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

Summary Minutes

Twenty-sixth Meeting of the Advisory Board on Radiation and Worker Health

August 24-25, 2004

Meeting Held at the Shilo Inn Suites
Idaho Falls, Idaho

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

Summary Minutes of the Twenty-sixth Meeting
August 24-25, 2004

The Twenty-sixth Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Shilo Inn Suites in Idaho Falls, Idaho on August 24 and 25, 2004. The meeting was called by the Centers for Disease Control and Prevention's (CDC's) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the ABRWH. These summary minutes, as well as a verbatim transcript certified by a court reporter, are available on the internet on the NIOSH/Office of Compensation Analysis and Support (OCAS) web site located at www.cdc.gov/niosh/ocas. Those present included the following:

ABRWH Members: Dr. Paul Ziemer, Chair; Dr. Henry Anderson; Dr. Antonio Andrade; Dr. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson; Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Robert Presley; and Dr. Genevieve Roessler.

Designated Federal Official: Mr. Larry Elliott, Executive Secretary.

Federal Agency Attendees:

Department of Defense: D. Michael Schaeffer

Department of Energy: Mr. Tom Rollow

Department of Health and Human Services: Ms. Lynda Brandal, Mr. Todd Braswell, Ms. Chia Chia Chang, Ms. Heidi Deep, Ms. Chris Ellison, Mr. Russ Henshaw, Ms. Cori Homer, Ms. Liz Homoki-Titus, Ms. Laurie Ishak, Mr. Ted Katz, and Dr. James Neton

Department of Labor: Ms. Diane Case, Mr. Larry Hoss, and Mr. Pete Turcic

Contractors: Dr. John Mauro, Mr. Joe Fitzgerald, Dr. Stephen Ostrow, and Dr. R E Toohey

Public Attendees: See Registration

Executive Summary

The Twenty-sixth Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Shilo Inn Suites in Idaho Falls, Idaho on August 24-25, 2004. All members were in attendance except Mr. Leon Owens. Others in attendance included staff of various Federal agencies, as well as members of the public. The Summary Minutes of Meeting Twenty-five was approved with minor changes.

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Tuesday, August 24, 2004

NIOSH Program Status Report

Mr. Larry Elliott introduced **Ms. Laurie Ishak**, who has joined the National Institute for Occupational Safety and Health (NIOSH) in the Office of Compensation Analysis and Support (OCAS) as a health communications specialist. **Ms. Ishak** offered a statistical update activities with figures through August 13, noting some periods would be incomplete.

The Department of Labor DOL has referred 16,735 cases for dose reconstruction, with 37 percent coming from the Jacksonville, Florida district office. The number of referrals peaked in the fourth quarter of '02 and has stabilized at roughly 800 cases per quarter.

Draft dose reconstruction reports to claimants total 4,588. Final reports to the DOL now total 4,097. NIOSH has made 16,653 requests to the Department of Energy (DOE) for exposure records, and has received 15,985 responses.

There are 16,230 cases for which at least one telephone interview has been conducted by Oak Ridge Associated Universities (ORAU). Draft interview summaries to claimants now total 21,813. NIOSH currently has 5,123 cases staged for dose reconstruction, and 1,466 have been assigned. **Ms. Ishak** also provided statistics and updates on the use of chronological case tracking numbers, administratively closed records, and reworks.

The Special Exposure Cohort (SEC) final rule 42 CFR 83 was published May 28, 2004. There are currently nine petitions being reviewed.

Recent NIOSH accomplishments included having exceeded 4,000 final dose reconsruction (DR) reports to DOL, over 300 physicians appointed to staff the DOE physicians panel, and a change in the conflict of interest policy to include work on site profiles.

Included in the OCAS staffing update was the announcement of **Dr. James Neton**'s move from

Technical Program Manager to Associate Director for Science.

Following her presentation, **Ms. Ishak** took questions from the Board.

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Department of Labor Status Report

The update was presented by **Mr. Pete Turcic**, who reported DOL had received 57,112 claims, with cancer still representing the greatest number. There have been 13,815 recommended decisions to approve and 21,953 recommended decisions to deny award. A total of 11,671 payments have been made representing $874,448,662 paid in compensation and $38,542,768 paid in medical benefits.

There have been 1,179 cases filed from Idaho National Engineering Laboratory (INEEL), with 395 receiving final decisions to deny and 37 receiving final decisions to award benefits. To date 14 payments totaling $2,100,000 have been issued.

DOL has referred 17,182 cases to NIOSH for dose reconstruction. NIOSH has returned 4,597. A total of 764 individuals have received compensation in the amount of $86,927,500 from cases with NIOSH dose reconstructions. In the past 12 months DOL has sent 3,400 cases to NIOSH and they have returned 4,142, a reflection of backlog reduction for which **Mr. Turcic** indicated he felt NIOSH should be complimented.

For the Board's edification, **Mr. Turcic** reviewed the process by which a claimant exercises his right to appeal a decision based on a dose reconstruction. He explained the Final Adjudication Branch allows a claimant the opportunity to pursue a hearing, review of the written record, or waiver of objections. From October '03 to June '04 there have been 420 requests for hearing, with 311 having been conducted. There were 653 requests for a written record review, 567 of which have been conducted. Waiver of objection triggers immediate process of a claim, usually an acceptance, and there have been 2,995 such waivers.

Assertions upon which a hearing or review request is based are generally a result of not understanding how information use is presented in the dose reconstruction report.

As of August 15, there have been 328 NIOSH cases remanded, 75 of which had a recommended decision to approve, with 36 receiving a final decision of approval; 263 had recommended decisions to deny, with 37 receiving a final denial. However two of those received a final decision to approve, 216 are pending final decision and eight cases have been closed or withdrawn.

Mr. Turcic entertained questions from the Board.

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Department of Energy Part D Status Report

Mr. Tom Rollow updated the portion of the program administered by DOE. Subtitle D provides assistance to workers making application for State Workers Compensation. Over 100 physician panel determinations are being produced weekly, with a goal of 300 per week by June.

DOE had underestimated the scope of the program and failed to gather resources necessary to set up and manage it. Congress provided an infusion of resources by reprogramming $9.7 million less than a year ago, with another reprogramming of $23.3 million this past June.

The physician panel rule was changed to allow a single physician to make a positive determination. That change has increased production dramatically. Development of a four-element path forward plan is designed to eliminate the backlog of cases to zero by the end of 2006.

Approximately 190 of the physician panel nominees are actively working. The numbers are climbing and many new appointees are interested in working full time.

DOE does not pay claims and has no control over how they're paid, but they do track the money. As of July 31, 378 applicants had received positive determinations, 87 had applied for Workers Compensation, 31 had received compensation. Local statistics indicate less than 1,000 cases for INEEL. DOE has completed 139, 29 of which were positive determinations. No Worker Comp payments have been issued for INEEL, and as best they can determine, none have applied under EEOICPA.

Mr. Rollow took questions from the Board.

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Privacy Act and FACA Requirements

Ms. Liz Homoki-Titus announced the promotion of Mr. David Naimon to Associate Deputy General Counsel, reminding the Board they could still use the same contact number for legal questions.

With the Board beginning to review individual dose reconstructions and SEC petitions, rules and regulations under the Privacy Act and Federal Advisory Committee Act (FACA) become important. **Ms. Homoki-Titus** first described the Privacy Act, commenting that the Department of Health and Human Services (DHHS) also has its own privacy policy, and explained the civil and criminal penalties for improper disclosure. She cautioned there is no reason for any Board member to

disclose Privacy Act-protected information, and SEC petitions should not be discussed outside the Board meeting. Requests for disclosure of that type information should be directed to OCAS.

Ms. Homoki-Titus described the thinking behind FACA on open meetings, public involvement, and reporting. She explained the functions and limitations of a body formed under FACA such as requirements for charter, presence of a Designated Federal Official (DFO), meetings, and agendas. She cautioned discussion of Board business in casual gatherings where enough members might be present to inadvertently constitute an unannounced meeting.

The Government in the Sunshine Act put forth guidelines for management and control of FACA committees which are followed by DHHS and this Board. Copies could be provided if there were any interest in reviewing them.

EEOICPA directed the establishment of an advisory board and the President established this Board. **Ms. Homoki-Titus** reviewed the Board's duties, reminding them they report to the Secretary of HHS, not the President.

Ms. Homoki-Titus entertained questions from the Board.

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Sanford Cohen & Associates

Access Issues:

Mr. Joe Fitzgerald announced three out of four site profile reviews were near completion. The SC&A approach is sound, but guidance is needed in some problem areas. The Board was briefed on the access issue in April and their letter to Secretaries of DHHS and DOE went out in July.

The attitude SC&A is picking up from DOE sites is they'd spent resources responding to NIOSH requests and before they do more they want assurance SC&A has cross-referenced against what's been provided. SC&A had pushed for months for access to the NIOSH database of recovered files, which was provided last week. The Memorandum of Understanding (MOU) lays out a process to ensure SC&A can ask for records and interactions and have that supported by resources set aside for that purpose. What SC&A is hearing is the sites want to cooperate, but someone has to pay.

Mr. Fitzgerald felt granting of Q clearances would be a key issue at Y-12, which is on the Board's schedule of reviews. He was reminded by **Mr. Rollow** that such could take six to 12 months. The clearances must be facilitated or SC&A will have difficulty in completing reviews at two or three other sites, as well. Although SC&A is not alone in dealing with national security issues, perhaps some consideration could be given to the schedule to reflect that reality.

The Savannah River review is nearing completion. Bethlehem Steel and Mallinckrodt don't have the site access issues and interviews are more straightforward.

Commenting he didn't feel the answer is to limit the planned scope of the reviews, **Mr. Fitzgerald** indicated that will be an issue in terms of readily available information.

SC&A interprets a final review as a one-time deliverable. Their concern is if they fall somewhat short because of the data access or security issue, they're not sure how to handle providing the Board incomplete analyses. Those then become timeliness and resources issues that are factors in increasing cost and time. **Mr. Fitzgerald** asked the Board to provide guidance on what would make sense in terms of preserving feedback while recognizing practicalities of information and security issues.

Mr. Fitzgerald took questions from the Board following his presentation.

Conflict of Interest Plan:

Dr. Stephen Ostrow noted the plan was for both organizational and personal conflict of interest. While lengthy, there are some basics. SC&A's commitment is not to bid on or perform work for NIOSH or any of its contractors. They will not accept work from DOE or DOE contractors dealing with radiological issues. They will seek guidance from the Board for resolution of any gray areas.

The plan administrator ranked the 36 individuals potentially available for work on the project based on their questionnaires disclosing past activities on other sites and project. From the 36 there are 21 in unrestricted status, 15 have some restriction, zero are precluded from working on the project, and none are pending review.

Information about the plan, individual responses, and the sites for which they are or are not cleared is maintained in a secure file at SC&A headquarters and is available for authorized audit. The goal is to provide a transparent process. The file also contains corporate conflict of interest certificates relative to SC&A and its subcontractors.

Since none of the 36 have any way of knowing what they may be asked to review in the future, task leaders must use a bit of judgment. SC&A stresses the need to consult the conflict of interest officer if there is any doubt. Any unresolved issues will be taken to the Board for determination.

Dr. Ostrow accepted questions from the Board.

Quality Assurance Plan:

Dr. Ostrow explained the goal is for everything to be done consistently according to the contract and regulatory requirements, while providing a record so the process is clear and transparent. The plan describes what has been done to comply with security and confidentiality provisions, and outlines who does what within the SC&A organization.

The plan ensures all work is done according to approved procedures, each person has the correct and most up-to-date version appropriate to his role in the project. A quality assurance (QA) file is also maintained in the SC&A secure file room and is available for proper inspection.

Dr. Ostrow answered questions from the Board.

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Site Profile Status Update and Database Use

Dr. James Neton explained NIOSH had initially targeted priority treatment on 16 DOE facility site profiles which would provide data to process the claims of approximately 80 percent of the claimant population. The nine completed site profiles allow almost 60 percent of that population base to be addressed.

When a site profile is described as complete, it means all six of its chapters have been reviewed and signed off on by OCAS. There are seven remaining site profiles out of the targeted 16. All chapters have at least one draft completed.

Four AWE site profiles have been issued. The AWE complex-wide document has been successful in freeing up a number of claims. An additional 20 AWE site profiles are under development.

Worker outreach meetings have been successful. A total of 13 have been held since the first one at Savannah River in 2003. A pattern of return visits is emerging. Meetings are formatted at a mini town hall, with return visits using a workshop format. Minutes are taken at all meetings and sent to attendees to ensure factual accuracy. After vetting, they appear on the OCAS web site.

At the last meeting the Board inquired about the site research database. **Dr. Neton** explained that is the entire database of all records captured from the inception of this project. When they go to a site, they scan records and put them in the database. It's intended to contain images and data files for all covered facilities. It is organized by facility. It has keyword searches available. There are almost 10,000 reference documents representing some 45,000 files. Savannah River Site has roughly 380 files. **Dr. Neton** had been unable to get a page count, but it contains 65 gigabytes of data.

This was the research database used for site profile development. It has since morphed into a

database containing key links to coworker data. The database is now being linked so that when information that could be used in a dose reconstruction or is unique to a particular claimant is available, a link is established to alert the dose reconstructor. **Dr. Neton** indicated this effort is nowhere near complete, but they are well into it. Claimant data from the 16,000 DOE responses which can be used as coworker data is being keyed into the worker profile database in the Richland office of Dade Moeller.

Other sources of information include the Oak Ridge Associated Universities Center for Epidemiologic Research database which contains, among other things, over 4 million records of bioassay monitoring results in catalogued form. The Health-related Energy Research Branch (HERB) within NIOSH has epidemiologic studies which contain coworker data. There is some overlap, but there are some unique facilities in the HERB database, such as INEEL. Epidemiologic studies are also available in the Comprehensive Epidemiologic Data Resource, or CEDR, database. NIOSH and ORAU will look at this entire compendium to develop coworker datasets. NIOSH and ORAU understand and recognize they can't use these datapoints until they have been validated to give the values credibility.

Y-12 is the first completed profile for external dose using coworker data for the '51 to '65 time period. **Dr. Neton** indicated OCAS has not yet signed off on it, but expects issuance within the next few days.

Dr. Neton answered questions from the Board.

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Public Comment Period

Public comment was solicited on both days of the meeting. Public input on the first day was in a separate evening session. Comments on the first day included the following:

- People in charge not knowing what they were doing.
- Being called a whistle-blower for raising safety concerns.
- Whether comments from site profile meetings would be incorporated into the site profile.
- Critical processes and buildings were missed in the site profile.
- Lack of credibility has led to small numbers of applicants from INEEL.
- Data could be presented more effectively.
- Caution should be taken in referring to site profiles as completed.
- SC&A has asked for help in organizing workers for their interviews. They should be paid for organizing meetings and providing technical support.
- A statement was read into the record regarding undocumented radiation exposures.
- Workers received unrecorded high levels of contamination doing jobs now done by robots.
- The chem plant had been known as the garbage dump of the world.

- High exposure incidents where no one wore their monitors.
- INEEL's recordings were never verified, generally considered dishonest.
- "SMC and everybody" hiding behind national security.
- Protection has evolved from half-face respirators with paper filters to bubble suits.
- Dose reconstructions might have different results if NIOSH really knew the conditions they'd worked in.

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Wednesday, August 25, 2004

Use of Uncertainty in Dose Reconstruction

Dr. Neton explained time did not permit him to go into extreme depth, and what he would present was probably a review for some. The statute uses the interactive radio epidemiological program (IREP) model, a Monte Carlo sampling program which applies uncertainty to the distributions for the risk coefficients.

The value for the central tendency of an uncertainty distribution will represent best estimate, and effort is made to determine best estimate of workers' exposures at the facility doing their job during that time period. The over-arching factor is if they don't know and science can't inform them, they will include favorable assumptions in the uncertainty distributions.

Regulation 42 CFR 82 details the efficiency process of making worst-case assumptions at the beginning of the DR to determine if a claimant is non-compensable under those circumstances. If so, the DR is terminated. The simplest distribution being a single value, under those conditions it may be represented by a constant.

Dr. Neton described some of the factors that are sources of uncertainty in probability of causation. He noted it was a complex issue and there is no simple discussion on it.

Dr. Neton listed and described types of uncertainty distributions used in dose reconstruction, presenting slides to illustrate them in graph form.

Arriving at an internal dose value involved more assumptions in the calculation. For simplification, they have considered all internal doses lognormally distributed with a geometric standard deviation of three. **Dr. Neton** indicated there are scientific publications which point to that as reasonable.

In many cases no real monitoring data is available for individuals, but there may be a distribution of air samples. From that they would develop an exposure model to be applied to the work force. Several had been developed. If the probability of causation (POC) is calculated to the 99th

percentile, it is being driven by some high values they believe are claimant-favorable. This value is assigned then to every worker. **Dr. Neton** reiterated that it was a complicated issue.

Discussion with the Board followed **Dr. Neton**'s presentation.

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Scientific Research Issues Update

Mr. Russ Henshaw explained that another version of IREP is maintained by the National Cancer Institute (NCI). Their lung model was revised last year. The difference in the two was thought to be in the probability of causation between smokers and non-smokers. NIOSH has learned that NCI has made a further change in that model to adjust for chronic alpha exposures. **Mr. Henshaw** indicated his understanding was the difference is minimal.

NIOSH put their evaluation for possible application of the NCI version under EEOICPA on hold. SENES has issued a preliminary report exploring the differences, and with certain recommendations, which is in internal review by OCAS at this time.

Another project is to review dose and dose rate effectiveness factor, or DDREF, an adjustment factor built into IREP to account for exposure differences between Japanese atomic bomb survivors and U.S. nuclear weapons workers. In creating NIOSH-IREP a decision was made to use a claimant-friendly uncertainty distribution, which was an issue of controversy.

Mr. Henshaw suggested it is now time to look at DDREF, re-evaluate assumptions and possibly propose an adjustment. SENES has submitted a complex draft report which is still in internal review in OCAS. They hope to reply with their comments very shortly. Ultimately any findings or recommendations will be submitted for independent review.

The upgrade of Analytica, the software package serving as the computational engine behind NIOSH-IREP, has been completed and the transition went smoothly.

Interviews have begun to fill the position of research health scientist, a long-standing vacancy at OCAS. **Mr. Henshaw** indicated he anticipates that person will be at the next Board meeting. The primary duty of the position will be applied research. First project is to conduct a feasibility study of current occupational dose-response data to improve the fit of cancer risk models in NIOSH-IREP.

Also of priority interest to the Board is the grouping of rare and miscellaneous cancers. **Mr. Henshaw** explained there are 32 risk models, but each falls into one of three major risk groups. Re-evaluation of how thee cancers are grouped dovetails into the feasibility study of occupational cohorts. This a project in the beginning stages.

Mr. Henshaw was available for questions from the Board.

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Subcommittee Status Report

Dr. Ziemer informed the Board the subcommittee charter had been approved and is now in effect. All members of the Board are members of the subcommittee, but would be called upon to serve in groups of three, along with a Chair and the DFO, for specific meetings.

A working group had met in Cincinnati to develop materials for subcommittee recommendation as procedures for selection of cases to be reviewed in the audit process. Those same individuals meet as the subcommittee and prepared a two-page document for the Board's consideration. They will become a recommendation and motion for the Board to adopt as a procedure.

Mr. Mark Griffon explained there are parameters of interest defined in the flow sheet. The first step is to select cases, using a random number generator selection process. The pool of cases available for review are those adjudicated to the point of final decision being proffered, currently approximately 1,400.

The parameters of interest -- POC category, facility, decade first employed, duration of employment and IREP risk model -- are searchable on the NOCTS system of the NIOSH database. **Mr. Griffon** described what the subcommittee felt was an appropriate number of samples by grouping, as well as their rationale for any weighting. He explained the numbers are preliminary and can be adjusted.

Other criteria discussed by the Board and subcommittee are important. They include cases using coworker data, job category, et cetera. They are not currently searchable fields. The subcommittee recommends tracking to assure they sample across those parameters.

The subcommittee discussed having two members of the Board responsible for each case, along with a person from SC&A to do the work-up.

Mr. Elliott indicated once case selection and assignment has been made, NIOSH will create a CD for each Board member containing his cases and all case information. This will be a Privacy Act-controlled disk to be delivered to each Board member and SC&A.

Mr. Griffon added SC&A was in the audience at the subcommittee meeting and had discussed logistics, but panel members would be able to conference call with SC&A. They had discussed presenting cases to the Board in closed session to discuss specifics, with an aggregate report by SC&A. Then in open session they could present the aggregate findings.

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Board Discussion/Working Session

The Board reviewed the subcommittee's recommendation in considerable detail, examining issues related to the flow sheet and its parameters of interest. After discussion, the subcommittee's recommendation on the procedure for selecting and tracking dose reconstruction cases was accepted, contingent upon the agreed-upon modifications.

The subcommittee had requested NIOSH prepare a list of 25 randomly-selected cases, which was presented to the Board for their selection as the 20 cases with which they would begin their dose reconstruction review process.

The Board examined the list in detail and ultimately selected 20 cases to be assigned to pairs of Board members as dose reconstruction review teams.

Dr. John Mauro reiterated his description of the audit process to be undertaken, explaining that it is laid out in detail in Appendix C to their proposal to the Board. He added that at any point in the process either the Board or NIOSH could step in.

Dr. Ziemer explained how the subcommittee envisioned the process would work, and **Dr. Mauro** agreed.

The Board discussed timing of receipt of the CDs containing the case information and who would have it. They discussed logistics and timing for presentation of cases and how those issues related to Privacy Act concerns. Board access to the NIOSH database was discussed and how that might be implemented.

The issue of basic review versus advanced was raised, with **Dr. Ziemer** suggesting the first 20 be basic reviews.

The manner of team selection was discussed, keeping in mind their conflicts.

Numbering the cases on the list for the Board's convenience was discussed. **Ms. Homoki-Titus** indicated the cases could be informally numbered to assist in their selection process, but when they're sent to the Board teams on the CDs, they'll be identified by their case numbers.

Mr. Elliott provided the Board with information on the system requirements their computers must have to use the CDs, which he indicated were standard. NIOSH will work with them to get access to the database systems at ORAU.

Mr. Elliott advised the Board members that Integrated Modules for Bioassay Analysis (IMBA) is now available and they will be handing out disks to each of them. SC&A will have a disk for their use. They were asked to sign a non-disclosure statement and **Mr. Elliott** pointed out the disk contained coded language so that if the information were shared, it could be traced back to a specific disk, so they should install the program only on a password-protected computer.

The Board discussed IMBA training, how and where it might be available. The ORAU training modules were explained by **Dr. Toohey** and offered for the Board's use. Modules are self-tutorial, and **Dr. Toohey** agreed to look into making them available on CD.

The document they were being requested to sign was discussed at length, with some confusion examined as a result of having to deal with a foreign country's regulations. It was concluded it was not very different from what they might agree to when purchasing any software program.

A commitment was made to **Mr. Elliott** that within the next two weeks NIOSH would deliver the IMBA disks, the IMBA training modules and whatever mechanism was needed to set up to allow access to the database.

Following discussion and adjustment for conflicts, 20 cases were assigned. Confirming the case assignments, **Mr. Elliott** indicated they would be receiving their disks next week and the members should let him know an alternate location for delivery if they were not going to be at their residence.

The Board was cautioned that SC&A will be assigning cases based on expertise, so the Board teams are not likely to have only one contact. Participation in the conference call is not mandatory. Comments can be transmitted, but they'll be getting feedback from the contractor in any event.

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Public Comment Period

Public comment was solicited on both days. Public input on the second day included the following.

- The latest site profile for Blockson Chemical had a blank page. Had the issue of how to handle radon had been resolved. Is the issue of which dose should be counted a sensible one for the Board to consider. Is there a way to get it on the agenda.
- The Mallinckrodt site profile, SEC petitions, actinium oozing out of the airport site, whether the dose was estimable, why isn't it part of what dose can and can't be reconstructed, is it part of the research.
- How the Board assesses the SEC petitions and dissatisfaction with areas of the rules and posted procedures.

- Anxiety over records access.
- Concern about the Q clearance issue.
- Comfort from **Mr. Rollow**'s reassurances and hope for cooperation from DOE.
- An apparent implication that NIOSH is not cooperating with SC&A, suggesting the Board "keep its ears closely attuned to this question."
- People who have met with SC&A feel good about being able to communicate and have a high sense of comfort level that they're being listened to.
- "Occupational environmental dose and external dosimetry hadn't been updated since April 28th," presumably in the INEEL site profile, although not specified.
- Dissatisfaction with answers to questions raised in site meetings.
- Concern that the Board would see a cleaner site in their tour than the environment the workers were in decades earlier, citing massive cleanups before every tour.
- Places they'd worked in had been decontaminated, torn down, and capped with five feet of concrete.
- Workers now aren't permitted to touch chemicals they'd worked with.
- The town had no other industry, so workers did whatever they were told to do to keep their jobs.

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The Board had two documents from SC&A requiring action, the Conflict of Interest and Quality Assurance Plans. The contractor had wanted to make some editorial changes. While minor, they were numerous and throughout the documents.

After review and discussion the Board determined they would delay acting on the documents until SC&A had implemented their own changes and the suggestions of the Board. They would consider approval of a clean copy of the plans at the next Board meeting.

The Board discussed with **Mr. Elliott** what would be involved in their SEC petition reviews and whether contractor support would be needed. He explained their role was statutorily mandated but had no audit or quality aspect to it. He noted it had to be a function of the Board.

After discussion it was determined the next meeting would include an agenda item to present and walk the Board through the procedures, highlighting the activities calling for direct Board involvement.

Contractor costs and how it was reported to the Board was discussed. **Dr. Ziemer** indicated the documentation was available at Board meetings, and called for a presentation on that to be added as a standing agenda item.

A suggestion was made to include on the agenda some historical perspective on a site when it is the location for a meeting. The purpose would be to let Board members know what had been done

there, and perhaps raise questions for public comment.

The possibility of a schedule for on-site outreach meetings was discussed. Since meetings are put together with short planning time, a long-range schedule, while desirable, is not feasible.

The procedure by which SC&A would present a site profile review to the Board was raised. The likelihood of receiving a site profile review draft prior to the time it's presented to the Board was discussed. NIOSH will receive a draft for purposes of reviewing for factual accuracy, but can only comment they don't agree; SC&A is under no obligation to make a change in their review. It was thought SC&A would have no problem with **Dr. Ziemer** receiving a copy while NIOSH does its factual accuracy review.

After discussion it was determined that the Chair would receive an advance copy of the site profile review at the time it was delivered to NIOSH, as well as a copy of the NIOSH comments, if any. The purpose is to create a paper trail and protect everybody. **Mr. Elliott** indicated he would hope that the NIOSH comments would become a part of the public record.

It was suggested the Board might be provided a copy of the evaluation plan before the next meeting in an effort to make their consideration of an SEC petition easier. After discussion, a working group was established to be on call to review the SEC petition evaluation plan and perhaps an evaluation report in the event such were in place before the next Board meeting. It was explained that the evaluation plan would be developed after a petition is qualified. The purpose of the working group would be to review and make a recommendation on the evaluation plan and on a petition should either or both be in a state for review.

The issue of resolution on SC&A's question of final report versus interim report was raised. After discussion it was the consensus of the Board that the issue was raised in order to alert the Board to a potential issue, but is not at this time ripe for resolution by any action they may need to take.

With no further business to come before the Board, the meeting was adjourned.

End of Executive Summary

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The Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health
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Department of Health and Human Services: Ms. Lynda Brandal, Mr. Todd Braswell, Ms. CC Chang, Ms. Heidi Deep, Ms. Chris Ellison, Mr. Russ Henshaw, Ms. Cori Homer, Ms. Liz Homoki-Titus, Ms. Laurie Ishak, Mr. Ted Katz, and Dr. James Neton

Department of Labor: Ms. Diane Case, Mr. Larry Hoss, and Mr. Pete Turcic

Contractors: Dr. John Mauro, Mr. Joe Fitzgerald, Mr. Stephen Ostrow, Dr. R E Toohey

Public Attendees: See Registration

Dr. Paul Ziemer called the meeting to order, welcoming the attendees. He asked everyone to register their attendance and described the sign-up sheet available for those who wanted to speak during the public comment session.

He noted that the public comment period on the first day would be an evening session beginning at 7:00 p.m. He commented that the printed agenda had inadvertently omitted showing the public comment period on the second day. **Dr. Ziemer** explained their meetings always included a public comment period, and it was planned to take place after return from the lunch break.

Mr. Larry Elliott added his welcome on behalf of Secretary Tommy Thompson of the Department of Health and Human Services (DHHS) and Dr. John Howard, Director of NIOSH.

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REVIEW AND APPROVAL OF DRAFT MINUTES

The first order of business on the agenda was approval of the minutes for meeting 25 held in Buffalo, New York. Some members had not reviewed the minutes and expressed a preference to delay that action until tomorrow's work session.

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NIOSH PROGRAM STATUS REPORT

Ms. Laurie Ishak
NIOSH/OCAS

Mr. Elliott introduced **Ms. Laurie Ishak** as the Presidential Management Fellow who had recently joined NIOSH/OCAS as a health communications specialist. **Ms. Ishak** offered a slide presentation of charts and graphs to illustrate a statistical update on program activities from the NIOSH perspective. All figures presented were as of August 13, so **Ms. Ishak** cautioned the Board that some periods shown would be incomplete.

The Department of Labor (DOL) has referred 16,735 cases to NIOSH for dose reconstruction. The majority of those cases, 37 percent, come from the Jacksonville district office, which includes cases from both Savannah River Site and Oak Ridge.

The number of referrals from DOL peaked in the fourth quarter of '02 when more than 2,700 cases were received at NIOSH. Those numbers began to level in late '03 and have stabilized at approximately 800 cases per quarter.

Draft dose reconstruction reports to claimants more than doubled from February to March '04 and has increased steadily since, breaking 500 in June and July. August figures appear to be on course, as well. The total number to date is 4,588.

Final dose reconstruction reports to DOL have likewise been increasing monthly. This is a figure over which NIOSH has little control, since an executed OCAS-1 form from the claimant is required before the report can be sent to DOL for final adjudication. The total now stands at 4,097.

NIOSH has made 16,653 requests to the Department of Energy (DOE) for exposure records relative to 14,981 cases. Claimants having worked at multiple sites entails making a request to each site. DOE has provided 15,985 responses relative to 14,226 cases. **Ms. Ishak** noted that all responses do not provide the information needed, but some may be notification that the information is not available or has not yet been located. To date only 160 requests have been outstanding for a period of time ranging from 60 to 150 days.

Ms. Ishak noted that NIOSH had made 669 requests to DOE for exposure information relative to INEEL claims and had received 651 responses, only 18 of which were outstanding for more than 60 days.

Cases may involve more than one claimant, and Oak Ridge Associated Universities (ORAU) conducts a telephone interview with each claimant in a case. At present there are 16,230 cases for which at least one interview has been completed. Following the interview, a draft interview summary report is provided to the claimants. Those now total 21,813. ORAU has a current interview capacity of 200 to 300 per week, utilizing about 20 staff members in that task.

NIOSH at present has 5,123 cases staged for dose reconstruction. This means ORAU has reviewed the file, a DOE response has been received, and a profile for the relevant site has been done.

Currently 1,466 cases have been assigned for dose reconstruction. This number differs because the DOE response may not have provided exposure history information, or the site profile section needed for that claimant's dose reconstruction may not be complete.

Each case received at NIOSH is assigned a chronological tracking number. Divided into increments of 1,000, **Ms. Ishak** noted that NIOSH is working with ORAU to reduce by 20 percent the number of incomplete cases with tracking numbers under 5,000. She indicated ORAU had a group going through those cases to determine why they can't be completed and attempt to do so in a timely manner.

The number of administratively closed records continues to be small. These are cases for which the dose reconstruction has been sent to the claimant and no OCAS-1 form is returned. After

appropriate efforts have been made by NIOSH to obtain the executed OCAS-1 form, the dose reconstruction process is closed and forwarded to DOL. This number currently stands at 27. DOL then makes a determination whether to administratively close the case.

DOL is currently returning approximately seven to eight percent of cases to NIOSH in the form of reworks. **Ms. Ishak** noted that while the chart may appear to demonstrate an increase, the number of cases being sent to DOL is what is increasing, with the reworks remaining consistent at seven to eight percent. To date 280 had been received by NIOSH and 108 had been completed and returned to DOL.

The Final Rule governing petitioning for Special Exposure Cohort (SEC) status, 42 CFR 83, was published Friday, May 28, 2004. The first petition was handed to **Mr. Elliott** at a meeting in Burlington, Iowa on June 15. There are currently 9 petitions in the process of being qualified.

The qualification process is a determination that the petition has been completed as required. For each qualified petition a notice will be placed in the *Federal Register* to notify the public of NIOSH's decision to evaluate that petition. That evaluation will be done in accordance with the provisions of Section 83.13 or 83.14.

Ms. Ishak described some recent NIOSH accomplishments, among them having exceeded 4,000 final dose reconstruction reports to DOL; more than 19,000 activity reports sent to claimants in the month of July; over 300 physicians recommended to staff the DOE physicians panel; implementation of the web-based status request program; and a change in the conflict of interest policy to include work on site profiles.

Included in the OCAS staffing update was the announcement of **Dr. James Neton**'s move from Technical Program Manager to Associate Director for Science. **Dr. Neton** will be monitoring existing and emerging scientific issues relating to dose reconstruction and risk models. The two new Fellows added to the program included **Ms. Ishak** as the Presidential Management Fellow and Heidi Deep as the ASPH Fellow. **Ms. Ishak** included an OCAS organizational chart demonstrating both filled and vacant positions.

Discussion Points:

Dr. James Melius asked for more specific information on sites not providing exposure information within the target time period. **Ms. Ishak** replied that Los Alamos National Laboratory (LANL) had experienced a database problem which had been resolved, but her list was fairly lengthy. **Dr. Melius** asked that the information just be included in future presentations, as it had been in the past.

Dr. Melius asked what the process was for addressing the older incomplete cases. **Dr. Neton** replied that the ORAU contract included a cost plus award fee provision, and NIOSH was working

to develop incentive language for the next six-month period to address reduction of that backlog by 20 percent.

Dr. Melius asked if some of those cases might not be SEC candidates and wondered at what point it would be determined a dose reconstruction could not be done. **Dr. Neton** asked to defer addressing that issue as it was part of his presentation for the following day.

Mr. Mark Griffon asked how many claims had been submitted for Idaho and how many completed. **Mr. Elliott** indicated **Mr. Pete Turcic** would provide that information in his presentation on behalf of the Department of Labor.

Dr. Henry Anderson inquired if processing 500 dose reconstructions a month was viewed as the maintenance position. **Ms. Ishak** replied that the original and current goal was 200 per week or 800 per month. **Mr. Elliott** added that was a goal set with full expectation of its being reached; and if not, they would investigate what is preventing that accomplishment from being recognized.

Dr. Genevieve Roessler commented that it would be helpful to have names attached to the positions shown on the organization chart, so the Board would be able to know who was where. She also asked that the chart provided in the handout be enlarged to be more easily read. **Mr. Elliott** indicated that would be provided.

Dr. Ziemer asked when the Board might expect to receive the first SEC petitions for review. **Mr. Elliott** replied he anticipated one or more would be available for review at the October Board meeting.

Mr. Griffon asked if the ORAU incentive mentioned by **Dr. Neton** would require a contract modification and what ORAU's status was within the original five-year budget. **Dr. Neton** replied that in answer to the first part of the question, contract provides for the cost plus award fee to be evaluated every six months. Money is available based on some pre-set amounts when the contract was awarded. The higher the contractor scores, the higher the amount out of a total work fee they can receive. It does require a modification if the provision is tweaked, which was anticipated from the outset. The award would not have been meaningful if it had simply been generic. In the last period it has been modified to tie more award points directly to completion of cases below 5,000. In the next period they anticipate adding the goal of 200 dose reconstructions per week.

Mr. Elliott added the current award fee also addresses the rework stream, and commented that the reason for reworks was primarily because case circumstances have changed. Another cancer has been diagnosed or additional employment has been developed by DOL, and that has to be factored into a revised dose reconstruction. Only a small percentage deals with how NIOSH did their work.

Mr. Elliott commented that another incentive aspect of the performance award fee is related to

NIOSH's Government Performance Results Act goals of 200 dose reconstructions per week.

Dr. Neton commented that, in answer to **Mr. Griffon**'s second question, ORAU has gone over significantly on the contract in relation to the original budget, although he didn't have the numbers available to discuss.

Dr. Roy DeHart asked for clarification on why an SEC petition had been filed from K-25, which is already recognized as an SEC site. **Dr. Neton** opined that it was likely related to covered exposure outside certain time periods. He noted the original SEC sites had certain prescribed time constraints.

Dr. Melius asked if the conflict of interest policy for ORAU relative to site profiles were the same as for dose reconstructions. **Dr. Neton** replied the language parallels almost exactly that for the dose reconstructions, adding that they had also taken the opportunity to add the same type provision for evaluation of SEC petitions. Principal reviewers on SEC petitions cannot have previously been employed at the site.

Dr. Melius inquired whether NIOSH has a task order with ORAU for doing the technical work on the SEC petitions. **Dr. Neton** replied ORAU will perform the bulk of the technical work, with NIOSH maintaining full responsibility and review over the final product. He commented that the title of the contract referred to dose reconstruction and SEC petitions, but ORAU had created a task within their organization to track cost and progress as a separate task. It was totally envisioned within the scope and budget of the original contract language.

Dr. Melius commented that the Board should think about and discuss how they're going to review and evaluate petitions at the next meeting and what procedures they'll want to have in place. **Dr. Ziemer** indicated that issue could be addressed specifically in the work session.

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DEPARTMENT OF LABOR STATUS REPORT

Mr. Pete Turcic
Department of Labor

Mr. Pete Turcic reported that DOL had to date received 57,112 claims, with cancer still representing the greatest number at 40,285. Beryllium sensitivity accounts for 2,549 claims; chronic beryllium disease, 3,770; and silicosis, 1,155. Radiation Exposure Compensation Act (RECA) claims total 6,243. Other claims include those for non-covered conditions and total 28,125. It is noted that these categories obviously overlap in some instances.

There have been 13,815 recommended decisions issued to approve claims and 21,953 recommended

decisions to deny. From those, final decisions have been issued to approve 13,046 claims, with final decisions to deny 18,268. A total of 11,671 payments have been made, representing $874,448,662 paid in compensation and $38,542,768 paid in medical benefits. The final decisions for denial were based on 10,013 claims for non-covered conditions; 2,789 claims in which the employee was not covered; 821 claims in which the survivor was not eligible; 2,723 claims in which there was insufficient medical evidence; and 1,922 claims in which the probability of causation was less than 50 percent.

Keeping in mind that multiple claimants may be involved in a single case, the aforementioned 57,112 claims are contained within 42,190 cases. There have been final decisions issued in 24,743 cases; currently 12,490 cases are pending at NIOSH; 2,636 cases are pending action in DOL district offices; and 2,321 cases are pending final decision.

A total of 17,182 cases have been referred to NIOSH for dose reconstruction. NIOSH has returned 4,597 cases, 4,375 with completed dose reconstructions and 222 where dose reconstruction was not required. There were 733 cases with a recommended decision to accept and 2,686 with recommended decisions to deny. There have been 660 cases with final decisions to accept and 1,534 cases with final decisions to deny. A total of 764 individuals have received compensation in the amount of $86,927,500 from cases with NIOSH dose reconstructions.

Mr. Turcic noted that in the past 12 months DOL has referred 3,400 cases to NIOSH for dose reconstruction and NIOSH has returned 4,142 cases, a reflection of backlog reduction for which he felt NIOSH should be complimented.

Mr. Turcic commented that he wanted the Board to understand a claimant's right to appeal a decision based on a dose reconstruction. It is DOL's goal to issue a recommended decision within an average of 21 days of receipt of the dose reconstruction report, and they are exceeding that standard.

The Final Adjudication Branch (FAB) allows a claimant the opportunity to pursue a hearing, a review of the written record, or a waiver of objections. The scope of a FAB review is limited to factual information and/or application of methodology. Potential outcomes from their review may be an affirmation of the recommended decision, a reversal of the recommended decision, or a remand to the DOL district office or NIOSH.

In reviewing the objection from October '03 to June '04, there have been 420 requests for hearing, with 311 hearings having been conducted. There were 653 requests for a review of the written record, with 567 reviews conducted. There have been 2,995 waivers of objections. Waiver of objection triggers immediate process of a claim, which is usually an acceptance. In a very short period of time a final decision and payment are issued.

As of August 15, there have been 328 NIOSH cases remanded, 75 of which had a recommended

decision to approve, with 36 of them receiving a final approval. The total included 263 with recommended decisions to deny, with 37 receiving a final denial. However, two received a final decision to approve, 216 are pending final decision and eight cases have been closed or withdrawn. Pending final decision may mean the case is back at the district office for further medical or employment development, or may be with NIOSH for a rework for some other reason. Cases closed or withdrawn generally indicates the claimant has passed away and DOL is attempting or has been unable to locate a survivor.

Some of the issues raised with the FAB include assertions information provided in the interview was not addressed; unmonitored dose treated as missed dose, incidents not addressed and others. These assertions are generally a result of not understanding how information use is presented in the report, and **Mr. Turcic** suggested a better job might be done of simplifying information use for those who are not health physicists.

An issue DOL is working with NIOSH on is a result of the efficiency process. **Mr. Turcic** noted that when the efficiency process produces a probability of causation (POC) of 40, for example, and another cancer is diagnosed, triggering a rework and full scale dose reconstruction and the resulting POC is then 20, claimants are raising objections because they don't understand.

As for local statistics, 1,179 cases have been filed from INEEL. There have been 395 cases receiving final decisions to deny and 37 receiving final decisions to approve. To date 14 payments have been issued totaling $2,100,000. There have been 707 cases sent to NIOSH, with 153 having been returned. Of those there have been eight final decisions to accept and 51 final decisions to deny. The 395 final decisions to deny consist of 51 cases where the cancer was not covered or POC was less than 50%; 235 condition not covered, 48 employee not covered, 53 insufficient medical evidence and 8 survivor not eligible.

Discussion Points:

Mr. Richard Espinosa asked what outreach was being done related to the SEC rule. **Mr. Turcic** replied that it's always discussed at public meetings, but has not been targeted specifically.

Dr. Melius asked for more information on what **Mr. Turcic** called remands and **Mr. Elliott** had referred to as reworks, presuming they were the same. **Mr. Turcic** explained they were not at all the same in that a rework involved a change in situation, such as an additional cancer, and it would be sent back so the additional cancer could be included in the dose reconstruction. A remand would involve factual information and the case would be sent back to address that specific issue.

Dr. Neton commented that he dealt with this issue every day and he thinks generally of reworks as something that comes up before the recommended decision goes out, before the claimant sees a draft dose reconstruction. The claims examiner notices an additional cancer has come up or employment

is different, et cetera. Once it gets to a recommended decision and a statement of factual accuracy has been challenged, it is a remand. **Mr. Turcic** added there could be any number of reasons.

Dr. Melius said someone had mentioned there were quality assurance issues NIOSH had with ORAU on and he assumed someone was not doing something right or something was getting through the system. He noted the numbers were small, but the implication was that it was a growing issue.

Mr. Elliott replied that in the discussion of the incentive for the cost performance award fee, he had drawn attention to what they called reworks. When ORAU sees them, they don't know which it is. Not all reworks are remands.

Dr. Melius indicated he would be interested in further information on policy-related issues that reflect on the dose reconstruction process. **Mr. Turcic** agreed they were policy issues and they're trying to work out the policy framework to apply for some of the issues that arise as a result of use of the efficiency process.

To be sure the members of the public understood the complicated issue being discussed, **Mr. Elliott** briefly described the use of the efficiency process in arriving at POC for one cancer. Addition of a second cancer could require a full dose reconstruction which may lower the original POC. NIOSH is concerned about the assumptions being used in the efficiency process. **Mr. Turcic** offered that by the next Board meeting DOL should have a precedent case on that issue and would be glad to say where DOL has come out on it and what the precedent-setting case established. **Dr. Melius** suggested NIOSH present also, along with where the issues are coming up.

Dr. Roy DeHart asked for clarification on the issue of remands. He noted 328 cases had been sent to NIOSH and 75 had gone to a decision for approval, inquiring if NIOSH made that decision. **Mr. Turcic** explained that it meant 75 had started out as a recommended approval, then was remanded by the FAB for any number of reasons, including use of the incorrect ICD-9 code by the district office.

Dr. Ziemer commented that it was made more difficult for DOL since the claimant would have seen the recommendation. **Mr. Turcic** agreed, noting that use of the incorrect ICD-9 code would mean the incorrect interactive radio epidemiological program (IREP) model was used. **Mr. Elliott** added that it could mean the dose was reconstructed to the wrong organ because NIOSH doesn't develop the claim with regard to the cancer diagnosis. That's the responsibility of DOL to give NIOSH a set of developed facts they're to use in their work.

Mr. Griffon asked what the DOL backlog is, since **Mr. Turcic** had commented on backlog reduction early in his presentation. **Mr. Turcic** indicated he had been referring to cases pending at NIOSH, which was down about 1,000 from the previous year. DOL has a NIOSH referral or

recommended decision in 99 percent of their cases within 120 days. They normally have about 2,500 cases under development and, at 200 to 300 a week, that's about a three-month working inventory.

Dr. Antonio Andrade inquired whether a second cancer diagnosis is sent back to a physician for determination whether it represents metastasis from the first cancer. **Mr. Turcic** replied that the only time metastasis would be sent to NIOSH would be if it were metastasis of unknown primary. The procedure then would be to run probable primaries for that metastasis. But a second cancer diagnosis, as he had been using it, must be a primary.

Dr. Andrade suggested the Board ponder the fact that there are many processes workers have been involved in involving manufacturing and processing of materials that include both chemicals and radiation. Primary cancers can result from either. Even though the Board tries to be very clear and meticulous in its review, that will always be a question mark and is a reason to suggest there may never be satisfaction at the differentiation between the two. Because efficiency measures are used in one case, it builds a gray area and if a rework is required, it's understandable why a POC may be lower.

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DEPARTMENT OF ENERGY PART D STATUS REPORT

Mr. Tom Rollow,
Department of Energy

Mr. Tom Rollow offered an update on the Subtitle D portion of the Energy Employees Occcupational Illness Compensation Act (EEOICPA), administered by DOE. The purpose of Subtitle D is to provide assistance to workers making application for State Workers Compensation and includes not only illnesses covered in Subtitle B, but extends to illnesses caused by toxic substances. **Mr. Rollow** wanted to share some observations about production under Subtitle D.

Physician panel determinations are being produced at over 100 per week. The goal is to reach 300 per week by next June.

Under Subtitle D, **Mr. Rollow** explained that DOE develops a case and sends it to the applicant, who has 30 days to review the case file for additions or changes. There is a 15-day review period for the employer. At this point DOEs work is largely completed.

The cases are then put in the physician panel process, either being reviewed or in a queue waiting to go to the physicians. There are approximately 3,000 in that category. Cases are completed by either

a positive or negative physician finding. DOE has largely completed its work in over 7,000 cases. There have been 25,000 total applications for the program to date.

Mr. Rollow reiterated that DOE had underestimated the scope of the program and failed to gather the resources necessary to set up and manage it, therefore they are still playing catch-up. He noted, however, that they were still preparing cases faster than they were going through the physicians panel.

The Congress provided an infusion of resources to give the program a boost. Less than a year ago Congress approved reprogramming for $9.7 million which was added to the budget and allowed case production to increase threefold. Another reprogramming of $23.3 was received in June, although $33.3 million had been requested.

DOE hired about 200 case processing people in Washington, D.C. over the last 12 weeks. **Mr. Rollow** indicated his contractors were confident they would be over 300 cases per week by the end of August.

The physician panel had always been a challenge because of the difficulty in gathering resources, physicians or physician time, particularly when working on a part-time basis. The physician panel rule was changed to allow a single physician to make a positive determination. If the review by a single physician results in a positive finding, the review is finished. If the finding is negative, it is sent to a second and/or third physician. The final result must be two out of three physicians in agreement. That change has increased production dramatically.

From five to seven physicians work in Washington full time every week. The second and third reviews are generally given to those physicians in order to streamline the process.

In September '02 DOE had just over 12,000 applications for the program and had not started to work the cases. By March '03 the number had grown to about 13,000. Last October or November they began to work those off and there are currently 5,000 cases for which document requests have not yet been made to the sites. Based on the $23.3 million from the reprogramming, DOE is requesting all data on all those cases in order to drive that number to zero and into the currently-worked part of the process.

Mr. Rollow announced the development of a four-element path forward plan designed to eliminate the backlog of cases to zero by the end of calendar year 2006. The first part of the plan is regulation changes, which has been accomplished.

The second element is legislation, minor changes which will help dramatically, such as removing the pay cap on physicians, as well as a change in the language of the legislation to expand hiring authority. There is also a requirement for a State MOU which has been rendered unnecessary as a

result of program design, but the requirement is a remaining artifact which creates problems.

The third element is budget. The reprogrammings moved money inside the DOE from one type account to another. It requires Congressional approval and entails a lot of steps, and is slow coming. The budget in Congress now requests a budget of $43 million for FY '05 and will provide sufficient funds to continue the path forward plan.

The fourth element is process changes, many of which have been implemented. DOE continues to look for opportunities to optimize and be more efficient. Claims have been reprioritized and they have also reconstituted the advisory committee, which will probably meet in October or November.

Mr. Rollow commented that DOE took pride in its performance improvement over the past year or two in providing support for NIOSH and their dose reconstruction information. DOE would continue to attack those requests not being handled within the 60-day time period agreed to.

Approximately 190 of the NIOSH physician panel nominees are actively working. Another 70-some nominations were received within the past few weeks as a result of recruiting activities through ACOEM. That seems to be working out well, with another 20 potential appointees being reviewed by NIOSH. The numbers are climbing and a number of new appointees are interested in working full time.

Mr. Rollow noted that although DOE does not pay claims and has no control over how claims are paid, they do track the money. Reminding the Board and the audience that DOE has completed its work on 7,000 cases and 3,000 are complete within the program, **Mr. Rollow** announced that as of July 31 there had been 378 applicants who received positive determinations and 87 had applied for Workers Compensation. There have been 31 who had actually received some compensation, either medical or a settlement payment. These applicants were from five sites and had been paid a total of $703,000, with another $750,000 in reserves for future medical costs, so the liability for those 31 applicants is around $1.5 million.

Local statistics include less than 1,000 cases for INEEL. DOE has completed 139 of those, 29 of which were positive determinations. There have been no Worker Comp payments issued for INEEL, and **Mr. Rollow** indicated that as best they could tell from communication with applicants, none of those have applied for Workers Comp under EEOICPA. DOE is still working to clarify information that three or four of those 29 positive determinations had received Workers Comp payments prior to existence of EEOICPA, so they may have applied just to have the physicians panel determination that the DOE work was responsible for their illness. There are 180 cases in the physicians panel process and 87 cases awaiting development.

Discussion Points:

Dr. Ziemer asked if DOE saw many cases that start out in one part of the program and clearly should be in the other. **Mr. Rollow** noted most applications are done at the resource centers which serve both Part B and Part D, so they're counseled by the people there. But occasionally an individual is just in the wrong program.

Dr. DeHart again raised a concern that the physicians on the DOE panel may be reviewing a case with radiation implications, yet not have the background. He inquired what was being done to assure those physicians are aware of the dose reconstruction program through NIOSH and know how to interpret that data. **Mr. Rollow** described changes that had been made in the program to make it more applicant-friendly, and indicated they had been working with NIOSH to find a way to provide the physicians more information on dose reconstructions.

Mr. Espinosa asked which states were reluctant to sign the MOU and whether the state statute of limitations could account for the difference between positive findings and Workers Comp applications. **Mr. Rollow** described why various states were reluctant to sign the MOU, mentioning specifically Florida and Missouri. He explained that when DOE orders its contractors not to contest a claim, that includes raising administrative defenses such as statute of limitations.

Mr. Espinosa asked how that was working out with site contractors who were not self-insured. **Mr. Rollow** replied that to his knowledge, no contractor under a DOE do-not-contest order had raised a statute of limitations defense.

Mr. Michael Gibson asked if any claims had been paid in Ohio. **Mr. Rollow** explained that Ohio has a Fernald Settlement Fund which pays physicians to look at illnesses Fernald workers may have received from their work at that DOE facility. A number of those claims have received positive findings and have gone on to the State and been paid for the same illnesses they've applied to the EEOICPA program for. The State of Ohio paid those claims out of the State Workers Comp fund. DOE has not yet found a way to legally reimburse the State for those costs. He indicated he didn't know whether any Portsmouth or Mound facility claims had made it to the State process. There have been no payments made under EEOICPA in Ohio, and DOE is working with the State to find a way to get around the state law. **Mr. Gibson** commented that in essence there was no willing payer in Ohio. **Mr. Rollow** responded that DOE is willing, but Ohio law doesn't have a way to get around it right now, although he thought a solution would be forthcoming.

Mr. Gibson inquired if there is still a resistance to transferring the DOE portion of the program to DOL so that each state doesn't have to be worked with and people can get compensated. **Mr. Rollow** stated the position of DOL, DOE, and the Executive Branch is that it would not be a good idea. DOE has fixed the production problems and has a plan to work off the backlog. It's inefficient to move a program from one agency to another. There are some tremendous challenges for DOL to run the program as the legislation is written.

Mr. Gibson commented that with a $40 million program budget request for next year and only $700,000 paid to claimants, there appear to be some serious impediments. **Mr. Rollow** agreed there had been a slow start, but asked that the focus be put on the volume of cases soon to be coming out, noting that numbers will go up dramatically in the next few months.

Mr. Griffon indicated he was trying to get a sense of the production. **Mr. Rollow** explained that 20,000 cases were currently being worked and 5,000 were not being worked. Of the 20,000, DOE has finished assembling the case file on 7,000 and they had been either sent to the applicant for review, were at the physicians panel, or were complete. **Mr. Griffon** commented he was trying to understand because it appeared the ineligible and withdrawn cases, which are exhausted at the outset, had been rolled into the total completed cases but never went to the physicians panel. **Mr. Rollow** agreed, noting that is not unlike the DOL program and that once ineligibility has been determined, it is a completed case.

Mr. Griffon observed that when the one-time hits were rolled into the percentage completed, it appeared inflated at 12 percent when only 1,100 cases have gone through the physicians panel. He asked if the new estimate of 800 cases per month is realistic. **Mr. Rollow** replied he expected to exceed that figure because they're now getting sufficient physicians and physician hours.

Mr. Griffon asked what was meant by case processors. **Mr. Rollow** described a case processing team as consisting of a medical person, generally a nurse, supported by technicians and administrative helpers who retrieve and assemble information.

Mr. Griffon inquired if there were any industrial hygienists or health physicists included in that group of 200. **Mr. Rollow** noted that a large number of the nurses have occupational medical experience, but were not industrial hygienists.

Mr. Griffon asked whether NIOSH requests for information from DOE go through **Mr. Rollow**'s office. **Mr. Rollow** explained it was facilitated through his office, but had been arranged so there was direct communication with the sites. **Mr. Griffon**'s inquiry was to determine whether the cost came out of **Mr. Rollow**'s budget, which it does, and whether it includes the cost of audit contractor requests for records. **Mr. Rollow** responded that he didn't think NIOSH was providing any additional funding for that support, so he would say it either came out of his funding or the sites' overhead.

Mr. Griffon asked if it had come up yet as an issue. **Mr. Rollow** replied it had not come to him, but he thought it was better handled by NIOSH and SC&A, commenting that he knew his people were involved in some discussions about making sure doors were open to SC&A at the Savannah River Site.

Mr. Griffon remarked this issue should be discussed while **Mr. Rollow** is present because it had

been his understanding that access would not be a problem for SC&A. **Mr. Rollow** explained that the MOU between HHS and DOE provided for full and open access to NIOSH and entities supporting NIOSH, so the courtesy is to **Mr. Elliott** and NIOSH. How **Mr. Elliott** extends that to contractors supporting NIOSH or the Board is up to him.

Mr. Griffon noted he was getting back to a point raised some time earlier by **Dr. Andrade** about questions at the site level regarding unfunded mandates and wanting to know who to bill for the work. He asked if it were **Mr. Rollow**'s impression that access and costs are covered. **Mr. Rollow** replied that he funded the DOL employment verifications and NIOSH requests for radiation dose information. He commented that he could fund a little bit of access to SC&A, but if it becomes a larger burden may be something NIOSH and DOL will have to take up with DOE to work out a solution.

Mr. Gibson asked if the local DOE office would have the right, once funding reaches that level, to take monies out of the contractor's operating fund and do something else with it. **Mr. Rollow** responded that he didn't know if they have the right, but they haven't done it and it's watched closely. **Mr. Gibson** asked if the Ohio sites in particularly were watched. **Mr. Rollow** replied that they didn't get a lot of money, but it was watched very closely.

Mr. Gibson offered that there are some DOE contractors vigorously fighting Workers Comp claims and putting employees injured on the job under the sickness and accident plan, and that if the worker chooses to go Workers Comp, the contractor is appealing all the way to the top. **Mr. Rollow** responded that his responsibility was the EEOICPA program and if those situations involved positive determinations under EEOICPA, he would be interested in the details and those contractors would be pursued.

Dr. Andrade commented that when he'd mentioned SC&A going onto a DOE contractor's site would be considered an unfunded mandate, it was to be used as the basis for asking DOE to support that. The letter has gone out and the order has been given. The contractors have been ordered to do so, therefore they will.

Dr. DeHart asked for an explanation of why the death of the claimant and the attendant benefit is different under Parts B and D. **Mr. Rollow** explained that under Part B there is a set survivor compensation payment of $150,000. Under Part D, if an offspring claimant is no longer dependent on the income of the worker, they may receive little more than a burial payment. If a worker dies during his career and a widow makes application to the program, there may be lost wages or a large death benefit.

Dr. Ziemer requested information on the quality control issue with physicians to determine patterns that may suggest other than objective evaluation. **Mr. Rollow** replied they did not score their physicians, but they did educate and communicate if they saw leaning in one direction or the other.

He noted that a single physician case is always going to be applicant-friendly because a positive finding completes the case. If a physician is always negative, there still has to be another negative finding on the same case.

Dr. Ziemer indicated he was more concerned about the luck of the draw for someone always positive. **Mr. Rollow** explained he had a medical director and 100 percent of the decisions were reviewed. If things appear skewed, that physician is approached to determine whether they need to clarify policy or provide medical or technical information to help them make better judgments. **Mr. Rollow** noted that the law establishes an arm's-length relationship between DOE and the physicians and they must be respectful of that distance.

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PRIVACY ACT AND FACA REQUIREMENTS

Ms. Liz Homoki-Titus, DHHS
Office of General Counsel

Ms. Liz Homoki-Titus of the Office of General Counsel, began her update on The Privacy Act and The Federal Advisory Committee Act (FACA) by announcing the promotion of Mr. David Naimon to Associate Deputy General Counsel. **Ms. Homoki-Titus** informed the Board they could still use their same contact number for legal questions, but would probably be dealing with her rather than Mr. Naimon.

Now that the Board is about to begin reviewing individual dose reconstructions, as well as SEC petitions, rules and regulations under these Acts become very important to remember. **Ms. Homoki-Titus** described The Privacy Act as a withholding statute prohibiting unauthorized disclosure of information on an individual to any third party. She asked that any Board member receiving a request for such information direct the person to OCAS, and then let OCAS know so that they can be aware and take proper care when it reached that office.

DHHS has its own privacy policy, which is to protect an individual's privacy to the fullest extent possible, while permitting the exchange of records necessary to fulfill Departmental responsibilities and disclosing records to which the general public is entitled under The Freedom of Information Act.

Ms. Homoki-Titus described the civil and criminal penalties available under the Act for improper disclosure. She noted that there are some permitted disclosures, but they would be handled by the Department and not by the Board. She reviewed the list of Privacy Act rules for Special Government Employees, and reminded the Board members that if they have any questions they could contact OCAS or the Office of General Counsel to discuss any limitations imposed on them by their Board service.

Dr. Melius interrupted the presentation to comment that most of the items were not Privacy Act issues and **Ms. Homoki-Titus** should be clearer.

Ms. Homoki-Titus continued that there is no reason for any member of the Board to disclose Privacy Act-protected information to anyone. Since it is not an appeals board, no one would know whose dose reconstruction is being reviewed. A claimant's information should not be discussed even with the claimant himself. SEC petitions should not be discussed outside the Board meeting. Requests for disclosure of that type information should be directed to OCAS, and **Ms. Homoki-Titus** asked that OCAS be notified such request had been received.

Ms. Homoki-Titus described the thinking behind enactment of FACA, and its special emphasis on open meetings, chartering, public involvement, and reporting. She explained the functions and limitations of a body formed under FACA, as well as requirements for charter, presence of a Designated Federal Official, meetings and agendas.

Referring to the Government in the Sunshine Act, **Ms. Homoki-Titus** described the necessity for open meetings, notification of meetings, and cautioned the Board members about discussing Board business at casual gatherings. She noted that if there were enough members present, discussion of Board business could inadvertently constitute a meeting deemed illegal under the statutes.

Ms. Homoki-Titus advised the Board that GSA had put forth interpretive guidelines for management and control of FACA committees which are followed by DHHS and this Board. She noted copies of those regulations could be provided if there were any interest in reviewing them.

EEOICPA directed the establishment of an advisory board with certain duties, and the President established this Board through Executive Order 13179. **Ms. Homoki-Titus** reviewed the duties of the Board relative to dose reconstructions and SEC petitions, reminding the Board that they report to and advise the Secretary of DHHS, not the President, in accordance with that Executive Order.

Discussion Points:

Dr. Henry Anderson commented that the Executive Order assigned all duties to the Secretary of HHS except appointment of Board members and the Chairman. Noting that he had received a letter of appointment from both the White House and the Secretary, he observed that this would apparently be the last meeting for some Board members. **Ms. Homoki-Titus** replied the letter from the Secretary was actually a welcome to the Board. The appointment came from the White House.

Mr. Elliott explained that the President retained the authority to appoint members to the Board. The letter from the Secretary was a confirmation of the appointment by the White House. Board members serve at the pleasure of the White House and will continue to do so until they are notified

by the White House that they have been relieved from service and replaced, or until a member resigns from the Board.

Dr. Anderson asked if they will get a new appointment from HHS for a four-year term. **Mr. Elliott** responded that it was unknown until the White House determined what it was going to do about appointments. They could decide to do nothing and just let it ride. Absence of a decision means members are serving at the pleasure of the White House and they will continue to serve until they hear otherwise. **Dr. Ziemer** commented that this had been a point of confusion because other advisory groups within HHS have specific terms and it had been his understanding the Secretary intended that pattern to extend to this Board. However, the overriding determination lies with the White House.

Dr. Anderson indicated his problem is that, as a State employee, he has to show a legitimate appointment in order to attend Board meetings. The letter he had received from HHS and then shared with his State administration said his appointment ended in August. He would need some indication that in fact the term did not end. **Mr. Elliott** assured **Dr. Anderson** that the Committee Management Office would work to resolve that issue. He noted that the Secretary's letter used standard language for all HHS FACA appointments, and that had caused the confusion.

Returning to Privacy Act issues, **Dr. Melius** commented he was trying to understand how the Board would be affected procedurally in trying to strike the balance between transparency in a process that was open to the public while dealing with individual claims records in dose reconstruction review activities. **Ms. Homoki-Titus** replied she believed that would be addressed in the subcommittee presentation on the procedures they've agreed to and will be asking the Board to approve.

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SANFORD COHEN & ASSOCIATES CONFLICT OF INTEREST AND QUALITY ASSURANCE PLANS ACCESS ISSUES

Mr. Joe Fitzgerald, SC&A
Access Issues

Mr. Joe Fitzgerald announced three out of four site profile reviews were near completion, which he felt was an opportunity to make the Board aware of some issues and perhaps address resolution in order to expedite the reviews. **Mr. Fitzgerald** cited requirements and provisions under the ABRWH task order contract and objectives from Sanford Cohen & Associates' (SC&A's) procedures, concluding that their approach is sound but guidance was needed in some problem areas.

Mr. Fitzgerald indicated access is an issue which has not stopped them, but keeps them from going as fast as they'd like. He reminded the Board that they had been briefed on this issue in April, and their letter to the Secretaries of DHHS and DOE had gone over in July.

He explained that SC&A was picking up from DOE sites that they had spent considerable resources generating records in response to NIOSH requests. They rightfully want to, before they provide additional records to SC&A, ascertain that SC&A has cross-referenced their request against what's already been provided. **Mr. Fitzgerald** indicated they had been pushing for several months to have ready access to the NIOSH database of recovered files. That was provided last week and was a major milestone.

An issue coming up quickly is a need to make use of the process laid out by the MOU to ensure SC&A can ask for records and interactions at the sites and have that supported by resources set aside for the MOU. Currently SC&A is hearing very clearly that the sites want to cooperate, but someone has to pay the contractors for the time they're going to spend with SC&A.

Mr. Fitzgerald stated he felt Q clearances would be a key issue at Y-12, Rocky Flats, and the Nevada Test Site in order to access and go through the records. He noted Y-12 is on the schedule of reviews given to SC&A by the Board. **Mr. Fitzgerald** commented that NIOSH has put this in motion and he had just gone through the Department of Defense (DOD) clearance process last week and anticipates top secret clearances are forthcoming, which is prerequisite to Q clearance. However, he had been reminded by **Mr. Rollow** that such could take six to 12 months. Therefore, either the clearances will have to be facilitated or SC&A will have difficulty accomplishing reviews at those two or three locations.

Observing that SC&A was not alone in having to deal with national security questions, **Mr. Fitzgerald** suggested there may be some consideration of how things are scheduled to reflect that reality. While the process is probably moving as fast as it can, it won't be fast enough to get to those sites in the near future.

SC&A will be able to deliver two or three essential reviews. Savannah River is nearing completion. Bethlehem Steel and Mallinckrodt, being AWEs, don't have as much in the way of site access issues and the interviews are more straightforward. **Mr. Fitzgerald** commented Hanford may be somewhat of an issue, and the balance of the sites will have security questions that may prove to be a problem.

Mr. Fitzgerald observed that there will be some issue as far as the scope laid out for the reviews in terms of readily available information, noting that he didn't feel the answer is to limit the planned scope. He indicated the reviews were very sound and the approach is strong.

Deliverables SC&A can give the Board is very specific. **Mr. Fitzgerald** indicated they were

interpreting a "final review" as a one-time deliverable. Their concern is that if SC&A falls ten or 20 percent short of completion because of the data access or security issue, they're not sure how to handle providing the Board incomplete analyses. The bottom line is that they're timeliness and resource issues that are going to be factors in increasing cost and time, and need to be addressed.

Mr. Fitzgerald stated that SC&A would like the Board to deliberate on the experience SC&A now has on the issue. They're asking the Board to provide guidance on what would make sense in terms of preserving the feedback but recognizing the practicalities of dealing with the information and security issues.

Discussion Points:

Dr. Andrade commented that looking at items called incidents had been mentioned, noting that "incidents" have a very specific meaning and "occurrences" are public information. He suggested that if SC&A asks for incident reports, that's more sensitive and they might expect a sort of push-back from people in some of the DOE sites.

Noting that **Mr. Fitzgerald** had mentioned he had DOD sponsors from whom he may get top secret clearances, **Dr. Andrade** described a method by which clearances might be transferred by way of special caveat to achieve a clearance recognized as having access to Q information. **Mr. Elliott** observed that **Mr. Fitzgerald** had a DHHS sponsor to get the top secret clearance and may have mis-spoken when he said DOD. After discussion about who was now doing the actual investigation for clearance, it was agreed that Homeland Security had changed some operations.

Mr. Fitzgerald inquired of **Dr. Andrade** if he agreed -- which he did -- that for places such as Los Alamos, lack of Q or equivalent would limit not only access to information but the ability to move around.

Mr. Robert Presley asked if they presently held any type of clearance. **Mr. Fitzgerald** replied they did not. The process NIOSH had instigated with HHS sponsorship would lead to top secret clearance within days, but would fall short of what's required for the DOE complex at weapons facilities. Since nothing less than Q clearance is required, that is the issue to be resolved if SC&A is to do Y-12, Los Alamos, and some other locations.

Dr. Melius inquired what constituted a report and how a contractor should report their findings. He suggested if a review could not be completed because of access or other issues, an interim report might be a possibility and wondered if the task order might be modified to reflect that. **Mr. Elliott** replied that it is appropriate to effect a modification on a task order for just cause. He noted the Board needed to come to grips with that and make decisions on how to manage the audit process and conserve resources.

Dr. Ziemer observed the question of what constitutes a final report was not a well-defined thing, but was described very generally. That was part of the issue. He suggested somewhere between perfection and doing a really sloppy job might be the point at which you say you've done all you can do, within whatever constraints -- time, resource, or access.

Mr. Fitzgerald noted that the other reality is that the site profiles are ever-changing documents. What SC&A is looking at is going forward and seeing unevenness. He observed that it wasn't foreseen in the beginning that access would be uneven and time-consuming, noting that they'll probably be okay by next year, if not sooner.

Dr. Melius commented he was more comfortable with some of the review not being done because of security clearance issues than one of not having the resources necessary to pay the contractor. You get at a point to say 70 percent of the site profile review can be done but the other 30 percent can't be without Q clearance access, then modifying the task order to allow an interim report with a final when the clearance issue has been addressed is pretty straightforward. **Dr. Melius** further observed that once some of the site profile reviews are done, the Board may want to look at their overall procedures and learn from that experience. He suggested he'd rather learn from having done too much than being in a position of not having had complete access and not doing all you thought should be done.

Dr. Melius indicated he also had a concern about scheduling and asked if he'd understood correctly that it's Mallinckrodt where SC&A now has access to the documents. **Mr. Fitzgerald** replied they were still waiting on additional documents on Mallinckrodt from NIOSH. He noted they had done quite a bit and felt they could finish it within weeks, but were still looking for some documents.

Commenting that the Board would discuss the SEC petition review tomorrow, **Dr. Melius** said he didn't want them to be in the position of having their contractor's review of the site profile review on Mallinckrodt pending and no report having been issued, NIOSH reviewing an SEC petition based on the site profile, and the Board reviewing the NIOSH SEC petition review. And while they may not be connected at all, they may be.

Dr. Neton observed that NIOSH was not aware of any documents they owed SC&A at this time. It sounded as though SC&A had requested documents. **Mr. Fitzgerald** replied that the question had been were they set with Mallinckrodt and he'd answered they needed some additional documents. Since SC&A received access to the NIOSH database last Thursday they have done searches against it on Mallinckrodt just to see what reference documents from the site profile they had access to and what they didn't. Some documents they wanted to look at are apparently not in the database. They're now prepared to ask NIOSH for access to those documents.

Dr. Melius asked for an explanation of the issue of site access and the MOU, payment mechanisms, et cetera because he was trying to understand if there's an issue or what's going on. **Mr. Elliott**

replied that no issue had been brought to his attention. NIOSH has been as cooperative and collaborative as possible in responding to requests. He commented that he was somewhat disconcerted that **Mr. Fitzgerald** would portray SC&A as awaiting documents that had yet to be requested. The arrangement with DOE under the MOU is that NIOSH will facilitate access. If they hear of a push-back because of funding, they'll work it out with DOE. **Mr. Elliott** stressed that no instances had been brought to his attention. **Mr. Elliott** added that he didn't believe they'd been brought to **Mr. Rollow**'s attention because he was sure **Mr. Rollow** would have talked to him about them. **Dr. Ziemer** added that **Mr. Rollow** seemed to indicate the field was prepared to assist in the Board's efforts.

Mr. Fitzgerald explained that DOE field operations want assurance that SC&A has cross-referenced their document requests with the NIOSH database, which they were unable to do until last Thursday or Friday. Without ability to provide that assurance, field operations were unwilling to respond. **Dr. Ziemer** observed that they didn't want to do double work. **Mr. Fitzgerald** agreed that was understandable.

Dr. Anderson commented that the Board wanted to see the available resources reserved so that when the clearances ultimately came through the reviews would be completed. With the first ones coming up, however, they may get a sense of where confirmation was strongest, et cetera. **Mr. Fitzgerald** acknowledged SC&A has a challenge to operate within an explicit budget and must find a way to conduct those reviews within that set budget. Otherwise it will truncate the entire process.

Mr. Griffon expressed concern about one of **Mr. Fitzgerald**'s slides which indicated some questioning of the comprehensive scope of reviews. He asked whether there were issues about the type or extent of data SC&A was looking to access as compared to the scope within the task order. **Mr. Griffon** commented that was not an issue that had been raised to the Board -- although SC&A has had conversations with NIOSH -- and he was wondering how, if it is an issue, it gets resolved.

Mr. Fitzgerald replied NIOSH was the contracting organization, noting they had to look at the expenditures. The discussions have been to assure there's not movement outside of defined scope for the review and what is the scope SC&A is trying to accomplish. **Mr. Fitzgerald** acknowledged the scope SC&A is operating against is what has been laid out very clearly in the original task order and the site profile procedures approved by the Board. He explained they had not been tested in the field, however, so to some extent they're finding out how this is going to be implemented. They're finding some things take more resources than originally envisioned, so there has been some discussion on scope. **Mr. Fitzgerald** agreed it is an issue requiring Board awareness. He noted that it will come up in the reviews to be seen in the next few months in terms of what should be the model, how deep you go and what kind of analysis is appropriate for these audits.

Dr. Ziemer commented that the Board had originally done an estimate that for a certain amount of money a certain number of reviews could be done. The contractor also bid without all the

information available as to what that would entail. As the work begins and what it takes to do it is realized, it may be the resources available are only sufficient to do ten reviews rather than 12. **Dr. Ziemer** observed that both the Board and SC&A are learning as they go what it takes in time, effort and resources to do the reviews.

Mr. Griffon remarked that part of what he's inquiring about is the decision-making process, because the Board isn't learning much about that step. They've seen there are some questions on the complexity or depth of scope, they understand there are budget constraints, they know NIOSH is the contracting entity, but the Board has also been very clear that they must have the determination on the scope. **Dr. Ziemer** noted **Mr. Fitzgerald** was simply alerting the Board to issues that may be emerging.

Mr. Griffon countered that he didn't know that the Board could wait for final reviews to come out, which perhaps goes back to the issue of interim reports. He noted that if issues are there now, the Board needs to perhaps resolve or clarify what they are. **Mr. Fitzgerald** responded that factors included the need to plan within available resources. Another is the issue of what the scope should be. It's defined in the procedures, but in practice how far do you go. Another is the question of a contingency when you can't touch all points. Those factors constrain what a solution might be. **Mr. Fitzgerald** explained SC&A didn't want to presume what the Board's guidance might be and they are now at the point where it would be helpful to understand what would make sense.

Mr. Presley suggested SC&A might consider changing their clearance goal from Q to L, in that there's no need for SC&A personnel to know design data and most of the documents are accessible at a lower level. He noted it takes much less time to get an L clearance. **Mr. Fitzgerald** commented that he had had a Q clearance for decades and his experience had been that in certain areas of the complex, without a need to know, even with a Q clearance he had sat in a waiting room for hours. He voiced a suspicion that these days it would be difficult to get past the gate and, for certain sites such as Y-12, mission cannot be accomplished without Q clearance. **Mr. Griffon** remarked he'd found a lot of records he needed to review only needed an L clearance, but they were stored in Q-cleared areas where he couldn't get access.

Dr. Melius opined that if the Board modified the task order to allow for an interim report he would foresee the contractor could make the case that when they bid, they assumed they would only need one visit -- or whatever the case is -- and there would be extra costs if they had to spread it out over time. He suggested it would be the contractor's burden to show that was their intent in how they made their original bid, but the Board would have to be ready to allow for some modification in the cost of the contract, especially if it gets split up into more than one interim report.

Dr. Melius commented that another matter was the schedule for seeing reports from the contractor, noting that some of these issues will be more easily dealt with once they've seen a report and had time to discuss it. He asked if the Board could assume Bethlehem Steel and Mallinckrodt would be

complete for the October meeting. **Mr. Fitzgerald** replied it was a possibility, although SC&A would send the report through NIOSH and then to the Board. He noted that process itself may take weeks and was something he couldn't account for, but SC&A would have the drafts by then which could be transmitted to NIOSH for review.

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Dr. Stephen Ostrow, SC&A
Conflict of Interest and Quality Assurance Plans

Dr. Stephen Ostrow commenced his presentation by noting the plan was not only for organizational conflict of interest, but also personal conflict of interest. SC&A took the Federal Acquisition Regulation and translated it into a procedure they could follow to assure the rendering of impartial judgment and advice to the Board.

Dr. Ostrow explained that while the plan was lengthy, there were some basics. Those include SC&A's commitment not to bid on or perform work for NIOSH, ORAU, or any of their contractors. They will not accept work from DOE or a DOE contractor dealing with radiological issues. Should any gray areas arise, SC&A will seek guidance for resolution from the Board.

The 36 individuals who may potentially work on the project were provided a copy of the plan, which they acknowledged they had received, read, and understood. A questionnaire was filled out and provided to the plan administrator disclosing past activities related to sites and projects on which they'd worked. The administrator then ranks their clearance to work on the project, from unlimited to some degree of restriction. **Dr. Ostrow** displayed a slide of the acknowledgement form and the questions on the questionnaire.

After a determination, SC&A maintains in a secure file in their headquarters information about the plan, the individual responses, findings on the individuals as well as sites for which they are cleared or not cleared. The goal is to provide a transparent process whereby if anyone who is authorized to do so wants to review the information, it is available for audit. There are also corporate conflict of interest certificates that SC&A and its subcontractors are not engaging in any contracts or work which may conflict with the work under its contract to support the Board.

Two summary lists are maintained. The first is a summary of the yes and no responses on the questionnaires and the certification results, by individual. The second is the restricted site list for each of the individuals.

Dr. Ostrow explained that from the 36 potentially available individuals, 21 are in unrestricted status, 15 have some restriction, and zero are precluded from working under the contract, with none pending review.

Dr. Ostrow noted that the plan has a general provision to be somewhat self-policing in that someone filling out the form ahead of time has no way of knowing exactly what they may be reviewing in the future, so task leaders have to use a bit of judgment. SC&A stresses that if there's any doubt, the conflict of interest officer must be consulted. If they can't reach resolution, it will be taken to the Board for determination.

Discussion Points:

Dr. Ziemer reminded the Board that the conflict of interest plan is a deliverable requiring their acceptance and approval. He noted the slides were merely a summary of the plan, which had been e-mailed to the Board earlier. He opened the floor for questions leading to a motion to accept or approve the plan.

Dr. Ostrow remarked that, in addition to the Board's comments, SC&A would like to make a few modifications of a housekeeping nature.

Dr. John Mauro of SC&A commented that eventually the material they had been summarizing would be available on a web site, similar to the conflict of interest information regarding ORAU, once the appropriate point is reached. **Dr. Ziemer** observed that once the plan had been accepted by the Board would be an appropriate point.

Dr. Anderson commented he was assuming NIOSH had reviewed the plan and would be interested in their comments. **Mr. Elliott** confirmed they had read the plan, but noted it was the Board's decision and NIOSH has no input to it.

Dr. Ostrow indicated the plan was very similar to what SC&A had included in their proposal, with perhaps better English.

Ms. Wanda Munn commented she had downloaded her copy of the plan but had not printed it, and was assuming the Board would have a hard copy of the plan and any changes undertaken.

Dr. Ziemer asked **Dr. Ostrow** who had a copy of the plan with SC&A's proposed changes noted. **Dr. Ostrow** commented he had in mind something he wanted to do, but had thought he'd get the Board's comments first.

After discussion it was agreed that copies of the plan would be made and distributed where necessary, and action on the matter would be deferred until the working session the following day.

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Dr. Ostrow remarked that this is the second quality assurance presentation on the project and was nothing new or novel. All work done by SC&A is governed by a quality assurance plan. SC&A wrote a project-specific plan governing how the process is done and reflecting both job and regulatory requirements on the project. The plan controls and documents all aspects of the project.

The goal is for everything to be done consistently according to contract and regulatory requirements, as well as providing a record of what, why and how a thing was done, the process is clear and transparent.

Dr. Ostrow indicated he was not going to go into all the details, but explained the plan also describes what has been done to comply with security and confidentiality provisions. It outlines the SC&A organization, who does what, what different functions are, who's responsible for different things.

The plan ensures that all work is done according to approved procedures, the proper people have the proper procedures, they acknowledge they have them and that they are up to date with the latest versions. Also included is an outline of the management process. This is how SC&A receives task orders from the Board, responds with task order proposals and manages the budget, the time and the work product.

Dr. Ostrow concluded by noting that everyone involved is required to acknowledge receipt and understanding of the QA plan, and that a QA file is also maintained in the secure file room, available for proper inspection should the Board choose to do so.

Discussion Points:

Dr. Ziemer reminded the Board the QA plan is a deliverable requiring action similar to that of the conflict of interest plan. Noting the slides and handouts were summaries and presuming the same issue existed with a hard copy, he asked if **Dr. Ostrow** anticipated any modifications to the QA plan. There were none anticipated.

Dr. Andrade commented he had read the plan a few days ago so it was not perfectly clear now, and asked if it included a section on problems that could exist between the Board and SC&A such as may require changing tasks or scope of tasks. **Dr. Ostrow** indicated it dealt with problems, but he would have to review it himself to see how much detail it contained and if such a situation were covered.

Dr. Ziemer announced action on this matter would be deferred until all members of the Board had a copy of the plan, and would probably be addressed in tomorrow's working session.

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SITE PROFILE STATUS UPDATE AND DATABASE USE

Dr. James Neton
NIOSH

Dr. Neton announced that in addition to what was becoming a standard presentation on site profile status, he wanted to include a description of the site research database. Accompanying that, he wanted to touch on the exciting area they're entering, the coworker database and analysis of claims using coworker data.

NIOSH initially had targeted priority treatment on 16 profiles for DOE facilities. The sites were selected jointly by OCAS and ORAU based upon sites with the greatest number of cases. When completed, they would provide available data to process approximately 80 percent of the claimant population at that time. That has been holding steady for the last year. There are now nine complete site profiles whereby almost 10,000 cases may be addressed, roughly 60 percent of the claimant population base. The two profiles completed since the last Board meeting are the Oak Ridge X-10 facility, which has 1,126 claims, and INEEL facility with 669 claims in the possession of NIOSH.

Dr. Neton reminded the Board and the audience that a site profile is, in most cases, a compendium of six chapters, each representing a specific aspect of a site. Those include site description, internal and external dosimetry, and similar topics. When a site profile is described as complete, it means all six chapters have been reviewed and signed off by OCAS. **Dr. Neton** commented that from time to time they will issue a chapter with a section labeled reserved. The rationale is that if it is substantially complete, claims that require only that portion of the data at hand can begin to be processed.

There are seven remaining site profiles out of the targeted 16. All chapters have at least one draft completed. But the reasons they're unfinished are many. K-25, Paducah, and Portsmouth are gaseous diffusion plants, SEC sites by definition. They're problematic. They were granted SEC status because of, among other things, issues with transuranic contaminations. Great caution is being taken to ensure an accurate portrayal of those sites. **Dr. Neton** observed that most of the cancers from those sites will be skin and prostate, and skin cancer dose reconstructions can be problematic at some sites, so they want to make sure factors such as the geometry have been addressed.

As for the remaining sites on the list, **Dr. Neton** described Mound as a compendium of the periodic table of isotopes, with a large number of legacy isotopes required to be fleshed out. Then on the national security sites they're still digging for documents to make sure there's an accurate portrayal of the site, given that some of the information there is classified.

There are nine additional site profiles under development beyond the targeted 16. The two Argonne facilities were added since the last Board meeting, one near Chicago and Argonne West in Idaho.

There have been four Atomic Weapons Employer (AWE) site profiles issued, Bethlehem Steel, Blockson Chemical, TVA Muscle Shoals, and AWE complex-wide. The Bethlehem Steel document was used to complete the majority of those cases in hand, and SC&A is well under way on its audit of that profile. **Dr. Neton** commented they looked forward to hearing the results of those findings.

Dr. Neton reminded the Board the AWE complex-wide document contained what had been developed as overestimates for certain processes at AWEs that used uranium. Particularly they're overestimates for non-metabolic organs -- pancreas, bladder, prostate -- which don't concentrate uranium. NIOSH is confident the overestimating doses have covered the range of exposures at those facilities. A number of cases have been done with this profile and has been successful in freeing up a number of claims, particularly at those AWEs where a profile has not been completed.

An additional 20 AWE site profiles are under development. **Dr. Neton** remarked it was unlikely more would be added to the list as a result of diminishing return, which has been discussed at previous Board meetings. The plan is to modify an existing document or write a larger dose reconstruction report to include all relevant information. That approach might make the dose reconstruction report a little less readable, but would be more time-efficient.

Worker outreach meetings have been successful. That is being headed by Bill Murray from ORAU, in close association with NIOSH. It's important that NIOSH be represented, as they have been at all 13 meetings since the first one at Savannah River in 2003. A pattern of return visits is emerging. This is either at the request of the work force or because there's a feeling there was some information not captured.

Meetings are formatted as a mini town hall, with return visits in more of a workshop format, trying to elicit from the folks any additional information they may have. **Dr. Neton** added that minutes are taken at all meetings. Once approved, they're sent to all attendees to make sure they're factually accurate. After those have been vetted, they appear on the OCAS web site.

At the last meeting the Board asked what was the site research database. More particularly, where are the incident files you talk about. **Dr. Neton** remarked he wanted to first talk about what the site research database was intended to be. **Mr. Fitzgerald** mentioned earlier they'd just had a training session on this within the last few days. It is the entire database of all the records captured from the inception of this project. Records in the public domain are not there, but they can and will do that. But these are the results of data capture efforts where they go to a site, scan records and put them in the database. It's intended to contain images and data files for all covered facilities.

Dr. Neton noted it was organized by facility. It is a SQL server database linked to the entire NOCTS scheme of things, with a user interface so it has keyword searches available.

A standard form is required to be completed for each file captured. The files are indexed by keywords and reviewed by someone knowledgeable about the operations of facilities. A mini abstract is prepared that tells what the content of the file relates to, the key parameters you might want to know about the file rather than having to read the entire contents.

Dr. Neton explained there were almost 10,000 reference documents representing nearly 45,000 files. He commented he had tried to get a page count, but anybody who works with computers will recognize that 65 gigabytes of data is fairly robust. Larger sites have more files. Savannah River Site has something like 380 files, and it varies from there.

Pointing out that this was intended to be, and was, the research database used for site profile development, **Dr. Neton** observed that it had since morphed into a database containing key links to capture coworker data.

Dr. Neton explained that initially these data files were just raw captured and put into bins because they were just trying to collect information. Then they realized many files had information that could be used for coworkers -- bioassay monitoring data, Thermo Luminescent Dosimeter (TLD) results, air sample, whatever there was. The database is now being linked so that when information that could be used in dose reconstruction is available, a link is established. If there is unique data for a particular claimant, a link is established to that claimant which alerts the dose reconstructor that information is available in the site research database that could be used to process that dose reconstruction. **Dr. Neton** cautioned this effort is nowhere near complete, although they are fairly well into it.

Dr. Neton indicated there is also claimant data which can be used as coworker data. That information is being keyed into the worker profile database. External monitoring information from the 16,000 DOE responses is keyed in at the Richland office of Dade Moeller, so that information then becomes available. So there is a combination of captured and keyed-in information.

Most of the first 4,000 claims reconstructed relied heavily on individual monitoring data, people who were monitored and characterized in some way in their work environment using personal samples. While there is some coworker data in the existing site profiles, they speak very directly to interpretation of individual monitoring data and exposure conditions at the facility. **Dr. Neton** remarked he wasn't saying they were finished with that, but they are being worked through and NIOSH now stands ready to develop the coworker database for people who were not monitored at all, or were poorly monitored and whose data files need to be supplemented.

There are other sources for the information, as well. The Oak Ridge Associated Universities Center

for Epidemiologic Research has done a large number of studies evaluating workers at these facilities. Their database contains a large portion of the available records in catalogued form. They are being reviewed to make sure full advantage is taken of that source. The Health-related Energy Research Branch (HERB) within NIOSH has conducted a number of epidemiologic studies which contain coworker data. Although there is some overlap with the Center for Epidemiologic Research, there are some unique facilities in the HERB database, such as INEEL. There may be some useful information to be found in the Comprehensive Epidemiologic Data Resource (CEDR) database. The CEDR is a DOE-funded where epidemiologic studies, as they are published, are stripped of personal identifier information and made accessible, with minor restrictions, to the public for use in further analysis and epi studies. NIOSH and ORAU will look at this entire compendium of information to develop the coworker datasets.

Dr. Neton commented that Y-12 is the first completed profile for external dose using coworker data for the '51 to '65 time period. He noted that OCAS had not yet signed off on it, but expected it to be issued within the next few days.

Future use of these datasets includes creation of external dose distributions for time periods and job categories as available. Internal bioassay data are being used to create effective air concentrations, using claimant-favorable assumptions, when exposure conditions are poorly characterized. **Dr. Neton** observed he was not aware of anyone having done this before at this level of magnitude. He noted additionally that the standard hierarchy of datasets is employed, as with dose reconstructions. Personnel monitoring is the best indicator of workplace exposure, followed by area monitors, then air samples.

To convey a sense of the magnitude of potential data, all of which is already computerized, **Dr. Neton** described some of the holdings. Over 4 million records of bioassay monitoring results are in the possession of ORAU including 834,000 Y-12 TLD badge results and a million X-10 urine samples. There's whole body counting information, which can be a good indication of what workers were accumulating long term. The values also go back to the earliest days of operation.

The pitchblende ore used at Mallinckrodt raised concerns about body burdens of radium. **Dr. Neton** explained that inhaled radium decays into radon gas. Measuring the amount of radon gas in a person's breath is an indirect measurement of the radium in their body. Commenting that he wasn't sure the technique was used much now, **Dr. Neton** noted there are almost 2,400 breath radon samples, along with 5,000 radon air sample measurements, for the Mallinckrodt facility.

NIOSH and ORAU understand and recognize they can't use these datapoints until they have been vetted and validated in order to give the values credibility.

Discussion Points:

Dr. Melius stated he understood the site profiles don't reference everything in the database, but asked if an individual's dose reconstruction report would reference a document from the database if that document were used in his dose reconstruction. **Dr. Neton** replied **Dr. Melius** was correct and gave the Y-12 criticality incident as an example. The Y-12 site profile mentions the criticality accident but doesn't go into elaborate detail because there's an entire report on it. Some of the dose reconstructions have referenced that report, where applicable.

Dr. Melius wondered if it would be helpful to have public access to a listing of available documents or the abstract of that document, but he didn't want to make extra work. **Dr. Neton** agreed publishing a list of the documents on the web site was a good suggestion. **Mr. Elliott** offered he didn't see it as extra work, in that the dose reconstruction report provides the reference. The abstract or the entire document are available upon request during the closeout interview, by e-mail or phone, or could be viewed at the public reading room at their office.

Dr. Neton agreed, but remarked that a listing on the web site wasn't much of a challenge, and a lot of people called to ask if NIOSH and ORAU were aware of a particular document. He thought it might be easier if they could access the web to see if they already had it and had covered it. **Dr. Melius** suggested there was a danger it could lead to extra work when people thought a document should have been used but wasn't, and the listing might help people understand all the work that's being done on the program.

Dr. Melius asked where NIOSH stood on the construction worker aspect of the site profiles and how it was affecting the processing of those claims. **Dr. Neton** replied that was progressing more slowly than they'd like. A meeting is scheduled at SRS with some construction workers. An issue is gaining access to construction workers to work with NIOSH on capturing their unique exposure characteristics, and that is delaying some construction worker claims, though not all. If they were in facilities where NIOSH is comfortable with the exposure characteristics, they'll do that.

Dr. Melius observed that a lot of the issue with coworker data is the uncertainty assigned to the extrapolation, noting that in some of the plutonium exposures at Rocky Flats it wasn't a very good predictor for two people doing similar processes standing side by side. **Dr. Neton** remarked they would rarely use side-by-side exposures but would tend to use a distribution, which is part of his presentation tomorrow, how they're assigning uncertainty.

Dr. Melius inquired if they'd considered holding site meetings earlier in the process. **Dr. Neton** replied they tried to tailor their visits based on individual needs, and some sites want them to come later in the process when there's a document to review and comment on. Linde is an example of a site wanting them to come early on to capture their story before too much is done.

Dr. DeHart commented that there was considerable discussion at Hanford followed by a multi-page letter from one of the union activities expressing concerns from their review of the site profile. He

asked how those concerns were used in adapting it, if necessary. **Dr. Neton** replied that when the organized labor people provide them with a detailed document, it is passed to the site profile team for evaluation and possible use in modification of that site profile. That's why they're called living documents, and if something casts doubt on what has been done and the generosity NIOSH and ORAU thought they'd built into it, they'll put it in.

Addressing Hanford specifically, **Dr. Neton** indicated meetings had been held on those issues and they will get them back into the profile, as well as feedback to the originators of the document as to what they found. **Dr. Neton** noted there is a database now of the concerns captured at the meetings and they are able to track and trend common themes, issues, et cetera and they're working hard to address those things. It isn't going as fast as they'd like, but they haven't been forgotten.

Mr. Griffon observed that given recent discussions of the case selection process and variables in the database for individual claims, it seems some of the key variables to linking workers aren't being collected in the claims files, such as job category. **Dr. Neton** replied that when he was talking about job categories, he was actually referring to the epidemiological databases where those are more typically present, and they would rely on those. **Dr. Neton** explained that although those are searchable fields, there are so many ways facilities have been categorized, to categorize them within the NIOSH database is more work than they've been willing to take on at this point.

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Dr. Ziemer declared the Board in recess until 7:00 p.m., at which time public comment would be received.

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EVENING SESSION

Dr. Ziemer welcomed the public to the evening public comment session. He introduced the members of the Board and explained the Board's purpose and how it operated, composition of membership, and the responsibilities of the Board as defined in EEOICPA.

Dr. Ziemer explained that the Board was not there to answer questions, but to listen to what they had to say. He pointed out that a public health advisor for the program would be at a table in the back, and would be available to direct specific questions on a claim to the information needed. **Dr. Ziemer** also indicated DOL had a table with other information they might find helpful.

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PUBLIC COMMENT PERIOD

Mr. Clinton Jensen,
Firth, Idaho

Mr. Jensen described a history of incinerating depleted uranium for 18 months and becoming severely ill. He spoke of people in charge not knowing what they were doing. He told of being called a whistle-blower for raising safety concerns. He claimed everything possible was done to shut him up, including an Army investigation and incarceration attempts. He has filed a claim and his medical records are available if anyone is interested.

Mr. David Fry, PACE Union
Idaho Falls, Idaho

Mr. Fry commented that in April when the site profile meetings were held, one for building trades and one at Paper and Allied-Industrial, Chemical and Energy Workers (PACE), there was no internal dose section to review. A lot of current and former employees were present and made comments, and they had received the minutes from the meeting. He wondered if their comments would be incorporated into the site profile.

Dr. Ziemer asked if **Dr. Neton** would respond, and he stated that the comments were passed on to the site profile team for consideration. If any of them would make a difference in the profile, it will be revised to reflect that information.

Mr. Fry remarked that some employees felt some critical processes and buildings had been missed, and inquired if there would be another meeting after the revision and when the internal dose section is completed. **Dr. Neton** replied the report on internal dose is finished and on the web site. He noted there is not another meeting planned in the near future, but if one were necessary or there were concern about the information on the web site, they would make arrangements to conduct another meeting.

Mr. Fry observed the general consensus had been that most people wanted a second meeting. **Dr. Neton** responded he had earlier mentioned there was some interest in a second meeting, but one had not yet been planned.

Mr. Knut Ringen
Seattle, Washington

Mr. Ringen thanked the Board for holding evening meetings and requested they do a better job of advertising them sooner. He stated he had four main matters on which to comment.

First, the Board is thought of as the conscience of EEOICPA. Lack of credibility in the overall

problem has led to the small number of applications for compensation from INEEL, 1,500 out of 20,000 people who generally should be eligible.

Secondly, data could be presented more effectively at the meetings and by NIOSH in general if it were done by site, by occupation and by probability of causation.

Thirdly, caution should be taken in referring to site profiles as completed because that suggests to him that nothing more is going to be done with them. The reality is they may be changed periodically.

Finally, SC&A has begun to ask **Mr. Ringen**'s organization if they can organize workers for SC&A to interview for their site profile reviews. He commented that is a time-consuming and very important function, but it was difficult for them to organize worker meetings and provide technical support without funding to pay for the workers' time. He noted that in particular construction workers don't get paid for time spent at meetings, and asked to consider funding be made available for site profile assessments or anything else that requires involvement of the local workers.

Mr. Gaylan Hanson, INEEL
PACE Union Health and Safety Rep

Mr. Hanson asked to read into the record a statement from a retiree who was too ill to attend the session. The statement described that employee's undocumented radiation exposure when he was called from his job watering the lawn to lay lead brick shielding in a tunnel to stop a radiation beam from coming from the reactor through an experiment insertion hole. He described other episodes of contamination and over-exposure when he had no film badge to record dosage levels.

Mr. Hanson commented a lot of workers and former workers feel there is a good job of documentation of what they have, but their concern is for the "unknowns."

H. Doyle Egbert, Retired
Terreton, Idaho

Mr. Egbert described some of the events in his 17-year career in which he had received high levels of contamination which were unrecorded, commenting that some of those tasks are now performed by robots.

Ms. Shirley Codding, Claimant
Idaho Falls, Idaho

Ms. Codding commented that the chem plant had been known as the garbage dump of the world, but noted things were better now as a result of public concern. She agreed that many times in the

'60's, '70's, and '80's her dosimetry badge was not on because they did whatever it took to get the job done. She described high exposure incidents when no one wore a dosimeter. She remarked that INEEL's recordings were never verified and she didn't know of anybody who believed their dose was reflected accurately, adding no one believed INEEL had been honest.

Mr. Clinton Jensen spoke again to say that "SMC and everybody" was hiding behind national security, but it was a fraud because a person's health was more important and it was denying him the ability to get proper medical care.

Mr. John D. Quinn, Retired
Idaho Falls, Idaho

Mr. Quinn worked at the chemical processing plant for 27 years and described how protection in that area had evolved. He spoke of half-face respirators with paper filters in the early days and bubble suits now. He mentioned ventilation problems and monitoring problems, and wondered if his dose reconstruction might have been different if the NIOSH personnel doing it really knew the conditions they had worked in.

Dr. Ziemer thanked everyone for coming and invited them to attend the next day's session, as well. He reminded the audience there would be another public comment period right after the lunch hour, although it did not appear on the schedule, should they or any of their colleagues wish to speak at that time.

With no further comments, the Board officially recessed until the following morning.

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Wednesday, August 25, 2004

Dr. Ziemer called the second day of the meeting to order and announced several administrative matters to take care of. **Dr. Ziemer** called for **Ms. Cori Homer** to update the members on the venue for the October meeting.

ADMINISTRATIVE AND HOUSEKEEPING

Ms. Cori Homer
NIOSH

Ms. Homer reminded the Board they had scheduled that meeting to be held in Washington, D.C., but with national elections coming up in early November, mid-October was a busy time for Washington and no hotel rooms could be reserved. Lodging was secured at the Westin St. Francis in

the alternate venue, San Francisco, California, for October 19, 20, and 21, allowing three days for the subcommittee and full Board to meet. After discussion it was determined Board turnout could be better accomplished by changing the dates to October 18, 19 and 20. **Ms. Homer** indicated she would communicate with the hotel and confirm that change.

The Board deliberated scheduling the final meeting for 2004 and tentatively decided on December 13, 14, and 15 in Washington, D.C., with the alternate location of Tampa, Florida, as there are claimants from Pinellas. The first week of February was selected as the time for the first meeting of '05. **Ms. Homer** indicated she would shop hotel availability using those choices.

Dr. Melius asked that **Ms. Homer** notify the members as soon as possible when changes are made or accommodations confirmed so they can maintain their calendars.

Ms. Homer discussed other matters related to travel orders, voucher information, and the approaching fiscal year end closeout. Information was provided for those members touring the INEEL facility the following day.

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USE OF UNCERTAINTY IN DOSE RECONSTRUCTION

Dr. James Neton
NIOSH

Dr. Neton prefaced his presentation by noting that the allotted time did not allow for an extreme amount of depth. He had put together a number of slides for an overview of how uncertainty is assigned for different applications in the dose reconstructions.

Commenting that what he was going to present was probably a review for some people, **Dr. Neton** explained he wanted to set the groundwork. The way Congress enacted the statute uses the IREP model, a Monte Carlo sampling program which applies uncertainty to the distributions for the risk coefficients. The front end input to the model is the dose reconstructions, which also use uncertainty distributions in that calculation.

The value for the central tendency of an uncertainty distribution will represent best estimate. Effort is made to figure out what really is the best estimate of the worker's exposure at the facility doing that job during that time period. With no way of knowing exactly, advantage can be taken of the probability distribution functions within IREP to assign some uncertainty about that distribution. **Dr. Neton** explained that the over-arching factor is that if they don't know and science can't inform them, they will include favorable assumptions in the uncertainty distributions. He added the distributions will vary considerably depending upon what they're doing with that dose

reconstruction.

Regulation 42 CFR 82 details the efficiency process of making some worst-case assumptions at the beginning of dose reconstruction to see if, even under those considerations, a claimant is non-compensable. If so, the dose reconstruction is terminated. Since the simplest distribution is a single value, under those conditions the distribution may be represented by a constant.

On the other hand, if there is no information available for individual workers, model distributions are developed based on the available data. **Dr. Neton** pointed out that uncertainty in organ dose is one of the huge number of variables involved in the calculation of excess relative risk.

Dr. Neton described some of the factors that are sources of uncertainty in probability of causation, such as the cancer model itself, dose and dose rate effectiveness factor, and radiation effectiveness factors. He commented that it was a complex issue and there was no simple discussion on it.

Dr. Neton listed and described the types of uncertainty distributions used in dose reconstruction, ranging from constant to uniform. There were slides presented illustrating the various distribution types in graph form. The process of doing a fully-researched dose reconstruction for an external dose was detailed in a step-by-step manner to describe how uncertainty distribution is handled within the external dose calculation.

Dr. Neton explained that arriving at an internal dose value involved more assumptions in the calculation. To simplify the calculation they have considered all internal doses to be lognormally distributed, with a geometric standard deviation of three. This alleviates the need to account for the variety of different values that have uncertain distributions in an internal dose calculation.

Dr. Neton commented there are scientific publications which point to the fact that a geometric standard deviation of about three is reasonable. He opined that it was probably a very fair, if not moderately claimant-favorable, assumption. Use of this assumption results in a range of values spanning several orders of magnitude at the 99 percent confidence interval. A slide was presented which illustrated in graph form an internal dose distribution using a geometric standard deviation of three.

Turning to uncertainty in exposure models, **Dr. Neton** reminded the Board he had pointed out the uncertainty they would use in doing a fully-researched dose reconstruction for which they had external badge measurements, et cetera. However, in many cases no real monitoring data is available for individuals from many of the Atomic Weapons Employers and others. There may be a distribution of air samples, and in that case they would develop an exposure model to be applied to the work force.

Explaining there are a number of exposure models one could develop, **Dr. Neton** used Bethlehem

Steel as an example of an exposure model that covers all workers because they did not know where those workers were in space and time in relation to their work environment. **Dr. Neton** illustrated his explanation with a slide demonstrating the Bethlehem Steel model in graph form.

Dr. Neton commented they had developed several of these exposure models and felt they had covered the range. He offered that if the probability of causation is calculated to the 99th percentile, it's being driven by some relatively high values they believe are claimant-favorable. This value is assigned to every single worker, regardless of where they worked, because they just don't know exactly. **Dr. Neton** reiterated it was a fairly complicated issue, but thought he had hit the highlights.

Discussion Points:

Dr. Melius asked if the lognormally geometric standard deviation of three should be adjusted for different types of tests. **Dr. Neton** replied if it were adjusted, it would be tightened. He commented that in his mind this would represent the upper range for some of the worst types of analyses, such as the actinides. There are better estimates for some of the nuclides, but the Geometric Standard Deviation (GSD) of three covers a myriad of possibilities and addresses the worst cases.

Dr. Melius indicated he had been thinking of changes over time and techniques. **Dr. Neton** responded that as you go back in time, uncertainty goes up because maybe detection limits weren't as good. But those are small compared to the differences in metabolic models and other factors. He commented they were pretty certain they had that bracketed. **Dr. Neton** stated the over-arching uncertainty in the calculation is the risk model, and he couldn't over-emphasize their contribution.

Mr. Griffon said he would be interested in the references to support the GSD of three. Remarking that the authors of Integrated Modules for Bioassay Analysis (IMBA) had at one point planned to construct some uncertainty analysis functions into it and inquired if that had ever been achieved. **Dr. Neton** replied the current version of IMBA has a maximum likelihood estimator function, but that only addresses the extrapolation of all the bioassay samples to the intake. He commented that while they had looked at it, and other kinds of possibilities, they didn't use it and believe the most straightforward is to assign the distribution to the internal dose.

Mr. Elliott asked **Dr. Neton** to comment on the sensitivity analysis function of IREP and what it points to when it's run. Acknowledging the presence of **Dr. Owen Hoffman** with the comment that he was probably better qualified to speak on it, **Dr. Neton** an advanced feature of IREP that can be selected after a run which will provide the relative contribution to the overall uncertainty for a number of factors. It also has contribution to the radiation effectiveness factor and to radiation dose, so it can show what's driving the uncertainty in the calculation for any IREP case run. They've done the sensitivity analyses, but there's no clear pattern because there are so many factors built in.

Dr. Hoffman added that the sensitivity analysis apportions the uncertainties of various components

of IREP and the uncertainty on the dose input to see which contributes most to the overall spread of values. If you're interested in what contributes most to the 99th percentile of PC, you go back into the model and fix a value as a constant and see what difference it makes, but it's a little bit more complicated calculation.

Commenting on the GSDs, **Dr. Hoffman** mentioned that in some of their analysis of internal dosimetry for some transuranics, GSDs might be somewhat greater than three. Oftentimes the uncertainty in the intake will dominate over the uncertainty in the internal dosimetric model, but that won't necessarily be the case for things such as plutonium.

Dr. Neton remarked that this is not an area that has been explored in a lot of detail. Since they're blazing the trail, they will certainly modify as they learn.

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SCIENTIFIC RESEARCH ISSUES UPDATE

Mr. Russ Henshaw
NIOSH

Mr. Russ Henshaw began his update by reminding the Board that another version of IREP, NIH-IREP, is maintained by the National Cancer Institute (NCI). Late last year they revised their lung model. NIOSH determined they would wait until the implementation of that model and evaluate it for possible application to the work force covered under EEOICPA.

The difference in the two versions was thought to be a difference in the probability of causation between smokers and non-smokers, with the NIH-IREP more claimant-friendly to male smokers and females exposed at younger ages. Since the last Board meeting NIOSH has learned that NCI has made a further change to their lung model to adjust for chronic alpha exposures. Reportedly the effect will be to smooth out differences in probability of causation results at the 99th percentile credibility limit for smokers and non-smokers. **Mr. Henshaw** remarked his understanding was that the difference is minimal.

NIOSH decided to put their evaluation on hold until the NCI change went into effect, and then resume. That change went into effect last week. SENES has issued a preliminary report exploring the differences and with certain recommendations which is in internal review by OCAS at this time.

Another project is to review the DDREF assumptions, values and distributions used in IREP. Dose and dose rate effectiveness factor, DDREF, is an adjustment factor built into IREP to account for differences in exposures between Japanese atomic bomb survivors and U.S. nuclear weapons workers.

The ICRP recommends a DDREF of two. In creating NIOSH-IREP a decision was made to use a more claimant-friendly uncertainty distribution weighted mostly between values of one and two. This was an issue of controversy at the time the probability of causation rule was published. **Mr. Henshaw** indicated they thought it was time to look at DDREF, re-evaluate their assumptions and possibly propose an adjustment.

SENES submitted a very complex and lengthy draft report to NIOSH/OCAS last May. It is still within internal review in OCAS, though they hope to submit their comments to SENES within the next week or two. Ultimately any findings or recommendations will be submitted to outside experts for an independent review.

Earlier **Mr. Henshaw** had reported on the intention to upgrade Analytica, the software package that serves as the computational engine behind NIOSH-IREP, with the new version. That has been done and the transition went smoothly. Their tests show this version processes cases two or three times as fast as the former. They can now process cases with 500-plus rows of exposure information. Previously that was not only difficult, if it could be done at all, but took a good bit of time.

Mr. Henshaw commented he had e-mailed the Board notification that IREP summary reports now have both the Analytica and IREP versions printed at the top. NIOSH-IREP is at 5.3; Analytica is 3.0.

Remarking that the position of research health scientist had been a long-standing vacancy at OCAS, **Mr. Henshaw** reported interviewing to fill the position had begun mid-August. He anticipates that person will be at the next Board meeting. The primary duty of this position will be applied research, with a first project of conducting a feasibility study of current occupational dose-response data to improve the fit of cancer risk models in NIOSH-IREP.

Incorporation of occupational studies into the risk models has been of major interest to both the Board and OCAS. **Mr. Henshaw** reminded the group that at the time the probability of causation rule was promulgated, NIOSH had determined the current state of knowledge of U.S. occupational studies was insufficient to incorporate it into the risk models. That rule only went into effect two years ago. And late last year when the NCI/CDC working group issued its report to revise the 1985 radioepi tables, they commented that estimates based on low dose studies are too imprecise to be used in risk modeling.

In any event, OCAS feels it's time to take another look, and will begin with a feasibility study. If there is indication of a sufficient quality and quantity of dose-response data among occupational cohorts, they will launch the next phase. That will be to incorporate the data as a supplement to NIOSH-IREP risk models wherever possible.

Another issue of priority interest to the Board is the grouping of rare and miscellaneous cancers. Cancers were originally allocated to risk groups based primarily on epidemiological data, but also on biological plausibility and uncertainties. **Mr. Henshaw** explained there are 32 IREP risk models, but each falls into one of three major risk groups.

The group one risk models depend on age at exposure and age at diagnosis. Those in group two also depend on age at exposure and diagnosis, but incorporate an age-independent excess relative risk per sievert, as multiplied by an age-dependent modifying factor. The major characteristic for group three cancers is the excess relative risk per sievert is constant, with no age dependency. Nine additional risk models are loosely gathered into group four, but each is unique.

Mr. Henshaw commented he felt re-evaluation of how these cancers are grouped dovetails into the feasibility study of occupational cohorts, noting a great deal of interplay that needed to be studied. This project is in the beginning stages.

Future projects include a review of the choice of organ sites for dose reconstruction and a look at the NIOSH-IREP latency adjustment for bone cancer. Finally, the Health Energy-related Research Branch in NIOSH received funds to conduct studies of chronic lymphocytic leukemia. A public meeting was held last month which three representatives from OCAS attended. **Mr. Henshaw** indicated he presumed a report would be issued from that meeting and they will proceed from there.

Discussion Points:

Dr. Melius asked if it would be possible to get a presentation on the smoking adjustment lung cancer issue from NCI or whatever appropriate entity when the Board meets in Washington. **Mr. Elliott** replied they would look at that, adding it would be nice if NIOSH had something to present as a companion so the Board could compare and contrast.

Dr. Melius suggested a briefing on the SENES work would also be good. **Mr. Elliott** offered a reminder that they develop their work and put it before subject matter experts for peer review and comment, as they did with probability of causation and IREP development during rulemaking. That process will be used for any substantive modification to any risk model or dose reconstruction methodology. NIOSH will gather subject matter expert and peer review comments for the Board's benefit when a proposal is brought for evaluation.

Dr. Melius indicated he agreed with the procedure, but thought there may be a way of briefing the Board as they go rather than all at once. **Mr. Elliott** agreed, noting they are putting more resources and energy into the Board's various research questions. He suggested it was appropriate to keep a standing agenda item the status of research issues.

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SUBCOMMITTEE STATUS REPORT

Dr. Paul Ziemer, Chair
Subcommittee for Dose Reconstruction
and Site Profile Reviews

In his role as Chair of the Subcommittee for Dose Reconstruction and Site Profile Reviews, **Dr. Ziemer** informed the Board the subcommittee charter had been approved by the Committee Management Officer and is now in effect. He reminded the Board that they were all members of the subcommittee, but would be called upon to serve in groups of three plus a Chair and the Designated Federal Official for specific subcommittee meetings.

Approximately a month earlier a working group had met in Cincinnati to develop materials for subcommittee review and ultimate recommendation to the full Board as procedures for selection of cases to be reviewed in the audit process. Those same individuals met as the subcommittee earlier in the week and had prepared a two-page document for the Board's consideration. **Dr. Ziemer** asked that they keep those documents at hand while the thinking of the subcommittee was explained. They would then become a recommendation and motion from the subcommittee for the Board to adopt as a procedure.

Dr. Ziemer asked **Mr. Griffon** to walk the Board through the document and explain the concept. He suggested the Board keep in mind their discussions of a matrix of dose reconstructions, an array representing various facilities, cancers, types of workers, probabilities of causation, all the parameters of interest. The idea was to sample from different parts of the array, depending on weighting.

Mr. Griffon commented there were parameters of interest defined in the flow sheet and he envisioned filling the matrix with a sampling of cases in those relative amounts by the time the Board finished sampling the whole set of available cases.

The first step on the flow sheet is to select cases, using a random number generator selection process. In answer to **Mr. Griffon**'s request for clarification of the proper terminology for the pool of cases available for review, **Mr. Elliott** replied they were the cases which have been adjudicated to the point where a final decision has been proffered, which currently numbers approximately 1,400.

Mr. Griffon described the parameters of interest as the POC category, facility, decade first employed, duration of employment, and IREP risk model. These are areas of interest to the Board, and are searchable on the NOCTS system of the NIOSH database. He described what the subcommittee had determined to be the appropriate number of samples by grouping, as well as their rationale for weighting. **Mr. Griffon** noted these are preliminary and can be adjusted at the Board's

pleasure.

For example, under POC they propose to sample 40 percent of cases with 0-44.9 percent POC, sample 40 percent of cases with 45-49.9 percent POC, and sample 20 percent of cases with greater than 50 percent POC. The 45-49.9 percent POC is seen as a very sensitive area. There are assumptions that when POC goes over 45 percent, NIOSH does a more refined dose reconstruction. They're closer to the award area so it's weighted a bit higher. And though they certainly wanted to sample some of those with POC greater than 50 percent, it was weighted at 20 percent.

Under the major criteria of facility, the suggestion is to sample based proportionately on the total number of claims from all DOE facilities. **Dr. Ziemer** clarified that if Idaho had ten percent of the total claims in the system, they would expect ten percent of the matrix to be Idaho. **Mr. Griffon** explained that sites with very few claims would be grouped together into a pool and a sampling of 2.5 percent would be taken from that pool. The overall sampling percentage goal is 2.5 percent, but larger sites would be sampled proportionately.

For weighting of decade first employed, the members of the subcommittee brought their experience to the discussion and gave consideration to when they thought there would be more difficult cases and more likely higher exposures. Consequently they recommend a sampling of ten percent from the '40s; 25 percent each from the '50s, '60s, and '70s; ten percent from the '80s and five percent from the '90s.

They used a similar approach for duration of employment, and rationalizing that very short durations could include some unique circumstances, the subcommittee recommends a sampling of 25 percent each of periods 0-1 year, 1-5 years, 5-10 years, and more than 10 years.

Finally, risk model was left relatively open, with the intent to examine cases representing each type of model. **Dr. Ziemer** added that their thought was if they started with about 20 sample cases, they weren't going to fill all the boxes anyway. Perhaps the three major groups **Mr. Henshaw** had mentioned earlier would be a starting point because they look at the variables in different ways. Those might be broken into some distribution.

Mr. Griffon called attention to some other criteria previously discussed by both the Board and the subcommittee, and which are important. They include cases using coworker data, monitored versus unmonitored, job category, et cetera. Currently they are not searchable fields, so the descriptors aren't displayed on a printout of random cases. The subcommittee recommends tracking them to assure they also sample across those parameters.

Dr. Ziemer asked the Board to turn back to the first page, where the first step is to ask NIOSH to generate a list of cases. The Board or the subcommittee would work down the list to see how they fit into the matrix, and either accept or reject a case for review.

What is not shown but was discussed in subcommittee was having two members of the Board primarily responsible for each case, along with a person from SC&A to work up the case since not everybody on the Board was a dosimetry expert.

Mr. Elliott commented that the only difference from their original process procedure is that, once case selection has been made, NIOSH has agreed to create a CD for each Board member with his cases on it with all the case information. It will be a Privacy Act-controlled disk to be delivered to each Board member and the contractor.

Mr. Griffon remarked that SC&A was represented in the audience at the subcommittee meeting and they had discussed logistics, which they may want to write in the procedure, but panel members could conference call with SC&A during development. They had discussed when the cases are brought back to the Board they might have a closed session the first day to discuss specific cases and case reports, and an aggregate data report might be brought by SC&A. Then in open session they could present the aggregate findings where they can't discuss privacy information.

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BOARD DISCUSSION/WORKING SESSION

Dr. Ziemer announced the matter comes as a recommendation from the subcommittee and is considered a motion to accept or modify, and opened the topic for discussion.

Dr. Melius remarked he liked the proposal, only questioning over-weighting on duration of employment. He indicated he felt 40 percent with less than five years' employment may be too high, suggesting more might be learned from cases with longer employment periods.

Dr. Ziemer reminded the Board these numbers were somewhat arbitrary. They don't know how this distribution compares with the claim distribution. It is appropriate to revise the numbers if someone wishes to do so. **Dr. Melius** added he was concerned it might not be a very representative population.

Mr. Elliott commented that AWEs have a contained employment period reconstructed against, usually short numbers of years. **Dr. Melius** replied he had also been concerned about how facilities were selected.

Ms. Wanda Munn expressed her understanding that job category was something very difficult to tie down for most claimants and so was concerned about the notation at the bottom of the flow sheet. **Dr. Ziemer** replied that the issue had to do with what words are used to describe a job, but once a case is opened, you can figure out what was done. A brief discussion followed on how that task

might be handled and by whom.

Ms. Munn raised a question of exactly what is meant by the word "statistics" as used in item six of the procedures. After discussion it was taken by consent that the word "statistics" would be replaced by the words "summary findings" in item six.

Ms. Munn inquired if there were any possibility the same case may be reviewed more than once, noting the procedure doesn't address that. **Dr. Ziemer** replied that could be added, as it was his understanding that reviewed cases were no longer in the pool. Discussion resulted in a decision to add a sentence at the end of paragraph 3 that reflected that intent.

Returning to the topic of employment duration, **Dr. Melius** suggested perhaps they could get some summary statistics off the first group of cases and get a better idea of how to set the parameters. **Dr. Ziemer** again reminded the Board this recommendation is conceptual and whatever is adopted can be modified at any time. He explained further that if the Board felt there weren't enough cases from a particular site, there was the capability to sample randomly within a site.

Mr. Griffon remarked that they'd had to use only final cases for POC so it hadn't occurred to him earlier, but for duration of employment and even decade first employed, NIOSH could be asked to query against the entire database. He suggested that might help define the categories better. They could look at decade first employed and duration for however many cases are in the system. Based on that, they may choose to sample proportionately for those categories, as well.

Dr. Melius indicated he thought they would end up having to first stratify on POC and sample within the current categories for efficiency purposes. **Dr. Ziemer** commented that if they went to a certain percentage of short duration employment, they may select heavily from AWEs, so the categories could work against each other if they aren't careful.

Dr. DeHart asked how they would go about assigning a number to the 1,400 available cases. **Dr. Ziemer** replied the proposal would use a random number and select from those. **Dr. DeHart** then raised the issue of bias, which **Dr. Ziemer** responded that was understood and the sample base will change as time goes on. They're still looking at a small total of what the eventual matrix will be.

Dr. Ziemer informed the Board that they were prepared to give them a list today if the procedure is approved. Information management at NIOSH had been asked to generate a list of 25, from which the Board could select 20. Then procedure then would be to assign the Board members, generate the disks and provide the information to the contractor. The list will tell the POC category, the facility, et cetera.

Mr. Griffon explained the challenge is to hand-select from those 25 cases as a Board. The list will only have some descriptive statistics to help selection. Those not chosen will go back into the pool.

Dr. DeHart suggested selecting ten percent from the '40s in the category of decade first employed might be too low because the assumption is dose might be higher in that group, with perhaps a greater chance of error. **Dr. Ziemer** explained their rationale was the number of employees was smaller in the '40s as the system was still building, with larger numbers reflective of the '50s.

Ms. Munn questioned the high percentage of claims filed for non-covered conditions which had been discussed earlier. **Mr. Elliott** explained those were DOL statistics and the dataset from which they were sampling did not include those cases pulled back by DOL.

Dr. Ziemer called for additional modification to the proposal and there were none at the moment.

The Chair called for a vote on the motion to accept the Procedure for Selecting and Tracking Dose Reconstruction Cases as amended. It was passed unanimously.

Dr. Ziemer informed the Board that because the contractor was prepared to assign 20 cases at a time, the subcommittee was recommending the selection of 20 cases from the list of 25 in order to give them all some experience.

While the list was being distributed, **Dr. Ziemer** outlined the contractor's role, the number of Board members to be assigned to a case, conflict of interest issues, timetables, privacy issues, et cetera as they related to the review and reporting on individual cases. He noted the list of 25 was comprised of 32 percent from Bethlehem Steel, 24 percent Savannah River, et cetera, and commented that the analysis on POC indicated none fell in the 45 to 50 percent category that was of such great interest to the Board.

Dr. Roessler commented the decade first employed included some from the '30s and wondered if that were an error. **Dr. Ziemer** remarked that was the decade they started working at the company.

Mr. Elliott indicated there were only 20 of 1,450 total cases in the category of 45 to 49 percent POC, and in this random sampling they didn't hit any of those 20. **Dr. Ziemer** remarked if they wanted at least one of those in the first run, they could go back and select by POC and randomly select one of those 20. He reminded the Board this is only a few of hundreds that will be sampled, however. **Mr. Elliott** added he had just been corrected; there were only eight cases in the 45 to 49.9 percent POC category from the 1,450 cases in the pool. There are 20 from the first 4,000 cases turned over to DOL. **Dr. Ziemer** acknowledged that for this initial run that may be fine. **Dr. Anderson** observed there were a lot of low POCs, but **Ms. Munn** noted there were a few high ones, as well.

A motion was made and seconded to approve the first 20 cases on the list of 25 as the first cases to be reviewed by the Board.

The motion was open for discussion.

Dr. Melius observed that included approximately eight Bethlehem Steel cases and he would prefer to eliminate five or so of those and put them back in the pool. **Mr. Griffon** argued other criteria should be considered. **Dr. Roessler** commented they should look at cancers and other parameters. **Dr. Ziemer** argued it was too early to do that. **Mr. Griffon** suggested a more specific proposal as a friendly amendment.

A motion was made and seconded to eliminate the last five Bethlehem Steel cases within the list of 25, return them to the pool of available cases, and replace them with the last five cases on the list, the result being the first 20 cases to be reviewed by the Board. The motion passed unanimously.

Dr. Ziemer asked if Board members associated with one of the facilities would have to be recused. **Mr. Elliott** agreed it was an issue they had to face and reminded them of their conflict of interest waiver letters saying specifically from which sites they must recuse themselves. He added he had a list available for those who didn't remember what their letter said.

The Board discussed whether their previous vote had been proper, and determined that since they were only dealing with the list, they were appropriate in that action. **Dr. Melius** noted that conflicts he might have would not be apparent from the available parameters. **Mr. Elliott** agreed it would require seeing the name on the individual case. **Dr. Melius** commented he presumed there was a procedure for reassigning such a case, which **Mr. Elliott** confirmed.

Dr. Ziemer called on **Dr. John Mauro** from SC&A to describe what his team will do and help the Board understand what has to be done.

Dr. Mauro explained there are five lead people called case managers. The cases would be distributed to them, in addition to, for example, providing Bethlehem Steel cases to the site profile task leader for Bethlehem Steel. The cases are in the form of CDs with all the records and perhaps eight or nine people within SC&A will get them all. They'll have a few days to scan them and then meet in McLean where they'll be dealt to the five case managers, four cases each. **Dr. Mauro** explained the procedures are laid out in Appendix C to their proposal to the Board. Each case manager will review his or her cases within a certain time period and within a work hour allocation, so they have a budget within which they can draw upon any one of 33 people on the team, some of which have very specialized expertise.

When they're through they will have their notes, findings and initial perspective on areas of strengths, weaknesses or problems with their particular cases. Assuming that can be done in a month, they will reconvene in McLean and each person will tell their story regarding each case,

what they found and their rationale for what they found, which will be discussed. Each person will require about half a day, so that will probably be a 3-day meeting to go over all 20 cases and interact.

Then each person will go back and write his report of findings in light of the discussions. Once completed, it represents a draft report which will undergo the QA process to make sure everything is signed off on as appropriate, and then it's delivered to the Board.

Dr. Mauro commented the Board had mentioned being involved, and at any point in the process either the Board or NIOSH could step in.

Dr. Ziemer explained the subcommittee's thinking was at the point the SC&A team meets the second time to share information but there is no written report, as each case came up the Board contacts would be on a conference call with the team, have an opportunity to comment and hear the discussion. SC&A will develop a written report for each of those cases. Then probably the day before the Board meeting the Board members would get together with their SC&A team person to review the final report. They would also have the opportunity to e-mail the SC&A team person with comments in between.

Dr. Ziemer went on to say the other thing that will have to happen is the rollup, which will constitute the official report. That public report rolls all the cases into the summary findings, a compilation of the reviews.

Dr. Mauro replied that what he was hearing was SC&A will have two-month increments to deal with 20 cases. Within that time they will go from 20 cases arriving at SC&A to being in a position to deliver hard copy or electronic versions of confidential reports on each case, and also prepare an aggregate report appropriate for public presentation to the Board. During that time there will be interaction between SC&A case managers and the two Board members assigned to each case. **Dr. Ziemer** confirmed that was how they envisioned the process. **Dr. Mauro** indicated that was fine.

Dr. Genevieve Roessler asked if the Board members got the CDs at the same time as SC&A. **Dr. Ziemer** replied they will have the same body of information as the person working it up.

Mr. Robert Presley inquired if that would give SC&A enough time to prepare the summary findings. He suggested perhaps the Board teams could make decisions on their four cases prior to the meeting to say they agree or disagree, or point out what they don't agree with, so that when they get to the meeting a lot of it is already done.

Dr. Mauro replied they would be listening to the oral presentations and get a sense of where SC&A is going. It will be a point where SC&A can get feedback on whether they're all seeing the issues the same way, which is good. There would be a whole month in front of them then, or more. **Dr. Mauro** indicated what he thought **Mr. Presley** is saying is SC&A will deliver their report in draft

form to all 20 a week before the meeting, and that would be ideal. If they could go from the oral presentation, three weeks later have a draft report to the Board with an opportunity to discuss it, that would be ideal. He said **Mr. Presley** was absolutely correct that the day before would not work.

Dr. Ziemer acknowledged that was a good point, commenting that the subcommittee had envisioned the Board sitting as various working groups. It now becomes a full Board closed session where each [SC&A] team presents their findings and [the Board teams] would have already seen what your cases involved. The Board would have an opportunity to look at the draft rollup at that time and consider it as a full Board.

Mr. Griffon wondered if the Board might gain access to the NIOSH reference database, along with the CDs. If the dose reconstructions referenced any documents they didn't have, it would be more efficient than going through the process of requesting them. **Mr. Elliott** agreed, but indicated he would need **Dr. Neton**'s input on the matter, and he was out of the room at the moment.

In the meantime, **Mr. Elliott** said he was a bit lost on the dialogue between **Dr. Mauro** and **Mr. Presley** related to the conference call. **Dr. Ziemer** explained they were talking about a conference call only with individual team members and their contact. They meant a closed Board meeting the day before the regular open meeting. **Mr. Elliott** reminded them he had to know how much time they wanted in order to effect a closed meeting. **Dr. Ziemer** indicated it would be the full Board to hear the cases summarized because they would all present to each other the cases for which they were responsible, and then the draft summary could be brought to the open meeting. **Mr. Elliott** informed them the draft summary could be sent as a pre-decisional, deliberative document they would be required not to share, but they could at least get their eyes on it.

Dr. Roessler asked about the mechanics of receiving the CDs and confidential materials, how they would arrive and how it would be handled if they were on travel, et cetera. **Mr. Elliott** explained the CDs would be prepared and sent in the next week, and so NIOSH would need to know where the individual Board members wanted them delivered. They will be sent FedEx or registered mail, to be opened only by addressee.

Mr. Presley observed they will have to use caution during the call-in conference call to make sure they aren't on line when anything is being discussed that would require their recusal. **Mr. Elliott** observed it was going to be a logistical nightmare for SC&A to coordinate the conference calls with the appropriate Board members on the appropriate cases. **Dr. Ziemer** offered that SC&A will have a list of who the team members are for each case.

Dr. Mauro agreed it was going to be difficult. Everything would have to be coordinated with when each case manager was making a presentation. Everyone would have to know the plans well in advance, but SC&A will provide that information.

Dr. Ziemer raised the issue that they have proceeded on the assumption that these are basic reviews. The Board has the option of choosing to do some advanced reviews, although it might be better to learn the process first. **Dr. Anderson** commented he thought they'd discussed starting them out as basic and then at the discussion meeting with SC&A maybe select some of them for advanced review. **Dr. Ziemer** agreed the had discussed selecting that way, but his recommendation was that these first 20 be basic reviews.

Mr. Espinosa asked how the teams would be selected. **Dr. Ziemer** replied they would get to that shortly, but it would be somewhat of a self-selecting process in that they all know their conflicts and they'll start looking for volunteers and see how things proceed.

Dr. DeHart asked if they could be numbered sequentially for convenience. **Dr. Ziemer** remarked they can be unofficially numbered, but he's been told they are not to associate any identification numbers with cases. **Ms. Homoki-Titus** interjected they could be numbered unofficially to assist them in their process, but once sorted, they'll be identified when they're sent to the Board's teams. **Mr. Griffon** offered he thought it would be easier to have the linkable number, remarking that in the CEDR database everything has an ID number linked back to a file and that's public domain. **Mr. Elliott** called attention to earlier runs showing A-1, B-1, et cetera, and said that could be done, just assign them a number. He commented they had probably already been assigned an identifier where they can key back to the claim number. **Mr. Griffon** argued that if that were on the sheet in front of them, the number assigned would be the number used and there'd be no confusion, although **Ms. Homoki-Titus** might disagree. And she did, commenting that she was not going to advise the Board to violate the Privacy Act in that manner, reiterating the cases can be informally numbered one through 20 for convenience. **Mr. Elliott** indicated that if the Board assigned a number, NIOSH would have the key.

Mr. Elliott advised the Board that everyone will need to have a PC that will handle a compact disk that will open PDF HTML files, which he thought was fairly standard. He told them NIOSH would work with them on getting access to the database systems ORAU has, but they're going to have to figure out how best to do that. It will probably entail loading what they call CITRX in order to access the database, but they'll have to work with each member individually.

Ms. Munn suggested that since the SC&A team people would obviously not have to be recused from their sites, if they knew the sites the Board members had to be recused from, in the long run it would be simpler for them to group their presentations to match with who can't be present during what. It would be difficult to set up, but the Board members should have no difficulty identifying which sites they must recuse themselves from. **Ms. Munn** also inquired who was going to present the rollup of summary findings to the Board.

Dr. Ziemer observed that this is an audit report coming to the Board from their contractor. His inclination is that SC&A would present their summary and the Board would then take action on it.

Dr. Ziemer mentioned that another related matter was the IMBA material which is now available. He asked if **Mr. Elliott** would provide the status on that.

Mr. Elliott announced they were ready to hand out IMBA, noting each Board member will receive a disk with their name on it, and SC&A will have a disk for their use. He indicated he would ask everyone to sign a non-disclosure statement at this time, and cautioned that the disk contained coded language so that if it were shared, it could be traced back to a specific disk, which is part of the end-user's license agreement that had been negotiated with NRPB. He added they should discuss a training session. **Dr. Ziemer** asked if he were speaking specifically to an IMBA training session, a more general one, or both.

Mr. Elliott responded perhaps an overall training session, but IMBA first, noting the biological models are complicated. He commented the engine that runs it is fairly intuitive, but it takes a bit of guidance and walk-through to ensure familiarity and understanding of the features and how it can work for you. He offered that ORAU has an approved set of tutorial procedures that has been used with their dose reconstructors, and those will be made available if they wish to make use of those procedures. He added it would provide some consistency in approach and give some insight into the type of training procedures ORAU has developed. **Dr. Ziemer** asked if this could be done without going to Cincinnati. **Mr. Elliott** asked **Dr. Toohey** to address how that would work.

In the meantime, **Dr. Ziemer** asked if each Board member could get a copy of what they were signing, adding that once he returned it, he wouldn't remember what he'd agreed to. **Ms. Homoki-Titus** indicated that would be provided. **Dr. Anderson** inquired how they would go about registering, as the document indicates they must. **Ms. Homoki-Titus** offered that it would be done through the software, as with any other, and asked if it would lead to a web site for registration. **Dr. Neton** indicated that would occur at the time the end-user license agreement is issued. He explained the EULA has not been finalized yet, so this is a conditional usage until the ultimate agreement is signed. At that point it will become clear how to register it with ACJ & Associates. He added there will be an additional requirement for the Board members to agreed with the conditions of their end-user license agreement.

Dr. Anderson countered that was not what they were signing, that it says they have to do it, and that they're required to register. **Dr. Anderson** indicated that it was a legal document, that he's agreeing to register, and he wanted to do that now for whatever it is he's supposed to. **Dr. Ziemer** observed it didn't say when it has to be done. **Ms. Homoki-Titus** indicated that since it didn't give a limitation, she was going on the record to say they don't have to register until they have a EULA. They'd just wanted to try to get this to the Board and it was the best they could come up with to protect the software manufacturer, HHS and the Board members, so there'll be a new agreement once the EULA's finalized.

After further discussion about what the document actually is and what terms are actually set forth, **Ms. Homoki-Titus** suggested that if **Dr. Anderson** is hesitant, they could take back the document, but the disk would also have to be returned. That was the best they could do. **Mr. Elliott** asked if it would help **Dr. Anderson** if they could summarize what's in the EULA as they understand it. **Dr. Neton** explained that to his knowledge the conditions are very similar to what you do when you get a program from Microsoft. It's just that they're dealing with a foreign country's regulations.

Dr. Roessler commented that in several places the document refers to version 3.1, but her disk is labeled version 3.2.03. **Dr. Neton** suggested that changing the version, initialing and dating it would suffice.

There was a discussion surrounding **Mr. Presley**'s trip out of the country for a few days immediately following the Board meeting and whether it might be safer for his disk to be mailed to his home, which **Ms. Homoki-Titus** agreed would be done. There was discussion related to how much memory was required for the program to run without crashing. There was discussion about only installing the disk on password-protected computers, with **Ms. Homoki-Titus** reiterating the individual Board members were the only ones permitted to use the program.

Mr. Elliott asked if **Dr. Toohey** might speak to the IMBA training before they proceed to assignment of cases.

Dr. Toohey described several training modules in the package for IMBA, beginning with a walk-through of the program. The final part is the test, which gives a couple of sets of bioassay data to run and if you don't get the right answer, you can't do dose reconstructions, under ORAU policy. That can be made available either through access to the server or stand-alone modules. **Dr. Ziemer** asked if he understood correctly that it is self-tutorial, which **Dr. Toohey** confirmed. **Dr. Ziemer** asked if it wouldn't be easier to do a disk. **Mr. Elliott** asked if that could be done. **Dr. Toohey** indicated he thought it could, but he wouldn't guarantee it until he spoke with his IT staff. **Dr. Ziemer** asked him to try to make the training available to everybody.

Mr. Elliott asked **Dr. Neton** how to assist the Board members in getting access to the site research database, as they had SC&A. Indicating that would go through ORAU and was outside the firewall, **Dr. Neton** asked how that had come up in relation to IMBA, commenting he must have missed something. **Mr. Elliott** replied it was simply in relation to their review of cases and how they can access reference documents. Acknowledging that was fair, **Dr. Neton** said they would have to work with ORAU and he believed it would require a Virtual Private Network setup on each of their computers, with some mandatory Privacy Act training under ORAU's policy. With **Dr. Toohey**'s offer to waive Privacy Act training, **Dr. Neton** observed it was technically doable, they'd just have to work out the logistics through ORAU.

Mr. Elliott indicated he wanted a commitment that that would be done quickly, inquiring if they

could say within the next two weeks they would deliver the IMBA disks, the IMBA training modules and whatever mechanism was needed to set up to allow access to the database. **Dr. Neton** indicated he would commit for **Dr. Toohey**, who was standing at his side.

In anticipation of assigning cases, **Mr. Elliott** commented that he could address each Board member's conflicts in case they don't remember. He reminded them that every year they go through a conflict of interest disclosure which triggers a new waiver letter, and that process is underway now. But they are to operate under their current waiver letter, and he has a chart that speaks to each Board member's conflict if there's any question.

Dr. Ziemer called for any suggestions on how to proceed with the case assignments. **Dr. Anderson** suggested that for the logistics of the phone call, it might help to have the same two people share their four cases rather than have 20 combinations of two. **Dr. Ziemer** agreed that would be helpful, if not always possible.

Dr. Ziemer asked if they had two individuals with no conflicts in the first four cases on the list. Following discussion and adjustment for conflicts, the first three cases on the list were assigned to **Dr. Anderson** and **Mr. Presley**. The second three cases were assigned to **Drs. Roessler** and **DeHart**. The next three cases were assigned to **Dr. Andrade** and **Mr. Griffon**. The next three cases were assigned to **Mr. Gibson** and **Dr. Ziemer**. The next four cases were assigned to **Dr. Melius** and **Mr. Espinosa**. The final four cases were assigned to **Ms. Munn** and **Mr. Owens**. Confirming the assignments, **Mr. Elliott** indicated they would be receiving the disks next week, and if they were not going to be at their residence, they should let him know an alternate location. He added they would probably go out Tuesday or Wednesday.

Dr. Anderson suggested that as soon as they could get a date for the contractor's meeting it would be helpful since they were going to have a narrow calling window. **Dr. Ziemer** called for **Dr. Mauro** to communicate with him and he would advise the Board members.

Dr. Ziemer cautioned the Board that SC&A will be assigning cases based on expertise, as opposed to their somewhat arbitrary assignments, so they are not likely to have only one contact at SC&A. He also added participation in the conference call is not mandatory, so if there are scheduling problems but you have comments, they can be transmitted, and they'll be getting feedback from the contractor in any event.

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PUBLIC COMMENT PERIOD

Dr. Ziemer noted for the record that **Dr. Anderson**, **Mr. Gibson** and **Dr. DeHart** had left and would not be present for the afternoon session, but with a quorum still in place the meeting would

proceed.

Dr. Ziemer commented that at the moment only two people have requested time, so the public comment period would begin with those and others could speak if they wished.

Mr. Richard Miller,
Government Accountability Project

Mr. Miller commented he wanted to discuss some topics which had already been discussed, including another site profile for Blockson Chemical, the latest of which had a blank page. He asked if the issue of how to handle radon had been resolved. **Dr. Ziemer** asked **Mr. Elliott** or **Dr. Neton** to respond. **Mr. Elliott** replied he would look at the site profile, commenting he was concerned about the blank page. **Mr. Miller** indicated it was the one that was supposed to refer to radon dose. **Mr. Elliott** remarked that may be why it was blank because it's reserved until they have fully considered the situation. He indicated he has not seen the *Federal Register* notice and they had not been notified by DOE that it was being changed.

Mr. Miller then asked if the issue of which dose should be counted is a sensible one for the Board to consider, and wondered if there is a way to get it on the agenda and get recommendations, whether they're accepted or not. **Dr. Ziemer** indicated he thought the answer was yes. **Mr. Elliott** agreed, but commented the Department had not determined it was an agenda item for the Board to consider at this time. They will have to come to their closure on it and will provide it to the Board for deliberation when it's appropriate. **Mr. Miller** commented he thought it was appropriate once a draft site profile had been published.

Mr. Miller then raised the issue of the Mallinckrodt site profile, SEC petitions, actinium oozing out of the airport site where raffinates had been dumped, whether the dose was estimable, why isn't it part of what dose can and can't be reconstructed, is it part of the research, et cetera. **Mr. Elliott** reminded **Mr. Miller** this is a public comment period. He indicated **Mr. Miller**'s comments were noted, but he was not going to answer premature questions such as he was raising, and invited him to continue with comments.

Mr. Miller then wanted to discuss how the Board assesses the SEC petitions and cited areas in which he was left unsatisfied with the rule and posted procedures. He described situations and asked questions such as what happens, who falls through the cracks, what's the logic of your decision point, et cetera. He commented on things he felt should be rethought or re-examined. **Dr. Neton** remarked he was aware he shouldn't respond to comments, but felt when factual issues are raised, it's best to correct them. He attempted to explain **Mr. Miller**'s misunderstanding and what the actual process is, which became a discussion of worst-case estimates, the efficiency process, capping dose, et cetera. **Mr. Griffon** joined the discussion to describe a similar position he'd raised in an earlier meeting. **Dr. Neton** concluded the discussion by commenting that the language covering the issue is

in the rule.

Mr. Miller then described his feeling of anxiety during the portion of SC&A's presentation the day before when they discussed records access, noting it was good news that it seems to be resolved. He expressed concern about the Q clearance issue and that it might become an obstacle and raised a question of "What can we do?" **Dr. Ziemer** remarked the comment was noted and they were asking the same question.

Mr. Miller expressed his comfort at **Mr. Rollow**'s reassurances and that there is hope for cooperation from DOE. He hoped metaphorically that "there are not some structural problems that are underpinning the multi-faceted role that NIOSH is having to play, which is a tightrope, a delicate rope to walk, but it is hard not to put it on the record and say it's noticed and that there's some difficulty there." Apparently **Mr. Miller** was implying NIOSH was less than cooperative with SC&A and suggested the Board "keep its ears closely attuned to this question."

Mr. Miller indicated he had gotten calls and communication from people who have met with SC&A and feel good about being able to communicate and that there was a high sense of comfort level that they were being listened to. He noted the site interviews give people a chance to provide information and data that may not be fitting into the current process, and it would be a reality check against the claimant interviews.

Mr. Miller asked if the SMC facility would be included in the INEEL site profile because he couldn't find it on there last night. **Dr. Neton** remarked it lagged behind a day or so.

Mr. David Fry, PACE Union
Idaho Falls, Idaho

Mr. Fry commented that after he was told at the meeting last night that something was on the web site, he'd looked for it and it wasn't there. He also noted the occupational environmental dose and external dosimetry hadn't been updated since April 28th. He described his dissatisfaction with answers to questions raised in the site meetings.

Ms. Shirley Codding, Claimant
Idaho Falls, Idaho

Ms. Codding remarked that she had spoken the night before, but then heard the Board was going to tour the site and was concerned they would see a much cleaner place than they'd worked in decades earlier. **Ms. Codding** described massive cleanups before every tour. She described places where they worked that had since been decontaminated, torn down and capped with concrete five feet thick. She described chemicals she'd worked with that now workers aren't permitted to touch.

She explained the site now is much safer, but she wanted the Board to be aware that they were not going to see the real site. She called the Board's attention to the fact that the town had no other industry, so whatever they were called on to do at the site, they did because they wanted to keep their jobs. She remarked that the clean and safe place they would see was that way because of public outcry over the stuff that was being dumped into the ground.

She described being told last summer to stop feeding the rabbits on the tank farm because a survey of rabbit feces showed it to be contaminated. The dirt out there has now been covered with asphalt. She just wanted the Board to be aware that what they would see is not what is.

Dr. Ziemer thanked **Ms. Codding** for her comment and noted the Board was aware of that. He remarked that was true for most of the sites they visit and they are thankful the situation has changed.

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REVIEW AND APPROVAL OF DRAFT MINUTES
CONTINUED BOARD DISCUSSION/WORKING SESSION

Dr. Ziemer called for changes or additions to the minutes of the last meeting.

Motion to approve the Executive Summary and Minutes of the Twenty-fifth Meeting of the Advisory Board on Radiation and Worker Health, with modifications as discussed, was seconded and passed unanimously.

Dr. Ziemer reminded the Board they had two documents from their contractor, SC&A, which required Board action. The Conflict of Interest Plan and the Quality Assurance Plan had been explained in presentation by the contractor's representative, with the caveat that there were some editorial changes they'd like to make to the written version. **Dr. Ziemer** indicated he had received a copy of the mark-up reflecting those changes. And while they appeared to be minor, there are so many of them and are throughout the document, **Dr. Ziemer** suggested the Board defer approval of them, with the understanding that SC&A is operating under the general principles reflected therein. The Board could, however, review the documents and see if there are any changes they would suggest, which could be referred back to SC&A for addition to theirs, and a clean copy could be presented for approval at the next meeting. **Dr. Ziemer** called for any objection to that proposal.

There being none, **Dr. Ziemer** called for comment on the Organizational Conflict of Interest Plan, which they are changing to simply Conflict of Interest Plan.

Mr. Elliott commented that both documents reflected NIOSH on the title page as "National Institute of" et cetera. And while that is more accurately "National Institute for", he didn't feel it appropriate

for the NIOSH name to appear on either document. SC&A is the contractor for the Advisory Board.

Dr. Ziemer indicated that, without objection, SC&A would be asked to strike those references, and called for other comment.

There being none, **Dr. Ziemer** remarked he would ask SC&A to provide a clean copy after they make their changes. Without objection, action was deferred to the next meeting.

Moving to the Quality Assurance Project Plan, **Dr. Ziemer** indicated they would strike NIOSH's name from the title, and called on **Ms. Munn** for her comment.

Ms. Munn expressed concern for an audit function which may follow their activities being able to see what the quality assurance manager had done with regard to an item on page 6 of 15 under the heading of "Quality Assurance Manager", and called for more specificity. **Dr. Ziemer** inquired if she were suggesting SC&A be asked to specify the frequency where it says "regularly"? **Ms. Munn** suggested also specifying what reporting system would be used.

Dr. Melius remarked he read that as a job description. Those specifics should more appropriately be referenced in section six, Plans and Procedures, but commented he didn't see it covered there, either. He agreed a quality assurance plan should include a schedule, and it could go either place. **Ms. Munn** observed that under Plans and Procedures the specific procedure of having each individual sign off is described. What she was asking for on the preceding page was more specificity as to the manager's responsibility.

Dr. Ziemer suggested that in item (3) under Quality Assurance Manager they ask for specification of frequency and documentation, either there or in section six. He asked if that would be suitable, and both **Ms. Munn** and **Dr. Melius** were satisfied. **Dr. Ziemer** indicated he would take it by consent that change would be requested.

Ms. Munn observed that on page 12 of 15 under QAPP Training where it says the QA manager supervises training of each individual working on the contract, she was assuming documentation would fall as a part of that. **Dr. Ziemer** clarified she was referring to the previous section and asked if she felt something should be added. **Ms. Munn** simply noted that doesn't mention training documents specifically, one place or the other. She was suggesting a tracker.

Dr. Ziemer called for any objection to that clarification.

Dr. Andrade asked to go back to page 6 of 15 under Quality Assurance Manager where item (1) says the quality assurance manager establishes and implements quality policy. He commented that anyone who had done quality assurance would know the QAPP is the umbrella document for implementing procedures. His question is will the quality assurance manager be responsible for

writing the procedures or will written procedures be provided. He called attention to a reference to the procedures on the following page, but noted nobody knows who's responsible for writing them or having them written, and that should be clear. He called for clarification of whether the quality assurance manager has overall responsibility for development of quality implementing procedures.

Dr. Ziemer called for objections to asking for clarification. **Dr. Melius** confirmed SC&A would just have to expand duty (1) with more specificity, and agreed. **Dr. Ziemer** confirmed they would request clarification of whether the QA manager is responsible for development of quality implementing procedures.

Mr. Elliott commented that in the QAPP on page 4 of 15 under Scope, and in the Conflict of Interest Plan on page six under 5.3, second paragraph, there is mention of SEC reviews. He noted that is not within the contractor's scope, commenting that it had been struck from the tasks when they were developed, but it's coming back. **Dr. Ziemer** observed that early in the process of finding a contractor there had been mention of a possible role in SEC evaluations, but that is not currently a task.

Mr. Griffon contended it is still part of the overall contract that was bid on, but just hasn't been issued as a task. **Dr. Neton** offered he didn't think it was. **Mr. Griffon** argued he could cite the page number. **Mr. Elliott** said it was in the request for proposals. When the Board put out the RFP, nobody knew whether there would be a role. But as the rule and procedures were developed, the Department doesn't view that there's a role for the Board contractor on SEC. He explained the time line for processing petitions and evaluation reports calls for the Board to say yes, we agree a class should be added; or no, we don't agree with the evaluation report, send it back to NIOSH to work on it.

Mr. Griffon asked if someone could check because he thought they took out specific reference to a regulation because none existed, but left a placeholder that the contractor could provide technical assistance to the Board in the SEC review process. He added he believed it was a section (c) in the task order contract. **Mr. Elliott** asked what the Board envisioned for technical support, but **Mr. Griffon** indicated he didn't know.

Dr. Ziemer suggested the Board should have this discussion. He noted there are nine petitions in some stage of the process, and an indication had been made some of them may be fully ready for something by the next Board meeting, but ready for what? Ready for review or just that they'll be in the *Federal Register*?

Mr. Elliott replied that the public will be noticed in the *Federal Register* that some number of petitions have been qualified, briefly describing those petitions by what sites they represent. He hoped, but couldn't promise, to have a class or two defined, with a research evaluation report for Board review.

Mr. Elliott explained that the Board's role, as statutorily mandated, is to review and evaluate the evaluation NIOSH does on petitions and advises whether to move them forward or send them back to NIOSH for more work. There is no audit or quality aspect to it. It's just accepted or not accepted, and it has to be a function of the Board.

Dr. Ziemer asked what the official petition and evaluation done by staff would look like in terms of its content. He suggested one question that arises is how much is technical information where some Board members may feel uncomfortable evaluating it without the assistance of a contractor. He commented that in this case they're in a different capacity because they're part of the decision now.

Mr. Elliott agreed, and noted they didn't have a lot of time. Commenting that they're not overseeing quality but are rather a part of the decision, **Dr. Ziemer** asked about the level of technical information the Board would have to evaluate. He cautioned the Board members would need to feel some comfort level in their ability to evaluate the document.

Mr. Elliott acknowledged that was an issue or concern the Board had. He indicated it was shared by NIOSH and explained they saw the Board, the petitioners and the public as an audience, so things will have to be couched in terms the public can understand. **Mr. Elliott** explained they envisioned a ten to 15-page document. A summary section encompasses the original petition, class definition, outlines the qualification process, presents a new or revised class definition, if necessary. In a case where they have multiple petitions for a given site, it may be a class definition that melds those together. A discussion section presents the case argument or rationale for either adding or not adding a class. Then there is a recommendation conclusion section.

Dr. Ziemer asked if there would be opportunity for public input, pro or con. **Mr. Elliott** confirmed that was correct, and the Board would hear that out in a manner similar to the rulemaking, but it would be public comment in the forum as an advisory body.

Dr. Ziemer called for comment or reaction from the Board. **Dr. Melius** remarked the issue was complicated by the issue of having site profile reviews and individual dose reconstruction reviews underway and parallel to this process which could cover some of the same sites. He noted **Mr. Elliott** had mentioned the day before that one site from which a petition might come up is Mallinckrodt. The site profile review on that is ongoing and could very well be ready for presentation at the next meeting for the Board's decision on approving that. **Dr. Melius** admitted he found it hard to figure out what, if any, technical help they might need, but stressed they are going to have to figure out how the two processes come together.

Dr. Ziemer observed they may have to go through the SEC process first, but at the moment there's no clear role for the contractor in that. He suggested that reference simply be removed from the conflict of interest and quality assurance plans, noting they can always be amended and added if

necessary. But clearly the Board's role is different in the SEC process.

Dr. Melius expressed a concern about delaying a decision due to the timeliness issues related to the petition reviews. He declared he didn't want to be in a position of having NIOSH present ten or so petitions and all of a sudden the Board realizes it needs contractor assistance. He called for a more complete discussion at the next meeting, with NIOSH being able to provide more detail on the nature of the recommendation and what the report will be like, what kind of information they'll have to review.

Mr. Elliott suggested an agenda item where they present and walk through the procedures, highlighting the activities calling for direct Board involvement. He acknowledged those things needed to be shared with the Board in a presentational format. He added that if they didn't have a research report or petition, they should have a shell of one so the Board could see it and give NIOSH input on it. He noted they were also required to have an evaluation plan as part of the procedures, so there was a litany of things to be attended to for the purpose of better edifying the Board on the process.

For purposes of the record, **Dr. Ziemer** clarified that in the quality assurance plan at section 3.0, second sentence, the words "and SEC review" would be removed. In the conflict of interest plan on page six under section 5.3, second paragraph, the words "SEC petitions" would be removed.

Dr. Andrade called attention to the organization chart and the description of the SEC program manager. **Dr. Ziemer** asked if those were the only two places, noting that on page seven they refer to a sampling of petitions they're reviewing, which is something the Board has never specified.

Dr. Ziemer called for other recommended changes. **Mr. Espinosa** asked if there were any way to add monthly or quarterly reports to the Board on cost projections. **Dr. Ziemer** asked to address that separately in a moment because that is being done and probably didn't need to be added. He called for other changes.

Mr. Griffon wondered if the web site where they published conflicts of interest might be included in the conflict of interest plan. **Mr. Elliott** offered to add a hot link to the OCAS web site directing people to the SC&A web site.

On the issue **Mr. Espinosa** raised, **Dr. Ziemer** commented there were available documents pertaining to each of the four tasks. They are proprietary, have cost information so they're not available to the public. There are monthly reports, progress reports, individual monthly billings, and deliverables. He explained when monthly billings comes in, he has to approve them before they're paid. There are charts showing the total spent on the tasks so far, percent of award, and that is updated monthly. **Dr. Ziemer** indicated it was being provided to him and to the person NIOSH has designated to track expenditures in the contract.

Mr. Elliott explained the procurement office receives the billings, which are sent to **Martha DiMuzio** in his office. She then provides a copy to **Dr. Ziemer** to evaluate and sign off on or kick them back. **Mr. Elliott** commented if the Board wished they could have a presentation on each task and status of progress of expenditures. They can summarize in a report to the Board, either in a public presentation or in written summary for each meeting. **Mr. Espinosa** said he'd personally just like to see a general overview of what's being done. **Dr. Ziemer** suggested they make it a regular part of each meeting, commenting it would only take 15 minutes or so. **Ms. Munn** commented she hoped it would only be a very, very high level overview as she had been impressed with the amount of detail in the financial tracking of the QA plan already. **Dr. Ziemer** remarked he thought it was going to be a bird's eye view, and he would take it by consent that will be provided in the future.

Dr. Ziemer called for other items. **Mr. Espinosa** suggested that when they go to sites he wondered if they could get a site overview of what that site does. He commented it would be helpful when the public speaks to know what they'd done. **Dr. Ziemer** replied he didn't know what is planned for the tour, but it would be helpful for those going on it to have an overview of the primary facilities on the site, what the site's role has been in the past. **Mr. Griffon** commented it would make sense on the agenda, if a site profile's been complete for the location, to have a summary presentation of that to bring up questions from the audience in public comment, as well as a way for the Board to learn about the site.

Dr. Ziemer suggested perhaps a description of the main processes done in the past so when workers refer to working on some line you can relate that to a location or a process. He commented it was a good suggestion, but wasn't sure how to implement it. He asked if anyone knew to what extent they'll be given an overview of the site on the tour tomorrow. **Ms. Homer** replied they would be given packets containing maps and a CD, although she didn't know what was on it. In Idaho Falls they would attend a movie, and on the site out she was sure they would be able to pose questions, as they usually were. **Dr. Ziemer** said he hoped there would be some historical information that lays the groundwork for the site. **Ms. Homer** declared she suspected that was in the packets. **Dr. Ziemer** commented perhaps in the future, particularly somewhere like Pinellas, they could be provided information on what went on there.

Mr. Espinosa declared on the outreach he would like to see a schedule for the site profile and would like to make sure DOL resource centers also receive the schedule. There was an outreach meeting at Pantex and DOL for New Mexico didn't receive it. **Dr. Neton** replied that was a good idea, but the practicality of it is that the meetings get arranged very quickly. It takes a lot of negotiation with union people and they rarely have more than three or four weeks' notice so they can't put out a six-month schedule. The best they can do is notify the affected people. They always notify DOL at the national level and invite their participation if they want to. It isn't their call to require DOL's presence, but they find it helpful if they are there.

Dr. Neton added that **Mark Lewis**, who used to be a union member at Portsmouth, has joined one of ORAU's contractors as the lead on this issue. One of his jobs is to do pre-meetings at sites. **Dr. Neton** commented they're doing a lot better job of groundwork now than they were even three or four months ago.

Dr. Melius observed that presumably by next meeting SC&A will have completed some of the site profile reviews. He queried the procedure for those being shared by the Board, as well as presented to the Board, if there is a format and approach for that. **Dr. Ziemer** replied there was not a set procedure for the site profiles, but believed it was in order to get a copy of the draft in advance. He asked if that could be done, from a legal perspective.

Dr. Neton reminded **Dr. Ziemer** he had been a part of the conversation with Sanford Cohen that NIOSH would be first afforded a review of the draft for factual accuracy before it was issued to the Board, commenting that at the time it's issued to the Board it becomes a public document. **Dr. Ziemer** replied that was his question, was it public or predecisional if it's distributed to the Board for review prior to a meeting. **Dr. Neton** remarked **Ms. Homoki-Titus**, who was sitting next to him, had said it was predecisional, so he presumed it was not publicly available until it is adopted by the Board. Which then became the Board's option on how to proceed with the predecisional draft, whether it would be closed session or have it vetted at a public session.

Dr. Ziemer asked the Board how they would prefer to proceed. He commented it would make sense to get a draft at some point when the contractor believes it's ready. They will have done a reality check with NIOSH on factual accuracy.

Dr. Andrade observed it is wholly appropriate for NIOSH to review for factual accuracy. After that, however, the review itself should be considered by the Board in closed session. **Dr. Ziemer** remarked it was his impression the reason for a closed session was Privacy Act issues on individual cases and didn't think that would be the case for a site profile. **Ms. Homoki-Titus** interjected she couldn't imagine that it would be. **Dr. Andrade** commented he could, especially if SC&A is going to do interviews with site personnel. **Dr. Neton** conceded there is the possibility that in order for the Board to understand what has been done, some Privacy Act information may need to be discussed to understand concerns or issues the Board might raise. **Dr. Ziemer** commented that what would have to happen is, once the draft document was ready, if the contractor had concerns that they had to identify individuals perhaps it could be in private session. Otherwise it's got to be in open session. **Mr. Presley** suggested if there are areas where the name of a person they went through was used, just leave it out and use the site. **Dr. Ziemer** declared it was going to be an evaluation of a site profile, so it was hard for him to envision why it would bring out individual issues.

Mr. Elliott offered that in their work NIOSH used personal communication when they consulted with people. And if they couldn't get a release from the individual, it is couched as a personal communication. He expressed hope that SC&A would use a similar approach, either obtaining a

release so they can use a person's name as a reference, or listing it as a personal communication. The only other thing would be if SC&A found a document NIOSH had not discovered which contained identifiable personal dose data, adding that in such a case he would hope they would redact it for public consumption.

Dr. Ziemer commented his sense of it is the document comes to the Board so they have a chance to see it before the meeting, but it is part of the open meeting. **Dr. Melius** expressed his concern about appearances, asking **Dr. Ziemer** if he would get a copy of it when it came to NIOSH for the fact-checking, which he will not. **Dr. Melius** inquired how a dispute about the facts between SC&A and NIOSH might be resolved.

Dr. Neton explained that, having worked with SC&A to this point, he felt there would be documentation if there were any changes to a record file. He also indicated he didn't think there would be any problem with **Dr. Ziemer** receiving an advance copy while NIOSH does a factual accuracy check so a paper trail could be followed as to what had changed. However, SC&A is under no obligation to change anything. NIOSH has no control over the ability to edit the document. **Dr. Ziemer** observed NIOSH could only comment they didn't agree that SC&A had perhaps characterized something correctly.

Mr. Elliott commented he hoped it would be the Board's pleasure and insistence that someone on the Board see the NIOSH comments that were given for factual accuracy and clarification, and understand then from that point of view what changes did or didn't take effect. **Dr. Ziemer** observed that would track both sides of the issue, so they would also want a copy of the comments. **Dr. Melius** suggested that may help resolve any issues because the Board will decide what can be presented, and he didn't think they wanted to be in a position of point/counterpoint. So at the same time there is a paper trail and it protects everybody involved. **Dr. Ziemer** remarked it was a good suggestion and he was willing to do it that way if there were no objections from the Board. **Mr. Elliott** added he hoped the NIOSH comments would also become part of the public record.

Dr. Neton reminded **Dr. Ziemer** that in the discussion on this with SC&A where **Dr. Ziemer** had participated, **Dr. Mauro** had agreed to take on the task of writing this up as an internal procedure to improve the transparency of the process so it didn't appear to be arbitrary. **Dr. Neton** commented he hadn't seen that yet, but since **Dr. Mauro** had volunteered to do it, perhaps the Board might inquire if it's been done.

Dr. Melius queried if it would be helpful to have a working group to interface with NIOSH between now and the next meeting to make the Board's evaluation of an SEC petition go easier, assuming NIOSH is going to be ready to present such. **Dr. Ziemer** asked if they were likely to be evaluating a petition at the next meeting. **Mr. Elliott** replied he expected they would have an evaluation plan to look at. He also hoped they might have at least one class petition evaluation report to look at. He remarked they are working very hard to push those things through, recognizing it may be at the cost

of not bringing the Board along fast enough. So if the Board wants a working group, he's willing to work with them.

Dr. Ziemer mused that would mean whatever SEC petition were ready to go would have to be ready for a working group prior to a meeting. And while it could be the day before, they are already moving their timetable back for the subcommittee. But they could set up a working group on standby so they could be marshaled into action, if needed. He asked, and **Dr. Melius** confirmed, that is his suggestion.

Mr. Elliott commented they could meet separately from the subcommittee but on the same day, if necessary. **Dr. Melius** remarked it would be contingent on whether NIOSH were ready.

Dr. Ziemer reminded everyone they were envisioning the review of 20 dose reconstruction cases as a full Board in closed session, implying an encroaching need for a fourth work day. He also observed a working group can work by phone if necessary, if they have something to look at. He asked the Board for their wishes on a standby working group for this activity, if necessary.

Mr. Presley commented that since the Board members were supposed to get a copy of the evaluation plan, perhaps they could go through that and, if any reports were ready, go through them. If a working group were needed after they could see how much work and detail were involved, establish one then. **Dr. Melius** remarked he thought a working group had to be established at a meeting. **Mr. Presley** noted it could be done at the next meeting. **Dr. Melius** clarified his thought was to have the working group look at the plan.

Mr. Elliott indicated he saw no problem with that at all. He agreed it made sense for the Board to see what the evaluation plan looked like, commenting that it's nothing more than telling them where they're going to look and how far NIOSH is going and what they're using in the research. **Dr. Ziemer** remarked they could set up a working group on a standby basis and they would have to establish a date based on what happens at NIOSH.

Observing that there appeared to be support for having a working group on call, **Dr. Ziemer** called for at least three volunteers to be in the working group. **Mr. Espinosa**, **Dr. Melius**, **Ms. Munn** and **Mr. Presley** volunteered. **Dr. Ziemer** explained their task will be to evaluate and make a recommendation on the evaluation plan and, if necessary, on a petition should one be in a state for review. He called upon **Mr. Presley** to serve as the coordinator for time, effort, and receipt of materials, to report back to the Board at the next meeting. **Mr. Presley** agreed.

Mr. Elliott explained that NIOSH is handling the petitions on a first things first basis. Their first step is to qualify the petition, then provide the evaluation plan. So they cannot give the working group the plan today.

Dr. Ziemer called for other comments, suggestions or recommendations. **Ms. Homer** reminded those attending the tour the next day they will need a photo ID and cash as they will be eating in the facility lunchroom.

Admitting that it was late in the day to be revisiting the issue, **Mr. Griffon** raised SC&A's question of final report versus interim report due to insufficient access. **Dr. Ziemer** interjected he had interpreted that as a heads-up issue of concern. He didn't think they were at the point of saying change the task, and the access issue has been taken care of and they're moving ahead. **Mr. Griffon** argued his understanding was they felt they were up against some deliverables. **Dr. Ziemer** reiterated his interpretation was that it had been a heads-up that they may get to a point where they aren't finished but can't proceed, but they aren't there yet. **Dr. Melius** agreed that was his recollection, as well, at least for the earliest deliverables, and they just have to see where things go with other issues later on.

Dr. Ziemer explained he thought SC&A was laying the groundwork to come back and say they can't go as far as they thought, and there isn't any action the Board could take now, although they may have to do something in the future. His thought was that SC&A didn't want to hit the Board cold with that at some point later on, and the Board may need to define what they consider a final report. **Mr. Griffon** suggested the Board may also need to make some interpretations as to technical scope.

With no further business to come before the Board, the meeting was concluded at 3:10 p.m.

End of Summary Minutes

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

_____
Paul L. Ziemer, Ph.D., Chair

_____
Date

Attachement 1

ACTION ITEMS

ABRWH Meeting 26
IDAHO FALLS, IDAHO

I. The document titled, "Procedure for Selecting and Tracking Dose Reconstruction Cases" was voted on and accepted by the Board with the following two changes:
Item 3, add the sentence, "Once a case is reviewed, it is removed from the sampling pool."
Item 6, change the word "statistics" to the words "summary findings."

II. The Board voted to accept the list of "First 25 Samples" for randomly selected claims reviews, with the exception of the last five Bethlehem Steels, and members were assigned specific facilities to review.

III. The Board discussed two documents, "Quality Assurance Plan" and "Conflict of Interest Plan," submitted by the contractor, Sanford Cohen and Associates. Dr. Ziemer concluded the discussion with: "We would ask the contractor to modify on the 'Quality Assurance Plan,' it's Section 3-0, second sentence, we would remove, 'and SEC review.' And on the 'Conflict of Interest Plan,' page six, under Section 5-3, second paragraph, remove the phrase 'SEC petitions.'"

IV. A working group will be on call. Dr. Ziemer stated its function: "to evaluate and make recommendation on the evaluation procedures plan and if necessary on a petition in a state for such review. The group will consist of Mr. Espinosa, Ms. Munn, Dr. Melius and Mr. Presley, who will coordinate the group, which will report to the Board at the next meeting.