improve documentation with respect to conflicts of interest and appearance

determinations for individuals serving on the Advisory Board on Radiation and Worker Health and will work closely on this with the HHS Office of the General Counsel's Ethics Division. I am enclosing a copy of the administrative review panel's report to me as well as NIOSH's requested response to issues raised in the report. I hope you find this information helpful.

Sincerely,



Michael O. Leavitt

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

December 29, 2008

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Special Exposure Cohort Administrative Review Panel

Dear Mr. Secretary:

As you know, the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. § 7384-7385 *et seq.*, established a compensation program for workers who may have contracted cancers associated with duties performed working on nuclear-weapons programs administered by the Department of Energy and its predecessor agencies. Unlike individual workers who file claims under EEOICPA, workers who are members of the Special Exposure Cohort (SEC) and who incur a specified cancer qualify for compensation from the Department of Labor (DOL) without the completion of a radiation dose reconstruction by the National Institute for Occupational Safety and Health (NIOSH) or determination of the probability of causation by DOL. Regulations that implement EEOICPA provide that the Secretary of HHS may consider petitions for a class of employees to be added to the SEC, and petitioners may obtain an administrative review of a final decision by the Secretary to deny adding a class to the SEC. *See* 42 CFR § 83.18(a). Pursuant to 42 CFR § 83.18(b), and because a challenge was filed by a class of workers from the Rocky Flats Plant in Golden, Colorado, who you determined should not be added to the SEC, you appointed us, a panel of three HHS personnel, independent of NIOSH, to conduct an administrative review. This letter serves as our final report. Set out below is background information regarding the challenge, our charge, the dates that we met, our main conclusions, and a point-by-point analysis.

Background

On August 6, 2007, as authorized under EEOICPA, 42 U.S.C. § 7384*q*(b), you designated the following classes of employees to be added to the Special Exposure Cohort (SEC):

> Employees of the Department of Energy (DOE), its predecessor agencies, or DOE contractors or subcontractors who were monitored or should have been monitored for neutron exposures while working at the Rocky Flats Plant in Golden, Colorado, for a number of work days aggregating at least 250 work days from April 1, 1952, through December 31, 1958, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort; and

> Employees of the Department of Energy (DOE), its predecessor agencies, or DOE

> contractors or subcontractors who were monitored or should have been monitored for neutron exposures while working at the Rocky Flats Plant in Golden, Colorado, for a number of work days aggregating at least 250 work days from January 1, 1959, through December 31, 1966, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

Also on August 6, 2007, you determined that, with respect to the following class of employees, it is feasible to reconstruct radiation dose with sufficient accuracy and, thus, this class of employees does not meet the statutory criteria for addition to the SEC:

> Department of Energy employees or its contractor or subcontractor employees at the Rocky Flats Plant in Golden, Colorado, who were exposed to radiation dose from 1967 through 2005 and who were exposed to any radiation dose other than neutron dose from 1952 through 1966.

, Rocky Flats United Steelworkers of America, Local 8031, and Official Petitioner-Designated Representative, ("petitioners"), filed a challenge to that decision in a "Formal Letter of Appeal of Determination by Michael O. Leavitt for SEC Status for Rocky Flats Workers Who Were Exposed to Radiation Dose from 1967 to 2005 and to Radiation Dose Other Than Neutron from 1952 to 1966."[1] A copy of petitioners' appeal letter is attached hereto. EEOICPA implementing regulations at 42 CFR § 83.18(a) provide that, in order to contest a final decision by the Secretary to deny adding a class to the Cohort, a challenge "must include evidence that the final decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures" set out in 42 CFR Part 83. The petitioners' appeal letter states "We ... understand that we can appeal based on violations in process and to challenge scientific facts that were used to deny our petition. We appeal based on both process and science in accordance with the points of appeal listed below." The letter then goes on to set out 11 "Process Basis: Points of Appeal" and 8 "Scientific Basis: Points of Appeal."

Our Charge

Because of that challenge and pursuant to 42 CFR § 83.18(b), you appointed us to a panel of three HHS personnel, independent of NIOSH, to conduct an administrative review and provide recommendations to the Secretary concerning the merits of the challenge and the resolution of the issues contested by the challenge. The undersigned, Alla Shapiro, M.D., Ph.D., Joseph M. Kaminski, M.D., and Kiyohiko Mabuchi, M.D., Dr.P.H., comprise that panel.

Pursuant to 42 CFR § 83.18(b), we examined the views and information submitted by the petitioners in the challenge, the NIOSH evaluation reports, the report containing the

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[1] In addition to filing the challenge to the Secretary's final decision, also submitted the original SEC petition on behalf of the United Steelworkers of America, Local 8031.

recommendations of the Advisory Board on Radiation and Worker Health, the recommendations of the Director of NIOSH to the Secretary, information presented or submitted to the Advisory Board, and the deliberations of the Board prior to the issuance of its recommendation. We were charged with considering whether HHS substantially complied with the regulatory procedures set out in 42 CFR Part 83 and whether the Secretary's final decision was supported by accurate factual information, and we reviewed the principal findings and recommendations of NIOSH and the Advisory Board.

Regulations at 42 CFR § 83.18(a) prohibit petitioners from introducing any new information or documentation that was not previously submitted to NIOSH or the Advisory Board. Our review was based on the written documentation in this case.

Meeting Dates

Our panel was invited to its first meeting on March 12, 2008, at which time we received an orientation and materials to review. We were not given a deadline for completion of our work, but we were asked to work expeditiously and to meet approximately every two weeks. We started to review materials in March and met regularly from April through December. Our meeting dates are listed below; unless otherwise indicated, meetings were held in-person, during the work day, and lasted approximately two hours. Phone calls were of varying lengths. All told, we met 43 times for a total of about 100 hours in the 42 weeks since our March 12 meeting. There also was a similar amount of time spent reviewing the record and otherwise preparing for meetings. Each of us also continued to carry out our regular duties from our regular full-time jobs at HHS. While our deliberations took longer than any of us would have expected, we closely examined all of the points in the petitioners' appeal letter, and several of the points raised additional questions that required additional information and warranted significant close examination. In the end, we believe we were able to give careful consideration to all of the issues and still complete a thorough review in a reasonable amount of time.

March 12
April 1, 7, 25
May 2, 12, 14, 27
June 13, 30
July 11, 14, 22, 24 (phone call), 29
August 1, 5, 6, 18, 22, 26
September 16, 19 (3 hours)
October 1, 4 (Saturday – 5 hours), 5 (Sunday – 4 hours), 10 (phone call), 23, 27, 29
November 5, 7, 14, 25
December 5, 9 (6 hours), 12 (3 hours), 15, 16, 18, 23 (8 hours), 24 (phone call), 29 (phone call).

Main Conclusions

In evaluating the petitioners' points of appeal, we have come to three categories of conclusions. In most instances, we find no merit to the issues raised in the points of appeal, and recommend no further action. In one instance, we find some merit to the issues raised in the point of appeal,

but do not recommend further action. In other instances, we cannot determine conclusively whether there is merit to the issues raised in the points of appeal, but we do recommended further action. In particular, we find the following:

No merit/No further action recommended:
- "Process Basis: Points of Appeal" #1, #3-5, #7, #8(a) and (b), and #9-11.
- "Scientific Basis: Points of Appeal" #1-6, #7(a) and (b) (which is a duplication of "Process Basis: Points of Appeal" #8(a) and (b)), and #8.

Some merit/No further action recommended:
- "Process Basis: Points of Appeal" #2.

Cannot determine conclusively whether there is merit/Further action recommended:
- "Process Basis: Points of Appeal" #6 and #8(c) .
- "Scientific Basis: Points of Appeal" #7(c) (which is a duplication of "Process Basis: Points of Appeal #8 (c)).

<u>Point-by-Point Analysis</u>

We address each of petitioners' points of appeal below. For each point, we have set out our views as to whether there is merit to the challenge and we have provided a recommendation regarding the resolution of issues contested in the challenge. In order to ensure that we would not mischaracterize petitioners' letter, we have included the headings used by petitioners in their appeal letter verbatim. Note that, by quoting petitioners' language, we are not agreeing with or endorsing the way in which they have described each of their points. Further details regarding each of the points raised by petitioners can be found in the attached appeal letter submitted by petitioners.

PROCESS BASIS: POINTS OF APPEAL

(1) "Failure to provide information to the petitioner in accordance with the provision of the law."

Petitioners state that:

> NIOSH and now the Secretary of Health and Human Services have exhibited a pattern of withholding and delaying communication of information to the Rocky Flats petitioner throughout this process – including "accidentally" removing the petitioner and petitioner representative from the e-mail distribution for notification of meetings for a six month period of time ... reports were prepared by the Advisory Board's contractor that were discussed at the meetings, yet NIOSH failed to distribute the reports to the Petitioner until minutes before or in some cases after meetings ... the Secretary of HHS did not even bother to notify the petitioner of this decision until three week[s] after he made it ....

With respect to notice of Board meetings, the only requirement is set out at 42 CFR 83.15(a), which requires NIOSH to "publish a notice in the *Federal Register* providing notice of a Board meeting at which a petition will be considered, and summarizing the petition to be considered by

the Board at the meeting and the findings of NIOSH from evaluating the petition." In addition, 42 CFR 83.15(b) provides that "the petitioner(s) will be invited to present views and information on the petition and the NIOSH evaluation findings" at the meeting. With respect to the materials discussed at meetings, 42 CFR 83.13(d) simply requires that "NIOSH will submit a report of its evaluation findings to the Board and to the petitioner(s)." No time period for notice is specified. Finally, the EEOICPA statute and implementing regulations also do not specify a time requirement for the Secretary to notify the petitioners of the final decision. Specifically, 42 CFR §83.16(b) states that:

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

NIOSH complied with all of these regulatory provisions.

Summary: NIOSH and the Secretary complied with all regulatory provisions relating to this point. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(2) "Timeliness."

Petitioners state that "NIOSH failed to meet the Congressionally mandated deadline of 180 days to make its recommendation on the Petition ... **the 2005 EEOICPA Act Revision required a recommendation by law, in 180 days**" (emphasis in appeal letter). The statute to which petitioners refer, 42 U.S.C. § 7384q(c)(1), was enacted on October 28, 2004, as part of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005. This section states as follows:

> 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 petitioners submitted a petition on February 15, 2005. The statute indicates that NIOSH must submit a recommendation to the Advisory Board 180 days "after the date on which the President receives a petition." Although not yet in effect, NIOSH followed the policies later set out in the Interim Final Rule published on December 22, 2005 (70 Fed. Reg. 75949), when it decided to count the 180 days from when the petition qualified for evaluation, not from when it

was "received." The Interim Rule provided that "... only submissions by qualified petitioners that meet the informational and procedural requirements of a petition under the rule will be considered 'petitions' and hence will be covered by the 180-day deadline ... the submission of a petition by an unqualified petitioner or the submission of an incomplete petition does not initiate the 180-day requirement." 70 Fed. Reg. 75949 at 75950.

NIOSH determined that the petitioners' February 15, 2005, petition needed additional information for evaluation, which was provided by a supplemental petition. The petition qualified for evaluation on June 16, 2005. In accordance with the policies set out in the Interim Final Rule being developed during that time, NIOSH provided a recommendation to the Advisory Board on that petition on December 13, 2005, which was within 180 days from the date that the petition qualified.

NIOSH's recommendation stated in pertinent part as follows:

> On December 8, 2005, the Board received a draft report from Sanford Cohen & Associates [the Board's contractor] entitled "Rocky Flats Plant Site Profile Review." NIOSH will review this document to determine whether any issues raised have implications for our evaluation of the Rocky Flats Plan SEC petition (SEC 00030). NIOSH recommends that the evaluation report on SEC 00030 be transmitted to the Board and petitioners after the resolution of any issues raised in the SC&A report that are relevant to the petition evaluation process.

The Sanford Cohen & Associates ("SC&A") report could qualify as "all supporting documentation," as required by the statute quoted above. Since this report previously had been transmitted to the Advisory Board, there was no need for NIOSH to attach the report to its letter. Although NIOSH provided "a recommendation," as required by 42 U.S.C. § 7384q(c)(1), its recommendation was to continue the process; it was not meant to be a final recommendation on whether to add Rocky Flats workers to the SEC. The Office of General Counsel at HHS indicated at that time that NIOSH's interpretation was legally acceptable.

The regulation at 42 CFR § 83.13(d), which was published on May 28, 2004 (prior to enactment of 42 U.S.C. § 7384q(c)(1), which contains the 180-day requirement) specifies what NIOSH's evaluation report and recommendation must include, but does not specify any deadline. The regulation at 42 CFR § 83.13(e), which was published on July 10, 2007 (after NIOSH completed its evaluation of petitioners' petition), specifies that this evaluation report and recommendation needs to be completed within 180 calendar days of the receipt of the petition by NIOSH, subject to the petition's qualifying as a valid petition. Thus, although the regulatory requirement that an evaluation report be completed by NIOSH was in effect while NIOSH was evaluating petitioners' petition, the provision of the regulation requiring that it be completed within 180 days was not. Nonetheless, the promulgation of 42 CFR § 83.13(e) indicates that a better approach would have been for NIOSH to have provided the Advisory Board with a final decision regarding whether the Rocky Flats workers should be added to the SEC within 180 days from the date that the petition qualified (i.e., December 13, 2005).

In this point of appeal, petitioners also raise additional concerns about the time it takes for dose reconstruction to be completed. However, they do not provide additional bases to indicate that the law or regulation concerning adding a class of employees to the SEC were not followed.

Summary: Since 42 CFR § 83.13(e), which cites to § 83.13(d) and interprets the statute on what constitutes "a recommendation on that petition, including all supporting documentation," was not yet in effect, we believe that the recommendation contained in NIOSH's letter to the Advisory Board was based on an interpretation of the statute that was legally permissible, but perhaps not the best. While there is some merit to the issues raised in this point of appeal, given the language of the statute that established the 180-day deadline and the fact that the regulations implementing the deadline were not yet in effect, we believe that NIOSH substantially complied with the required procedures set out in the statute and regulations that were in effect at that time.

Recommendation: We agree with the current interpretation of 42 U.S.C. § 7384q(c)(1) set out in the current regulations at 42 CFR § 83.13(d) and (e), which describe what needs to be contained in NIOSH's recommendation to the Advisory Board and the time requirement for submitting this recommendation. We do not recommend further action regarding this point of appeal.

(3) **"Conflict of Interest Invalidates the Process."**

Petitioners state that:

> As noted by [former] Congressman Hostettler in a March 9, 2007, letter, "At Rocky Flats, a manager of health physics programs prepared NIOSH's site profiles, TIBS, is actively involved in the evaluation of a SEC petition, which includes validation of results used in his previous work."

However, petitioners do not provide the name of the "manager of health physics programs," underlying letter, or other supporting documentation as evidence to support this allegation, as is required by 42 CFR § 83.18(a). For example, we do not even know if the Rocky Flats manager referred to in this point had anything to do with the SEC petition filed by Rocky Flats workers.

In this point of appeal, petitioners also state that, "Individuals who have testified AGAINST workers in worker compensation hearings are serving key roles in the NIOSH process" (emphasis in appeal letter). However, again, petitioners provide no documentation or specific information regarding this allegation, such as names of those who testified against workers in worker compensation hearings and whether these hearings had anything to do with Rocky Flats or any other DOE facility. Furthermore, we believe that there is not necessarily a conflict of interest if an individual testifies against workers in worker compensation hearings when serving as key roles in the NIOSH process. Based on the information reviewed, we have seen no evidence showing that NIOSH had a conflict of interest when evaluating whether Rocky Flats

workers should be included in the SEC or otherwise.

Summary: Petitioners have provided no documentation or other evidence that there is a conflict of interest in this situation. Thus, based upon the information reviewed, we conclude that there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(4) "Non-Cohesion in the Board."

Petitioners state that: "The Board vote of 6 to 4 showed considerable dissention in opinion of the Board members. This vote is not a strong endorsement for the Board's recommendation."

However, the Advisory Board based its decision on a majority vote, which is a reasonable approach.

Summary: The Board's recommendation was based on a majority vote, which is a reasonable approach. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(5) "Actions Outside the Boundaries of the Authority under the Act."

The petitioners state that:

> The Board's role was to evaluate and recommend, never to fix. The Board, albeit with good intentions, became intertwined with a process to develop a set of new science, methods, models, guidance, technical basis documents and assumptions over the last two years. These were directed at serving as the basis to deny the Rocky Flats petition.

Petitioners have provided no documentation or other information as evidence to show that the Board was trying to deny the RFP petition. In addition, we have seen no evidence that the Board acted outside its authority on any occasion, such as by creating new science or models. The role of the Board is set out in statute,[2] Executive Order,[3] and regulation.[4] These authorities

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[2]For example, 42 U.S.C. § 7384o(b)(2) provides "The Board shall advise the President [delegated to the Secretary of Health and Human Services in Executive Order 13179] on– ... the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program." In addition, §7384q(a)(2) provides that the advice of the Board "shall be based on exposure assessments by radiation health professionals, information provided by the Department of Energy, *and such other information as the Advisory Board considers appropriate*"

specifically make clear that the Board is not only permitted, but required, to advise the Secretary on the scientific validity and quality of dose reconstruction efforts. As part of this, the Board may consider additional information, such as relevant research findings and technological advances, when considering a petition. We have seen no evidence that the Board was acting outside of its authorities while considering the Rocky Flats Plant petition.

In addition, the Board based its decision on well established models, such as on the International Commission on Radiological Protection (ICRP)-66,[5] which was developed independently from NIOSH and the Board. (*See* response to "Scientific Basis: Points of Appeal" #2 for a detailed description of ICRP-66).

Petitioners also state that:

> These new document[s] will ultimately result in thousands of dose reconstructions that must now be redone in accordance with the new standards. The fact that dose reconstructions are being declared 'invalid' and are being redone serves as strong evidence ... that it was, in fact, not possible for NIOSH to reconstruct dose for the Rocky Flats workers at the time the petition was submitted."

However, the petitioners provide no documentation or names as evidence to support their contention that "dose reconstructions are being declared 'invalid' and are being redone." The dose reconstruction process could involve error, improvement, uncertainties, and refinement of the models; however, this is a permissible process that can occur with science.

Summary: NIOSH and the Board did not develop a set of new science and acted within its authority in evaluating the Rocky Flats Plant petition. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

(emphasis added).

[3]Executive Order 13179, Section 4(b)(ii), which essentially repeats the language of 42 U.S.C. § 7384o(b)(2), provides that the Advisory Board shall advise the Secretary of Health and Human Services "on the scientific validity and quality of dose reconstruction efforts performed for this Program."

[4] For example, 42 CFR §83.15(c) provides, "In considering the petition, the Board may obtain and consider additional information not addressed in the petition or the initial NIOSH evaluation report. Furthermore, 42 CFR § 83.15(d) provides that "NIOSH may decide to further evaluate a petition, upon the request of the Board. If NIOSH conducts further evaluation, it will report new findings to the Board and the petitioner(s)."

[5]ICRP Publication 66, which was published in 1994 by Pergamon Press, is entitled "Human Respiratory Tract Model for Radiological Protection: A report of a Task Group of the International Commission on Radiological Protection."

Recommendation: We do not recommend further action regarding this point of appeal.

(6) **"Inconsistent Application of Conflict of Interest Requirements."**

Petitioners state that:

> NIOSH inconsistently applied conflict of interest standards to stack the Advisory Board on Radiation [and Worker] Health to deny worker petitions in accordance with political pressure and statements made by top leaders in HHS. For example Mark Griffon was allowed to vote in spite of his relation with the union, while Josie Beach was denied her right to vote based on her membership in a union at the Hanford Site.

Initially, we note that petitioners have provided no documentation or other evidence to show that NIOSH had intent to "stack the Advisory Board," to "deny worker petitions," or that there was "political pressure or statements made by top leaders in HHS." Without evidence regarding these allegations, we cannot conclude that there is merit to these issues.

With respect to petitioners' allegations regarding inconsistent application of conflict of interest standards, we will first address decisions made regarding Josie Beach, and then address Mark Griffon below.

Josie Beach

On February 2, 2007, Department officials issued a Conflict of Interest Waiver for Ms. Beach under 18 U.S.C. § 208(b)(3) for participation on the Advisory Board. The Federal conflict of interest statute, 18 U.S.C. § 208, prohibits Federal employees from participating personally and substantially in any particular matter that may have a direct and predictable effect on the employee's personal financial interests or one imputed to them - imputed interests may include those of an organization in which the individual is serving as an employee. The waiver included language stating that Ms. Beach could participate in matters of general applicability, but would affirmatively recuse herself from participation in specific matters in which she has a financial or imputed financial interest, such as "claims brought by the United Steelworkers Union." This language was based not on the fact that Ms. Beach was a union member, as petitioners assert in this point of appeal, but on the fact that Ms. Beach was employed by the United Steelworkers (USW) union.[6] USW Local 8031 was the petitioner for the Rocky Flats SEC petition. Thus, under the conflict of interest statute, the financial interests of the USW were imputed to Ms. Beach based on her employment relationship. Based upon the initial determination that Ms.

[6] FOIA Exemption (b)(3), Title I of the Ethics in Government Act of 1978 (5 U.S.C. App) [redacted] In her curriculum vitae, Ms. Beach indicated that she was presently employed as the "Lead Occupational Safety Health Environmental Committee (OSHEC)/United Steel Workers (USW) Hazardous waste worker trainer" and as a "United Steel Worker Curriculum, Adaptation, Training and Support Team Member."

Beach could not participate in the Rocky Flats matter due to a conflict of interest, Ms. Beach recused herself from the deliberations and voting that took place during the Board meeting related to the Rocky Flats SEC on May 2-3, 2007.

Subsequent to that, on May 21, 2007, petitioner sent an email to NIOSH requesting that the determination that Ms. Beach had a conflict of interest be reconsidered given that the USW union no longer had members who were Rocky Flats workers since the plant had closed down. Related to this, in this point of appeal, petitioners state that "The Petitioner requested for the Conflict of Interest to be re-evaluated based on the fact that there was no longer one and NIOSH said it did [a re-evaluation] but refused to provide any evidence that such a re-review was conducted or the name of the attorney who conducted the review." However, the documents we reviewed revealed that a re-review was, in fact, conducted, and we have seen email correspondence confirming that a conversation on this subject took place during the morning of June 11, 2007, prior to the Rocky Flats Plant follow-up meeting in Denver. These emails make clear that Department officials reconsidered their prior decision that Ms. Beach had a conflict of interest, and determined that she continued to be conflicted. It was decided that, even if the 18 U.S.C. § 208 conflict of interest statute did not apply, Ms. Beach still would need to recuse herself from participation due to appearance concerns.

Regulations at 5 CFR § 2635.502, the "appearance standard," provide in pertinent part that where an employee (1) knows that an individual or entity with whom he/she has a covered relationship (which includes any individual or entity for whom the employee has, within the last year, served as a consultant, contractor, or employee) is or represents a party to a particular matter involving specific parties and (2) determines that a reasonable person with knowledge of the relevant facts may question his/her impartiality, the employee must not participate unless authorized by the agency designee. Department officials concluded that Ms. Beach could not participate under this regulation due to the appearance of conflict or bias on her part. Ms. Beach was a current employee of USW and, thus, had a covered relationship with USW; USW was a party to the Rocky Flats matter; the determination on whether the Rocky Flats workers qualified in the SEC was a specific party matter; and a reasonable person knowing that Ms. Beach was an employee of the USW might question her impartiality in her recommendation to the Secretary on whether the Rocky Flats workers should be included in the SEC. Note that, contrary to petitioners' contention that "There was no financial tie or benefit or association and so there was no reason that Ms. Beach should have been denied her right to participate," the financial interests of USW are not relevant to the appearance analysis – the appearance concern arose simply because USW was or represented a party (i.e., the Rocky Flats workers) to the Rocky Flats matter. Furthermore, it was decided that while the closure of the Rocky Flats Plant site and the subsequent shutdown of the local USW union could perhaps alter USW's financial interest in the Rocky Flats matter and, consequently, alleviate the conflict of interest concern with respect to Ms. Beach's participation on the Advisory Board, Ms. Beach would nevertheless still have an appearance problem under 5 CFR § 2635.502. Based upon this decision, Ms. Beach was advised to again recuse herself from participating in the deliberations regarding the Rocky Flats SEC at the June 11-12, 2007, meeting in Denver.

Summary: We agree with Department officials' determination that Ms. Beach had an appearance concern under 5 CFR § 2635.502 based upon her employment

with the USW union. Since the decision was made that she could not participate in the Rocky Flats SEC matter based upon appearance concerns, it was not necessary to make a final determination regarding whether she continued to have a conflict of interest under 18 U.S.C § 208 after the Rocky Flats Plant closed. We also note that we have seen documentation showing that Department officials did reconsider its decision regarding Ms. Beach's conflict of interest at petitioners' request, and concluded that she still needed to recuse herself at the Rocky Flats site due to appearance concerns. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding Josie Beach raised in this point of appeal.

Mark Griffon

On October 6, 2006, Department officials issued a Conflict of Interest Waiver for Mr. Griffon under 18 U.S.C. § 208(b)(3), for participation on the Advisory Board. Like Ms. Beach, the waiver included language stating that Mr. Griffon could participate in matters of general applicability, but would affirmatively recuse himself from "participation relating to specific matters in which he has a financial or imputed financial interest, such as claims of specific claimants or potential claimants submitted by the Steel Workers International Union for workers at the Paducah, K-25, INEL, Mound, or Portsmouth sites ..." This language was based on the fact that Mr. Griffon received consulting fees from USW as the President of Creative Pollution Solutions (CPS), and his waiver reflects that he may be conflicted where USW has filed claims for sites for which he performed work for the union.[7] Under the conflict of interest statute, the

[7] FOIA Exemption (b)(3): Title I of the Ethics in Government Act of 1978 (5 U.S.C. App) In his undated curriculum vitae (CV), Mr. Griffon listed the following (emphasis in original):

> **President**, Creative Pollution Solutions, Inc., Environmental Consulting Services, 1992 - present
>
> During the past nine years I have performed consulting services in the radiation and hazardous waste fields. Creative Pollution Solutions, Inc. was formed in 1992. Recent work includes:
> **Steel Workers International Union (previously Paper, Allied Industrial, Chemical, and Energy Workers International Union (PACE)**, contracted to provide radiological technical support for local unions at DOE sites throughout the complex. This has included consultation with the local unions at the MOUND site in Ohio, Oak Ridge [this site is listed in the waiver as "K-25" because the K-25 plant is located on the Oak Ridge reservation], Portsmouth, Paducah, INEEL [INEEL is the Idaho National Engineering and Environmental Laboratory - it is incorrectly listed on the waiver as INEL), Hanford, and Metropolis Illinois.

financial interests of CPS were imputed to Mr. Griffon - thus, although his waiver allowed him to participate in matters of general applicability, he was prohibited from participating in any matter involving specific parties that would affect his or CPS' financial interests. It appears that Department officials were concerned that if Mr. Griffon was permitted to participate in specific party matters that involved a site to which he provided consulting services, such participation could lead to additional business for him in the future and, thus, his participation could result in a financial benefit to him and his company. Thus, as noted by petitioners "Mark Griffon was allowed to vote in spite of his relation with the union" - Department officials apparently concluded that since Mr. Griffon did not provide consulting services for the local USW at Rocky Flats, he was allowed to participate in the Advisory Board deliberations and vote regarding whether to add the Rocky Flats workers to the SEC.

Because Mr. Griffon was a consultant and not an employee of USW, the financial interests of USW would not have been imputed to him. However, Mr. Griffon or his company could have benefitted financially through his consulting agreement with USW. If Mr. Griffon participated in a matter that would affect the financial interests of USW while he had a concurrent consulting agreement with them, USW could provide him additional business as a result of his participation. Consequently, Mr. Griffon was advised in his waiver to recuse himself from specific party matters, such as petitions submitted by the Steel Workers International Union for workers at certain USW sites, that may have a direct and predictable effect on his personal financial interests or those of CPS. The executive secretary would then evaluate the conflict of interest or appearance concern and advise an appropriate remedial measure, including another waiver or recusal. In this regard, we have not seen any documentation showing why Department officials decided that Mr. Griffon was only conflicted for claims brought by workers at the USW sites where he provided consulting services, rather than at *all* USW sites. We note that if Department officials had concluded that specific party matters included claims brought by workers at *all* USW sites, then Mr. Griffon's waiver would not have applied and he would have had to recuse himself from the Rocky Flats matter. We believe that a potential conflict may have existed for Mr. Griffon if he or his company was concurrently providing consulting services to USW, as reported on his CV, even if it was limited to sites other than Rocky Flats. However, without documentation of a policy or underlying rationale, and given our review panel's limited role with regard to fact-finding beyond the written record, we cannot determine whether we believe this decision was appropriate. We would urge ethics officials at NIOSH and/or CDC, in consultation with OGC, to review this matter, including the policy described in this paragraph, to determine whether Mr. Griffon should have been recused from participation in this matter, and what the policy on such recusals should be in the future.

We note that Mr. Griffon listed the United Steelworkers union as the "Steel Workers International Union"on his CV. We also note that the list of consulting positions in Mr. Griffon's curriculum vitae appears to be illustrative rather than exhaustive ("Recent work includes ..."). Given that it is not clear from Mr. Griffon's CV as to whether he performed any consulting services for sites other than the ones listed, Department officials should have inquired to determine whether Mr. Griffon had performed any consulting work for the USW at Rocky Flats. While it is possible that such an inquiry was made, we have seen no evidence of such an inquiry.

We also regard the language of the waiver itself to be somewhat ambiguous. For example, the waiver states that Mr. Griffon may not participate in specific party matters - in some places the waiver includes a list of specific party matters that appears to be illustrative (by use of the words "such as" or "e.g.,") [8] and in other places, the listing of specific party matters appears to be exhaustive.[9] In addition, although Mr. Griffon's waiver indicates that specific party matters include claims filed by the USW for workers at the DOE sites listed on his CV, the waiver does not include Hanford or Metropolis Illinois (which also were listed on his CV); there is no documentation as to why this was done. Regardless of what was meant by the language of the waiver, Mr. Griffon participated in the Rocky Flats SEC decision.

Mr. Griffon's conflict of interest waiver also specifically states that:

> Mr. Griffon will remain subject to the disqualification requirements imposed by 5 CFR § 2635.502 [the appearance standard] with respect to specific party matters ... . . that involve, as a party or representative of a party, persons or entities with which he has a "covered relationship," such as any ... organization that he serves, or within the last year has served, as a consultant or advisor.

Each individual Board member, with the assistance and guidance of Departmental officials, should monitor all the Board issues for other actual or potential conflicts of interest and ensure proper recusal if necessary.

Again, we have not seen evidence that Department officials looked into the possibility that Mr. Griffon might have had an appearance concern that would have required him to recuse himself from participation in the Rocky Flats matter. To this end, Mr. Griffon had a covered relationship not only with CPS, but with any organization for whom he provided consulting services either personally or through CPS. The Confidential Financial Disclosure Form (OGE Form 450) requires all filers to report all outside positions held, including the position of consultant, for the time period of 12 months prior to the filing date.

FOIA Exemption (b)(6): Personal Privacy Information

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[8]The waiver states that (emphasis added): "If the work of the board moves ...to specific party matters (*e.g.*, those of specific petitions submitted by the Steel Workers International Union for workers at the Paducah, K-25, INEL, Mound, or Portsmouth sites ...) ..." The waiver also states that (emphasis added): "This waiver ... will not allow participation relating to specific matters in which he has a financial or imputed financial interest, *such as* claims of specific claimants or potential claimants submitted by the Steel Workers International Union for workers at the Paducah, K-25, INEL, Mound, or Portsmouth sites ..."

[9]The waiver states that: "This waiver ... will not allow participation relating to specific matters in which he has a financial or imputed financial interest, such as ... recommendation of approval for addition to the Special Exposure Cohort for any worker for whom Steel Workers International (for claimants at Paducah, K-25, INEL, Mound, and Portsmouth) ... is the petitioner ...."

FOIA Exemption (b)(6): Personal Privacy Information

In any event, we believe that there was adequate information from the CV at least to flag for Department officials an issue that should have been explored prior to Mr. Griffon's participation in the Rocky Flats matter - Department officials should have asked Mr. Griffon when he last provided consulting services to the USW, both at Rocky Flats and at other sites, and we suggest that they do so now. If Mr. Griffon provided consulting services to USW or any of its locals (including Rocky Flats and those other than Rocky Flats) within the 12 months prior to his participation on the Board's review of the Rocky Flats matter, we believe it may have created an appearance concern. However, without documentation of Mr. Griffon's consulting services to USW, and given our review panel's limited role with regard to fact-finding beyond the written record, we cannot determine whether such an appearance concern for Mr. Griffon existed. We would urge ethics officials at NIOSH and/or CDC, in consultation with OGC, to review this matter from an appearance standpoint to determine whether Mr. Griffon should have been recused from participation in this matter.

In our review of the documents provided, we did see an email dated July 28, 2006, from Department officials to Mr. Griffon regarding his 2006 conflict of interest waiver - in the email, Mr. Griffon was asked to review a draft of the 2006 waiver "and make changes, corrections, or comments as necessary." On September 11, 2006, Mr. Griffon replied that "Nothing has changed regarding my conflict of interest status since we developed the Griffon06 document [presumably, an earlier draft of the 2006 waiver] and thus I have no edits." It is possible that this email constitutes an inquiry by Department officials regarding Mr. Griffon's consulting services for the preceding 12 months. On the other hand, Mr. Griffon was not directly asked, nor did he directly answer, any questions specific to his consulting services for the USW or local unions. We also cannot determine whether his answer "Nothing has changed" meant that all of the information provided on his CV was still current (in which case, there may have been an appearance concern, as described above), or whether his description of past activities was still true - but in the past (in which case, there would be no appearance concern since his consulting work would be before the 12 month period). (*See* footnote 7 for quoted language from Mr. Griffon's curriculum vitae).

As pointed out above, if Department officials had kept better records regarding the determinations made about Mr. Griffon, it would have been easier for us to assess whether the correct decisions were made. For example, since we have seen no documentation at all regarding the appearance issue other than the email correspondence described above, we cannot tell whether: (1) Mr. Griffon provided consulting services to the USW or its locals within the 12 months prior to his participation on the Rocky Flats matter, which may have created an appearance concern; or (2) whether Department officials made the proper inquiries about the nature and duration of Mr. Griffon's consulting services to USW prior to his participation.[10]

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[10]Department officials may have made the proper inquiries and learned that Mr. Griffon did provide consulting services within the 12 month period to USW local unions, but not to the Rocky Flats USW, and concluded that this did not amount to an appearance problem. It is also possible that Department officials failed to make the proper inquiries, but if they had, they would have discovered that he did not provide consulting services within the 12 month period and so there was no appearance problem.

Given the difficulty we have had in assessing the actions that were taken with respect to Mr. Griffon because of lack of documentation, we suggest that Department officials keep better records of these determinations in the future.

Summary: We believe that a potential conflict of interest and/or an appearance concern may have existed for Mr. Griffon, but we do not have adequate documentation to assess: (1) whether Mr. Griffon had an appearance concern and possibly a conflict of interest based upon the consulting services that he provided to the USW; (2) whether Department officials made the proper inquires to determine the nature and duration of Mr. Griffon's consulting services to USW; and (3) the basis for the decision that Mr. Griffon was only conflicted for claims brought by workers at the USW sites for which he provided consulting services, rather than at all USW sites. Thus, we cannot determine conclusively whether there is merit to the issues raised by petitioners in this point of appeal.

Recommendation: With respect to Mr. Griffon, we recommend that ethics officials at NIOSH and/or CDC, in consultation with OGC, make a determination regarding whether or not Mr. Griffon had a conflict of interest or an appearance concern, and then take appropriate remedial actions if necessary. In addition, we generally recommend that in the future there be more fact-finding to determine whether a conflict of interest or appearance concern is present prior to the participation of Board members in decisions regarding additions to the SEC. Finally, we recommend that Department officials use more explicit language in the waiver and keep more adequate records with respect to conflict of interest and appearance determinations.

(7) "Inappropriate Expansion of the Rocky Flats Class of Workers from its Original Submittal as a 'Steelworker' Petition to include all Rocky Flats Workers."

In this point of appeal, petitioners allege that the decision to expand the class of workers to be considered for addition to the SEC from members of the Rocky Flats United Steelworkers of America Union, Local 8031, who initially filed the petition, to all Rocky Flats workers, was "extraordinarily inappropriate" because:

> (1) The U.S. Steelworkers of America, Local 8031 had no right of legal representation for members of the expanded class and therefore those new class members were unrepresented; (2) no information was gathered on behalf of the expanded class or included in the petition; (3) they are now, effectively, denied based on a petition that submitted no information on their behalf and so they went unrepresented in the process.

Initially, we note that NIOSH was within its regulatory authority to include groups of employees for addition to the SEC that were not specified in the original petition. For example, 42 CFR § 83.13(c)(2) states that "NIOSH will define the ... characteristics of a class, taking into account the class definition proposed by the petition and modified as necessary to reflect the results of the evaluation ... ." With respect to the concerns listed by petitioners above, we note that neither

the EEOICPA statute nor the implementing regulations require that when new members are added to a class they be entitled to union representation or that new information must be submitted on their behalf. Nonetheless, the record reflects that NIOSH did review additional information regarding the new class members. For example, NIOSH reviewed affidavits prepared by non-union, non-production Rocky Flats workers regarding their exposures that were submitted to NIOSH in August 2005.

Petitioners also allege that NIOSH expanded the class "to make the Class unpalatably large so that it would have to be denied - they had no intention of granting SEC status for Rocky Flats workers so they wanted to deny everyone in one action."

However, petitioners provide no documentation or information as evidence to support this allegation. Based upon the information reviewed, we have seen no evidence showing that NIOSH expanded the class for the purpose of denying SEC status to Rocky Flats workers.

Summary: NIOSH's decision to expand the class, even though new members were not represented by the union, was consistent with statutory and regulatory requirements. There is no evidence that NIOSH expanded the class so that SEC status would be denied to Rocky Flats workers. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(8) "Politics and Budget Denied the Rocky Flats Petitioners a Fair Review Based on Science, Instead the Board and NIOSH Were Pressured to Find Any Reason to Deny Petition 00030."

In this point of appeal, petitioners first state that "We are concerned that politics and budget were a major factor in the decision process." However, petitioners provide no documentation or information as evidence to support this allegation. Based upon the information reviewed, we saw no evidence showing that politics and/or budget played a role in the decision process.

Next, petitioners state that:

> In making this expansion, NIOSH stated in its April 7, 2006, recommendation, "NIOSH determined that all employees were similarly or identically exposed, and therefore, cannot be disaggregated from the union workers with respect to their work and exposures." This statement is a gross error in representation. The union Collective Bargaining Agreement clearly defines the work scope of the Steelworkers facilitating ease in disaggregating the union workers from other workers with respect to both work and exposure. The hourly Steelworkers were the only ones that performed hands-on (hands in gloves) weapons production and chemical recovery operations at the Rocky Flats site and therefore are a distinct and separate class with clear and inherent danger in their positions for the highest occupational exposures.

With respect to this allegation, the petitioners are correct that NIOSH determined that the class

should be expanded to include non-union employees. NIOSH's justification for this determination was set out in the April 7, 2006, Evaluation Report, which said at page 3 that "all employees [at the Rocky Flats Plant] were similarly or identically exposed, and therefore, cannot be disaggregated from the union workers with respect to their work and exposures." In considering whether this was an adequate justification, we first looked to 42 CFR § 83.13(d)(2), which provides that NIOSH's evaluation report must include "A proposed definition of the class or classes of employees to which the evaluation applies, and a summary of the basis for this definition, including, as necessary: (i) Any justification that may be needed for the inclusion of groups of employees who were not specified in the original petition(s) ... ." Although it is not entirely clear what the regulation means in terms of the requirement that "the evaluation report include "*as necessary* ... any justification *that may be needed*" (emphasis added) for expanding a class, it does seem that NIOSH had discretion with respect to how much justification to include in its report and, thus, substantially complied with the regulatory procedures.

We also twice requested additional information from NIOSH regarding its justification to expand the class to include non-union workers. In addition to the April 7, 2006, Evaluation Report, the evidence that NIOSH provided to us included a "Professional Judgment" document dated June 13, 2005 ("Special Exposure Cohort (SEC) Submission 00030 - Rocky Flats Plant - Submission Documents Review"), which was provided to NIOSH by its contractor for dose reconstruction, Oak Ridge Associated Universities (ORAU), and three affidavits prepared by non-union, non-production Rocky Flats workers regarding their exposures that were submitted to NIOSH in August 2005. Under 42 CFR § 83.9(c)(4) evidence provided by affidavits "would not, in and of itself, be sufficient to confirm the facts presented by that evidence. NIOSH will consider the adequacy and credibility of any evidence provided." NIOSH did not provide us with additional information about how it considered the adequacy and credibility of the affidavits. Based upon our review of all of the relevant documents, we do not believe that NIOSH provided evidence or sufficient explanation to support its statement that "all employees were similarly or identically exposed, and therefore, cannot be disaggregated from the union workers with respect to their work and exposures." Thus, even though NIOSH substantially complied with 42 CFR § 83.13(d)(2) when it included a justification in its Evaluation Report, without evidence supporting this justification, we cannot determine whether NIOSH based its decision to expand the class on factually accurate information.

Petitioners also refer to "an undated memo" from the Office of Management and Budget (OMB) that "outlined a plan to contain growth in benefits from new SECs" and that "calls for a White House led interagency task force to 'address any imbalance' in the Advisory Board's membership ... this appears to intend a tilt in the Advisory Board's composition against approval of SECs." However, petitioners did not attach the document from OMB to which they refer and, without this document as evidence, we cannot make a determination that there is merit to this issue. We also note that under 42 CFR Part 83, OMB does not have any role in the decision making process about whether or not the Secretary of Health and Human Services should add a class of employees to the SEC. In addition, petitioners have provided no evidence demonstrating an "imbalance in the Advisory Board's membership" that would favor disapproving additions to the SEC.[11]

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[11]In fact, balance on the Advisory Board is required by Executive Order 13179, section 4(a) ("Members shall include affected workers and their representatives, and

Summary: (a) Petitioners provided no documentation or information as evidence to show that politics and/or budget played a role in the decision process.
(b) NIOSH substantially complied with the regulatory procedures set out in 42 CFR Part 83.
(c) Since NIOSH did not provide evidence or sufficient explanation to support its justification for expanding the class in its April 7, 2006, Evaluation Report, we cannot determine whether NIOSH based its decision to expand the class on factually accurate information.
There is no merit to (a) and (b) above. With respect to (c), we cannot determine conclusively whether there is merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding (a) and (b) above. Regarding (c), a more detailed explanation on the record of NIOSH's justification for expanding the class should be provided to the Secretary. In the future, NIOSH should provide more detailed evidence and explanation to support its justification for expanding a class.

(9) **"Deputy Secretary Applied Pressure Against SECS."**

The petitioners cite to several emails written by Shelby Hallmark, Director, Office of Worker's Compensation, Department of Labor (DOL) to allege that Mr. Hallmark initially favored SEC status for Rocky Flats workers ("If there's a justification for an SEC anywhere, common sense suggests that it should be at Rocky") and then later opposed the SEC (" ... we should do everything possible to oppose these SEC (special cohort status) amendments") and also that he publicly criticized the validity of dose reconstruction ("Does it make any sense to continue to defend a dose reconstruction process that will just get more complicated and attenuated?"). However, petitioners have not attached any of these emails to their letter of appeal as evidence. Based upon the information reviewed, we have seen no evidence supporting this allegation.

In any event, DOL, including Mr. Hallmark, has no role under 42 CFR Part 83, in the decision making process about whether or not the Secretary of Health and Human Services should add a class of employees to the SEC. DOL's role is to determine whether the individuals within the cohort qualify for compensation and to administer the compensation. In fact, Executive Order 13179, section 2(b)(ii) makes clear that "The Secretary of Health and Human Services shall ... [i]n accordance with procedures developed by the Secretary of Health and Human Services, consider and issue determinations on the petitions by classes of employees to be treated as members of the Special Exposure Cohort."

Summary: Petitioners did not attach documents as evidence to support their allegations. In any event, DOL has no role under the EEOICPA

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representatives from scientific and medical communities") and by the EEOICPA statute at 42 U.S.C. § 7384o(a)(2), which states that "The President shall make appointments to the Board in consultation with organizations with expertise on worker health issues in order to ensure that the membership of the Board reflects a balance of scientific, medical, and worker perspectives."

regulations in the decision of whether or not to add a class of employees to the SEC. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(10) "Suppression of Scientific Points."

Petitioners state that "Members of the Advisory Board's Contractor SC&A were silenced and pressured not to discuss views contrary to the position of NIOSH." However, based upon the information we have reviewed, we have seen no evidence to support this allegation. In fact, the Board transcripts reveal that SC&A participated in much debate and other discussions about various scientific issues.

Summary: We have seen no evidence that SC&A was silenced or pressured not to discuss views contrary to the position of NIOSH; in fact, we found evidence to the contrary. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(11) "Methods were used as Basis of Denial that did not exist when the Petition was submitted."

In this point of appeal, petitioners essentially reiterate the issues raised in "Process Basis: Points of Appeal" #2 regarding timeliness and "Process Basis: Points of Appeal" #5 regarding the roles of the Advisory Board and NIOSH. Please see our responses to points #2 and #5 above. In addition, we note that petitioners have provided no documents or information as evidence to support their allegation that "NIOSH blatantly ignored legal time requirements" in order to "stall" and "coerce the Advisory Board into voting against the petition." The dose reconstruction methods that NIOSH used were in place and internationally well established prior to the time that the petition was filed on February 15, 2005.

Summary: See **Summary** to "Process Basis Points of Appeal" #2 and #5. In addition, petitioners have provided no evidence that dose reconstruction methods were used as a basis for denial that did not exist when the petition was submitted. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

SCIENTIFIC BASIS: POINTS OF APPEAL

(1) "Missing Data."

Petitioners state that:

> We are very concerned that between 1964 and 1992, that 33% of the worker cases reviewed were found to have missing data. To quote the Board's contractor - "There are large gaps in internal dose data, notably for 1964-1992."

However, we have found no evidence to suggest that 33% of the worker cases reviewed were found to have missing data. In fact, David Sundin, Deputy Director, Office of Compensation Analysis and Support (OCAS)/NIOSH, specifically addressed this issue in an email to one of the petitioners, dated June 5, 2007 (Re: Rocky Flats Requests for Information (part 8)), which states as follows:

> We are not "extrapolating from 32 random samples to the entire Rocky Flats population," nor did we find that "33 percent of those sampled had missing records." The Working Group instructed SC&A to randomly select 32 cases, and to select 20 additional cases from the workers identified by the Medical Recall program as being highly exposed. SC&A then evaluated the cases to determine the time periods when monitoring was present, and when it wasn't. NIOSH then evaluated the time periods without monitoring data to determine whether such data would have been expected. Out of the thousands of man-years examined, there was only a single instance where records were "missing" (one year of external monitoring data for a single individual could not be located, as clearly identified in the file). In every other case, the time periods without monitoring data matched periods when the workers were either not onsite or were working in low exposure potential jobs, and therefore not required to be monitored. As has been discussed numerous times, most recently at the last ABRWH [Advisory Board on Radiation and Worker Health] meeting, the records were complete.[12]

Petitioners also state that:

> To quote from the Board's contractor - ... "NIOSH has not demonstrated its ability to fill existing data gaps for external dose in a manner that would produce bounding dose estimates that would satisfy the requirement of 42 CFR, Part 83.

However, NIOSH was able to estimate dose for dose reconstruction according to the procedures explained in detail in its April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030. These procedures were consistent with 42 CFR Part 82 and Part 83. We conclude that NIOSH was, therefore, able to estimate the level of radiation doses of individual members of the class with sufficient accuracy pursuant to 42 CFR § 83.13(c)(1).[13]

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[12] The Advisory Board discussion on this point on May 2, 2007, can be found in the transcript from that meeting at several points, including at pages 303-309.

[13] The regulation at 42 CFR § 83.13(c)(1) provides in pertinent part as follows:

> Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any

We also generally note that both the EEOICPA statute[14] and the implementing regulations[15] specifically contemplate that data will be missing and that is precisely why dose reconstruction is necessary. In fact, according to the Preamble accompanying the final rules at 42 CFR Part 82, the purpose of dose reconstruction is as follows: "Dose reconstructions are used to estimate the radiation doses to which individual workers or groups of workers have been exposed, particularly when radiation monitoring is unavailable, incomplete, or of poor quality." 67 Fed. Reg. 22315 Therefore, the fact that data is missing does not, in and of itself, preclude proper dose reconstruction.

Summary: Petitioners provided no documentation or information as evidence to show that 33% of the worker cases between 1964 and 1992 had missing data. NIOSH had enough data to reconstruct dose in accordance with the proper procedures for dose reconstruction set out in 42 CFR Part 82 and Part 83. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

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member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose.

[14] *See, e.g.,* 42 U.S.C. § 7384n(d) ("Methods for Radiation Dose Reconstructions"), which directs the President (through a Federal agency or official) to establish by regulation methods for arriving at reasonable estimates of the radiation doses received by employees who were not monitored for exposure to radiation, who were monitored inadequately for exposure to radiation, and whose records of exposure to radiation are missing or incomplete.

[15] Several sections in 42 CFR Part 82 address ways in which NIOSH can deal with missing data. For example, § 82.2 ("What are the basics of dose reconstruction?") provides that "A hierarchy of methods is used in a dose reconstruction, depending on the nature of the exposure, conditions and the type, quality, and completeness of data available to characterize the environment.". Part (a) of this regulation states that "If found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and bioassay sample results, are given the highest priority." Part (b) provides that "If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment ... alternatively, workplace area monitoring data may be used to estimate the dose." Finally, § 82.2(c) states that "If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model." *See also* 42 CFR § 82.16 ("How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missed dose?") and 42 CFR § 82.17 ("What type of information could be used to supplement or substitute for individual monitoring data?").

Recommendation: We do not recommend further action regarding this point of appeal.

(2) "Lack of Scientific Evidence to Support Particle Size Selected for High Fired Oxides."

Petitioners state that "NIOSH used one single data point to determine what particle size to use, but no research has been done to support it." However, according to 42 CFR §82.2(a), "If radiation exposures in the workplace environment cannot be fully characterized based on the available data, default values based on reasonable and scientific assumptions may be used as substitutes." In addition, NIOSH based its internal dose reconstruction on models published by the International Commission on Radiological Protection (ICRP)-66, which is the document used for internal dose reconstruction and other scientific methods established by the radiation safety scientific community. In fact, in the Preamble to 42 CFR Part 82, the Department noted that "The methods for calculating internal dose under this rule use current models published by the International Commission on Radiological Protection (ICRP) ... These models currently provide the most widely accepted methods for mathematically describing the uptake, transport and retention of radionuclides in the body." The model used by NIOSH for dose reconstruction, published by the ICRP and widely accepted by the scientific community, was developed to assess radiation doses for occupationally exposed individuals and to evaluate accidental exposures. This model, even though particle size or material class might not be known in all radiation occupational situations, still serves as a reliable and appropriate one for estimating internal dose, especially when using claimant favorable estimations as discussed in more detail below. The models are based on the collective knowledge gained from both animal and human studies. In addition, we note that regulations at 42 CFR § 82.16(b) specifically direct NIOSH to use ICRP models – this section states that "Using ICRP biokinetic models, NIOSH will estimate the internal dose and include an associated uncertainty distribution."

In this point of appeal, petitioners also include the following quote from PNNL-MA-860 Chapter 8.0 issued January 2003, a document that pertains to the internal dosimetry program at the Hanford site: "The precise nature of super class Y material is not known, although it appears to have been associated with processes involving high fired plutonium oxides." Our assumption is that the reference to the "nature of super class Y material" refers to both particle size and solubility. We will address both of these below.

With respect to petitioners' allegations regarding particle size, we note that NIOSH used one default single particle size, 5 micrometers (μm), as recommended for dose reconstruction by the models published in ICRP-66. *See* April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030, Table 6-1 at page 33, and Table 6-2 at page 34. The ICRP-66 models recommend 5 μm because it is a large particle size and is claimant favorable.

With respect to petitioners' allegations regarding material class (solubility), NIOSH agrees that there is evidence of high-fired plutonium oxides at the Rocky Flats Plant. The presence of such materials does not, however, affect the feasibility of dose reconstructions. One issue the petitioners have focused on is the "high fired plutonium oxides." Petitioners seem to be concerned that "Super Class Y material" (an insoluble form) was released during the various fires that occurred at the Rocky Flats Plant site. The approach used by NIOSH for dose

reconstructions was to use Super Class Type Y (also known as Super Class S in ICRP-66) in determining lung dose and more soluble forms for non-respiratory organ doses thus overestimating both respiratory and non-respiratory organ doses. *See* April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030, Section 7.51.1. This approach also results in claimant favorable dose estimates for respiratory and non-respiratory organs. Furthermore, in adopting this approach, NIOSH was in compliance with 42 CFR § 82.2(a), which states in pertinent part as follows:

> If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. For example, if the solubility classification of an inhaled material can not be determined, the dose reconstruction would use the classification that results in the largest dose to the organ or tissue relevant to the cancer and that is possible given existing knowledge of the material and process.

Summary: There is scientific evidence to support the particle size and material class selected by NIOSH for conducting dose reconstructions. In addition, NIOSH's approach was in compliance with 42 CFR § 82.2(a). Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(3) "Lack of Research or Scientific Basis for how High Fired Oxides are metabolized in the body."

Petitioners reiterate the same concerns raised in "Scientific Basis: Points of Appeal" #2 above, regarding the alleged lack of scientific basis to support the model used by NIOSH for dose reconstruction. Please see our response to point #2 above.

Summary: See Summary to "Scientific Basis: Points of Appeal" #2. There is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do no not recommend further action regarding this point of appeal.

(4) "Unproven Scientific Models employed."

Petitioners state that "New models were created and not adequately proven." However, as described above in our response to "Scientific Basis: Points of Appeal" #2, NIOSH did not create new models. Instead, NIOSH utilized existing, well-established models such as those included in the ICRP-66 which were developed through scientific consensus independent from NIOSH. For a more detailed description of the ICRP-66, please see our response to point #2 above.

The petitioners also assert that the "Defense Threat Reduction Agency Dose Reconstruction Program stated '...upper-bound doses from external gamma, neutron, and beta exposure are often under estimated, sometimes considerably, particularly when doses are reconstructed.'" However, petitioners gave no context or explanation of the relevance of this statement to dose reconstructions at Rocky Flats. The dose reconstruction program of the Defense Threat Reduction Agency could be completely different, in population, setting, types of exposure, time, model and methods of estimating dose than the dose reconstruction program for Rocky Flats workers.

Summary: NIOSH utilized existing well-established models for dose reconstruction. There was insufficient information about a statement from the Defense Threat Reduction Agency to determine the statement's relevance to NIOSH's program. There is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(5) **"Faulty Co-Worker Model."**

Petitioners state that they "are very concerned about the co-worker model's reliance on the ability to remember or track what buildings workers were in for periods of time given the transient nature of the hourly work force."

However, while petitioners described "the transient nature of the hourly work force," in fact we found the opposite to be true – workers were generally restricted to specific locations. Thus, we believe that NIOSH's decision to use co-worker data when individual data was missing was appropriate in this instance. For example, as plutonium was phased into the Rocky Flats Plant site, the uranium and plutonium production areas were separated and, in most cases, employees worked within a specific facility for security reasons. *See, e.g.*, April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030, Section 7.2.3; December 8, 2005, Sanford Cohen & Associates draft report entitled "Rocky Flats Plant Site Profile Review," at pages 153, 175, 189, 206, and 222.

Petitioners also state that "We are very concerned that fundamental facts and understanding about the processes and radionuclides present in the buildings (for example Building 881) remain unclear to NIOSH even after 28 months of review of the petition."

However, petitioners have provided no documentation or specific information as evidence to support this allegation. In fact, our review of the documents provided revealed the opposite – the Oak Ridge Associated Universities (ORAU) (NIOSH's contractor for dose reconstruction) report entitled "Technical Basis Document for the Rocky Flats Plant - Site Description" (ORAUT-TKBS-0011-2, Rev. 00) dated January 10, 2004, describes in sufficient detail the buildings at the Rocky Flats Plant, including the operations, radionuclides present, etc.

Finally, we note that NIOSH's use of co-worker data is clearly within its regulatory authority. In fact, several sections within 42 CFR Part 82 provide authority for NIOSH to use co-worker data

to reconstruct dose when individual monitoring data is not available.[16]

Summary: The use of co-worker data was appropriate for dose reconstruction for this population and is permitted by regulation. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal

(6) **"Inaccuracy of Model to account for undocumented exposures to the head and back."**

Petitioners state that "We are concerned about the inaccuracy of monitoring of external exposure to the upper torso, head and back when dosimeter is blocked or pointed in opposite direction."

However, the personal external monitoring techniques for individuals at the Rocky Flats Plant were appropriate and dosimeters were placed in the standard and appropriate location, which was the front unilateral torso, and met the scientific standards for adequate dose monitoring. Furthermore, in special circumstances, workers were monitored with extremity dosimeters when performing tasks in which the extremity dose might be considered to be significantly greater than the whole body dose. *See* April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030 at page 57 and 72. We consider these methods to be appropriate for dose reconstruction. In fact, 42 CFR § 83.13(c)(1)(iv) does not require this type of monitoring.[17]

Petitioners also state that "We are concerned about the validity of dose records for workers in high dose jobs." However, petitioners have provided no documentation or other information as evidence to support this statement. Our review of the records revealed that dose records for internal and external monitoring were sufficient for proper dose reconstruction. *See* April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030, Section 7.7, at page 80, which says:

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[16] For example, 42 CFR § 82.2(b) states that "If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment," § 82.16(a) provides that "For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation, using available monitoring results from other time periods close to the period in question, or based on monitoring data on other workers engaged in similar tasks," and § 82.17(a) states that information that can be used to supplement or substitute for individual monitoring data include "Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment."

[17] The regulation at 42 CFR § 83.13(c)(1)(iv) reads as follows:

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

> This report evaluated the feasibility for completing dose reconstructions for employees at the Rocky Flats Plant between April, 1952, and February, 2005. NIOSH found that the monitoring records, process descriptions, and source term data available are sufficient to estimate radiation doses with sufficient accuracy for this class of employees. NIOSH did not identify any groups of employees at the facility during this time period for which it would not be feasible to complete dose reconstructions.

Finally, petitioners generally reiterate the concerns they raised in "Scientific Basis: Points of Appeal" #5 above regarding the co-worker model, stating that they "are concerned about the adequacy of the co-worker model and NIOSH's ability to apply it." Please see our response to point #5 above.

Summary: External monitoring techniques used at the Rocky Flats Plant were standard and appropriate. Dose records for internal and external monitoring were sufficient for proper dose reconstruction. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

(7) "Gross Error in Fact Contributed to NIOSH's Decision to Expand the Class."

In this point of appeal, petitioners reiterate the concerns raised in "Process Basis: Points of Appeal" #8 regarding NIOSH's decision to expand the class of Rocky Flats Plant workers to be considered for addition to the SEC. Please see our response to this point above.

Summary: See **Summary** to "Process Basis: Points of Appeal" #8.

Recommendation: See **Recommendation** to "Process Basis: Points of Appeal" #8.

(8) "Significant Divergence in Scientific Opinion."

In this point of appeal, petitioners indicate that, with respect to Rocky Flats, there was a "Significant Divergence in Scientific Opinion" and they reiterate several concerns raised in previous points of appeal. For example, they restate the allegations raised in "Scientific Basis: Points of Appeal" #2 and #3 regarding the lack of scientific basis to support the models (including use of particle size and material class) used by NIOSH for dose reconstruction; the allegations raised in "Scientific Basis: Points of Appeal" #4 regarding NIOSH creating new unproven models for dose reconstruction; and the allegations raised in "Scientific Basis: Points of Appeal" #5 regarding faulty co-worker models. Petitioners also reiterate the concerns raised in "Process Basis: Points of Appeal" #9 regarding statements made by Shelby Hallmark. Please see our responses to all of these points above.

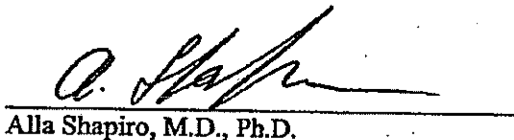
In this point of appeal, petitioners also express their concern "that the standard being applied appears to be whether something is 'plausible' or not. We repeatedly [hear] things like it is plausible that a model will work or it is plausible that the 0s recorded [meant] that the dosimeter was not turned in." As we indicated in response to "Scientific Basis: Points of Appeal" #1, the EEOICPA statute and the regulations specifically contemplate that data will be missing. The standard for whether a class of employees should be added to the SEC is whether it is feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy.[18] While we agree with the petitioners that "plausibility" is not the appropriate standard, petitioners have not provided, nor have we seen, any specific evidence suggesting that NIOSH did not apply the regulatory standard. For example, NIOSH appropriately accounted for the zero value for the dose entry, as indicated in the April 7, 2006, SEC Petition Evaluation Report: Petition SEC-00030, at pages 47, 60, and 61.

We note that NIOSH's dose reconstruction procedures were based upon valid science and used established models for dose reconstruction.

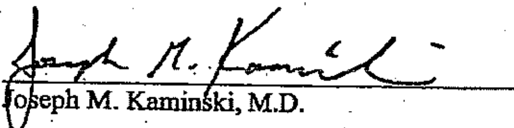
Summary: We see no significant divergence in scientific opinions that would invalidate the Secretary's final decision. Thus, there is no merit to the issues raised by petitioners in this point of appeal.

Recommendation: We do not recommend further action regarding this point of appeal.

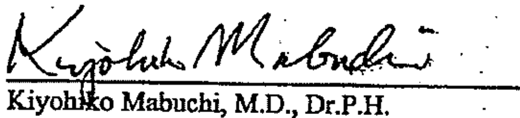
Sincerely,



Alla Shapiro, M.D., Ph.D. — 12/31/08 Date



Joseph M. Kaminski, M.D. — 12/29/08 Date



Kiyohiko Mabuchi, M.D., Dr.P.H. — 12/31/08 Date

Attachment

[18] *See* 42 CFR § 83.13(c)(1), as quoted in footnote 13.

Rocky Flats SEC00030
Petitioner
On behalf of:
Rocky Flats United Steelworkers of America, Local 8031
2280 E. 139th Avenue
Brighton, CO 80602

09-12-07P12:56 RCVD

SEC00030
Office of Compensation Analysis and Support, NIOSH
MS C-47
4676 Columbus Parkway
Cincinnati, OH 45226

ocas@cdc.gov

RE: Formal Letter of Appeal of Determination by Michael O. Leavitt for SEC Status for Rocky Flats Workers Who Were Exposed to Radiation Dose from 1967 to 2005 and to Radiation Dose Other Than Neutron from 1952 to 1966

Dear Secretary Michael Leavitt,

On behalf of the Rocky Flats workers who were members of the Rocky Flats United Steelworkers of America, Local 8031, we write to formally appeal your decision dated August 6, 2007, and yet oddly not sent to the petitioners until August 27, 2007 – three full weeks after the decision was made. This delay in notification simply highlights a long and troubled process in which timeliness has always been an issue at the forefront. Perhaps the Secretary figured that since the sick and dying Rocky Flats workers have already been waiting two and a half years for a decision, that an extra 21 days wouldn't kill us – or would it? Sadly 10 percent of our sick workers die waiting for their claims to be processed by the U.S. Government.

Mr. Elliott's letter stated that "Information regarding your right to request an administrative review of this decision will be provided to you shortly." Today, 14 days after this letter was posted, we have yet to receive any such information and as we, unlike you, will be held to the legal time limits, we have decided to file this request for administrative review/legal protest absent the provision of any information from NIOSH.

Our understanding of our legal rights under the Energy Employees Occupational Illness Compensation Program Act of 2000 allow us to appeal to the Secretary of Health and Human Services in writing and that you will then appoint your own 3-person "independent" panel to review your decision. We, hereby, formally appeal. We also understand that we can appeal based on violations in process and to challenge scientific facts that were used to deny our petition. We appeal based on both process and science in accordance with the points of appeal listed below. Please notify us regarding the membership of your panel as soon as you have appointed it and advise us if any additional information is required from the Petitioner. I encourage you to break with the consistent untimely nature of your office and this process and to appoint the panel immediately and get a final ruling so that we can take our next steps

with respect to Legislative and Legal remedies before too many more of our workers die waiting for the Government to make good on the Congressional promise to take care of our sick workers.

Process Basis: Points of Appeal

1) **Failure to provide information** to the petitioner in accordance with the provision of the law. NIOSH and now the Secretary of Health and Human Services have exhibited a pattern of withholding and delaying communication of information to the Rocky Flats petitioner throughout this process – including "accidentally" removing the petitioner and petitioner representative from the e-mail distribution for notification of meetings for a six month period of time. The petitioners were added back to the list and an apology was issued by NIOSH for their accidental mistake. Several times including before the May 3, 2007, and June 12, 2007 meetings, reports were prepared by the Advisory Board's contractor that were discussed at the meetings, yet NIOSH failed to distribute the reports to the Petitioner until minutes before or in some cases after the meetings – thus preventing the Petitioner from being able to prepare for the meetings. Board members voiced similar complaints about the timely provision of information by NIOSH at its June 11 and 12 meeting in Denver. This pattern of blatant disrespect for the Petitioner's rights is further evident in that the Secretary of HHS did not even bother to notify the petitioner of his decision until three week after he made it – leaving it up to the news media and frustrated members of the Colorado Congressional delegation to do his dirty work – indicating a lack of pride in his own decision. It took a call from Carolyn Boller in Congressman Udall's office before Mr. Elliott finally issued a letter on behalf of the Secretary.

2) **Timeliness.** NIOSH failed to meet the Congressionally mandated deadline of 180 days to make its recommendation on the Petition. The recommendation was not made until 440 days after the Petition was submitted February 15, 2005. **The Rocky Flats petition should be approved based on the Government's failure to meet timeliness requirements of the Act.** The Rocky Flats Petition was submitted on February 15, 2005. The Secretary did not issue his decision until August 6, 2007 – 902 days after the petition was submitted – 902 days while our workers, sick with cancer, suffered and many died. The NIOSH recommendation on this petition was issued 440 days following receipt in spite of the fact that the **2005 EEOICP Act Revision required a recommendation, by law, in 180 days.** The Advisory Board on Radiation Safety and Health (the Board) recommendation did not occur until June 2007. The law requires timeliness and fairness. This process has been neither timely nor fair to the Rocky Flats workers who are sick with cancer. Furthermore, it is unacceptable that individual Rocky Flats claimants wait an average of 742 days for their claims to be processed from submittal to the time a positive ruling is made. This delay has meant that 67 Rocky Flats workers (10 percent of those ultimately approved), who would have been compensated, died waiting. It is clear that timeliness is not being met in the case of individual Rocky Flats claimants or in the case of the Rocky Flats Petition. This factor alone is enough to warrant approval in full of the Rocky Flats Petition. The question was not could NIOSH ever reconstruct dose with accuracy. It has been two and a half years and substantial issues are still

outstanding. The law did not say – petitioner point out flaws in the government's ability to reconstruct dose; NIOSH fix some of the flaws (admitting inabilities) and then recommend denial of \ petition based on a new set of standards that did not exist at the time the petition was submitted. The law clearly states: "The purpose of the compensation program is to provide timely, uniform, and adequate compensation. . . . " **Justice Delayed is Justice Denied.**

3) **Conflict of Interest Invalidates the Process.** As noted by Congressman Hostettler in a March 9, 2007, letter, "At Rocky Flats, a manager of health physics programs prepared NIOSH's site profiles, TIBS, is actively involved in the evaluation of a SEC petition, which includes validation of results used in his previous work." Individuals who have testified AGAINST workers in worker compensation hearings are serving key roles in the NIOSH process. The Government's own General Accounting Office identified conflicts of interest.

4) **Non-Cohesion in the Board.** The Board vote of 6 to 4 showed considerable dissention in opinion of the Board members. This vote is not a strong endorsement for the Board's recommendation. In fact, many issues were left unresolved at the time of the vote, as evidenced by the split vote. In addition, the Board's expert contractor Sanford Cohen and Associates (SC&A) had identified many open issues and concerns with NIOSH's approaches. The Board has not given a strong endorsement to the Department of Health and Human Services.

5) **Actions Outside the Boundaries of the Authority under the Act.** This process was intended to include a timely evaluation and recommendation regarding the merit of the petition – to answer the question, did the petitioner prove that there was a class of workers for which the Government could not accurately reconstruct dose. The Board's role was to evaluate and recommend, never to fix. The Board, albeit with good intentions, became intertwined with a process to develop a set of new science, methods, models, guidance, technical basis documents and assumptions over the last two years. These were directed at serving as the basis to deny the Rocky Flats petition. These new document will ultimately result in thousands of dose reconstructions that must now be redone in accordance with the new standards. The fact that dose reconstructions are being declared "invalid" and are being redone serves as strong evidence to the Department of Health and Human Services and the members of Congress that it was, in fact, not possible for NIOSH to reconstruct dose for the Rocky Flats workers at the time the petition was submitted. We are gravely concerned that this action and the Secretary's decision to deny the petition based on this action opens the entire EEOICPA process up to severe scrutiny either as part of a Congressional investigation or litigation. This situation would severely tarnish the U.S. Government, the U.S. Congress and your agency in particular.

6) **Inconsistent Application of Conflict of Interest Requirements.** NIOSH inconsistently applied conflict of interest standards to stack the Advisory Board on Radiation Health to deny worker petitions in accordance with political pressure and statements made by top leaders in HHS. For example Mark Griffon was allowed to vote in spite of his relation with the union, while Josie Beach was denied her right to vote based on her membership in a union at the Hanford Site. Interestingly, because

of NIOSH's delay in the petition process, the Rocky Flats workers were in fact no longer members of the United Steelworkers union at the time of the Board's vote. There was no financial tie or benefit or association and so there was no reason that Ms. Beach should have been denied her right to participate. The Petitioner requested for the Conflict of Interest to be re-evaluated based on the fact that there was no longer one and NIOSH said it did one but refused to provide any evidence that such a re-review was conducted or the name of the attorney who conducted the review. The following is a direct quote from the Petitioner's Presentation to NIOSH on May 3, 2007 – "We have learned that some members of the Board have been instructed that they cannot vote on the Rocky Flats petition based on relationship with the United Steelworkers. As a direct result of NIOSH's delay in addressing this petition, if ever valid, such a restriction is no longer valid today for the following reasons: 1)The Rocky Flats workers on behalf of whom this petition was filed no longer have any financial or contractual relationship with the United Steelworkers; 2) Local 8031 no longer has a single nuclear worker in its membership; 3) The United Steelworkers no longer receive any dues from the former Rocky Flats members nor do they provide representation or services to the members; 4) The United Steelworkers do not benefit in any way from the approval of this petition; 5) NIOSH on its own right expanded the class to include all RF employees so it is no longer a "Steelworker" petition. Therefore no relational conflict exists today. No legal basis was ever provided.

7) **Inappropriate Expansion of the Rocky Flats Class of Workers from its Original Submittal as a "Steelworker" Petition to include all Rocky Flats Workers.** This decision was extraordinarily inappropriate for the following reasons: 1) the U.S. Steelworkers filed the petition on behalf of its membership under the special provisions for labor organizations. The U.S. Steelworkers of America, Local 8031 had no right of legal representation for members of the expanded class and therefore those new class members were unrepresented; 2) no information was gathered on behalf of the expanded class or included in the petition; 3) they are now, effectively, denied based on a petition that submitted no information on their behalf and so they went unrepresented in the process. We believe NIOSH did this on purpose to make the Class unpalatably large so that it would have to be denied – they had no intention of granting SEC status for Rocky Flats workers so they wanted to deny everyone in one action.

8) **Politics and Budget Denied the Rocky Flats Petitioners a Fair Review Based on Science, Instead the Board and NIOSH Were Pressured to Find Any Reason to Deny Petition 00030.** We are concerned that politics and budget were a major factor in the decision process. This is particular disturbing in light of the deliberate action on NIOSH's part to expand the class from its original size of 4,000 Steelworkers potentially, with less than 1,400 expected to be ultimately compensated to a class, with no basis, of 20,000 people. In making this expansion, NIOSH stated in its April 7, 2006, recommendation, "NIOSH determined that all employees were similarly or identically exposed, and therefore, cannot be disaggregated from the union workers with respect to their work and exposures." This statement is a gross error in representation. The union Collective Bargaining Agreement clearly defines the work scope of the Steelworkers facilitating ease in disaggregating the union workers from

other workers with respect to both work and exposure. The hourly Steelworkers were the only ones that performed hands-on (hands in the gloves) weapons production and chemical recovery operations at the Rocky Flats site and therefore are a distinct and separate class with clear and inherent danger in their positions for the highest occupational exposures. An undated memo roughly late 2005, from White House's Office of Management and Budget to Labor Department OMB Passback outlined a plan to contain growth in benefits from new SECs by requiring "administrative clearance" before the HHS Secretary can make a decision, and calls for a White House led interagency task force to "address any imbalance" in the Advisory's Board's membership. In this context, this appears to intend a tilt in the Advisory Board's composition against approval of SECs.

9) **Deputy Secretary Applied Pressure Against SECS.** "Just in case there was any question, it's my strong belief that we should do everything possible to oppose these SEC (special cohort status) amendments".— June 18, 2004, e-mail from Shelby Hallmark, Department of Labor deputy assistant secretary Oddly, just months before (before the OMB Passback memo), Mr. Shelby was singing a different tune. "If there's a justification for an SEC anywhere, common sense suggests that it should be at Rocky." — Feb. 26, 2004, e-mail from Shelby Hallmark, Department of Labor deputy assistant secretary for the Office of Workers' Compensation Programs. He also was previously so bold as to publicly criticize the validity of dose reconstruction: "Does it make any sense to continue to defend a dose reconstruction process that will just get more complicated and attenuated?"—Shelby Hallmark, Department of Labor deputy assistant secretary. Someone needs to look into what made him change his tune. Was it science or politics?

10) **Suppression of Scientific Points.** Members of the Advisory Board's Contractor, SC&A, were silenced and pressured not to discuss views contrary to the position of NIOSH.

11) **Methods were used as Basis of Denial that did not exist when the Petition was submitted.** NIOSH blatantly ignored legal time requirements in favor of stalling to allow time to develop band-aid fixes to coerce the Advisory Board into voting against the petition. The development of new TIBs is not part of the Petition review process and it is for this reason that it took two and a half years for a determination to be issued. ***Our workers died while NIOSH desperately dabbled in science under the threat that its program would be eliminated spelling an end to the multi-million dollar business that is dose reconstruction – a NIOSH and HHS jobs program at the expense of the workers and the taxpayers.***

Scientific Basis: Points of Appeal

1) **Missing Data.** We are very concerned that between 1964 and 1992, that 33% of the worker cases reviewed were found to have missing data. To quote the Board's contractor – "There are large gaps in internal dose data, notably for 1964-1992" "NIOSH has not demonstrated its ability to fill existing data gaps for external dose in

a manner that would produce bounding dose estimates that would satisfy the requirements of 42 CFR, Part 83."

2) **Lack of Scientific Evidence to Support Particle Size Selected for High Fired Oxides.** NIOSH used one single data point to determine what particle size to use, but no research has been done to support it. PNNL-MA-860 Chapter 8.0 issued January 31, 2003 "The precise nature of super class Y material is not known, although it appears to have been associated with processes involving high fired plutonium oxides.

3) **Lack of Research or Scientific Basis for how High Fired Oxides are metabolized in the body.** PNNL-MA-860 Chapter 8.0 issued January 31, 2003 "The precise nature of super class Y material is not known, although it appears to have been associated with processes involving high fired plutonium oxides. How can you go from knowing little to having it all figured out to the point you can model it without doing any scientific research or studies? Garbage in --- garbage out.

4) **Unproven Scientific Models employed.** New models were created and not adequately proven. Fly-by-night, overnight science – NIOSH thinks they can develop in three months, what still has been failing after three decades. Dose Reconstruction is not a science. Defense Threat Reduction Agency Dose Reconstruction Program stated" . . . upper-bound doses from external gamma, neutron, and beta exposure are often under estimated, sometimes considerably, particularly when doses are reconstructed."

5) **Faulty Co-Worker Model.** In addition, we are very concerned about the co-worker model's reliance on the ability to remember or track what buildings workers were in for periods of time given the transient nature of the hourly work force. We are very concerned that fundamental facts and understanding about the processes and radionuclides present in the buildings (for example Building 881) remain unclear to NIOSH even after more than 28 months of review of the petition.

6) **Inaccuracy of Model to account for undocumented exposures to the head and back.** We are concerned about the inaccuracy of monitoring of external exposure to the upper torso, head and back when dosimeter is blocked or pointed in opposite direction. We are concerned about the validity of dose records for workers in high dose jobs. We are concerned about the adequacy of the co-worker model and NIOSH's ability to apply it.

7) **Gross Error in Fact Contributed to NIOSH's Decision to Expand the Class.** NIOSH's part to expand the class from its original size of 4,000 Steelworkers potentially, with less than 1,400 expected to be ultimately compensated to a class, with no basis, of 20,000 people. In making this expansion, NIOSH stated in its April 7, 2006, recommendation, "NIOSH determined that all employees were similarly or identically exposed, and therefore, cannot be disaggregated from the union workers with respect to their work and exposures." This statement is a gross error in representation. The union Collective Bargaining Agreement clearly defines the work scope of the Steelworkers facilitating ease in disaggregating the union workers from other workers with respect to both work and exposure. The hourly Steelworkers were

the only ones that performed hands-on (hands in the gloves) weapons production and chemical recovery operations at the Rocky Flats site and therefore are a distinct and separate class with clear and inherent danger in their positions for the highest occupational exposures.

8) **Significant Divergence in Scientific Opinion.** SC&A stated that it, too, has concern over NIOSH's ability to implement its stated methods, approaches, and coworker models to enable "dose reconstruction with sufficient accuracy," as prescribed by 42 CFR Part 83.". We are concerned that while the Pacific Northwest Nuclear Laboratory stated in 2003 that "the precise nature of Super Class Y material is not known", that NIOSH developed adjustment factors to accommodate these exposures and used only one single data point to determine particle size for modeling. Fundamental facts remain unknown about high fired oxides. We are concerned that the standard being applied appears to be whether something is "plausible" or not. We repeatedly here things like it is plausible that a model will work or it is plausible that the 0s recorded met that the dosimeter was not turned in. The Webster New World Dictionary defines the word plausible as "seemingly true; often implying disbelief" or "applies to that which at first glance appears to be true . . . but which may or may not be so." We do not plausibility is an appropriate standard by which to make decisions as important as whether or not sick workers should be compensated. The fact that it has been more than two years and significant factors are still unresolved means the petition was valid and should be approved. The fact that NIOSH has modified the site profile, added new TIBs, changed the particle size for high fired oxides, developed new co-worker models, added adjustment factors, tweaked other models, Etc. , means that NIOSH could not accurately reconstruct dose otherwise they would not have made all the changes. Department of Labor Official Shelby Hallmark asked the question "Does it make any sense to continue to defend a dose reconstruction process that will just get more complicated and attenuated?" As evidenced by the addition of nine new technical guidance documents in the time since the Rocky Flats Petition was submitted, we would have to agree with Mr. Hallmark, this process has gotten far too attenuated to allow accurate dose reconstruction.

It is for these reasons and based on the facts described above, that we hereby formally request a review of the Secretary of HHS's decision dated August 6, 2007, that determined Rocky Flats workers from 1967 to 2005 and those exposed to dose other than neutrons from 1952 to 1966 "do not meet the statutory criteria for addition to the SEC." Please count this letter as our formal request for administrative review and our appeal of the Secretary's decision.

Respectfully,

USWA, Local 8031 Official Petitioner-Designated Representative

NIOSH Response to Report from HHS Special Exposure Cohort (SEC) Administrative Review Panel re: Rocky Flats Plant SEC

Introduction

Pursuant to HHS regulations at 42 C.F.R. § 83.18, petitioners for the Rocky Flats Plant filed an appeal of the determination of the Secretary, HHS, to not include a class of workers at the Rocky Flats Plant in the Special Exposure Cohort (SEC) created by the Energy Employees Occupational Illness Compensation Program Act (EEOICPA or the Act). The Secretary appointed a three-person panel of HHS personnel to conduct an administrative review of this appeal. The Panel has concluded its work and largely agrees with the findings and actions of the National Institute for Occupational Safety and Health (NIOSH) in this matter. The Assistant Secretary for Health, HHS, requested NIOSH submit additional information on two items where the Panel determined that it did not have adequate information to reach conclusions. NIOSH understands that the information and materials it submits in this response will be included in the information provided for consideration by the Secretary, HHS, and may also be included in the information provided to the petitioners and public once the Secretary reaches a decision. The items addressed by NIOSH are numbered below according to their enumeration in the draft Panel report provided to NIOSH for response.

Item # (6) "Inconsistent Application of Conflict of Interest Requirements"

Petitioners raised concerns about the consistent application of conflict of interest requirements for members of the Advisory Board on Radiation and Worker Health (ABRWH or the Board), specifically questioning the determinations made regarding two ABRWH members, Josie Beach and Mark Griffon. The Panel's report did not find merit with the petitioners' concerns relating to the conflict of interest determination for Ms. Beach and recommended no further action on that issue. The Panel did, however, express concerns regarding the potential of a conflict of interest for Mr. Griffon. The Panel's summary of the discussion regarding Mr. Griffon, states that "a potential conflict of interest and/or an appearance concern may have existed for Mr. Griffon," but the Panel lacked adequate written documentation to conclusively determine "whether there is merit to the issues raised by petitioners" on this point. (See Item # (6), Summary, page 16 of Report). The Assistant Secretary for Health has requested NIOSH provide additional information regarding the conflict of interest determination for Mr. Griffon.

It important first to note that the policy approach taken by NIOSH in identifying and managing conflicts of interest for ABRWH members is to seek to maximize the participation of Board members in Board activities, consistent with applicable conflict of interest requirements. As directed by EEOICPA, the ABRWH reflects a balance of scientific, medical, and worker perspectives with expertise in the health physics and

radiation fields. The narrowness of these particular areas of expertise and the necessary familiarity with the U.S. weapons complex makes the potential for perceived conflicts on the part of Board members, as viewed by lay persons in the public, nearly unavoidable. The Board requires qualified, competent members to accomplish its statutory duties. Nevertheless, NIOSH must ensure, so far as possible, that no actual or perceived conflicts of interest are allowed that would impair the objectivity or credibility of the Board. Accordingly, NIOSH very carefully examines the particulars of the Board members' work experiences, finances, arrangements, and other matters to neither exclude a Board member's contributions unnecessarily nor allow a Board member's participation when a clearly perceived or actual conflict exists.

ABRWH members are Special Government Employees and thus, Government employees for purposes of conflict of interest laws. To assist members in meeting their obligations, HHS requires them to file financial disclosure documents (OGE Form 450) pertaining to their financial interests in the last 12 months, submit a curriculum vitae (CV), and undergo annual ethics training. Upon submission of Board members' information, the Designated Federal Official (DFO) of the Board (this person is also the Executive Secretary of the Board) works with the CDC Federal Advisory Committee Management Office (part of CDC's Management Analysis and Services Office) and the HHS Office of the General Counsel (OGC) Ethics Division to determine if conflicts exist and, if so, whether a waiver under 18 U.S.C § 208(b)(3) is necessary and appropriate to allow the Board member to participate in certain ABRWH activities.[1] These discussions also cover whether any impartiality concerns under the Standards of Ethical Conduct for Employees of the Executive Branch (found at 5 C.F.R. § 2635.502) are at issue. NIOSH strives to maintain a consistent process for developing waivers and discussing potential areas of conflict with Board members. Throughout the process, NIOSH is advised by attorneys in the HHS Office of the General Counsel's Ethics Division, who review waivers for legal sufficiency.

The Panel's concerns and findings related to the waiver for Mr. Griffon do not reflect the care and thoroughness of this process as applied to all Board members and especially Mr. Griffon in this instance. There are two likely reasons for this discrepancy.

First, the Panel's expectations for the documentation associated with a waiver differ from actual practice by NIOSH and other CDC organizations. In practice, waivers do not routinely address circumstances that are examined by the agency and found not to represent actual or perceived conflicts. The waivers are practical documents intended to guide the Agency in governing the allowable participation and prohibitions from participation of the individual. The waivers are generally limited to addressing conflicts or perceived conflicts that appear to meet the threshold of 18 U.S.C. § 208. Where appropriate, these waivers may also address impartiality concerns under 5 C.F.R. § 2635.502. and, sometimes, 5 C.F.R. § 2635.502. Where the officials responsible for

[1] For the sake of brevity, this collective group of Departmental and Agency officials is sometimes referred to as the "conflict of interest officials" in this document. This shorthand is merely intended to indicate those persons (including a representative from the Office of the General Counsel Ethics Division) who are charged with signing the waivers granted to Board members.

making the conflict of interest determination do not determine a potential conflict to be at hand, that information would not necessarily be included in the waiver.

Second, the Panel is only briefly acquainted with conflict of interest considerations applied to this particular Board, whereas this is daily work on the part of NIOSH and its participating colleagues in OGC and CDC. NIOSH believes the Panel members would be likely to agree with the conflict of interest determinations made by NIOSH, given similar experience and context.

To thoroughly address NIOSH concerns with the section of the Panel's report concerning the issuance of Mr. Griffon's waiver, NIOSH will offer a paragraph by paragraph discussion of the report (beginning on page 12 of the report):

- The first paragraph concerning Mr. Griffon on page 12 of the report indicates that a waiver was issued for Mr. Griffon on October 6, 2006. This is true; in fact Mr. Griffon had been issued several waivers since his appointment to the ABRWH in March 2002. The October 6, 2006 waiver required Mr. Griffon to affirmatively recuse himself from participation in specific matters including claims submitted by the Steel Workers International Union (USW) at sites where Mr. Griffon was under contract to perform work for USW; specifically: Paducah Gaseous Diffusion Plant, K-25 Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, INEL (Idaho National Engineering Laboratory), and Mound Plant. Although Mr. Griffon has a contractual relationship with USW, his work for the union was and is limited to work at specific sites for medical surveillance. Several of the contracts involved were actually between Mr. Griffon's company (CPS) and the Paper, Allied-Industrial, Chemical and Energy union (PACE), which formed an alliance with the USW in early 2004 and completed a merger with USW in early 2005. Given the nature of the multiple contracts Mr. Griffon had with USW and PACE and the fact that the medical surveillance work performed by CPS did not always concern radiological issues which would be relevant to work under EEOICPA (either for Site Profiles or SECs), a policy determination was made by the necessary conflict of interest officials (the DFO, CDC Committee Management, and OGC Ethics Division) that Mr. Griffon would only be considered conflicted for those sites where he performed radiation-based work for the USW, versus finding Mr. Griffon to be conflicted throughout the DOE complex for any claims involving the USW. A decision made by the responsible official to grant a waiver pursuant to section 208(b)(1) constitutes a determination and sometimes a limited authorization under 5 C.F.R. § 2635.502 that the Government's interest in having an employee participate in a particular matter outweighs any questions concerning an employees impartiality.[2]

  This determination was appropriate due to the combination of considerations presented by Mr. Griffon's potential involvement and most of these considerations are set forth in the waiver document itself. First and foremost, Mr.

[2] 60 Fed. Reg. 47208, 47222 (Sept. 11, 1995).

Griffon was not involved in radiological activities at the other sites where USW had a presence. Thus he lacked any knowledge of the radiological activities at these other sites and therefore his relationship to the outcome of those sites is more attenuated than his ties to the radiological activities that were directly impacted by his consulting activity

Second, the likelihood of any future financial benefit to Mr. Griffon from the USW due to his work on the Board arising in connection with other sites where USW had a presence was speculative at best. To consider Mr. Griffon conflicted with any site with a USW presence or involvement would substantially impede his ability to contribute to the ABRWH. Obviously, this determination required a balancing of issues by Departmental and Agency officials. The officials charged with making the conflict of interest determination viewed the importance of Mr. Griffon's significant potential contributions to the work of the ABRWH to greatly outweigh this remote, speculative concern and exercised their judgment as allowed within the confines of the waiver process.

- Although not a substantive matter, it should be noted that the Panel's report mistakenly indicates that Mr. Griffon's 2006 waiver is incorrect in naming one of the specific sites where Mr. Griffon must recuse himself from participation as "INEL." (See Panel Report, page 12, footnote 7, note within the CV excerpt). This site has had multiple names including Idaho National Engineering Laboratory (INEL), Idaho National Engineering and Environmental Laboratory (INEEL), and others.[3]

- The second paragraph of the Panel's report discussing Mr. Griffon's potential conflicts of interest properly lays out the initial determination of the conflict of interest officials regarding specific party matters at specific sites where Mr. Griffon was contracted to perform work for the USW. This paragraph does not correctly portray the conflict of interest officials' decision-making process. As explained above, this determination was made after an informed discussion and was based on the regulatory criteria, including (but not limited to) the speculative nature of any financial gain for Mr. Griffon if he were allowed to participate in Board deliberations regarding other sites with USW involvement measured against the importance of Mr. Griffon's potential contributions to the Board's deliberation. This discussion was not documented in the waiver because such was not the practice, as discussed above. Based on requests from the Panel, the Panel was informed of these conversations between conflict of interest officials and participants in the discussions, and notes from those discussions were made available to the Panel. It is unclear whether the Panel considered this information. It should be further noted in this regard that NIOSH is unaware of any guidance from the Department or other sources instructing that all discussions regarding conflicts of interest for Federal Advisory Committee Act members be documented in writing.

[3] The list of covered facilities under EEOICPA is publicly available on both the NIOSH Office of Compensation Analysis and Support and Department of Energy EEOICPA websites.

- The Panel indicated "that a potential conflict may have existed for Mr. Griffon if he or his company was concurrently providing consulting services to USW...." The Panel was unable to make a determination regarding the existence of such a conflict based on a lack of written documentation. Accordingly, the Panel urges ethics officials to review this matter, including the policy, to determine whether Mr. Griffon should have been recused from participation in this matter and what the policy on such recusals should be in the future. (See Panel Report, page 13, paragraph 2).

  Based on 5 C.F.R. 2635.502(b)(1)(iv), the Panel's description of the existence of a "covered relationship" between Mr. Griffon and USW is correct. However, as noted above, NIOSH considered this conflict in its review prior to the issuance of the conflict of interest waiver. For the reasons given earlier, the issuance of the waiver simultaneously constituted a limited authorization for Mr. Griffon to participate in certain ABRWH deliberations. After reviewing this matter, NIOSH has determined that this decision was correct. It was and is NIOSH's understanding that Mr. Griffon did continue to perform work for USW (at least at the Mound Plant) during the period of time that the Rocky Flats SEC was under consideration. This issue was fully vetted and addressed by the conflict of interest officials prior to the issuance of any waivers or allowing Mr. Griffon to participate in the Rocky Flats discussions. The proper ethics officials were involved in the determination that Mr. Griffon's conflicts with USW would be site-specific only and it was a wholly proper exercise of agency discretion. NIOSH stands by the decision that was made at the time and intends to continue to follow the same policy. NIOSH does, however, take heed of the Panel's concerns regarding documentation and will work with conflict of interest officials, specifically the OGC Ethics Division, to ensure that this policy is properly recorded.

- The third paragraph in the section of the Panel's Report pertaining to Mr. Griffon raises some concern regarding the use of illustrative rather than or in addition to exhaustive language in the waiver itself. (See Panel Report, page 14, paragraph 1). The language in the waiver is consistent. Both the "illustrative" and the "exhaustive" language cited in the footnotes include the same term, "such as." This word choice was purposeful and is intended to allow for the addition to the Board member's waiver of other sites where a conflict might exist and recusal be deemed necessary during the course of a waiver year. NIOSH may revisit the issue at any point during the year, rather than waiting for the next annual financial disclosure filing. ABRWH members often have new professional responsibilities or opportunities arise during the year (such as, invitations to lecture or sit on other boards, work at other covered facilities, opportunities to serve as expert witnesses in litigation not related to EEOICPA). In order to fully and completely address conflict concerns, NIOSH may reissue a waiver mid-year when new information comes to light. The "such as" language in the memo is intended to allow for this

eventuality. This language should not be read to imply that the waiver is not complete and accurate upon the date of its issuance.

- The third paragraph of the Panel's Report also questions the lack of inclusion of two facilities listed in Mr. Griffon's CV, Hanford and Metropolis Illinois, in his waiver. The Panel appears to assume that if a specific item appearing in Mr. Griffon's CV is not addressed in the waiver then it was not discussed by the conflict of interest officials. This is not the case. By its nature, a CV represents a cumulative listing of all professional work, publications, etc., over the career of the individual. Mr. Griffon's work at both Hanford and Metropolis Illinois occurred in the 1990s, prior to his appointment to the Board and outside of any financial disclosure reporting periods. Furthermore, the nature of Mr. Griffon's work at Hanford was related to training radiation workers to handle hazardous waste and therefore was different in kind from the work examined under EEOICPA. Mr. Griffon's work at Metropolis Illinois involved investigating an incident and would give rise to a conflict if it fell within the appropriate time period and if the facility were a covered facility under the Act.[4] However, Metropolis Illinois is not a facility covered by the Act and therefore Mr. Griffon's work there would not in any case raise a conflict of interest matter for his work on the Board.

- The final paragraph on page 14 of the Panel's Report reiterates the lack of formal documentation of Department officials' consideration of a potential conflict of interest appearance concern under 5 C.F.R. § 2635.502 for Mr. Griffon at Rocky Flats. As stated above, NIOSH and conflict of interest officials did consider this issue. FOIA Exemption (b)(6): Personal Privacy Information It should also be noted that Mr. Griffon has filed numerous OGE 450's since his appointment to the Board in 2002 and the conflict of interest officials at NIOSH routinely review items from previous OGE 450 submissions as well as a Board member's CV during each waiver discussion. These discussions are far-reaching and appropriately consider potential concerns represented in the OGE 450s and CVs of the Board members, including Mr. Griffon.

The Panel could not reach a determination as to whether an appearance of a conflict exists for Mr. Griffon because they did not have all the information necessary to make such a determination. At no point did the Panel actually discuss the issues of concern with Mr. Griffon, nor with any of the conflict of interest officials actually involved in the decision. Furthermore, it is unclear how the Panel considered the additional information and context that was provided to them. The Panel recommends that Department officials look at these issues now and decide (or redecide) the matter. NIOSH again must state that it stands by the original decision as made and notes that these issues were fully considered.

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[4] See Footnote 2, above.

NIOSH notes that attorneys from the Office of the General Counsel's Ethics Division were concurring signatories on all waivers issued for Mr. Griffon.

- The second paragraph on page 15 of the Panel's Report indicates that the Panel was unclear about an email exchange between CDC's Federal Advisory Committee Management Office and Mr. Griffon. Information was provided by NIOSH for the Panel's consideration regarding conversations between Mr. Griffon and conflict of interest officials on this subject. It is unclear how the Panel considered this information. CDC did receive a new OGE 450, as required, from Mr. Griffon on July 25, 2006. Since there were no changes to the financial disclosure information, the Committee Management staff began the process of determining if the previous waiver could be reissued. The email exchange indicates that initial step.

- The final paragraph in the Panel's Report discussing Mr. Griffon's conflict of interest waiver (see pages 15-16) again remarks on the lack of documentation in this case. As previously stated, NIOSH acknowledges and appreciates these concerns and will work with Department officials, specifically the Office of the General Counsel's Ethics Division to consider future improvements. NIOSH must also point out, however, that certain predecisional policy discussions are not required to be formally documented nor are they typically reduced to writing, therefore, NIOSH will continue to exercise its discretion in these matters. As speculated by the Panel in footnote 10, despite the lack of documentation in the waiver, NIOSH and its advisors did indeed make full and proper inquiries, learn that Mr. Griffon did not provide consulting services to Rocky Flats USW, and conclude that this did not result in an appearance problem.

Regarding specific questions raised by the Panel in their Report, NIOSH held a conference call with Mr. Griffon as well as representatives from the CDC Federal Advisory Committee Management Office and the Office of the General Counsel's Ethics Division on January 6, 2009 to once again address these issues and provide the Secretary with a more complete explanation of Mr. Griffon's involvement with the USW. Specifically, Mr. Griffon was asked the following questions which were derived from the Panel's Report:

- Were the consulting fees you and/or CPS received from USW paid by the national union or various local chapters of the union?

  Response: The consulting fees paid to CPS came from the international USW union, with the possible exception of the contract for work at the Mound Plant. The contract for work at Mound predates USW and possibly even the involvement of the PACE union at the site.
- Did you have a single contract with USW that covered multiple sites (if so, which sites?) or did you have several contracts which were specific to particular sites and types of work?

Response: CPS and Mr. Griffon had several contracts covering multiple sites with both PACE and USW (some contracts may have even predated the involvement of PACE, as noted above). To the best of Mr. Griffon's recollection (he did not have time beforehand to study his files), those contracts included a contract from approximately October 1996 – 2005 or 2006 to perform medical surveillance work at Paducah Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, and K-25 Gaseous Diffusion Plant; a contract from approximately 1998 – 2007 to perform medical surveillance work at Idaho National Laboratory (INL, also known as INEL and INEEL); and, a current contract originating in approximately 2002 to perform medical surveillance at the Mound Plant. Mr. Griffon would need additional time to verify and/or expand on this information. Mr. Griffon described his medical surveillance work as consisting of conducting exposure assessments for toxic exposures (this includes both chemical and radiological exposure) for various groups of workers arranged by particular identifiers (e.g., years worked, job titles, etc.). This work did not include analysis of any individual records of workers, only aggregate records of groups of workers. This surveillance was conducted in order to identify and target workers for medical monitoring and intervention, therefore, the focus was not usually on workers ill with cancer, but rather those with various lung problems.

- Please identify all DOE facilities at which you performed work for USW and describe the dates and nature of that work (environmental vs. radiological, etc.).

  Response: See previous response and number six, this is an exhaustive list to the best of Mr. Griffon's recollection at this time.
- Did you ever perform work for USW related to Rocky Flats?

  Response: No
- During the period that the Rocky Flats SEC was under consideration (including the 12 month period prior to that – approximately June 2004-September 2007), did you do any work for Rocky Flats? For USW?

  Response: Mr. Griffon did not do any work for Rocky Flats during this period. He did work for USW during this period under his contract on Mound Plant and he may have also been completing work under the other two contracts referenced above (see number 2, these were originally PACE contracts) at Paducah, Portsmouth, K-25, and Idaho. Mr. Griffon would need additional time to more completely determine his work on these latter contracts during the period.
- Your CV lists Hanford and Metropolis Illinois as facilities where you performed work for USW, please describe the dates and nature of this work.

  Response: The work at Hanford was during the late 1990s (approximately) and involved providing technical assistance for training offered to radiation workers on handling hazardous waste. The work at Metropolis Illinois related to assessing an incident at the facility. It required only 2-3 days of work and occurred in the late 1990's (approximately). It should also be noted that Metropolis Illinois is not a covered facility under EEOICPA.

Item # (8) "Inappropriate Expansion of the Rocky Flats Class of Workers from its Original Submittal as a 'Steelworker' petition to include all Rocky Flats Workers"

Two points of appeal ("Process Basis" #8 and "Scientific Basis" #7) addressed the fact that NIOSH expanded the class that was evaluated to include employees not represented by the Steelworkers (USW). The administrative review panel made no recommendations for further action regarding point of appeal #7. For point of appeal #8, the administrative review panel found that NIOSH substantially complied with the regulatory procedures concerning the provision of justification in the evaluation report for the inclusion of additional groups of employees.. Notwithstanding this finding, the panel recommended that a more detailed explanation of NIOSH's justification should be provided to the Secretary, and that more detailed evidence and explanation in support of similar class expansions should be provided in future evaluation reports.

The following additional details relevant to this issue are offered:

- NIOSH first expanded the class that was initially proposed by the petitioners at the time the petition was determined to have established an adequate basis for evaluation. The petitioners initially proposed inclusion of only union employees who were monitored or worked in positions that were required to be monitored and/or who worked in areas of plutonium exposures. Because NIOSH found that several of the documents included in the petition were relevant to workers outside of this initial proposed class (i.e., workers who may not have worked in areas of plutonium exposures), NIOSH, in consultation with the petitioners, determined that adequate bases had been established for all union represented workers who worked at the site between April 1952 and February 15, 2005.

- The petitioners did not provide specific information concerning which set of employees or jobs were represented by the USW. Rather, the petition included a listing of "some of the job titles under our union contract at Rocky Flats." This listing consisted of a table from the Rocky Flats Plant –Site Description document approved by NIOSH (ORAUT-TKBS-0011-2, Rev 00), that is a partial listing of potential hazards associated with various job descriptions and locations. Further, while the petitioners' "points of appeal" suggested that the union Collective Bargaining Agreement provided sufficient information to disaggregate union worker from other workers in terms of work and exposures, this document was not provided by the petitioners at any point in the process, nor would that document necessarily have been informative with respect to the question of what portions of the workforce were covered by previous unions under earlier agreements. Because there was no practical way to define the specific employees or jobs that had been represented by unions during the 53 years represented by the petition, and because the very documents that provided the basis for evaluating issues

concerning the completeness and adequacy of monitoring records were not limited to union employees, the class was expanded to include nonunion workers. There is no reasonable basis upon which to conclude that management or supervisory employees, who may not have been members of the USW or predecessor unions, would not have been required to enter the work areas of the employees they supervised and thus have an opportunity to be exposed to the same sources of radiation as union members. Therefore, NIOSH found that all employees were similarly or identically exposed, and included this determination in its evaluation report. It was not clear to NIOSH at the time the petition qualified, nor is it clear today, how any of these qualifying bases would exclusively affect employees represented by the USW, and not other employees at the site. Therefore, NIOSH deemed that it would be infeasible and illogical to consider these issues only as they related to union members, and not other similarly affected employees.

- As reflected in the verbatim transcript of the meeting of the Advisory Board on Radiation and Worker Health held at the Four Points by Sheraton, Denver, Colorado, on April 27, 2006 (available at http://www.cdc.gov/niosh/ocas/pdfs/abrwh/tr042706.pdf), NIOSH stated the following:

  p.46, lines 11-23:
  "The original proposed class in the petition was all United Steelworkers of America members employed between April of 1952 and February of 2005. We fairly quickly determined that we couldn't really just limit this -- this class to just union members. It -- it wouldn't be feasible for us to do that, and non-union members, we determined, should also be considered in this petition because they also had potential for the kinds of exposure and the kinds of concerns expressed in the petition. So we expanded that class to include all employees in that time frame."

  This statement is consistent with the justification provided in NIOSH's Evaluation Report and Submission Documents Review.

- It is not clear to NIOSH how expansion of the proposed class to include all site employees selectively disadvantages union members. In fact, NIOSH considered it favorable to the petitioners to expand the class so that any concerns that surfaced in the subsequent deliberations could be considered, whether they were raised by union members or not. Had any of those concerns formed the basis of an eventual addition to the SEC, NIOSH judged that it would be favorable to former Rocky Flats workers to open the class to as many workers as met the class criteria, regardless of union membership.