

**Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health**

**Sixth Meeting of the
Advisory Board on Radiation and Worker Health**

August 14-15, 2002

**Meeting Held at the Hyatt Regency Hotel
Cincinnati, Ohio**

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**National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Executive Summary of the Sixth Meeting
August 14-15, 2002**

The sixth meeting of the Advisory Board on Radiation Worker Health (ABRWH) was held on August 14-15, 2002, in Cincinnati, Ohio. All the members were present, including two new members representing labor who have been approved by the White House but not yet seated. The minutes of the previous meeting were approved with minor edits and are available on the NIOSH Website, as are transcripts of the meetings. The status of action items was reported, as was the imminent award of the dose reconstruction contract.

The **Dose Reconstruction Workgroup** reported on its work the previous day with the NIOSH/OCAS staff to assess what will be involved in the processing of a case. The staff was commended for the thoroughness with which the cases are investigated. Six completed cases of different "efficiency" categories were reviewed, accounting for low and high potentials of internal or external exposure.

The resulting alterations to the Workgroup's recommendations of the last meeting on the independent review panel, case selection, and the workgroup's/panel's scope and protocol, were reported. Most likely, the greatest challenges will be posed by the mid-level exposure cases where data are incomplete. A way will have to be developed to assess the upper limit of exposure for the low exposure cases. The copious documentation of some cases indicates the time required of the Board members, even with an expert reviewer, to do their reviews. (One claim reviewed by the Workgroup exceeded 700 pages.) Levels of review are likely. The site profiles under development are expected to help greatly. A quarterly sampling method was discussed. An audit list and matrix will be maintained to ensure that factors such as dose ranges, geography, gender, etc., are all reviewed.

Discussion of the **SEC Cohort Rule** was the primary focus of the agenda. Comments by Board members and the public were reviewed. Further comments from the public will be provided and incorporated as appropriate. Presentations were heard on the dose reconstruction activities of the Department of Defense's (DOD) Nuclear Test Personnel Review (NTPR) program and the Department of Veteran's Affairs' (DVA) claims adjudication and probability of causation processes.

NTPR: The NTPR confirms the participation and radiation dose to military and DOD civilian personnel (~205,000) who participated in U.S. atmospheric nuclear testing from 1945-1962 and those in the occupation force (~195,000) of Hiroshima and Nagasaki from September 1945 to July 1946. Most inquiries come through the DVA, and most of the balance are direct. The NTPR process was described and is similar to that of OCAS. About ~75% of inquiries are answered within 90 days and some veterans are presumptively qualified. NTPR dose reconstructions are done with "off the shelf" data before an NTPR inquiry, assigning common activities and participation to all unit members. Individual dose reconstructions proceed from

there, customized to the individual.

Challenges encountered by the program include the weaknesses of film badge data; changes in the NTPR program; improved radiation safety processes; and more accurate dose reconstruction. The latter two factors indicated lower doses, which were not welcomed by the public since that reduces the likelihood of a successful claim. The program therefore has elected to use the historic doses, unless later science lowers the dose. An expert review done of 99 NTPR dose reconstructions and of selected cases where veterans requested an NAS review will be reported in April 2003.

DVA adjudication of (statutory listed) disability claims by “atomic veterans” are based on exposure during the occupation of Nagasaki and Hiroshima; participation in atmospheric testing; and occupational exposure. Of 21,135 radiation compensation claims received by Spring 2002, about 2,000 have required a dose reconstruction.

The DVA’s Office of Public Health and Environmental Hazards (OPHEH) provides medical opinions to assist adjudication for some veterans’ claims, particularly those cases of “non-presumptive” conditions. If an outside physician declares a cancer to be radiogenic (e.g., for pulmonary condition claims rather than a cancer), the OPHEH makes the determination. A dose estimate from a “credible source” can be provided by the veteran as an alternative to the service’s estimated dose. An independent expert is consulted if the doses differ by at least one order of magnitude, and the NIH may be asked to name people who could generate a “tie breaker” third dose opinion, when needed. The use of the IREP is also being tested. In the meantime, the OPHEH is re-evaluating the policy of not using current models when they do not benefit the claimant.

Public comment was provided by several individuals and is reported in detail in the minutes. The topics addressed included:

- NIOSH’s need for increased staffing; the need to address how to approach non-SEC cancers; and how to handle conflicts of interest among the small group of contractors qualified to do this review work. Since the contract was still in negotiation, NIOSH could not be specific, but the Board was reassured that the latter will be addressed. The dose reconstruction report will include the name of the person who performed the dose reconstruction and the reviewer. However, the report is a NIOSH product and only NIOSH is accountable for the result.
- Comment that the amount of time necessary to form an SEC is “ridiculous” at 180 days plus 200 days for congressional action. Many are already sick and people are upset with such delays. Uniform doses for workers were not favored since exposures could differ between people even in the same room.
- DOE’s health and safety professionals’ standards had suffered lapses, due to the failure of DOE to follow up on reported violations and due to pressure. Some records were sanitized even before DOE received them. Those ethical lapses caused DOE worker injuries and illnesses, but have never been questioned, and their reports bear on claim determination. One person stated that all the Oak Ridge data should be suspect. These comments were

supported by another report of health physicists, industrial hygienists, and health and safety staff. Reports were “cleaned up” before DOE even saw them.

- The workers are very wary of the OCAS program; word of mouth in the field is very negative.
- The Oak Ridge union did a risk mapping of the site using the medical surveillance information, which could provide a lot of information.
- Complexity of records access: some may be obtainable only from the surveillance study projects and not from DOE; and some principal investigators have assured workers that their data will not be shared. NIOSH reported work with several such PIs and others to gather construction workers’ work history data from 5 sites’ different programs.
- Concern about equity issues related to the difference between the Rulemaking/guidelines for the original cohort groups and subsequent SECs.
- Concern about records retention, especially at sites scheduled for closure. NIOSH agreed, and reported a continued DOE moratorium on destruction of the ~27 records systems defined as suitable for epidemiological studies of exposure associated with health outcome. Closed sites’ records must be properly stored and traceable.
- The Board was urged to strive to “do the right thing right the first time, and for the right reasons.” If additional time is needed to complete the framework for the process, it should be taken.

Discussion of comments on the SEC rule included recommendations to alter the text to allow for the following: 1) state that NIOSH will be diligent in identifying/assisting claimants who may qualify for a new class; 2) state that the SEC process cannot be used as a route of appeal for a denied claim; 3) add a maximum time period to complete the work; 4) clarify that NIOSH cannot/will not submit the petition itself; 5) clarify that NIOSH is involved early in these processes, not the ABRWH; and that NIOSH will present the petitions for the Board’s evaluation, along with its own evaluation plans; 6) clarify that the Board is advisory, not adjudicatory; and 7) specify that “other procedures” adopted in the future must not conflict with those already established in the Rule.

Other comments throughout the meeting addressed the need for more emphasis on the group petitioning process for SEC status than on individual dose reconstructions; the need for guidelines for determining when an adequate dose reconstruction cannot be completed; simplification of the petitioning process to encourage more applications and to streamline the claims process; and the establishment of a time limit in which to complete individual dose reconstructions. If not done in that time and the claimant meets the other criteria, the claim should be awarded.

The Board’s conclusions were to:

- Emphasize to the public that the options are balanced between petitioning as a group or individually and, either way, specify how NIOSH can help that along.
 - Recommendation: Reformat the preamble with descriptive information for each section and add language stating, for example, that “NIOSH should emphasize the group petitioning process (as opposed to individual petitions) and explain/describe the possible

types of groups that might consider petitioning (e.g., groups of workers with undocumented exposures at a facility.) Perhaps change “as opposed to” to “vis a vis” or something similar to balance the two types of petitions.

- A definition of “sufficient accuracy” was felt to be needed, in the absence of quantitative criteria, to ensure program consistency, the fairness of this process and its assessment by any appeal judge, and to enable the Board’s review. The premise for an SEC is that NIOSH does *not* have all the information, thus preventing a dose reconstruction. The line of demarcation needs to be clarified between when NIOSH can calculate a dose for a potential class to compare that to the level of endangerment, but cannot do so for an individual through a dose reconstruction. NIOSH reassured the Board that all possible source terms relevant to a claim will be explored (another area in which the site profiles will help.) Recommendations were as follow:
 - ▶ To ensure a fair and consistent resolution of individual claims the Board recommended adding wording to Section E’s definition of “insufficient information” (e.g., “incomplete information on source, processes, practices, or source terms.”)
 - ▶ Clarify that there is no barrier to an individual in a class in applying for other compensation. DOL will send to NIOSH any claim for a non-SEC cancer.
 - ▶ NIOSH, with the Board, needs to determine if “class” doses could be added to an individual dose reconstruction to determine PC for non-SEC list cancers. As now written, the regulation does not appear to allow the inclusion of a “class” upper-bounded dose with an individual dose reconstructed from outside the class definition.
- “Endangered health” may be better measured qualitatively; for example, simply by presence in an area where the risk to one worker can be extended to the whole cohort, reasonably bounding the un-reconstructable dose for those likely exposed. The problem pointed out was that putting even a “flimsy” number into the elegant IREP model not only results in accounting for uncertainty, but also implies some degree of accuracy.

In a related vein, the Board unanimously agreed to **write the Secretary a letter urging completion of the MOU as soon as possible**, to ensure that complete exposure records will be readily available to enable the dose reconstructions to be done in a timely and fair fashion.

Town Hall Meeting Comments on the Rule

The comments received at the OCAS town hall meetings held in Buffalo, NY, Cincinnati, OH, Hanford, WA, and Española, NM, were summarized. Attendance ranged from <20 at the early meetings to ~350 at Hanford. Questions voiced included why they were not included in Congress’ cohort; why cancer is the only covered illness; why all toxic exposures and employees of atomic weapons employers during periods of residual contamination are not covered; how long a dose reconstruction (or determining it cannot be done) will take, how long to get contractor support for dose reconstructions, and how long to decide the outcome of a petition. Concern was expressed about all delays. Other inquiries addressed the definition and size of a class, if members of a class can opt out, if a claim can be withdrawn in order to submit a petition and why a claimant has to petition if a NIOSH dose reconstruction cannot be done; and how NIOSH will reconstruct the doses.

In response to Board inquiry, NIOSH reported that the six-month progress report of the residual contamination study was in interdepartmental clearance and would shortly be sent to the Hill.

The **framework for Board review of dose reconstructions** was refined at this meeting. Among the changes were:

- The dose reconstruction reviews will be basic (review of the records NIOSH used), comprehensive (review of the entire administrative record, consistency check), and perhaps a “blind” category in which the review will proceed from the raw case file data, blind to the NIOSH analysis determination.
- Two or three teams of one independent expert and two Board members will do the reviews. The expert will do much of the work and report to the team, which will report back to the Board or refer the case back to the expert for further work.
- The Board does not approve dose reconstructions; this is a quality control check. If a systemic issue is indicated that the Board recommends be changed, NIOSH and DOL will review and decide how to address that.
- Sampling would be done using NIOSH’s efficiency process categories and by time period and diversity.

Discussion included the following:

- It is hoped that gender, race, ethnic issues, etc. will be addressed through the site selection process. Clarification was suggested that language deleted about claims awarded, claims denied, or doses not reconstructable also should be captured through the NIOSH efficiency strata. The Workgroup’s criteria addresses the individual level.
- Weighting schemes suggested included categories of compensation or denial, but most heavily weighting the middle category.
- An added sentence was suggested that these selection criteria can be changed if a different mix is desired.
- To reinforce credibility, ensure that the contractor has a list of expert site workers who can help assemble the site profiles. These will be most important in the beginning of the process, since the profiles are still sketchy. Also suggested was placing the present profiles on the Web site for individuals to comment on and perhaps add information not in the official record. The diverse data sources to be used for profile development include the dose reconstruction and claimant interviews, documented accidents, databases developed in recent years of site activity, DOE’s summary reports, and the needs assessments done prior to the work.
- Expansion is underway of four classes of site profile information: characterization of the internal and external monitoring programs, medical radiation monitoring program and the environmental monitoring program. Later, site histories of processes, air sampling, environmental survey data, etc., will supplement claim information.

Further **discussion of the SEC Rule** included the following:

- *Endangered health*. The determination of “endangered health” currently relies on the estimate of potential dose. Comments included:
 - ▶ The statute’s definition is sufficient and could be operationalized according to duration of

- exposure and monitoring status.
- ▶ Those who believe in linear effects will say that any exposure is a danger to health.
 - ▶ Tie the definition to new information about an exposure event that could cause the new dose to be added to the IREP analysis done for an incomplete dose reconstruction.
 - ▶ Specify situations where the dose reconstruction cannot be done with sufficient accuracy and the person worked in a facility for one year in an area where they were or should have been monitored, and define “monitored.”
 - ▶ Any specification of time or any parameter will infer that there is a point of endangerment, but using a time frame has the advantage of being understandable, transparent, and easily applied. Although it may be counterintuitive, it is reasonable and parallels the 250 days specified in the legislation. However, some class members might not meet the 250-day cutoff.
 - ▶ Recommendation: NIOSH needs to clearly define for the Board’s review how the dose reconstruction is done, the criteria governing when it cannot be done (using the regulation’s language), state in the preamble that such guidelines exist, and explain how this applies in different situations.
 - ▶ Recommendation: The Board will explain in a letter to the Secretary its concerns about NIOSH’s definition/approach to “health endangerment,” and perhaps suggest alternative approaches (e.g., time period), referencing the definitions used in the statute.
- *“Proving the negative” when no records confirmation is received.* Recommendations were:
 - ▶ Rule language should be included that a demonstrated good faith effort to get records will suffice.
 - ▶ Re-emphasize the original DOE memo about records retention.
 - ▶ Specify concern that classes of employees not be defined in such a way as to preclude non-SEC listed cancers. NIOSH will look through the Rule to see where that applies.

The Board agreed to hold a conference call soon to approve the revised language.

The advantages/disadvantages of using an Interim Final Rule were discussed. This would allow moderate changes to be effected more easily than with the formal process to change a Final Rule. However, the Board’s recommended operational guidelines could handle most changes. The stated disadvantages included potential public perception that an interim Rule means the system is not yet ready and may affect how the claims are handled, and that the Secretary may choose not to designate any SEC until there is a Final Rule. Upon a close vote (5-4 against), the Board decided not to include consideration of an Interim Final Rule in the recommendation to the Secretary.

In closing comments, public concern about the adequacy of NIOSH’s staffing to handle their workload was reported, to the Board’s general agreement. An action item was made to ensure OCAS’ staff sufficiency after the contractor is in place. The next meeting agenda should include an update on the contract’s award and how it will be handled (including issues regarding conflict of interest); the status of the claims process; and the status of staff to handle this in the future. The next meeting will be held on October 15-16 in Santa Fe, NM.

**Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health**

**Records of the Sixth Meeting
August 14-15, 2002**

August 14, 2002

The sixth meeting of the **Advisory Board on Radiation and Worker Health** (ABRWH, or the Board) was held at the Hyatt Regency Hotel in Cincinnati, Ohio, on August 14-15, 2002. A court reporter transcribed the deliberations of the Board and a complete transcript is available on the Internet, along with the meeting minutes. The meeting was convened by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the Board. The administration is carried out by NIOSH's Office of Compensation Analysis and Support (OCAS).

All of the Board members were present:

Paul L. Ziemer, Ph.D., Chair

Larry J. Elliott, M.S.P.H., C.I.H., Executive
Secretary

Henry A. Anderson M.D.

Antonio Andrade, Ph.D.

Roy L. DeHart M.D., M.P.H.

Richard L. Espinosa

Sally L. Gadola, M.S., R.N., C.O.H.N.-S.

Mark A. Griffon

James M. Melius, M.D. Dr.P.H.

Wanda I. Munn

Robert W. Presley

Genevieve S. Roessler, Ph.D.

Federal agency representatives present were:

Department of Defense (DOD), Defense Threat Reduction Agency (DTRA): D. Michael Schaeffer

Department of Energy (DOE): Joe Carson

Department of Health and Human Services (DHHS):

■ Office of General Counsel: Liz Homoki-Titus

■ NIOSH: Larry Elliott, Cori Homer, Ted Katz, Jim Neton

Department of Labor (DOL): Jeffrey L. Kotsch, Rose Toufexis

Department of Veterans Affairs (DVA):

■ Veterans Benefits Administration (VBA): Jerry Steele

■ Veterans Health Administration (VHA): Neil Otchin

Presenters to the Board or members of the public who attended over the course of the meeting were:

Everett Beatty, Sr., Fernald Atomic Trades and Labor Council, Lawrenceburg, IN
Gary F. Benjamin, Fernald II Workers' Settlement Fund
Eula Bingham, University of Cincinnati College of Medicine, Dept. of Environmental Health
E. Julia DeHart, Nashville, TN
Michael Gibson, President, Mound facility local chapter, Paper, Allied-Industrial, Chemical and
Energy Workers International Union (PACE)
Ray Green, Atlanta, GA (court reporter)
Eric H. Kearney, Trustee, Fernald II Workers Settlement Fund, Cincinnati, OH
Bruce D. Lawson, PACE Medical Screening Program, Oliver Springs, TN
Mark Lewis, PACE, Waverly, OH
William McGowan, University of Cincinnati
Richard Miller, Government Accountability Project, Washington, D.C.
Marie Murray, Atlanta, GA (recorder)
Leon Owens, President, Paducah facility local chapter, PACE
Susan Pinney, University of Cincinnati
Herman Potter, PACE, Nashville, TN
MayBeth Potter, RN, Murfreesboro, TN
Louise A. Presley, Clinton, TN
Sam Ray, PACE, Lucasville, OH
Robert G. Tabor, Fernald Atomic Trades and Labor Counsel, Harrison, OH
Jerry Tudor, United Sick Oppressed Laborers (USOL), Coalition for a Healthy Environment
(CHE)

Opening Comments

Chair Dr. Paul Ziemer convened the meeting at 1:02 p.m. He welcomed Mr. Michael Gibson and Mr. Leon Owens, two new ABRWH members who were recently approved by the White House but not yet seated. Mr. Gibson serves as president of the PACE union local at the Mound site; Mr. Owens is president of the PACE union local at Paducah. The agenda of the meeting is attached to this document (Attachment #1).

Review of the minutes of the July meeting produced several minor edits. Dr. Melius **moved to accept the minutes** as edited and Ms. Munn seconded. The motion was **unanimously passed**.

Review of Action Items

Executive Secretary Mr. Larry Elliott drew the members' attention to the Board's chart of action items and their status (Attachment #2), and asked the members to prioritize their information requests. He reported the Memorandum of Understanding as now in negotiation at the Deputy Secretary's level, and the dose reconstruction contract at the "best and final" stage of negotiation. It will be awarded shortly.

Dose Reconstruction Workgroup Report

Mr. Mark Griffon reported on the meeting of the Dose Reconstruction Workgroup on the previous day and this morning, to assess what is involved in the processing of a claim. Dr. Jim Neton and the staff of NIOSH's Office of Compensation Analysis and Support (OCAS)

reviewed the entire process, from receipt of the package from the Department of Labor (DOL) through the database entries. The workgroup thanked them, particularly for demonstrating the thoroughness with which the cases are investigated. The workgroup heard an actual interview conducted and commended the manner in which it was done.

Six completed claims of different “efficiency” categories were reviewed, accounting for low and high potentials of internal or external exposure. In some cases, the low dose claims are given more attention; the high doses are often clear enough to not require much more detail. The workgroup commended the small NIOSH staff for the lion’s share of work done in getting the OCAS operation underway. As a result, the workgroup fine-tuned its recommendations of the last meeting regarding the independent review panel, case selection, and the workgroup’s/panel’s scope and protocol. Their discussions included:

- Criteria for the independent review panel experts will probably use the language of the request for proposal (RFP).
- Selection of cases for review will probably be stratified along NIOSH’s efficiency process, which groups them according to complexity, to suggest categories from which cases will be selected. Geography, chronology and gender will also be considered.
- Agreement to the need to develop a sense of the number of cases to be reviewed, and the expected length of the review process. Each panel will have one independent reviewer and two Board members.
- Scope: The issues of scope include the depth of the review to ensure that NIOSH had adequate data with which to determine causation, and how to review the “completeness” of the data, including how to define an end to that process. Since the subcontractor will conduct the dose reconstructions and NIOSH will review them, errors in math are less likely. But this review can add value by ensuring, for example, the consistency of the data within the interviews conducted, the claimants’ allegations, site profiles, etc.; and ensuring consistency/fairness between coworkers (i.e., dose reconstructions done for claims without much supporting information sent to NIOSH should not be less successful than those that do).

Discussion included:

- The challenge will be in the mid-level exposure cases where data are incomplete. A way will have to be developed to assess the upper limit of exposure for the low exposure cases lacking adequate data. The cases reviewed by the workgroup indicated the benefit of using the efficiency process.
- One case included >700 pages of records and occupied a full week of one staff person’s time. The reconstructed dose wound up being considerably higher than the dose of record. This infers some time required of the Board members, even with an expert reviewer, to review the hundreds of records of the ~8000 cases received by OCAS thus far.
- The inventory of site profiles will take time to build, but could help the low-dose cases. The latter’s challenges in particular, with incomplete records, involve avoiding a false negative, which relates to reviewing the consistencies across factors.
- One sampling method discussed was to do this quarterly, while maintaining a matrix to make sure the dose range, geography, etc., is covered. An audit list will be needed, which

- will also help estimate the Board's needed time commitment.
- To avoid a breakdown of the system, levels of review are likely; for example, checking that all documents listed were reviewed and not missed, reviewing the inevitable subjective judgements, and ensuring that issues raised by the claimant are addressed in the dose reconstruction and examining how those are resolved.

The workgroup agreed to further refine the framework of the review process on that evening for presentation and further discussion on the following day.

SEC Cohort Discussion

A document was distributed of the comments submitted on the proposed Rule 42 CFR Part 83, "Procedures for Designating Classes of Employees as Members of the SEC." A letter will be drafted to the Assistant Secretary to report on the Board's work to date and to transmit attached comments on the Rule. Discussion of the input gathered in the OCAS' public meetings included:

- Further comments from the public will be provided and incorporated as appropriate, but their representativeness cannot be assessed until the minutes of the public meetings are complete. No requests for extension of the comment period have been received. The transcripts will be added to the regulatory docket, and be available at all relevant public meetings.
- Other sites (Oak Ridge, Denver) requested a town hall meeting, but this could not be done due to NIOSH's tight schedule. That interest supports the Board's wish to meet at places near the sites.
- Comments from the meetings have indicated the need for clarification, of several items such as:
 - ▶ Suppose a person in a class is eligible for compensation for non-SEC illnesses through the normal dose reconstruction process. Clarify that having monitoring records to support dose reconstruction for other periods of work history does not preclude filing a claim and having a dose reconstruction, nor should it exclude an individual as a member of a class.
 - ▶ The definitions of "ill effects" and "endangered health" needs clarification (i.e., an individual dose reconstruction cannot be done but a worst case estimate can be used by the IREP to generate a quantitative estimate of general health.)
- In defining the potential class, for example, a 48% probability of causation (PC) negates the class. But in addition, the class dose cannot be applied to workers who worked 10 years before or after and who do not have that type of cancer, because the class dose is not an individual dose. This conundrum is part of the OCAS research that would go into evaluating the petition to produce a recommendation on how to handle that situation.
- Dr. Melius brought the discussion back to the issue of criteria pertaining to: 1) when a sufficiently accurate dose reconstruction cannot be done; 2) the endangerment issue; and 3) non-SEC cancer claims in which exposures incurred during the designated SEC time period might be added to exposures outside of the SEC period. Doing this process on a case-by-case basis risks arbitrary and unfair decisions.

The SEC Workgroup (Dr. Andrade, Ms. Munn, Ms. Gadola, Dr. Anderson and Dr. Ziemer) agreed to meet that evening to review the comments on the Rule.

Dose Reconstruction - Atomic Veterans

Mr. Michael Schaeffer, a senior health physicist with the Defense Threat Reduction Agency (DTRA), Department of Defense (DOD), outlined the Nuclear Test Personnel Review (NTPR) program. There are >50 DTRA offices nationally. The NTPR confirms the participation and radiation dose to the 205,000 military and DOD civilian personnel who participated in U.S. atmospheric nuclear testing from 1945-1962 and the 195,000-strong occupation force of Hiroshima and Nagasaki from September 1945 to July 1946. The program is governed by 13 public laws, most importantly Public Law 98-542, enacted in October 1984, which requires dose reconstruction standards for atomic veterans. The dose reconstruction requirements originating from 98-542 include the Department of Justice's (DOJ) 28 CFR 79, under the Radiation Exposure Compensation Act (RECA); the Department of Veterans Affairs' (DVA) 38 CFR 3; and the DOD's 32 CFR 218, which provides guidance for determining and reporting nuclear radiation doses for DOD veterans exposed to atmospheric testing.

The NTPR's tasks are: 1) veteran outreach, 2) providing participation verification and dose information; and 3) providing information to agencies performing health effects studies (e.g., the National Academy of Sciences study of a 40,000-person cohort of the Navy's Operation Crossroads.)

There are four ways that veterans can make contact with the NTPR program. They can file a claim with the DVA or with DOJ, they can reach us through their Congressional representative, or they can contact us directly via our 1-800 hotline number. DVA inquiries account for 60% of activity, and most of the rest comes from calls or write-ins. With the information from two separate contractors that do archival research and dose research, the response is sent and databased. This information can enlighten later inquiries from veterans with similar experience.

The process, which was described and is similar to that of OCAS, generally takes 90-120 days, but can take as long as six months, depending upon the complexity of the claim. The goal is to resolve 75% of claims within 90 days, and they are achieving that. Also similar to the SEC, some veterans are presumptively qualified. The dose reconstruction baseline was developed from contemporaneous activity and radiological data: 1) personnel identification, activity, location; 2) unit identification, activity, location; 3) weather; terrain; 4) fallout intensity and duration; 5) field radiation surveys; 6) shot-specific radiochemical data (fission elements and transuranics); 7) personnel exposure data; and 8) post-test site project report identification.

The exposure scenarios range from exposure to neutron and gamma radiation at the time of detonation, or delayed exposure from neutron-induced radioactivity near Ground Zero and radioactive fallout on the surface and in the air. No test participants were closer than 2000 feet; a few (~1000) were at 2000-10,000 feet; and ~25% (50,000 of the cohort) were up to 6 miles away. The balance of participants were even further away and thus were exposed to delayed sources of radiation.

The NTPR's group dose reconstructions were generally done before the NTPR inquiry with "off the shelf" data. They assigned the same activities to all unit members and assumed full participation in unit activities. The individual dose reconstructions, done upon NTPR inquiry, are based on the veteran's activities and anecdotal information, and assigned personal participation time. The process was outlined for the Board in some detail. It involves constructing tentative scenarios with historical data, identifying and resolving gaps and inconsistencies, constructing final activity scenarios (applying health physics data to archived data and applying time/motion analyses to troop movements), identifying and quantifying uncertainties, and finally, reporting the dose.

Similar detail was provided on the calculation of internal dose, using data on radiological conditions and urine bioassays to confirm badge data, checking pathway assumptions, and doing pathway analyses. The reporting requirements of 32 CFR 218 were outlined. Doses are provided as reported by the DVA and the veteran. The veteran does not need to report a dose as a condition of filing an inquiry.

Challenges encountered by the program over the years are related to:

- Film badge data, necessary to mirror the values in the archival records. The weaknesses include variable use until 1956, film damage [in which case a dose reconstruction is done], and badge measurement of only external gamma doses.
- Records reflect that improved radiation safety processes lowered the limits over the course of testing. Personnel and extensive monitoring data are used to report doses regardless of the practices or limits of the time.
- Better science and dosimetry from dose reconstruction seem to conflict with public policy directions. The refined dose conversion factors produced after the NTPR was established indicated that the doses should be lowered. The 1990 NAS report provided bases for badge accuracy and uncertainty (.7), but that led to public perception that the NTPR lowered the doses, which reduced the possibility of successful claim outcomes.
- Ultimately, the outcomes of early program redirection, which fostered a lack of public credibility, the public's perception that science has failed to help in obtaining compensation, and greater emphasis by Congress to implement compensation schemes not based on science, led to a program decision elected to use the historic doses. However, if later science lowered the dose, they use it on a case-by-case basis.
- Sporadic oversight of the program has been provided over time by the NAS (independently and as directed by Congress) and by the GAO. Both found the program's doses to be accurate enough to support the intended compensation, but asked that an independent review process be established. DVA compensation regulations provide the benefit of the doubt to the veteran and consider high-end doses. The NTPR credibility estimates use the mean and upper-bound (95%) doses, and use the high-end dose alone if best-available data is provided. The goal is to err in favor of overestimating, rather than underestimating, veteran doses.
- The program's policy is that, if a worst case dose is still not high enough to be compensable, the investigation is dropped; but if the dose is very high and compensability is clear, the question is whether to do the extra work to generate an accurate radiation dose. But if that is

the main content of the program, Dr. Schaeffer suspected that doing the epidemiology will be difficult or impossible. He advised the Board that they may need to sacrifice accuracy for efficiency.

- Major issues identified by the NAS committee included whether the doses were right or fair. Recommendations were given on a permanent system of review. An expert review done was based on a sample of 99 of the NTPR's dose reconstructions and of selected cases where veterans requested an NAS review of DTRA files. The results are to be released in April 2003.
- The DVA compensation process is independent of the DTRA dose reconstruction; basically, it's an interface without interaction.

Discussion included:

- The NAS review panel's methodology and scope of work, protocols/procedures, etc. have not been released. Congress has asked them to do so.
- The NTPR has not yet processed a claim in which they were unable to assign a dose. The special cohorts are formed according to congressionally mandated compensation for certain classes of diseases or other special categories.

DVA Adjudication of Claims by Atomic Veterans

Mr. Jerry Steele, of the Veterans Benefits Administration (VBA), the component of the DVA responsible for disability compensation, outlined the legal background and process used to compensate a radiation-exposed veteran or a survivor. The categories of exposure are: 1) participation in the military occupation of Nagasaki and Hiroshima prior to July 1, 1946; 2) participation in atmospheric testing of nuclear weapons; and 3) occupational exposure, such as to x-ray or incurred by nuclear weapons technicians or nuclear propulsion staff. Service records without a detailed dose are referred to the service's dosimetry section.

For those cases without presumed causation, DVA first determines that a specific disability is claimed and that it was not previously present, if not listed under Sec. 3.308 or 3.311 (b). If it is listed, DVA regional offices obtain the medical evidence of the claimed condition and verify from the DTRA the claimant's participation in a radiation-risk activity from Hiroshima and Nagasaki exposure. As of Spring 2002, a total of 21,135 radiation compensation claims were received and 2582 were granted under a service connection. An additional 515 fell under PL 100-321; of those, 333 were based on atomic testing and 182 were based on participation in the occupation of Japan.

Determining PC for Atomic Veterans

Dr. Neil Otchin, of DVA's Office of Public Health and Environmental Hazards (OPHEH), part of the Veterans Health Administration (VHA), reported how they establish the probability of causation (PC) for compensation claims. Upon request by the VBA, the OPHEH provides medical opinions to assist adjudication for some veterans' claims. The DVA provides enhanced health care to veterans who participated in radiation-risk activities: ~195,000 veterans who occupied Hiroshima and Nagasaki, some former POWs with a similar likelihood of exposure to radiation, ~210,000 veterans who participated in atmospheric nuclear weapons tests, some

veterans stationed at DOE facilities, and veterans who participated in Alaskan underground tests.

A list of “presumptive” and “non-presumptive” diseases was provided. Adjudication of “non-presumptive” cases requires a medical opinion on the PC of radiation for the claimed condition. If the veteran disagrees with the service’s estimated dose, s/he can submit an alternate dose estimate from a “credible source.” In the absence of monitoring data, the case is referred to an independent expert if the estimated doses (DTRA, service, other) differ by an order of magnitude. The DVA uses CIRRPC screening dose tables at the 99th percentile to assist in formulating their medical opinions. Other factors also considered include tissue sensitivity, gender, family history, age at exposure, etc. The use of the IREP is also being tested.

Discussion included:

- Few outside consultants unfamiliar with DOD could generate an alternate dose, and the cost also eliminates many veterans from doing so. Dr. Otchin has discussed asking the NIH to provide the names of people who could generate a “tie breaker” third dose opinion when needed, to provide veterans with another option.
- The health physics experts consulted by DVA for dose development assistance are often themselves former military and are familiar with the site in question.
- Outside physicians could conceivably declare cancers to be radiogenic, as allowed by the amended Section 311. For example, a claim for a pulmonary condition rather than a cancer would be sent to Dr. Otchin for a determination.
- OPHEH is re-evaluating the policy of not using current models when they do not benefit the claimant, particularly looking toward the time when the IREP values have been formally reviewed by the NIH committee.

Public Comment

Mr. Richard Miller, of the Government Accountability Project (GAP) raised three topics.

1. He raised again his concern about the potential conflict of interest among the relatively small group of contractors qualified to do dose reconstructions. GAP encourages the Board to provide guidance to NIOSH on this. GAP also encourages the Board to discuss with NIOSH what constitutes an appropriate level of disclosure to the claimant about the individuals performing the dose reconstructions.
2. He noted that the Senate Appropriations Committee commended NIOSH for its work on this program, and that the Committee encouraged the CDC to allocate more staff to it.
3. NIOSH has noted the seriousness of creating a class that prevents compensation for a different cancer than those listed under EEOICPA. The Rule needs to address how to approach non-SEC cancers. For example, he asked if any dose received outside the time/space parameters of an SEC could be considered, and could the SEC dose be applied to other claims? He suggested that NIOSH staff should develop a paper on options with which to deal with this for the Board’s or the SEC Workgroup’s review. He noted that such questions will apply whenever any SEC does not cover the entire history of a facility.

Dr. Melius asked that the next meeting agenda include discussion of conflict of interest if the dose reconstruction contract is awarded by then. Dr. Anderson asked if the dose reconstruction

will be anonymous, or if the claimant will know who developed it, to determine for themselves any conflict of interest. Mr. Elliott responded that the dose reconstruction report will include the name of the reviewer and the peer reviewer, but the report is a NIOSH product and only NIOSH is accountable. He assured the Board that conflict of interest is being addressed in the contract negotiations as a key component.

Mr. Joseph Carson was a DOE safety inspector and self-described whistle blower who reviewed the safety of DOE reactors after the Chernobyl event. He stated his concern that DOE was and remains very dependent on support service contractors. He investigated serious accidents at Oak Ridge, none of which ever had any verification of corrective action. That non-response led to staff failure to report events. He became a whistle blower 10 years ago and is still battling DOE. He charged that DOE considers its employees expendable, citing a 1984 fire which contaminated an area that he had cited for safety violations which were not mentioned in the final report. He defined this lack of regard and lapse of safety professionals' standards as a health and safety problem of national scale. They are being investigated, but no one is investigating the lapses in ethics codes and regulation implementation by safety professionals that caused worker injuries and illnesses in the DOE complex. He charged that DOE is attempting to discredit him to take the focus off the real issues.

He stated that the reports of the safety professionals cannot be trusted, and they bear on determination of claims. He challenged DOE and the Board to acknowledge the possibility that the DOE health physicists' and safety professionals' code of ethics has broken down, to investigate the cited fire to check his veracity, to investigate whether DOE's discretionary function has allowed them to suppress damaging information, and to pursue the issues of conflict of interest, including its applicability to professional ethics.

In discussion, he reported that his site's data safety records were erased three times and had to be replaced, another fact not recorded. He cited "midnight negatives," for example, which he described as emissions released at night that could not be seen and that were not kept track of. He questioned the completeness and accuracy of the DOE's records and challenged the Board to determine whether the technicians were subject to a bias to record data at less than reality. In his opinion, all the Oak Ridge data should be suspect.

Ms. Gadola stated that she has also expressed concerns about changing safety records and reporting practices in private industry. She appreciated his comments, noting that the more light that's shed on the whole picture, the sooner we can get more truthful information.

With no further comment, the meeting adjourned at 5:35 p.m. and reconvened on the following morning at 8:32 a.m.

August 15, 2002

Discussion of Comments on the SEC Rule

Dr. Ziemer summarized the comments made on the SEC Rule by himself, Ms. Munn, Ms.

Gadola, Dr. Anderson, and Dr. Andrade.

- §83.1: Insert text that NIOSH will be diligent in identifying/assisting claimants who may qualify for a new class.
- §83.2: Insert as “b” that the SEC process is not to be used as a route of appeal for a denied claim.
- §83.5(c): Add the phrase “during similar time periods” after “at the same DOE or AWE facility.”
- §83.7: Clarify that NIOSH cannot/will not submit the petition itself.
- §83.10: Clarify that NIOSH is involved early in these processes, not the ABRWH; and that NIOSH will present petitions selected for evaluation, together with its evaluation plans, to the Board for review.
- §83.13: Clarify that the Board’s role is advisory, not adjudicatory.
- §83.14: Specify that “other procedures” that might be used in the future must not be in conflict with those already established in the Rule.

Other comments by Dr. Melius were:

- It appears as worded that the petitioner must go through the dose reconstruction process before the group can be formed. Place more emphasis on the group petitioning process for SEC status.
- No parameters are presented for evaluating when data are inadequate to do a dose reconstruction with sufficient accuracy. Develop guidelines for determining when an adequate dose reconstruction cannot be completed and put those guidelines out for public comment.
- The petitioning process places too much burden on applicants to prove that data is inadequate for dose reconstruction. Simplify the process to encourage more applications; this will ultimately streamline the claims process.
- Include a time limit during which individual dose reconstructions are done. If not done in that time and the claimant meets the other criteria, award the claim.

Discussion included:

- Cases of the deceased workers also will require review to put them in a group on behalf of the survivors.
- Emphasize to the public that the options are balanced between petitioning as a group or individually, and either way, specify how NIOSH can help that along.
- “Sufficient accuracy” needs to be quantitatively defined (e.g., if all or a percentage of TLD or film data is available for the class AND bioassay for relevant radionuclides AND data are consistent with knowledge of site processes AND NIOSH could complete the dose reconstruction).
- However, “accuracy” is not the main goal for compensation; these are not epidemiologic studies. A definition of “sufficient” or “insufficient” accuracy is needed to ensure program consistency, the fairness of this process and to allow any appeal judge to assess that, and to enable the Board’s review.
- On the other hand, one cannot prove a negative (i.e., there is no more information). The

Rule already has NIOSH making every effort to work to the benefit of the claimant. It may be impossible to craft language to provide adequate guidelines without unduly burdening the agency and the petitioner. But perhaps examples could be provided of why a dose reconstruction cannot be done (e.g., missing data, no supplementary coworker data that are useful to estimate external dose.)

- The line is not defined between when NIOSH can calculate a dose for a potential class to compare that to the level of endangerment, but cannot do so for an individual through a dose reconstruction.

NIOSH's response was that it first determines the benchmark of the health endangerment dose and asks health physicists if the dose could have reached that mark or higher. The whole DOE experience can be drawn upon to assess that possibility, and the determination is also reviewed by the panel, this Board, the public and others. Even if sites primarily handled one element (e.g., plutonium), NIOSH will explore and identify all possible source terms. The example of the neutron dose was cited; it was not monitored, but if present, could have pushed a group over a 50% PC.

- However, it was pointed out that the premise for this SEC group is that NIOSH does *not* have all the information, which prevents a dose reconstruction. And while the endangerment review of groups will come to this Board, it will not for individual claims. Guidelines are needed on how the different categories will be assigned according to the available or missing information, while maintaining sufficient flexibility to handle circumstances not considered in advance.
- IREP may be another way to handle this problem; it is now in the background.

Dr. Melius also recommended a Board statement that the MOU with DOE must be in place to ensure that exposure records be made readily available to enable the dose reconstructions to be done in a timely and fair fashion. Dr. Ziemer suggested separating this comment from those on the Rulemaking. Ms. Munn **moved that the ABRWH write the Secretary a separate letter urging completion of the MOU as soon as possible.** Dr. DeHart seconded the motion. This was supported in discussion, with added suggestions to specify the “timely availability of complete exposure records”; to note that the records across the DOE complex are of value not only to epidemiologic study but also to compensation, and to reiterate the need to retain them. Mr. Griffon also suggested asking for the timely release of DOE and Atomic Weapons Facility records, to ensure that NIOSH does not have to retrieve them, even though this is already covered in DOE's umbrella responsibility. Ms. Munn agreed to draft the latter with Dr. Melius' help.

Vote: A voice vote **passed the motion unanimously** with no abstentions.

Mr. Griffon offered several more comments and raised several questions on the Rule:

- Clarify that there is no barrier to an individual in a class in applying for other compensation. DOL will send to NIOSH any claim for a non-SEC cancer.
- *Can doses be added to an individual dose reconstruction to determine PC for non-SEC list cancers?* This has not yet been encountered and is not yet answered. One option is to again estimate if a dose could have exceeded a benchmark. NIOSH will need to consider that

- situation, and will need the advice of the Board.
- *Can reconstructable doses outside the class definition be included?* Not exposures outside the time period of the class, the way the regulation is now written. But since all the class members have to have a common exposure to be considered as a class, they could perhaps be included. Perhaps a class definition criterion could be an additional exposure, including periods of adequate as well as inadequate records, with everyone in the class having to meet both criteria.
 - The definition of “endangered health” needs to maintain the intent of the original Act’s language. It may be better measured qualitatively. NIOSH explained that, for example, workers not badged or exposed at too-low levels can be assigned an upper limit of exposure, and the risk to one unknown worker can be extended to the whole cohort. The check for health endangerment would be simply their presence. While the dose cannot be reconstructed, it can be upper-bounded in a reasonable way for those likely exposed.
 - However, it was also noted that unmonitored material does not necessarily endanger health and that the Rule already defines health endangerment.
 - The rejoinder pointed out the problem that the elegant IREP model’s accounting for uncertainty implies some amount of accuracy, even though a “flimsy estimate based on weak data” will be plugged into that.
 - One Board recommendation could be that NIOSH ensure they have not precluded other options. Some situations require flexibility; we should not become too proscriptive.

Town Hall Meeting Comments on the Rule

Mr. Elliott announced that the transcripts of the last two town hall meetings should be on the Web site early the following week. Mr. Katz outlined the comments and questions gathered at the town hall meetings. Common questions were:

- “Why didn’t Congress include us in the cohort; why is the burden of proof higher for us? We worked with same radioactive materials as employees at the GDPs, and our exposures may have been higher than theirs.”
- “Why is cancer the only covered illness related to radioactive materials?”
- “Why aren’t all toxic exposures covered, such as from non-ionizing radiation and chemical exposures?”
- “Why aren’t employees of atomic weapons employers (AWE) who worked during periods of residual contamination covered?”
- “How long will it take to: 1) do a dose reconstruction or 2) to determine it cannot be done, 3) get contractor support for dose reconstructions, and 4) decide the outcome of the petition?” Concern also was expressed about the delay due to the congressional review period, as was anger about duration of all procedures.
- “What is a class, how is it defined, what is its size? Can it be a whole facility?” Many believed that their facility should be added as a class.
- “Can members of a class opt out when the class is added?” (It was explained that other cancers will come to NIOSH anyway.)
- “Can a claimant withdraw a claim before adjudication is final and submit a petition?” (It was explained that the procedures do not preclude claimants, at any point, from doing that.)
- “Why does a claimant have to petition if NIOSH can’t do a dose reconstruction? Why not

- just evaluate a class?” (It was answered that the law requires a petition to start the process.)
- “Why are the SEC procedures so complicated?”
 - “How will NIOSH reconstruct the doses?”

Attendance in Buffalo and in Ohio was under 20, due to little lead time from the published meeting announcement. But there was much better turnout at the meetings in the west. Hanford drew ~350 people and about 50-60 came in Española, NM. In Buffalo, the employees seemed to have even less information than at other sites and a lot of frustration was evident.

Mr. Griffon asked the status of the residual contamination study. Mr. Elliott reported that its six-month progress report was currently in inter-department clearance and would shortly be sent to the Hill.

Dose Reconstruction Workgroup Report

Mr. Griffon reviewed Version 2.0 of the review process framework developed by the Workgroup.

Independent panel: Additions to Version 1.0 noted that two Board members (perhaps on a rotating basis, not the same ones each time) and one expert would comprise a panel team. Three to four subgroups could be meeting concurrently (e.g., with 30 dose reconstructions, a team could have 5 of the 30 to review). The review panel will meet prior to the ABRWH meeting to reduce the travel burden. The independent expert will do the bulk of the work and provide a preliminary reading to the two Board members. The panel will then recommend to the Board for its approval the next day, as well as any particulars the Board should review as well. The team could also remand the case back to the expert for further examination.

Dr. Ziemer emphasized that the Board does not approve the dose reconstructions, per se; this is only a quality control audit. In many cases, the decision will have been made and the compensation paid. But if it appears that there is a systemic issue with the dose reconstructions that the Board recommends NIOSH change, then NIOSH and DOL would review that and decide how to address the issue.

Case selection. Additions to Version 1.0 included that sampling would be done along the strata of NIOSH’s efficiency process categories, as well as by time period and diversity. A sample size of about 2-3% of total claims would be appropriate, and this would also be consistent with the DTRA approach. These could be selected on a quarterly basis by the Workgroup, but the cases will be continually tracked to ensure that a representative sample is achieved.

The Board suggested adding to the “diversity” (gender, race, ethnic issues, etc.) the type of work and the claimant’s level of involvement in it. In response, it was hoped that the site selection would address that, while these criteria address the individual level. Also recommended was the addition of language to clarify that the deleted language concerning claims awarded, claims denied, or doses not reconstructable should be captured through the NIOSH efficiency strata.

Mr. Elliott suggested a weighting other than by the number of claims or by site. For example, 1) considering a category of compensation or denial; with the heaviest weight placed on the middle category; and 2) adding a sentence that these selection criteria can be changed in response to a different mix desired (e.g., “and other criteria that may arise . . . ,” as long as it is not too vague.)

Scope/protocol. Version 2.0 added a protocol on how to conduct the dose reconstruction reviews; basic, comprehensive, and, possibly, a small number in a “blind” review category. The latter would not show the NIOSH determination; NIOSH would provide the administrative record used to calculate individual dose and the panel then would reconstruct the dose and generate the IREP inputs, rather than being provided those up front.

Mr. Griffon explained that the main difference between basic and advanced dose reconstruction reviews is that the latter reviews the entire administrative record while the basic one only reviews the records NIOSH used for the dose reconstruction. The comprehensive review also assesses the consistency of the dose estimate to relevant radiologic information within the NIOSH site profile, and compares case information and assumptions with relevant coworker case information and assumptions for consistency. All reviews are then reported to the Board.

Discussion included compliments to the Workgroup on its product, and the following:

- *A credibility issue involved in the information not included/considered in the review arises in this approach of just a records review. Interviews of site personnel/experts to explore any other missing information could help to ascertain how complete NIOSH’s site profiles are and ensure that all relevant information is considered.* That is a good idea but not practical to implement. This also would necessitate auditing the data gathered, not an appropriate task for the dose reconstruction Workgroup.
- Ways to develop a comfort level about the information used in the site profiles were suggested:
 - ▶ Ensure that NIOSH has the necessary resources to develop them (e.g., with panel experts and staff on each site). However, caution on expanding this activity was advised, as investigative work site audits will complicate/delay the process. It should not be part of the Board’s inherent process. At the least, however, a list of such sources for each site could be made available to the contractor to explore any gaps in information.
 - ▶ Place the material in hand on the Website for individuals to comment and perhaps add information not in the official record. In view of sketchy profiles, the opinion was expressed that this is an important option to consider, as well as other ways to confirm that information within the restraints of resources and time. In the future, when profiles are more complete, that input may be less important.
- Dr. Andrade noted that the site profiles will emerge from: 1) the dose reconstruction and claimant interviews; 2) documented accidents; and 3) development in recent years of incident databases, which include updates or intakes of radioactive material. Such diverse sources of data will have to be recognized in the profiles’ development.
- Dr. Neton followed up on Dr. Andrade’s comments by noting that a site profile is dynamic in nature. The present ones have such basic information as the frequency of the badge exchange, but the more complex cases will require more. Expansion of four classes of site

profile information is underway: characterization of the internal monitoring program, the external monitoring program, the medical radiation monitoring program, and the environmental monitoring program. Although dose reconstructions can be done even with limited site profiles, the site histories of processes, air sampling, environmental survey data, etc., could eventually supplement our claim information. The contractor will devote a group to exclusively address these profiles immediately, since they will aid the individual dose reconstructions.

Public Comment

Mr. Jerry Tudor, of Clinton, TN, is a member of the United Sick Oppressed Laborers (USOL) and the Coalition for a Healthy Environment (CHE.) Mr. Tudor, who suffers from prostate cancer, stated that he met with congressional aides in Oak Ridge on the previous day about this program. He found the amount of time necessary to form an SEC to be “ridiculous” at 180 days plus 200 days for congressional action. Many are already sick and people are upset with such delays. He was disturbed by the comment recorded in the minutes of the July conference call that the majority of claims will be denied, since no dose reconstructions had even been done. He noted that the occupational exposures of different workers at one site are not necessarily comparable, since exposures could differ between people even in the same room. Based on his work at Y-12, he is sure that the records there are inadequate; he stated that a worker’s time was clocked to whatever program had sufficient funds, regardless of what the worker’s actual job duties were.

Mr. Bruce Lawson, of Oliver Springs, TN, is with the PACE Medical Screening program. Mr. Lawson worked at the Oak Ridge K-25 site for more than 30 years, and for the last 9 years of his tenure there he served as the union’s health and safety representative. He stated that he witnessed firsthand what Mr. Carson alluded to regarding the inaccuracy of records. He saw health physicists, industrial hygienists, and health and safety staff rewrite records and redo reports under only minimal pressure from superiors. The staff was under the onus to clean up reports before DOE even saw them. Mr. Lawson now works with the medical screening program, which is often the first point of contact for the EEOICPA program, where they daily hear the comments made at the recent OCAS public meetings. Many claimants’ survivors are virtually illiterate and know little or nothing about their spouse’s work, or even what plant they worked in, and many cannot get their records from the plant, doctors, or hospitals. As an example, a woman subsisting on Social Security requested her records, but was told she would be charged \$300 for them. Since she couldn’t afford the fee, she left without them. The screening program finally persuaded them to provide the records to her at no charge. Others, whose records were reportedly lost, just gave up. The workers are very wary of the program and suspect that far more worthy claimants will not be compensated. The “word at Oak Ridge is if you didn’t work at K-25, you can forget it,” he said. The entire process is the subject of very negative word of mouth. He applauded this Board’s process and encouraged the members to proceed quickly. And, although the Board is bound to consider only radiation, he noted that most workers were exposed to greater hazards from chemicals than from radiation. Finally, he stated that claimants are definitely deserving of compensation, and he urged the Board to not hesitate to push a claim along.

Discussion included:

- *Can the workers in general provide information for missing records?* Not in every case, and the “experts” are the men/women out in the field every day. However, the union did a risk mapping of the site that could provide a lot of information, a project Mr. Griffon was involved in that used the medical surveillance information. The risk mapping included interviews with the workers themselves.
- Records access is complex. One principal investigator, Eula Bingham, of the University of Cincinnati Department of Medicine, acceded to workers requests to not provide their data to DOE, except in de-identified form. This supports the notion that some data can be provided by each of the surveillance projects and not by DOE. DOE owns only the monitoring data used by the investigators, and that is protected from release under the Privacy Act. Mr. Griffon noted that, alongside the union’s sharing with NIOSH some of the institutional history of the processes, DOE’s summary reports and the needs assessments done prior to the work could also add to the site profiles’ development.

Mr. Elliott reported NIOSH’s work with several such principal investigators and, in some specific situations, with the Center for the Protection of Worker Rights to procure construction workers’ work history data from 5 sites’ different programs. Any worker at those study sites can get their individual information back and submit it as part of the claim.

Mr. Robert G. Tabor, of the Fernald site’s Atomic Trades and Labor Council, appreciated the appointment of the new Board members. He supported the comments made on how to address non-SEC cancers. Since Fernald is not a designated site, those workers now have to explore their SEC status. They are concerned about the equity issues inherent in the fact that the Rulemaking/guidelines for the original cohort groups differ from those of any subsequent additions. Related to that are the issues of endangered health raised at this meeting. He asked, and had confirmed, that more than exposure records are collected, and that where one worked in an operation or job function does bear on the dose reconstruction. The latter issue pertains to the records retention, especially those sites scheduled for closure in the near future. He was unsure that DOE had developed good guidelines on what should be done with those records, and hoped that the Board’s letter to the Secretary about the MOU will recommend a reimposition of the records moratorium.

Mr. Elliott stated that the moratorium on destruction of the ~27 records systems (process records, historical practice changes, medical records, etc.) defined as suitable for epidemiological studies of exposure associated with health outcome, is still in place and protected. NIOSH is also concerned, however, about ensuring that the records of closed sites are properly stored and traceable.

Mr. Mark Lewis, of Waverly, OH, is with PACE and coordinates the worker health protection program in Piketon, OH. Mr. Lewis agreed, from personal experience, to the wisdom of using the workers’ expertise and memory to fill in data gaps. He once requested his own onsite records regarding an acute exposure to high grade weapons material, but was told that no records existed.

Discussion of the SEC Rule

Dr. Ziemer noted that the deadline for comments on the Rule is August 26 and summarized those proposed by the Board to this point (see page 9).

Discussion of Dr. Melius' recommendations included the following:

- Reformat the preamble with descriptive information for each section and add language to state, for example, that "NIOSH should emphasize the group petitioning process (as opposed to individual petitions) and explain/describe the possible types of groups that might consider petitioning, such as groups of workers with undocumented exposures at a facility." Dr. Andrade suggested changing "as opposed to" to "vis a vis" or something similar to balance the two types of petitions.
- Add wording to Section E (*Federal Register* page 42963) to define "insufficient information" as "incomplete information on source, processes, practices, or source terms." Specifying more than that (e.g., the availability of one or 7 film badge readings) was thought to be inadvisable. This would allow sufficient flexibility and avoid being overly prescriptive to those doing the work, but still identify for claimants the information desired.

Mr. Griffon's comments were addressed as follows:

- "*Endangered health*" now relies on the estimate of potential dose. Ms. Munn thought the statute's definition to be sufficient. The "reasonable likelihood" that the cancer may be radiation induced can be determined from short-term radiation health effects for other class members, description of shortcomings of radiation protection measures, etc. This could be operationalized, as other cohorts were, based on duration of exposure and monitoring status.
- Opinions differed on whether different criteria than those used for dose reconstruction should be adopted. Mr. Griffon found it illogical to say a dose reconstruction cannot be done if the endangerment is based on the conduct of another "dose reconstruction" of some sort. He posed an example of people who were monitored despite little likelihood that they were exposed and who may be inappropriately incorporated to the cohort. Using the IREP approach will also be counterintuitive to claimants to hear that data are insufficient to do an individual dose reconstruction, but enough for a group estimate that still disqualifies everyone.
- Dr. DeHart noted that those who believe in linear effects will say that any exposure is a danger to health. Mr. Elliott replied that NIOSH included this as a test of reasonableness, to provide the dose necessary to endanger health and achieve parity with those for whom a dose reconstruction could be done.
- Dr. Andrade suggested tying the definition to new information about an exposure event that could cause the new dose to be added to the IREP analysis done for an incomplete dose reconstruction. Such new information could relate to site processes and unexpected exposures, or for an old facility, the poor or absent monitoring or records. But it remains problematic, in the latter case, of using a "wild guess" in the calculation or risking the inclusion of trivial or non-exposure cases, without some arbitrary cutoff.
- One alternative definition, offered by Dr. Melius, could be a situation in which NIOSH cannot do a dose reconstruction with sufficient accuracy and the person worked in a facility for one year in an area where they were or should have been monitored, fleshed out by a

definition of “monitored.”

- Mr. Griffon noted that NIOSH’s definition of “sufficient accuracy” is that they can do an individual dose reconstruction. The low/low internal/external dose cases in the efficiency will be tested against IREP using a worst case scenario, and will drop out at the first hurdle. The question is, should the data left be used to generate a worst case estimate to compare against IREP for the class, or should there be another set of criteria similar to that of the SEC? Would the efficiency process prevent the inequity of including a person with insignificant doses into the class?
- How can the review panels evaluate the appropriateness of NIOSH’s “guesstimate” and ensure that it stays consistent and fair between cases. This is particularly important in dealing with very different situations such as workers in labs versus those in production facilities.
- Richard Miller stated that the one-year threshold of the original cohort was based on the RECA model, which uses a working month to determine compensability (i.e., time/duration in the mines or mills). It was noted that this may be applicable to radon exposure, but not others. Any specification of time or any parameter will infer that there is a point of endangerment.

Dr. Ziemer posed the question of whether NIOSH’s method is reasonable. Concerns expressed included that:

- The current Rule method is counterintuitive, posing a problem to claimants, and the current arbitrary manner of selecting dose poses problems to the applicant and reviewer as to how it is being applied. The advantage of using a time frame is understandable, transparent, and easily applied. Although it may be counterintuitive as well, it is reasonable and parallels the 250 days specified in the legislation. However, are there better ways to do it?
- NIOSH’s response was that some class members might not meet the 250 day cutoff. But clearly a better articulation is needed that the class brought forward for the Board’s review would establish the time frame that would support the test for endangerment of health, and is appropriate for a given situation of a class experience. Perhaps a mockup of a class definition could be provided. And the number used is not arbitrary; rather, IREP will indicate the radionuclide of most concern (from the demographics of the class) and where the 50% PC lies.
- Dr. Melius noted that there are not likely many with exposure <250 days where a dose reconstruction cannot be done adequately to pass this test, although a few false negatives could occur. NIOSH needs to clearly define how the dose reconstruction is done, the criteria governing when it cannot be done, and how this applies in different situations. Without such criteria, this discussion is taking place in a vacuum.
- Suggestions offered were as follow:
 - ▶ *Criteria:* The Board should recommendation that NIOSH develop a set of guidelines for how they will determine when a dose reconstruction cannot be done (using the regulation’s language), present it to the Board for review, and state in the preamble that such guidelines exist.
 - ▶ *Endangerment:* Explain in a letter to the Secretary that Board members have concerns about the definition/approach by NIOSH, and could suggest alternative approaches, one

of which (time period) was discussed. Reference the definitions used in the statute. Dr. Melius agreed to work with Mr. Griffon to draft a letter.

- “*Proving the negative*” when no records confirmation is received. Reported responses vary from site to site. The Rule’s intent was to allow people to take information off the shelf, not that they would hire an expert to do a records search. Language should be included that a demonstrated good faith effort to get records will suffice.
- NIOSH should re-emphasize the original DOE memo about records retention; NIOSH agreed to determine when it was issued and reference it.
- The Board agreed to specify concern that classes of employees not be defined in such a way as to preclude non-SEC listed cancers. NIOSH will look through the Rule to see where that applies. This will be a general comment not applied to a specific section.

The Board agreed to hold a conference call to approve the revised language. The call was to be announced early the following week in the Federal Register.

Use of an Interim Final Rule

The Board discussed whether there would be any advantage to making this an Interim Final Rule, since new information could answer remaining questions as to health endangerment, working with insufficient information, and non-SEC cancer issues. Mr. Katz responded that an interim Rule would allow NIOSH to operate and address petitions and still make moderate changes with another public comment period. But a Final Rule only allows minor technical adjustments to be effected (e.g., inserting a missing decimal point or an agency name change). Any changes must be such that the public can see how they came about, and another Notice of Proposed Rulemaking would have to be issued while the program continued to operate under the existing final Rule.

The Interim Rule seemed useful to some Board members, at least for the early part of the process. This would allow some non-major changes to be made without requiring a new Rulemaking process, while still allowing the work to go forward. But lingering concern was expressed about expending time and work to clearly delineate something that may never be clear. And the Secretary may decide not to make a final class petition decision until there is a Final Rule. The Board has addressed this issue by advising the generation of operational guidelines, which could handle most changes. Also noted was the public perception of an interim Rule, which could infer that the system is not yet ready and may affect how the claims are handled.

Dr. Andrade moved to vote on whether the Rule should go forward with the recommendations sent to the Secretary that were adopted on this day, and addressing the two remaining issues in the guidelines or preamble to go forward. However, since the final wording was not yet decided, he changed his motion and **move to pursue an Interim Final Rule**. Ms. Munn seconded the motion.

Dr. Andrade proposed a stepped process to continue this discussion such that, if the Board finds value added in an Interim Final Rule, the planned teleconference can include discussion of the

final language for the Final Rule to be placed in the preamble or the body itself, perhaps with a clearer definition, and address these last two issues. Dr. Ziemer called for a vote on whether to include consideration of an Interim Final Rule in the recommendation to the Secretary, with a no vote equating to no interim Rule.

Vote: Four members voted in favor and four were opposed the motion. The Chair voted against it and the **motion did not carry**. Dr. Melius agreed to develop wording to be discussed again at the teleconference.

Closing Comments

Dr. Ziemer reported for the record a concern raised by a member of the public in an e-mail to him about whether NIOSH has sufficient staffing to handle their workload. The Board was in general agreement that NIOSH may not be adequately staffed to do its work. Since this may not be an appropriate concern to advance to the Secretary until the contractor is in place, an action item to ensure OCAS' staff sufficiency was made. NIOSH was requested, at the next meeting, to include in the agenda an update on the contract's award, how it will be handled, the status of the claims process, and the status of staff to handle this in future.

The Board agreed to hold the next meeting on October 15-16 in Santa Fe, NM.

A last **Public Comment** was offered by Mr. Tabor. He urged the Board to strive to do the right thing right the first time, and for the right reasons. If the framework for the process is not "clear and clean," and if additional time is required, including for a public comment period, he advised not beginning it until everything is ready.

With no further comment, the meeting adjourned at 4:50 p.m.

I hereby confirm that these Minutes are accurate to the best of my knowledge.

/s/

Paul L. Ziemer, Ph.D., Chair

October 31, 2002

Date

ATTACHMENTS

Attachment #1

Draft Agenda
Advisory Board on Radiation and Worker Health
Hyatt Regency Cincinnati
151 West Fifth Street
Cincinnati, Ohio 45202
(513) 579-1234
August 14-15, 2002

Wednesday - August 14, 2002

| | | |
|------------------------|--|--|
| 12:30 p.m. - 1:00 p.m. | Registration and Welcome | Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary |
| 1:00 p.m. - 1:15 p.m. | Review and Approval of Draft Minutes | Dr. Paul Ziemer, Chair |
| 1:15 p.m. - 1:30 p.m. | Review of Action Items | Mr. Larry Elliott, Executive Secretary |
| 1:30 p.m. - 2:30 p.m. | Dose Reconstruction Workgroup Report | Mr. Mark Griffon, Workgroup Chair |
| 2:30 p.m. - 2:45 p.m. | Break | |
| 2:45 p.m. - 3:30 p.m. | Adjudication of Claims – Atomic Veterans | Mr. Jerry Steele, Department of Veterans Affairs |
| 3:30 p.m. - 4:15 p.m. | Dose Reconstruction - Atomic Veterans | Mr. Michael Schaeffer, Defense Threat Reduction Agency |
| 4:15 p.m. - 5:00 p.m. | Probability of Causation - Determination for Atomic Veterans | Dr. Neil Otchin, Department of Veterans Affairs |
| 5:00 p.m.- 5:30 p.m. | Public Comment Period | |
| 5:30 p.m. | Adjourn | |

Agenda items are subject to change as priorities dictate.

Draft Agenda
Advisory Board on Radiation and Worker Health
Hyatt Regency Cincinnati
151 West Fifth Street
Cincinnati, Ohio 45202
(513) 579-1234
August 14-15, 2002

Thursday - August 15, 2002

| | | |
|-------------------------|---|--|
| 8:00 a.m. - 8:30 a.m. | Registration and Welcome | Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary |
| 8:30 a.m. - 10:00 a.m. | Board Discussion - Special Exposure Cohort NPRM Comments on the Rule | |
| 10:00 a.m. -10:15 a.m. | Break | |
| 10:15 a.m. - 11:45 a.m. | Board Discussion - Process to Review Completed Dose Reconstructions | |
| 11:45 a.m. - 12:00 p.m. | Public Comment Period and/or Board Discussion | |
| 12:00 p.m. - 1:30 p.m. | Lunch | |
| 1:30 p.m. - 2:30 p.m. | Board Discussion - Special Exposure Cohort NPRM Comments on the Rule | |
| 2:30 p.m. - 2:45 p.m. | Break | |
| 2:45 p.m. - 4:00 p.m. | Board Discussion - | |
| 4:00 p.m. - 4:30 p.m. | Administrative Housekeeping and Board Work Schedule | Ms. Cori Homer, NIOSH Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary |
| 4:30 p.m. - 5:00 p.m. | Public Comment Period | |
| 5:00 p.m. | Adjourn | |

Agenda Items are subject to change as priorities dictate.

Attachment #2
NIOSH/ABRWH Action and Topic Items

| Meeting/ Date | NIOSH Action/Topic Item(s) | Status |
|--------------------------|---|--|
| Meeting 2 2/02 | | |
| 1. | Experts to present (action needed by Board members: clarify whom, on what?) | Clarified at 5/02 meeting. COMPLETED |
| 2. | Provide program history/background, particularly as applied to the SEC | Dr. Michaels presented 5/02. COMPLETED |
| 3. | Discuss IREP issues. | 5/02 Dr. Lamb presented; further list developed. COMPLETED |
| Meeting 4 5/02 | | |
| 1. | The next meeting was scheduled for July 1-2, 2002. | Meeting held 7/1-2 /2002 COMPLETED |
| 2. | Add, to the beginning of past minutes and to future minutes, that "A court reporter transcribed the deliberations of the Board and a complete transcript is available on the Internet." | Done as of the May 2002 minutes. ON-GOING |
| 3. | Maintain a "to do" list of meeting topics. | Begun 5/02/2002 ON-GOING |
| 4. | E-mail members of Website documents postings. | Begun 5/02/2002 ON-GOING |
| 5. | Present the state of the art on synergistic effects. | |
| 6. | Provide copies of the technical reviewers' comments. | COMPLETED 6/02 |
| 7. | Provide name/affiliation of commenting responders. | COMPLETED 6/02 |
| 8. | Provide more IREP model details to the Board, including raw data. | SENES presentation 7/02; August work scheduled - ON-GOING |

| Meeting/ Date | NIOSH Action/Topic Item(s) | Status |
|-------------------|--|---|
| Meeting 4 5/02 | | |
| 9. | Present the questions and opinions about, or what else the experts and NCI would like IREP to include | |
| 10. | Overview presentation by the Office of General Counsel (OGC) of what ABRWH can and cannot tell the claimants. | Member's advisement complete at the time of appointment. COMPLETE Board presentation at October meeting. Pending 10/02 |
| 11. | Explain the records request process; will the dose reconstruction contractor have direct access on site? How will the kinds of records that are relevant be decided, and how will they be pursued? | |
| 12. | Address access to information from DOE sites: * If no MOU by next meeting, update status of information needed/received, etc.; the extent work required by NIOSH to get the information available, etc. * When MOU is in place, discuss records missing or unavailable; how far NIOSH should go into the search; how the applicant will be assured that the search was complete. | Reported 8/02 Pending |
| 13. | Describe what criteria determine that information is insufficient to award a claim. | |
| 14. | Identify research gaps and how this Board can help fill them. | |
| 15. | Present the plans to publish this process as well as results such as number of cancers identified. Can results also be analyzed by site or geographic area? | |
| Meeting 5 7/02 | | |
| 1. | Public input meetings on the SEC Rule will be held the week of July 23-25 in Amhurst, New York and in Cincinnati; and during the week of August 5 in Richland, WA and Espanola NM. | COMPLETED AND REPORTED AT 8/13-14 MEETING |

| Meeting/ Date | NIOSH Action/Topic Item(s) | Status |
|-------------------|--|---|
| Meeting 5 7/02 | | |
| 2. | <p>ABRWH Meeting schedules: August: Dose Reconstruction Working Group, in Cincinnati, 8/13-14 (half day); Board: 8/14 (half day) and 15. Agenda: finalization of the SEC rule comments, perhaps input on the oversight of dose reconstructions. Outside speaker: DTRA (VA) on the afternoon of 8/14.</p> <p>October 15-16; alternate date is November 18-19.</p> | <p>Meeting held 8/13-14/2002</p> <p>COMPLETED</p> <p>Meeting scheduled for 10/15-16/2002 Pending</p> |
| 3. | The OGC will look at the SEC rule text regarding public presentations of testimony and evidence to ensure the ABRWH meeting does not turn into a hearing. | |
| Meeting 6 8/15 | | |
| 1. | Next meeting: 10/15-16 in Santa Fe, NM. Agenda should include an update on the contract awarded, how it will be handled (including conflict of interest), status of the claims process, and status of NIOSH staff to handle this in future. | Pending 10/2 meeting |
| 2. | Provide a mockup of a class definition. | |

| Meeting/ Date | ABRWH Action Items | Status |
|-------------------|--|--|
| Meeting 2 2/02 | | |
| 1. | Discuss the statutes/language regarding ABRWH future role; it is vague if not misleading. | Clarification needed for NIOSH |
| Meeting 4 5/02 | | |
| 1. | Comment on the public's perception of the misleading character of the Sense of the Congress statement. | COMPLETED 7/02 |
| 2. | Discuss how ABRWH will review the quality of the dose reconstructions. | Begun at 7/02 meeting ON-GOING |

| Meeting/ Date | ABRWH Action Items | Status |
|-------------------|---|--|
| Meeting 4 5/02 | | |
| 3. | Discuss using as a metric DOE's requirement to provide information within a certain number of days | |
| Meeting 5 7/02 | | |
| 1. | The Dose Reconstruction Working Group will meet in Cincinnati on August 13-14 (half day). They will meet with Dr. Neton and some of his staff, review some case studies, CD ROMs of data, etc., to prepare for the dose reconstruction reviews. | Meetings held 8/13-14/2002 COMPLETED |
| 2. | Ms. Gadola, Dr. Anderson, Ms. Munn, Mr. Presley and Dr. Ziemer comprise the workgroup to formalize the Board's SEC recommendations. | Letter prepared 8/22 and sent to Scty. COMPLETED |