

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

**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 Thirty-first Meeting
July 5-7, 2005**

The Thirty-first Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Chase Park Plaza Hotel in St. Louis, Missouri on July 5, 6, and 7, 2005. 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. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson (via telephone); Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Leon Owens; Mr. Robert Presley; and Dr. Genevieve Roessler.

Designated Federal Official: Dr. Lewis Wade, Executive Secretary.

Federal Agency Attendees:

Senator Christopher Bond, US Senate

Department of Energy:
Ms. Kate Kimpan

Department of Health and Human Services:

Mr. Fred Blosser, Ms. Anstice Brand, Ms. Heidi Deep, Ms. Chris Ellison, Ms. Nichole Herbert, Mr. Stuart Hinnefeld, Ms. Cori Homer, Ms. LaShawn Shields, Ms. Liz Homoki-Titus, Mr. Ted Katz, Mr. Judson Kenoyer, Relada L. Miller, Dr. James Neton, Mr. LaVon Rutherford, Mr. Dan Stempfley, Mr. Tim Taulbee, Chris Underwood

Department of Labor:

Mr. Shelby Hallmark, Mr. Jeff Kotsch, Mr. Jeff Nesvet, Mr. Peter Turcic

Government Accounting Office:
Ms. Mary Nugent

Contractors: Dr. Hans Behling, Ms. Kathy Behling, Mr. Joe Fitzgerald, Dr. John Mauro

Public Attendees: See Registration

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Executive Summary

The Thirty-first Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Chase Park Plaza Hotel in St. Louis, Missouri on July 5, 6, and 7, 2005. All members were in attendance. Others in attendance included staff of various Federal agencies, as well as members of the public. The Summary Minutes of Meeting Thirty were approved without comment.

* * * * *

Tuesday, July 5, 2005

**Bethlehem Steel Technical Basis Document
Status of Revisions**

Dr. Jim Neton of NIOSH presented a history of the Bethlehem Steel Site Profile Revision and the NIOSH responses to SC&A's review. He included information regarding five motions passed by the Board at the February 7th meeting in St. Louis as a result of those revisions.

Questions were entertained from the Board following the conclusion of **Dr. Neton**'s presentation. The Board determined a smaller workgroup or subcommittee should be assembled to identify and review issues items and coordinate resolution with SC&A's comments and findings.

* * * * *

Comments by Members of Congress

Senator Christopher Bond of Missouri reiterated previous reminders of the urgent need to designate former workers at the Mallinckrodt downtown site as members of the Special Exposure Cohort, or SEC. He also addressed the Board regarding dose reconstruction feasibility and timely worker compensation.

* * * * *

Privacy Issues

Ms. Liz Homoki-Titus from the Office of General Counsel of the Department of Health and Human Services addressed the Board regarding conflict of interest and conditions under which a Board member might be required to recuse himself. She also suggested that the Board establish a procedure to follow when they may be called upon to provide public comment.

Ms. Homoki-Titus answered questions from the Board.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Y-12 Site Profile Review

Mr. Joe Fitzgerald of Sanford Cohen & Associates briefed the Board in general terms on accomplishments in the last 30 days regarding document review and interviews. He noted the workers were very mobile at the site, certain worker classes were not monitored, and the high-fired oxide workers had been switched from periodic urinalysis and lung count monitoring to only periodic fecal analysis.

Mr. Fitzgerald stated he would like to follow the issue resolution process with NIOSH and ORAU to isolate what is important regarding issues of concern.

Following his presentation, **Mr. Fitzgerald** took questions from the Board.

* * * * *

**Y-12 Special Exposure Cohort (SEC) Petition
Evaluation Report and Board Discussion**

Mr. Robert Presley recused himself and stepped away from the table.

Mr. Larry Elliott, Director of NIOSH's Office of Compensation Analysis and Support, acknowledged the work SC&A and **Mr. Fitzgerald** did on the Y-12 site profile, noting it would provide for a more comprehensive technical basis document.

Mr. Elliott described the three Y-12 petitions (18, 26, and 28) received on behalf of employees at the plant. He reminded the Board of the statutory requirements required for adding a class of worker to the Special Exposure Cohort.

The original class definitions from the petitions were described by **Mr. Elliott**, with time periods ranging from January 1944 through December 1957. Noting that no data existed for the early years at the facility, he described NIOSH's use of portions of the site profile in evaluating the petitions. Documents provided by the petitioners were included in that review.

Mr. Elliott summarized the NIOSH conclusions, in part stating that:

- The workers described in Petitions 18 and 26, and in Petition 28 through December 1947 be combined, and provided the Board with wording for the new proposed class definition.
- That combined class of worker had met the feasibility and health endangerment requirements of the two-pronged statutory test.
- The evaluation process would continue relative to the remainder of the Petition 28 workers in the period January 1948 through December 1957, with a further evaluation report to be presented at a subsequent meeting.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Elliott added the work done by the SC&A site profile review would be important in completing NIOSH's evaluation of Petition 28.

Mr. Elliott answered questions from the Board. Petitioners available via telephone indicated they had no comments regarding the evaluation report.

Following extensive discussion, a motion carried recommending the combined class of worker be granted inclusion in the Special Exposure Cohort.

* * * * *
**IAAP SEC Petition
Evaluation Report and Board Discussion**

Dr. Wade and Dr. Ziemer acknowledged Mr. Presley's return to the table.

Mr. Larry Elliot of NIOSH presented information regarding industrial radiographers who conducted radiography on a nonradiological high explosive weapon components at the Iowa Army Ammunition Plant from May of 1948 to March of 1949. He provided details of the evaluation report and concluded the presentation by defining the proposed class.

After extensive discussion, the Board passed a motion granting an SEC petition for the industrial radiographers who worked at the Iowa Ammunition Plant from May 1948 to March 1949.

* * * * *
Public Comment Period

The following is a list of the members of the public who spoke. A full transcript of their comments is available on the OCAS web site, www.cdc.gov/niosh/ocas.

Mr. Richard Miller, GAP; Mr. Dan McKeel, Missouri Coalition for the Environment; Mr. Clarence Schwendesen, Mallinckrodt; Mr. Ed Lamzik, Mallinckrodt; Ms. Eileen Adams, Destrehan Plant; Ms. Marilyn Schneider, Mallinckrodt; Ms. Mary Generi, Mallinckrodt; Mr. George Vogt, Mallinckrodt; Mr. Roni Steger, Mallinckrodt; and Mr. Ed Walker, Bethlehem Steel.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Wednesday, July 6, 2005

Dr. Wade reviewed the meeting items and provided background information on previous Board actions dealing with Mallinckrodt.

**Supplemental Review
Mallinckrodt Site Profile**

Dr. Arjun Makhijani of Sanford Cohen & Associates reiterated what the Board charged SC&A to do -- basically to review the data reliability issue and the usability of the site profile for the Mallinckrodt downtown site for the '49 to '57 time period, the St. Louis Airport Site, and the decommissioning section.

Dr. Makhijani briefly reviewed the three categories of doses: the minimum dose, reasonable dose, and maximum dose. He provided the Board technical issues regarding why they believe reasonable dose estimates will not likely be possible.

A question-and-answer session ensued with **Dr. Makhijani** regarding his presentation.

* * * * *

Mallinckrodt Site Profile

Dr. Jim Neton of NIOSH presented information concerning the data issue and raffinate issue with respect to Mallinckrodt dose reconstruction process. **Dr. Neton** outlined to the Board the dose reconstruction process and gave a detailed description of the raffinate extraction process. Data is collected from the DOE, claimant files are reviewed along with CER data set (unique to Mallinckrodt,) site profiles, and then the data is interpreted using procedures and implementation guides, Technical Information Bulletins and claimant interviews.

Dr. Neton presented to the Board information on the data sources:

- The only data is the individual and summary film badge reports.
- The CER database is a compilation of all the information at the site.

Dr. Neton presented statistical values of the data set that compared the air dust data against the urine data for a subset of workers for the ether house. He concluded that based on the lognormal fit of the urine and air data, the integrity of the data is not an issue.

Dr. Neton concluded his presentation with a couple of slides on raffinate whereby he stated that NIOSH would pick the higher of the air and urine test results to assign the dose to the worker. Before stating his conclusion, he gave a detailed process description of the raffinate process.

Following his presentation, **Dr. Neton** answered questions from the Board.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

* * * * *

**Mallinckrodt SEC Petition
Evaluation Report**

Mr. Larry Elliott of NIOSH began his presentation by reviewing, as required by statute, the two-pronged test that must be met. Next he summarized pertinent dates of the petition and outlined for the Board the three class definitions.

Additional issues were identified by the Board at the February meeting following the presentation of the evaluation report. NIOSH responded to those additional issues in a supplemental report.

Mr. Elliott briefed the Board that NIOSH concluded, based on the monitoring activities of employees and work areas established in 1949 by Mallinckrodt, as well as the information on radiological sources and processes, there is sufficient information to validate the dose estimates for the period 1949 to 1957 and notwithstanding any data reliability concerns raised for the earlier time period.

Mr. Elliott further presented information regarding three items outlined in SEC petition Report 00012-2, Section 7.3.

Mr. Elliott concluded information on Item 4 by stating that they would use the highest and most claimant favorable data set between the urine and air data for use in dose reconstruction.

Mr. Elliott concluded his presentation by summarizing that for the years 1949 to 1957 NIOSH finds that radiation dose estimates can be reconstructed and validated for compensation purposes for this particular class. It is feasible to do dose reconstruction and, therefore, while it is believed that health was endangered here, there is no need to address that particular prong of the two-part question.

* * * * *

**Mallinckrodt SEC Petition
Board Discussion**

Dr. Ziemer opened the floor for discussion.

Dr. Melius requested confirmation on the verification of data issue and examples of dose reconstruction using actual data. **Dr. Neton** and **Mr. Elliott** both provided input on the dose reconstruction issue.

Dr. Neton provided additional comments stating that 100% of the 109 active cases in possession who worked in the 1949 to 1957 time period would fall into the evaluation report. **Dr. Neton** added that there are an additional 50 or 60 cases that have employment that spill over into the 1949 to 1957 time period that are also members of the original class.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Dr. Anderson followed up with comment regarding feasibility of actually doing dose reconstruction. **Dr. Melius** raised the feasibility issue and also raised issue with what the Board previously requested concerning dose reconstruction feasibility and what was actually presented.

Dr. Neton elaborated by stating that his understanding was to present to the Board examples of graphical data using real data versus the graphically presented information at the Cedar Rapids meeting which utilized hypothetical data.

Comments from Petitioners

Ms. Denise Brock provided to the Board an account regarding events since filing the SEC petition for the Mallinckrodt workers from 1942 to 1957 a year ago. She cited to the Board at a February meeting a decision was made to split the cohort. SEC status was granted for workers during the time period 1942 to 1948, and to table a decision on the workers from 1949 to 1957 based on recently discovered data and the so-called Mont Mason memo.

Ms. Brock stated that NIOSH felt that the newly discovered data information and on-going site profile revision provided enough information to conduct an accurate dose reconstruction on the workers from 1949 to 1957. Board allowed more time for NIOSH and SC&A to complete their analysis at the April meeting in Iowa.

Ms. Brock expressed concern regarding the timeliness of written information being relayed to her. She cited to the Board findings of the Rev. 1 report does not appear to provide a basis to do accurate dose reconstruction. She quoted to the Board examples regarding Mallinckrodt site profile audit.

Ms. Brock spoke to specific examples dealing with lack of data issue and worker interview information. **Ms. Brock** restated to the Board for the record what Congress directed NIOSH to do with respect to Special Exposure Cohorts. She emphasized to Board members that feasibility concept goes beyond just scientific and technical issues, it should also consider the timeliness and cost of dose reconstruction in the absence of relevant or missing data. She mentioned the lack of proper procedures to provide petitioners information regarding meeting notification and written document transmittal.

Ms. Brock urged the Board to add the Mallinckrodt workers from 1949 to 1957 to the Special Exposure Cohort.

Mr. George Blue testified regarding his working experience in the raffinate extraction process. He described his specific duty was to reheat the raffinate in an acid for the purpose of extracting an element.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Blue testified that he had to be catheterized to obtain urine sample. He also mentioned that he was not aware of radon exposure with his work. He relayed in detail to the Board a specific tank explosion incident and sampling of drums procedure.

Mr. Anthony Windisch stated that he worked at the Mallinckrodt uranium plant in St. Louis from 1945 to 1957, and the Weldon Springs plant from 1958 to 1967. He acknowledged he was a certified computer professional and testified that Mason memo shows that most of the recently-found computer keypunch cards and other radiation records was a bunch of garbage and useless. He referenced a meeting with the audit investigator where he testified that as an electrician at the Mallinckrodt uranium plant he witnessed and/or experienced production mishaps at almost every processing step during the production of uranium metal.

Mr. Windisch cited to the Board the frequency of occurrence when uranium processing bomb exploded and he had to repair the electric furnaces. He made reference that safety department maintained a current dose reconstruction profile for each unique work site at the Destrehan uranium plant.

Mr. Windisch concluded his remarks by stating that there is no specific dose reconstruction profile to measure ether house explosion, exploding radium processing bombs, overflowing raffinate tanks and other production mishaps.

Mr. Steven Eugene Pape stated that his father was Eugene C. Pape and worked at the Destrehan Mallinckrodt Chemical Company plant from 1945 until his death May 10, 1977. He stated his father was diagnosed with carcinoma lung cancer April 21, 1977. He commented that he did not know any answers to their questions, except to state that his father worked seven days a week for a number of years.

Mr. Robert Leach commented that he went to work for Mallinckrodt in 1950, transferred to uranium plant in 1952, worked in plant 4 from 1952 to 1957, transferred to Weldon Springs in 1957 and worked there until the plant closed in 1965. He stated his job was to clean up the inside of the furnaces after they cooled down. He testified that more than once the molten metal came through the bottom of the furnace and would run into the work area. Mr. Leach stated that in case he was not around for Weldon Springs petition, that he worked 40 to 76 hours per week.

Mr. Ed Luecke stated he began working at Mallinckrodt May 6, 1947 in plant 4. He described for the Board that he worked in plant 4, which he referred to as the coffin area. He commented they wore no monitoring badges and there were fumes all over the place. He commented that he moved to plant 6E and worked as a utility man where he stated he was exposed to a lot of dust.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Ms. Brock felt that NIOSH should incorporate workers' statements into site profile. She felt time was being wasted because there are no assurances that once the revisions take place, actual dose reconstruction could be done.

* * * * *

**Mallinckrodt SEC Petition
Board Discussion**

Dr. Ziemer opened the floor for discussion. **Mr. Owens** opened the discussion with a question for **Dr. Makhijani** concerning the completeness and accuracy of the records as presented earlier.

Dr. Makhijani summarized by stating that aside from the radionuclides ratios and Fernald K-65 silos there are data sufficiency problems in several areas. He further defined those areas as infrequent incidents, environmental doses, and roving workers.

Dr. Neton added comment regarding the issue of the inability to reconstruct infrequent incidents.

Dr. Makhijani clarified by stating that a claimant favorable way or maximizing way hasn't been demonstrated for modeling infrequent incidents.

Dr. Anderson commented on the timeliness and feasibility issue regarding the dose reconstruction of the 109 cases. If tasked with dose reconstruction, what is the time frame. **Mr. Elliott** responded that four months would be required for 107 cases of dose reconstruction; the first month reserved for ironing out remaining issues and three months for work on the claims.

Dr. Anderson and **Dr. Neton** provided comments regarding the meaning of the statistical information presented in **Dr. Neton's** presentation. **Dr. Melius** provided comments with options to address how to put together issues from the SC&A evaluation of the site profile and NIOSH's evaluation of the SEC petition.

Dr. DeHart asked for clarification regarding the issue of self-identified exclusion for dose reconstruction. He restated his question, can you identify an individual in which dose reconstruction cannot be done and move along toward identifying a specific cohort. **Mr. Elliott** said yes, and cited regulation that allowed that.

Dr. Ziemer at this time reminded the Board to consider the timeliness of the various options discussed. He posed a question to **Denise Brock** regarding raffinate workers and subcohort. **Ms. Brock** responded she thought plant 6 was raffinate area. **Dr. Ziemer** further asked if the information could be retrieved from the job description information.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Dr. Neton and **Dr. Ziemer** exchanged dialogue regarding the issue of job description information, K-65 digestion process, and dose reconstruction. **Dr. Neton** responded that the dose reconstruction would be by an individual case-by-case basis if job category information is utilized. He added that it is the Department of Labor's responsibility to qualify a subset of workers based on their application as to whether they are in the SEC.

Mr. Elliott gave a timeline of development of a case file.

Dr. Melius commented that an interim step that would allow SC&A comments to be resolved could help identify if dose reconstruction would apply to a larger percentage of workers than previously anticipated.

Dr. Ziemer agreed with **Dr. Melius's** comment, but noted how hard the Board was pushing SC&A and NIOSH to meet the Board's deadlines. **Dr. Melius** suggested that the committee or subcommittee continue dialogue to resolve SC&A site profile comments.

Ms. Brock asked that probability of causation chart be developed for the next meeting.

Mr. Gibson questioned how NIOSH can provide accurate and reasonable dose reconstruction for the raffinate workers in plant 6 with the lack of individual bioassay data. **Dr. Ziemer** informed **Mr. Gibson** that there are a lot of urinalysis data and air data for the dose reconstruction effort.

Ms. Brock expressed concern to the Board about time issue regarding dose reconstruction issue, especially regarding thorium-230, actinium-227, protactinium raffinates. **Dr. Neton** suggested the use of the air monitoring data to support inhalation intakes from the raffinate material.

Dr. Makhijani remarked that there are a significant number of issues to be resolved. SC&A will engage the issues at the Board's direction and report those findings at a time mandated by the Board.

Mr. Griffon felt that the Board, SC&A and NIOSH, on the subcommittee level, should identify or prioritize issues that need to be resolved for the purpose of resolving this SEC petition. He also added that he would like to see specific representative cases of dose reconstruction, especially for the raffinate assumption.

Mr. Elliott said he agreed with **Mr. Griffon**, but clarified that they couldn't bring an example dose reconstruction case unless it's an adjudicated case. **Ms. Homoki-Titus** presented clarification on bringing cases before the Board that haven't been adjudicated by the Department of Labor.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Elliott commented to the Board regarding questions raised from Cedar Rapids meeting explaining how to validate the data and how to use the data in dose reconstruction.

Ms. Munn commented on the effort to gather and analyze as much information as possible about exposures of the workers in the proposed class.

Dr. Ziemer pointed out to the Board that a delay has the same effect as denying the petition.

Mr. Espinosa wanted to know if adjudicated claims could be discussed by the Board in executive session. **Ms. Homoki-Titus** remarked to the Board that they are an advisory board not an appeals board for individual claims.

Dr. Melius made a comment that the Board still must decide on issues related to contractor doing SEC evaluations. He stated preference for postponement on a decision on the Mallinckrodt petition until NIOSH has had time to evaluate the SC&A report.

Dr. Ziemer inquired if building 6 workers are being viewed as a possible subset of the cohort that might contain eligibility status on its own.

Dr. Melius stated once NIOSH had a chance to comment on the SC&A evaluation of the site profile they would be able to come to a conclusion on building 6 issues.

Ms. Brock provided comment that she has not had an opportunity to take in all the information. She asked for clarification on the issue if halting the decision will also not halt the dose reconstruction.

Mr. Elliott clarified that work on the Mallinckrodt claims had been suspended for the Destrehan facility unless there was a claim that allowed NIOSH to move forward using the efficiency process. NIOSH could move forward on dose reconstruction of specific claims where SC&A site profile comments have been resolved. Claims with outstanding site profile issues will have to wait for dose reconstruction until issues are resolved.

Ms. Munn commented that there was no need for a Special Exposure Cohort since NIOSH has committed that they can do the dose reconstruction.

Mr. Elliott remarked that two things have happened to put the Mallinckrodt claims on hold that were not reconstructable using efficiency approaches: review of the revision for the site profile and the petition. He added that the 75 claims completed were all lung and prostate cancer claims.

Dr. Wade proceeded to remind the Board of the requirements of the SEC legislation by reading pertinent portions of the Special Exposure Cohort rule 42 CFR 83.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

A motion was made and seconded that the SEC petition for the 1949 through 1957 time period at the Mallinckrodt Destrehan facility be denied. Motion was tabled.

A motion was made and seconded for the Board to consider formulating a letter of apology or regret for delaying SEC petition. Motion passed.

Dr. Ziemer proposed postponement until tomorrow on the SEC policy issue discussion so that working group may get underway. The Board proceeded with future meeting logistics discussion before **Dr. Ziemer** formally recessed the meeting.

* * * * *

Thursday, July 7, 2005

SC&A Task III/Workbook Issues

Dr. Hans Behling of Sanford Cohen & Associates opened the presentation by providing background dealing with Task III. He defined Task III as being procedures and methods used by NIOSH to do dose reconstruction and outlined Task III subject matters as follows:

- Procedures that deal with external dosimetry,
- Procedures that deal with internal dosimetry,
- Procedures that deal with CATI interviews, quality assurance, documentation and record management.

As directed by the Board, SC&A developed a method to conduct a review of the 33 procedures. Task III was broken down into two phases:

- Phase I -- develop method to systematically review and standardize the review process that was presented to the Board September 2004.
- Phase II -- review of the NIOSH and ORAU procedures that was presented to the Board in January of 2005.

Dr. Behling presented information on the development of a checklist comprised of secondary questions and rating system for evaluating the procedures based on the previously presented seven objectives.

Dr. Behling identified for the Board seven basic objectives followed for Task III work.

Following the presentation, Dr. Behling entertained questions from the Board.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Report on the Review of the First 20 Dose Reconstructions

Dr. Ziemer explained to the Board the matrix details. He pointed out Items 1 through 7 are the ones on which the Board will have to take action.

Dr. Ziemer and **Mr. Griffon** explained the definitions of the 7 categories. The Advisory Board then proceeded on with the task of categorizing the first 20 procedures. The Board produced a modified matrix.

A motion was made and seconded to accept the summary of findings matrix as part of the Board's report on the first 20 cases. With no discussion, the motion carried unanimously.

* * * * *

Board Discussion

The Board then proceeded to discuss the modified summary of findings matrix. **Dr. Ziemer** noted the Board also has to consider the narrative wording to the Secretary of Health and Human Services report on dose reconstruction findings. The only wording change to the latest report version as reported by **Mr. Griffon** dealt with case ranking and site/program-wide ranking totals.

A motion was made and seconded to approve the modified report document, along with the modified summary of findings matrix document as the report to the Secretary.

A friendly amendment was filed to the motion for a slight change in the report wording to include all the pertinent attachments together with the table that NIOSH will supply and the matrix be included in the report. The motion was amended and passed without opposition.

Dr. Ziemer next identified for the Board recommended changes in a document entitled "Priority Issues for Demonstrating Feasibility of Dose Reconstruction for MCW Destrehan Street Workers for the Time Period 1949 to 1947, List of Tasks."

After discussion and after a few amendments the Board unanimously approved the amended document.

With that **Dr. Wade** cited to the Board how the engagement process should proceed. Workgroup meetings will be noticed in the *Federal Register* opened to the public and a transcript officially recorded.

Ms. Munn commented on the requirement that subcommittee meetings be noticed in the *Federal Register*.

Dr. Ziemer identified the subcommittee workgroup participants as Mark Griffon, Wanda Munn, Jim Neton, Mike Gibson, with Rich Espinosa as an

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

alternate.

Dr. Melius proposed a motion dealing with the provisions governing communication and program direction with the Board's audit contractor.

A motion was made and seconded that the Advisory Board on Radiation and Worker Health adopt provisions governing communication and program direction with the Board's audit contractor.

A written copy of the motion was distributed to all Board members and **Dr. Ziemer** presented each item of the motion. Items 1 and 2 as read were commented on and slightly modified. Item 3 as read was commented on and slightly modified through friendly amendments.

The Board voted on amended motion and was unanimously passed with one abstention.

A motion was made that the Board recognize Cori Homer for her superior administrative support and assistance to individuals and the Board. This was seconded and overwhelmingly passed.

Ms. Homer informed the Board that her duties would now be in the capable hands of **LaShawn Shields**.

The Board continued the meeting. **Dr. Melius** commented on the conflict of interest issue brought up in the public comment period.

Dr. John Mauro of SC&A commented that their conflict of interest planned procedures and forms have been completed and signed by project members and are on file in hard copy at corporate headquarters. **Dr. Toohey** informed the Board that all ORAU forms are posted on project web site at www.oraucoc.org.

Dr. Wade reminded the Board about the SC&A SEC task order developed by the Board. The task order has been submitted to the contractor SC&A for approval. The Board will consider the proposal in closed session when received.

* * * * *

**Report on Review of the Second Round,
18 Dose Reconstructions**

Ms. Kathy Behling of Sanford Cohen & Associates started the presentation by outlining three key elements of SC&A's approach to doing dose reconstruction review.

Ms. Behling reviewed for the Board NIOSH and ORAU's approach to the dose reconstruction process. **Ms. Behling** presented a chart detailing how the 18 cases and the 113 findings broke down by category.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Ms. Behling then presented a chart of the breakdown of the findings for all 30 cases reviewed. She summarized for the Board the majority causes of the 113 findings were due to procedural issues made by the dose reconstructor.

Ms. Behling entertained questions from the Board.

Dr. Ziemer before closing out the board discussion commented that the contractor and NIOSH should proceed on the development of the matrix for the 18 cases just as what was presented earlier for the first 20 cases.

* * * * *

SC&A Contract Issues

Dr. John Mauro of Sanford Cohen & Associates updated the Board relative to the four tasks performed by the contractor over the past year and a half. He felt that based on the fact that NIOSH was moving more toward doing realistic dose reconstruction and away from the minimum/maximum procedure, this has resulted in more sophisticated TIBs and workbooks produced for best estimate dose reconstruction.

Dr. Mauro further stated that he felt minimum/maximum cases reviewed so far were showing the same conclusions and weren't adding any real value. He recommended that for Task IV more realistic cases for testing be selected.

Dr. Mauro fielded questions from the Board.

A quorum was not available for the Board to act on issues discussed, so the Board halted the discussion. **Dr. Wade** concluded that Board members should continue this discussion via a phone conference.

* * * * *

Public Comment Period

Dr. Ziemer introduced **Colonel Ed Taylor** from the newly formed advisory board administered through the National Council on Radiation Protection and Measurements. This will be a parallel group handling the veteran's cases. Colonel Taylor thanked the Board for allowing him to sit in all week and learn.

The following is a list of the members of the public who spoke. A full transcript of their comments is available on the OCAS web site, www.cdc.gov/niosh/ocas.

Mr. Dan McKeel, Missouri Coalition for the Environment; Mr. Larry Gassei; Ms. Denise Brock, UNWW/Mallinckrodt; Mr. Roni Steger, Mallinckrodt.

End of Executive Summary

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

**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 Thirty-first Meeting
July 5-7, 2005**

The Thirty-first Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Chase Park Plaza Hotel in St. Louis, Missouri on July 5, 6, and 7, 2005. 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. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson (via telephone); Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Leon Owens; Mr. Robert Presley; and Dr. Genevieve Roessler.

Designated Federal Official: Dr. Lewis Wade, Executive Secretary.

Federal Agency Attendees:

Senator Christopher Bond, US Senate

Department of Energy:
Ms. Kate Kimpan

Department of Health and Human Services:
Mr. Fred Blosser, Ms. Anstice Brand, Ms. Heidi Deep, Ms. Chris Ellison, Ms. Nichole Herbert, Mr. Stuart Hinnefeld, Ms. Cori Homer, Ms. Liz Homoki-Titus, Mr. Ted Katz, Mr. Judson Kenoyer, Relada L. Miller, Dr. James Neton, Mr. LaVon Rutherford, Mr. Dan Stempfley, Mr. Tim Taulbee, Chris Underwood

Department of Labor:
Mr. Shelby Hallmark, Mr. Jeff Kotsch, Mr. Jeff Nesvet, Mr. Peter Turcic

Government Accounting Office:
Ms. Mary Nugent

Contractors: Dr. Hans Behling, Ms. Kathy Behling, Mr. Joe Fitzgerald, Dr. John Mauro

Public Attendees: See Registration

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

**Summary Minutes of the Thirty-first Meeting
July 5-7, 2005**

Tuesday, July 5, 2005

Dr. Paul Ziemer called the meeting to order, welcoming the attendees. He asked that everyone register their attendance and discussed the sign-up sheet for anyone desiring an opportunity to speak during the public comment session. Dr. Ziemer noted that Michael Gibson would not physically be in attendance, but they would try a phone hookup. Dr. Ziemer also noted that Senator Christopher Bond would arrive to address the committee and they would interrupt the presentation at that time for his comments.

Dr. Ziemer recognized **Dr. Lew Wade**, the Designated Federal Official, for his opening remarks.

Following a reminder regarding the Subcommittee on Dose Reconstruction and Site Profile Review meeting the following morning at 7:30, Dr. Ziemer then went on to the next agenda item.

* * * * *

**Bethlehem Steel Technical Basis Document
Status of Revisions**

Dr. Jim Neton,
NIOSH

Dr. Neton presented a history of the Bethlehem Steel Site Profile Revision and responses to SC&A's review. He discussed five motions passed by the Board at the February 7th meeting in St. Louis as a result of those Bethlehem Steel Site Profile Revisions.

Those motions were:

- that the Board accepted NIOSH's response to the SC&A review;
- that the Board concurred with the use of the 95th percentile for estimating worker intakes;
- that the Board request NIOSH review the use of the ICRP default values for heavy work and oro-nasal breathing;
- that the Board concurred with the NIOSH characterization of the aerosol default particle size, as well as the default density;
- and that the Board also concurred with NIOSH's approach to characterizing external exposure.

Dr. Neton went on to state that they have added more rationale behind the approaches used to reconstruct doses such as the background on rolling operations; the appropriateness of Simonds Saw & Steel as a surrogate facility; information from Joslyn Steel, also used to roll

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

uranium; and characterized in more detail the air sampling program.

Dr. Neton's presentation continued with a discussion of the internal exposure model adopted for Bethlehem Steel. **Dr. Neton** described background information on data evaluation and interpretation from several studies he utilized in arriving at his conclusions. The presentation ended by concluding that both the ICRP default value for heavy workers and for nasal augmentation are appropriate for Bethlehem Steel.

Questions raised and observations made included the following:

- The five Board motions relative to the SC&A comment items.
- Percentiles on model.
- The letter from Mr. Ed Walker from the Bethlehem Steel claimants' group.
- Coming to closure on the site profile revisions.

The Board determined a smaller workgroup or subcommittee should be assembled to identify and review issue items and coordinate resolution with SC&A's comments and findings. This group was charged with providing a recommendation to the Board regarding issues. Formal Board action was deferred until the recommendation could be made.

* * * * *

Comments by Members of Congress

Senator Christopher Bond of Missouri reiterated earlier comments regarding the urgent need to designate the remaining class of former workers at the Mallinckrodt downtown site as members of the Special Exposure Cohort, or SEC. He thanked the Advisory Board for the inclusion of those workers covering the period 1942 to 1948 into the SEC. He outlined the statutory requirements he believes are applicable to the Mallinckrodt downtown workers from 1949 to 1957 which would justify their inclusion as well. He also addressed the Board regarding worker dose reconstruction feasibility and timely compensation.

* * * * *

Privacy Information

Ms. Liz Homoki-Titus, Office of the General Counsel
Department of Health and Human Services

Ms. Homoki-Titus addressed the Board regarding conflict of interest. She briefed the Board on the proper action that Board members should follow regarding conflicts of interest for a dose reconstruction or an SEC site consideration. **Ms. Homoki-Titus** presented information regarding document review and document comments. She suggested that the Board establish a procedure to follow when they may be called upon to provide public comments.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Ms. Homoki-Titus entertained specific questions from Board members regarding conflict of interest examples. A discussion ensued among Board members regarding public documents. From this discussion it was agreed upon by Board members that they would post public documents on the NIOSH web site.

* * * * *

Before commencement of the next presentation, a suggestion was made that the Board discuss the site profile review, if one has been made, before its consideration of any SEC petition from said site.

Y-12 Site Profile Review

Mr. Joe Fitzgerald,
Sanford Cohen & Associates

Mr. Fitzgerald began his presentation by briefing the Board in general terms, noting a lot had been accomplished in the last 30 days regarding document review and interviews. He expected the report should be ready later this month. **Mr. Fitzgerald** gave a short perspective and background on Y-12, recognizing work conducted by Hap West regarding health physics. **Mr. Fitzgerald** described information gathered by interviewing various worker classes at the site. He explained the workers were very mobile at the site, certain worker classes were not monitored, and the high-fired oxide workers had been switched from periodic urinalysis and lung count monitoring to only periodic fecal analysis.

Mr. Fitzgerald had learned from conducting interviews that workers were concerned that management did not pick the most maximally exposed individual for monitoring. He discussed information that monitoring data obtained were subject to variations in what worker categories were monitored, monitoring periods, and the monitoring medium utilized. **Mr. Fitzgerald** further reported that not enough information had been captured or recorded for support category workers at the site to adequately develop doses and he felt the issue should be addressed. He also touched upon the ability of bioassay monitoring programs to capture acute releases.

Mr. Fitzgerald presented findings on radon, radium, and nuclide exposure in the site profile.

He concluded his presentation by summing up what he considered the issues of concern:

- Attention to the bioassay program in terms of its ability to detect uranium oxides, high-fired oxides in particular.
- Acute exposure.
- Radionuclides other than uranium.
- Coworker and recycled uranium issues.
- Spectral field measurements for neutrons.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

- Unmonitored or intermittently monitored workers.
- Environmental dose methodologies.

Mr. Fitzgerald remarked he would like to follow the issue resolution process with NIOSH and ORAU to isolate what is important regarding issues of concern.

Questions raised and observations made by the Board included the following:

- Acknowledgement that this is a work in progress.
- Information acquired from interviews with regard to service workers handling uranium.
- Exhaust systems.

* * * * *

Y-12 Special Exposure Cohort (SEC) Petition

Mr. Robert Presley recused himself and stepped away from the table.

**Mr. Larry Elliott, Director
Office of Compensation Analysis and Support, NIOSH**

Mr. Elliott began by acknowledging the work done by SC&A and **Mr. Fitzgerald** on the Y-12 site profile would provide for a more comprehensive technical basis document. He noted the site profile under review had reserved the early years due to absence of data. However, he observed his presentation and the ensuing discussion would address the issue of three SEC petitions from that facility.

After describing the Y-12 petitions (18, 26, and 28) received on behalf of employees at the plant, **Mr. Elliott** reminded the Board of the statutory requirements for adding a class of worker to the Special Exposure Cohort. This included the requirement of meeting the two-pronged test, detailed in earlier Board meetings and outlined briefly in his presentation.

Mr. Elliott described the original class definitions from the petitions. Each addressed a specific group of worker, and the three time periods covered ranged from January 1944 through December 1957. Reiterating that no data existed for the early years, **Mr. Elliott** explained NIOSH conducted a review of information available through the site profile to examine process history, monitoring, radiation source description, and primary documents relevant to various radiological operations at the facility. Their review also included documents provided by the petitioners.

Following their review, NIOSH proposed combining the workers described in Petitions 18 and 26, as well as the workers described in Petition 28 through December 1947. Announcing NIOSH had concluded the combined

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

group of workers had met the requirements of the two-pronged test of dose reconstruction feasibility and health endangerment, **Mr. Elliott** presented the Board with wording for the new proposed class definition.

Mr. Elliott explained the evaluation process would continue for the remainder of the workers described in Petition 28 for the period January 1948 through December 1957. An evaluation report would be presented on that group at a later meeting. **Mr. Elliott** added **Mr. Fitzgerald's** observation of site profile issues would be important in completing NIOSH's evaluation of Petition 28.

* * * * *

Board Discussion

Questions raised and observations made by the Board included the following:

- Confirmation that the lack of data was not due to the information being classified, but that no data exists.
- The revised class definition broadened both the category of worker and the relevant time frame.
- Clarification of final definition of worker classes included in the petition.
- Clarification on potential change of outcome on completed individual dose reconstructions that overlap with the subject petitions.
- When a plausible maximum dose might be calculated.

* * * * *

Response by Petitioners

Mr. James Duvall and **Ms. Betty Duvall** were available via telephone. They acknowledged they had listened to the presentation of the evaluation report and the ensuing discussion, but had no comments.

Board Action

A motion was made and seconded that the Board recommend a Special Exposure Cohort be accorded to all Department of Energy (DOE) DOE contractor or subcontractors, or DOE employees who worked in uranium enrichment operations or other radiological activities at the Y-12 facility in Oak Ridge, Tennessee from March 1943 through December 1947, and whom were employed for a number of days occurring either solely under this employment or in combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC, and that this SEC petition be granted.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

The motion was open for discussion, which included the following issues:

- How NIOSH concluded maximum plausible dose calculations were impossible for the original Petition 18 class of workers.
- Uranium as the radionuclide of concern was known, but not the quantity nor degree of enrichment.
- How was conclusion of significant intakes reached relative to health endangerment.
- In dealing with enriched uranium in loose form, inhalation exposure and lung cancer are not unlikely scenarios.
- Concern was expressed that class parameters become over-broad.

The motion was put to vote and passed with one abstention.

* * * * *

**IAAP SEC Petition
Evaluation Report**

Dr. Wade and **Dr. Ziemer** acknowledged **Mr. Presley**'s return to the table.

Larry Elliott, NIOSH

Mr. Elliott provided detailed background information on pertinent dates, initial class definition, regulatory guidelines utilized for the evaluation, NIOSH class definition, and other supporting relevant information. He presented only information regarding industrial radiographers who conducted radiography on nonradiological high-explosive weapon components at the Iowa Army Ammunition Plant from May of 1948 to March of 1949. **Mr. Elliott** gave details of the evaluation report and concluded the presentation by defining the proposed class.

* * * * *

**IAAP SEC Petition
Board Discussion**

Following **Mr. Elliott's** presentation the Board discussed the following:

- Concern about the time period being less than 250 days.
- Follow-up question about the proposed definition presented in the evaluation report.

Mr. Elliott clarified the issue by stating that a worker who worked only during this time period (May 1948 to March 1949) would not acquire 250 days. The worker would have had to work at some other Special Exposure Cohort class to aggregate the days.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

A motion was made and seconded that an SEC petition be accorded to all DOE employees or its contractor or subcontractor employees who worked as radiographers from May 1948 to March 1949 in support of Line 1 operations of the Iowa Ordnance Plant and whom were employed for a number of work days aggregating at least 250 work days occurring either solely under this employment or in combination with work days of employment occurring within the parameters, (excluding aggregate work day requirements) established for other classes of employees included in the SEC and based on two factors, which he outlined.

The motion was then opened for discussion by the Chair.

The wording of the motion was questioned as it pertains to the 250-day issue.

After continued discussion on the issue the Chair proposed a friendly amendment to the motion. Dr. Melius amended the motion to say and whom were employed for a number of work days aggregating at least 250 work days occurring under this employment in combination with work days of employment occurring within the parameters. Discussion ensued, and the chair proposed a vote on the amended motion. The amended motion passed without opposition.

Mr. Elliott read a prepared statement from Mr. Robert Anderson on behalf of the Iowa petitioners thanking the Board and NIOSH for their addition of the X-ray workers on Line 1 into the petition.

Dr. Ziemer reminded the members about the morning subcommittee meetings and other housekeeping items before officially recessing the meeting until 7:30 p.m.

* * * * *

Public Comment Period

The following is a list of the members of the public who spoke. A full transcript of their comments is available on the OCAS web site, www.cdc.gov/niosh/ocas.

Mr. Richard Miller, GAP; Mr. Dan McKeel, Missouri Coalition for the Environment; Mr. Clarence Schwendesen, Mallinckrodt; Mr. Ed Lamzik, Mallinckrodt; Ms. Eileen Adams, Destrehan Plant; Ms. Marilyn Schneider, Mallinckrodt; Ms. Mary Generi, Mallinckrodt; Mr. George Vogt, Mallinckrodt; Mr. Roni Steger, Mallinckrodt; and Mr. Ed Walker, Bethlehem Steel.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Wednesday, July 6, 2005

Dr. Ziemer opened the second day by repeating some of the previous announcements related to registration and availability of handouts.

Dr. Ziemer introduced **Dr. Wade**.

Dr. Lew Wade, Designated Federal Official, commented that the day's agenda was almost exclusively devoted to Mallinckrodt-related issues. He also provided background on previous Board actions dealing with Mallinckrodt:

- Board approved an SEC for the addition of a class to the SEC for Mallinckrodt for the years '42 to '48.
- NIOSH presented a petition evaluation to the Board to deny adding a class to the SEC for the years '49 to '57 for Mallinckrodt.
- After the Board debated the NIOSH denial, it asked that NIOSH review and report back on data reliability issue and that the SC&A continue with detailed review of Mallinckrodt site profile.

Dr. Wade ended his opening remarks by stating that once the Board hears the reports about the Mallinckrodt data reliability issue and site profile issue, then the Board will proceed with discussion on the SEC petition for the years '49 to '57.

* * * * *

**Supplemental Review
Mallinckrodt Site Profile**

Dr. Arjun Makhijani, Sanford Cohen & Associates

Dr. Makhijani opened his presentation by acknowledging **Denise Brock, Kay Drey** and **NIOSH** for their hard work. **Dr. Makhijani** reiterated the Board had asked SC&A to review the data reliability issue and the usability of the site profile for the Mallinckrodt downtown site for the '49 to '57 time period, the St. Louis Airport Site, and the decommissioning section.

Dr. Makhijani stated SC&A's previous conclusion was the same as before: to do anything other than minimum doses for compensation, major modifications to the site profile would be necessary.

Dr. Makhijani touched upon the three categories of doses: the minimum dose, reasonable dose, and maximum dose. He provided the Board the following technical issues regarding why reasonable dose estimates will not likely be possible:

- Radon exposures were primarily puff exposures.
- Unclear of the residue processing history of the plant and it would not be possible to make an accurate assumption about radionuclides ratios and the composition of the air or the existing data.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

- Only one radium 226 data taken in 1947.
- No radionuclide specific bioassay data for the most important radionuclides (thorium 230, radium 226, actinium 227, and protactinium 231) for most workers.
- No environmental release data in the site profile and not enough data on incidents to construct accurate doses for rare incidents.
- Worst-case assumptions will need to be made at airport site due to lack of air monitoring data.
- Maximizing assumptions will have to be made for unmonitored workers because there was risk of significant exposure.
- To obtain TBD for maximum dose, an incorporation of all the available radon data, the residue composition, processing history, and development of worst-case assumptions need to be done.
- Air concentrations cannot be used for dose reconstructions.
- Ratios have to be developed for the bioassay data to be utilized.
- Need to develop correction factor for Board's hospital data.
- Air concentration measurements in Table 22 of the site profile are not useful.
- Thorium 230 doses cannot be reconstructed without bioassay data.
- Based on review of data SC&A is not comfortable that a defensible or worst-case approach can be demonstrated for infrequent incidents.
- There are serious data gaps with regard to incidents.
- Mallinckrodt job type data was good and could be utilized for the development of corrections factors by job type and by organ.
- Worker monitoring history of plant 1 and 2 decommissioning needs to be established.
- Current default working hours are not good enough.
- Incorporation of breathing rates for heavy work periods.
- Proper consideration of the importance of environmental release data.
- Commented that the decommissioning bioassay data were done in triplicate with some quality control.
- Remarked he didn't see clear evidence that the SLAPS workers were monitored.
- Has concerns with the way NIOSH is handling ingestion issue.
- Concluded that due to the absence of reliable data reasonable dose reconstructions are unlikely to be possible at Mallinckrodt, and if possible only maximum doses reconstructions will be made, but pointed out that quite a bit of work remains for establishment of maximum doses.
- All six cases that have been denied at Mallinckrodt have been reviewed and feels that the use of the internal doses are not scientifically defensible.

* * * * *

Questions/Discussions

The Board raised the following issues with **Dr. Makhijani** following his presentation:

- Pertinence of slide 13, decommissioning of 1958 onward, with regard to this petition which ends with the 1957 period.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

- ▶ Clarification needed of sixth slide, "Bases for finding that reasonable dose estimates are unlikely," but then the following slide suggests or implicates that if a number of changes to the TBD were made, then reasonable dose estimates could be made. What is SC&A's position.
- ▶ Response provided that there could be some items that fall into the reasonable dose category, but for the most part the majority of items were related to the development of scientifically defensible worst-case assumptions. There could be some items that fall into the reasonable dose category, but for the most part the majority of items were related to the development of scientifically defensible worst-case assumptions.
- ▶ Issues need to be clearly characterized with respect to Barnes data.
- ▶ With respect to Barnes data, they didn't find any evidence of contaminated urine samples, but that based on the standard itself deteriorating over time that a systematic error of overestimation could have occurred.
- ▶ There seems to be a systematic overestimation error of the Barnes data due to the standard precipitating which artificially jacked up the calibration curve back up to expectation. This issue is well documented and characterized and should be taken into account.

Mr. Gibson requested (via telephone) if a copy of the presentation could be e-mailed to him. **Dr. Ziemer** complied with Mr. Gibson's request and introduced Dr. Neton as the next presenter.

* * * * *

Mallinckrodt Site Profile

Jim Neton, NIOSH

Dr. Neton began his presentation to the Board by outlining the subject of his presentation. He stated he would be presenting two issues in regard to the Mallinckrodt dose reconstruction. One is the integrity of the data issue and the other is the raffinate issue. **Dr. Neton** outlined to the Board the dose reconstruction process. NIOSH collects data from DOE, reviews claimant file, reviews CER data set (unique to Mallinckrodt,) reviews site profiles, and use procedures and implementation guides, Technical Information Bulletins and claimant interviews to interpret the data. **Dr. Neton** presented to the Board information on the data sources:

- ▶ The only data is the individual and summary film badge reports.
- ▶ The CER database is a compilation of all the information at the site.

He cited for the Board specific data information; such as:

- ▶ Over 9,000 air dust cards representing 1,443 workers through 1955.
- ▶ 13,600 urine sample results almost exclusively for uranium, but do have some for thorium.
- ▶ 8,000 person-years of film badge results.
- ▶ 4,700 area radon measurements.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

- 2,400 radon breath measurements.

He stated that radon measurements could be utilized to trace workers who were involved in the raffinate processing.

Dr. Neton presented statistical values of the data set that compared the air dust data against the urine data for a subset of workers for the ether house. He stated that ether house was where raffinate extraction process occurred. **Dr. Neton** concluded that based on the lognormal fit of the urine and air data, the integrity of the data is not an issue.

Dr. Neton cited information on the percentage of workers monitored:

- 15 to 20 percent of workers monitored for breath radon, terminated in '55.
- Less than 60 percent in '48 and increasing over time to about 80 percent of the workers in '55 being monitored by urine samples, followed by a slight downturn after 1956 because of declining production operations.

Dr. Neton stated that '57 and '58 was the end of production for the Mallinckrodt facilities. The workers monitored for air dust was 50 percent in '50, increased to 80 percent plus in '51 and '52. The film badge data percentages ranged from 75 to 80 percent to almost 100% of the workers monitored in later years.

Dr. Neton stated that they went back and looked at the records available for claims presented. This includes 109 cases that are not part of the SEC with employment start dates between 1949 and 1957. He concluded that based on this review, reliable urine data for dose reconstruction does exist.

Dr. Neton concluded his presentation with a couple of slides on raffinate where he stated that they would pick the higher of the air and urine test results to assign the dose to the worker. Before stating his conclusion, he gave a detailed process description of the raffinate process.

* * * * *

Question/Discussion

The Board raised the following issues with **Dr. Neton** following his presentation:

- Clarification needed as to radon breath analysis having nothing to do with radon in the environment, but rather how much radium is in the body and comes out in breath.
- Response was if they knew about the radon breath analysis, then a likelihood existed workers monitored for radon in breath also had a potential for raffinate exposure.
- Is assumption being made based on the fact that these people might

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

have been expected to be exposed to radium, did they know back then about the raffinate, protactinium and thorium and other radionuclides of concern.

- Is there any documentation regarding the sampling.
- What is the reality and feasibility of doing the dose reconstruction of the 109 individual cases, even though technically it could be done.
- The efficiency process or maximum credible dose could be used in lieu of doing full complete, refined dose reconstructions.
- Has any of the employee information of petitioners been reported.
- Comment made regarding the representativeness of air sampling data and default assumptions.
- The use of worst-case values when comparing air and urine data for dose calculation.

* * * * *

**Mallinckrodt SEC Petition
Evaluation Report**

Dr. Wade reminded the Board that after they hear information from NIOSH on the SEC petition evaluation report and from petitioners as to the report, the Board will proceed with deliberation to make a recommendation. He outlined the procedural steps to the Board once a recommendation is formed.

Larry Elliott, NIOSH

Mr. Elliott opened his presentation by reviewing, as required by statute, the two-pronged test that must be met. Next he summarized pertinent dates of the petition:

- July 21, 2004 -- petition submitted to NIOSH.
- November 24, 2004 -- petition qualified for evaluation.
- December 20, 2004 -- *Federal Register* notice provided and petitioners notified regarding qualification of the petition.
- February 2, 2005 -- NIOSH submitted a summary of findings and petition evaluation report to the advisory board and petitioners.
- February 3, 2005 -- evaluation report summary was published in the *Federal Register*.
- February 8, 2005 -- presented evaluation reports and proposed three class definitions.

Outlined for the Board the three class definitions:

- Class one, All DOE, DOE contractors or subcontractors employed by the uranium division of Mallinckrodt during the period from 1942 through 1945;
- Class two, all DOE, DOE contractors or subcontractors who worked at the uranium division at the Mallinckrodt Destrehan Street facility during the period of 1946 through 1948;
- Class three, all DOE, DOE contractors or subcontractors who worked at the uranium division of the Mallinckrodt Destrehan Street facility

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

during the period from 1949 through 1957.

Additional issues were identified by the Board at the February meeting following the presentation of the evaluation report. NIOSH responded to those additional issues in a supplemental report.

- March 11, 2005 -- Board sent recommendation to SEC of Health and Human Services. In that recommendation the Board asked that an SEC designation for all DOE contractors or subcontractors or Atomic Weapons Employees who worked at the uranium division at Mallinckrodt Destrehan Street facility during the period from 1942 through 1948, the first two classes that were identified, be added to the Special Exposure Cohort. The Board reserved judgment for workers employed during the period of 1949 through 1957 until NIOSH had completed its supplemental report on that time period and answered some of the questions the Board had raised.
- April 6, 2005 -- Director of NIOSH sent a recommended decision consistent with the board's recommendation to add a class of workers for the time period 1942 to 1948.
- April 11, 2005 -- Secretary of Health and Human Services sent his decision to Congress to add the uranium division employees at the Mallinckrodt Destrehan facility for the period of 1942 through 1948 to the Special Exposure Cohort.
- April 27, 2005 -- NIOSH presented supplemental report to the Board. At the presentation the Board requested verification of data and examples of dose reconstructions using actual data. **Dr. Neton** presented that information to you today. Also at that time the Board reserved judgment pending that information from NIOSH for workers employed during the period 1949 to 1957.

Mr. Elliott briefed the Board that NIOSH concluded, based on the monitoring activities of employees and work areas established in 1949 by Mallinckrodt, as well as the information on radiological sources and processes, there is sufficient information to validate the dose estimates for the period 1949 to 1957 and notwithstanding any data reliability concerns raised for the earlier time period.

Mr. Elliott presented information regarding three items outlined in SEC petition report 00012-2, Section 7.3.

- Item 2 dealt with radon breath issue and the limited data and the use of zeroes in the data. Stated that **Dr. Neton** presented to you today a solution to Item 2 by using urinalysis data to fill the data gap.
- Item 3 dealt with unconfirmed lost medical records that NIOSH has been unable to confirm to date.
- Item 4 dealt with a 1949 dust study that was never finalized, believed due to altered records and conscious cover-up.

Mr. Elliott reviewed the solution to this presented earlier in the day by **Dr. Neton**. The solution consisted of using available data collected in a program that had oversight from AEC HASL Laboratory for the time

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

period 1949 to 1957 and the ability to cross-reference data streams and validate the data sources.

Mr. Elliott referenced the part of **Dr. Neton's** presentation dealing with statistical evaluation of the data that revealed no significant data alterations, and these were consistent with expectations. **Mr. Elliott** concluded information on Item 4 stating NIOSH would use the highest and most claimant favorable data set between the urine and air data for use in dose reconstruction.

Mr. Elliott concluded his presentation by summarizing that for the years 1949 to 1957 NIOSH finds that radiation dose estimates can be reconstructed and validated for compensation purposes for this particular class. NIOSH finds it is feasible to do dose reconstruction and, therefore, an answer to that particular prong of the two-part question is not warranted.

* * * * *

**Mallinckrodt SEC Petition
Board Discussion**

Dr. Ziemer opened the floor for discussion.

Dr. Melius requested confirmation on the verification of data issue and examples of dose reconstruction using actual data. **Dr. Neton** and **Mr. Elliott** both provided input on the dose reconstruction issue. **Dr. Anderson** asked how many individuals in the existing claims filed would fit into dose reconstruction. **Mr. Elliott** responded by referencing information presented in the program status reports.

Dr. Neton provided additional comments to **Dr. Anderson's** question by stating that 100% of the 109 active cases in possession who worked in the 1949 to 1957 time period would fall into the evaluation report. **Dr. Neton** added that there are an additional 50 or 60 cases that have employment that spill over into the 1949 to 1957 time period that are also members of the original class. He also pointed out that the 109 cases have no employment in the SEC classes that have already been awarded.

Dr. Anderson followed up with comment regarding feasibility of actually doing dose reconstruction. **Dr. Melius** commented that the only new thing on record from NIOSH was Jim Neton's recent presentation. **Mr. Elliott** confirmed **Dr. Melius'** comment. **Dr. Melius** also raised the feasibility issue and also raised issue with what the Board previously requested concerning dose reconstruction feasibility and what was actually presented.

Dr. Neton stated his understanding was to present to the Board examples of graphical data using real data versus the graphically presented information at the Cedar Rapids meeting which utilized hypothetical data. **Dr. Melius** commented that the Board will have a more difficult

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

decision-making process based on the fact that example cases have not been conducted with full feasibility.

* * * * *

Mallinckrodt SEC Petition
Comments from Petitioners

Ms. Denise Brock provided to the Board an account regarding events since filing the SEC petition for the Mallinckrodt workers from 1942 to 1957 a year ago. She cited to the Board at a February meeting a decision was made to split the cohort. SEC status was granted for workers during the time period 1942 to 1948, and to table a decision on the workers from 1949 to 1957 based on recently discovered data and the so-called Mont Mason memo.

Ms. Brock stated that NIOSH felt that the newly discovered data information and on-going site profile revision provided enough information to conduct an accurate dose reconstruction on the workers from 1949 to 1957. Board allowed more time for NIOSH and SC&A to complete their analysis at the April meeting in Iowa.

Ms. Brock voiced to the Board her concern why she was not appropriately notified of a June 1st and 2nd meeting between SC&A, NIOSH, and the Board. She also expressed concern regarding timeliness written information was relayed to her. She cited to the Board findings of the Rev 1 report that it does not appear it provides a basis to do accurate dose reconstruction. She quoted to the Board examples regarding Mallinckrodt site profile audit.

Ms. Brock spoke to specific examples dealing with lack of data issue and worker interview information. She described to the Board detailed plant work practices that occurred in several different areas of the plant. **Ms. Brock** restated to the Board for the record what Congress directed NIOSH to do with respect to Special Exposure Cohorts. She emphasized to Board members that feasibility concept goes beyond just scientific and technical issues, it should also consider the timeliness and cost of dose reconstruction in the absence of relevant or missing data. She mentioned the lack of proper procedures to provide petitioners information regarding meeting notification and written document transmittal.

Ms. Brock pledged to the Board to add the Mallinckrodt workers from 1949 to 1957 to the Special Exposure Cohort. She urged the Board that if they determine that entire group should not be included, then they should consider a specific sub-cohort of workers at the facility. At this time she notified the Board that there were several workers who would provide comments.

Mr. George Blue testified regarding his working experience in the raffinate extraction process. He described his specific duty was to reheat the raffinate in an acid for the purpose of extracting an

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

element. He explained to the Board in detail a work incident in which he was covered (80% of his body) with the tank contents and hospitalized at Barnes Hospital for eight days.

Mr. Blue remarked he has scars on his body as a result of this incident. A few days after being released from the Barnes Hospital, the plant called him back to work and said he would not have to do anything. However, the foreman asked him to clean up something and upon starting the work, he got real weak and was sent home. After a few days he went back to work and plant personnel told him that getting sick had nothing to do with the recent accident.

Mr. Blue testified that he had to be catheterized to obtain urine sample. He also mentioned that he was not aware of radon exposure with his work. He relayed in detail to the Board a specific tank explosion incident and sampling of drums procedure.

Mr. Anthony Windisch stated that he worked at the Mallinckrodt uranium plant in St. Louis from 1945 to 1957, and the Weldon Springs plant from 1958 to 1967. He reminded the Board that at an earlier meeting he previously testified that in 1962 he began working with computers at the Weldon Springs plant. He acknowledged he was a certified computer professional and testified that mason memo shows that most of the recently-found computer keypunch cards and other radiation records was a bunch of garbage and useless. He referenced a meeting with the audit investigator where he testified that as an electrician at the Mallinckrodt uranium plant he witnessed and/or experienced production mishaps at almost every processing step during the production of uranium metal.

Mr. Windisch cited to the Board the frequency of occurrence when uranium processing bomb exploded and he had to repair the electric furnaces. He informed the Board that beginning in 1962 he worked as a computer programmer and analyst. This work involved worker badge monitoring data, and felt he was well versed in obtaining air monitoring data for creating a site dose reconstruction profile. He made reference that safety department maintained a current dose reconstruction profile for each unique work site at the Destrehan uranium plant.

Mr. Windisch concluded his remarks by stating that there is no specific dose reconstruction profile to measure ether house explosion, exploding radium processing bombs, overflowing raffinate tanks and other production mishaps.

Mr. Steven Eugene Pape stated that his father was Eugene C. Pape and worked at the Destrehan Mallinckrodt Chemical Company plant from 1945 until his death May 10, 1977. He stated his father was diagnosed with carcinoma lung cancer April 21, 1977. **Mr. Pape** stated that his father never spoke to him about his work and he never knew what his father did until October 28, 2004, when he had to do the NIOSH dose reconstruction. He found that he was a production operator in building 7. He commented

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

that he did not know any answers to their questions, except to state that his father worked seven days a week for a number of years.

Mr. Robert Leach commented that he went to work for Mallinckrodt in 1950, transferred to uranium plant in 1952, worked in plant 4 from 1952 to 1957, transferred to Weldon Springs in 1957 and worked there until the plant closed in 1965. Mr. Leach commented that plant 4 was the dirtiest and filthiest place he had ever worked in. He stated his job was to clean up the inside of the furnaces after they cooled down. He testified that more than once the molten metal came through the bottom of the furnace and would run into the work area. Mr. Leach stated that in case he was not around for Weldon Springs petition, that he worked 40 to 76 hours per week.

In closing, **Mr. Leach** commented that there is no way in the world that you can figure out one man's exposure.

Mr. Ed Luecke stated he began working at Mallinckrodt May 6, 1947 in plant 4. He described for the Board that he worked in plant 4 which he referred to as the coffin area. He commented they wore no monitoring badges and there were fumes all over the place. The company issued respirators, but were very uncomfortable to work with. He commented that he moved to plant 6E and worked as a utility man where he stated he was exposed to a lot of dust.

Ms. Brock felt that NIOSH should incorporate workers' statements into site profile. She felt time was being wasted because there are no assurances that once the revisions take place, actual dose reconstruction could be done.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

**Mallinckrodt SEC Petition
Board Discussion**

Dr. Ziemer called the meeting to order and opened the floor for discussion. He briefed the Board on procedure. **Mr. Owens** opened with a question for **Dr. Makhijani** concerning the completeness and accuracy of the records presented earlier.

Dr. Makhijani summarized by stating that aside from the radionuclides ratios and Fernald K-65 silos he felt there are data sufficiency problems in several areas: infrequent incidents, environmental doses, and roving workers.

Dr. Ziemer confirmed **Mike Gibson's** participation via telephone and recognized **Jim Neton** for follow-up.

Dr. Neton added comment regarding the issue of the inability to reconstruct infrequent incidents. He voiced his concern that the SC&A report contends somewhat frequent incidents can be reconstructed using chronic inhalation intake, but infrequent incidents cannot be.

Dr. Makhijani clarified his remarks by stating that he didn't say that infrequent incidents couldn't be modeled, but that a claimant favorable way or maximizing way hasn't been demonstrated. He proceeded to expound on the issue by summarizing previously presented information.

Dr. Anderson commented on the timeliness and feasibility issue regarding the dose reconstruction of the 109 cases. He wanted to know a time frame if tasked with dose reconstruction. **Mr. Elliott** responded that four months would be required for 107 cases of dose reconstruction; the first month reserved for ironing out remaining issues and three months for work on the claims.

Dr. Anderson and **Dr. Neton** provided comments regarding the meaning of the statistical information presented in **Dr. Neton's** presentation. **Dr. Anderson** observed that a lot of the questions previously raised have been addressed.

Dr. Melius provided comments with options to address how to put together issues from the SC&A evaluation of the site profile and NIOSH's evaluation of the SEC petition. One option is to take NIOSH's word that individual dose reconstruction are feasible and let them proceed. Another option would be to let NIOSH and SC&A work together to resolve the site profile issues and postpone any decision until this work is completed. A third option is to have NIOSH actually work through some representative number of dose reconstruction cases to determine the actual feasibility of the process. Another option would be to incorporate third option and have SC&A work to resolve comments on site profile and present results to the Board.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Dr. Ziemer asked for additional comments. **Dr. DeHart** asked for clarification regarding the issue of self-identified exclusion for dose reconstruction. He restated his question, can you identify an individual in which dose reconstruction cannot be done and move along toward identifying a specific cohort. **Mr. Elliott** cited regulation that allowed that. **Dr. Neton** added to **Mr. Elliott's** comment by stating that there is a possibility that there is something out there that was not anticipated.

Dr. Ziemer at this time reminded the Board to consider the timeliness of the various options discussed. He posed a question to **Denise Brock** regarding raffinate workers and subcohort. **Ms. Brock** commented that she thought plant 6 was raffinate area. However, **Dr. Ziemer** stated he understood that part, but wanted to know if the information could be retrieved from the job description information.

Dr. Neton and **Dr. Ziemer** exchanged dialogue regarding the issue of job description information, K-65 digestion process, and dose reconstruction. **Dr. Neton** responded that the dose reconstruction would be on individual case-by-case basis if job category information is utilized. He added that it is the Department of Labor's responsibility to qualify a subset of workers based on their application as to whether they are in the SEC.

Mr. Elliott added that when DOL makes its determination of eligibility for a class, case file information that has been developed is relied upon. **Ms. Brock** asked for clarification.

Mr. Elliott said development of case file starts when a file is submitted to DOL by the claimant. DOL claims examiner determines if the claim is eligible based on medical history records and site job information. Once DOL deems the case eligible, the case is referred to NIOSH to work up the claimant's work history. NIOSH utilizes interviews, document review, and any other information that would benefit the claimant. NIOSH provides all the information gained back to the Department of Labor for eligibility determination.

Dr. Melius commented that an interim step that would allow SC&A comments to be resolved could help identify if dose reconstruction would apply to a larger percentage of workers that would require dose reconstruction than previously anticipated. He also commented that actual individual dose reconstruction examples were necessary to resolve the SC&A comments on the site profile.

Dr. Ziemer agreed with **Dr. Melius's** comment, but noted how hard the Board was pushing SC&A and NIOSH to meet the Board's deadlines. It is difficult for NIOSH to provide comment on a report that was presented to them a day or two before the meeting. **Dr. Melius** suggested that the committee or subcommittee continue dialogue to resolve SC&A site profile comments.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Elliott reiterated **Dr. Melius's** suggestion. **Ms. Brock** concurred with **Dr. Ziemer's** comment regarding difficulty with interpreting the information given on such short notice. She also asked that probability of causation chart be developed for the next meeting. **Mr. Elliott** stated it could be a competing resource problem. **Dr. Neton** expanded on **Mr. Elliott's** resource issue in constructing the charts.

Mr. Gibson questioned how NIOSH can provide accurate and reasonable dose reconstruction for the raffinate workers in plant 6 with the lack of individual bioassay data. **Dr. Ziemer** informed **Mr. Gibson** that there are a lot of urinalysis data and air data for the dose reconstruction effort. **Dr. Neton** and **Mr. Gibson** continued dialogue concerning data information.

Ms. Brock expressed concern to the Board about time issue regarding dose reconstruction issue, especially regarding thorium-230, actinium -227, protactinium raffinates. **Dr. Neton** suggested the use of the air monitoring data to support inhalation intakes from the raffinate material. He also commented that there are a number of approaches that can be used to bound these estimates.

Dr. Makhijani remarked that there are a significant number of issues to be resolved. He will engage the issues at the Board's direction and report those findings at a time mandated by the Board. He concluded by stating that there's no guarantee of an answer.

Mr. Griffon felt that the Board, SC&A and NIOSH, on the subcommittee level, should identify or prioritize issues that need to be resolved for the purpose of resolving this SEC petition. He also added that he would like to see specific representative cases of dose reconstruction, especially for the raffinate assumption. This would provide us with an evaluation of feasibility and timeliness for the dose reconstruction effort.

Mr. Elliott said he agreed 100% with **Mr. Griffon**, but clarified that they couldn't bring an example dose reconstruction case unless it's an adjudicated case. **Dr. Anderson** stated that this is a very complex site and site profile is complex, and would like to try to simplify the process. He remarked that he wasn't sure of resolving the data uncertainties, but it's a matter of addressing the uncertainties in the dose reconstruction.

Ms. Homoki-Titus presented clarification on bringing cases before the Board that haven't been adjudicated by the Department of Labor. **Dr. Melius** pointed out that they were not asking for complete data on individual cases that would violate legal issues. All we're asking to do is go through and show that it's feasible. **Dr. Ziemer** commented that the Board is not for specific cases, but possibly a group of cases could be summarized.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Elliott commented to the Board regarding questions raised from Cedar Rapids meeting explaining how to validate the data and how to use the data in dose reconstruction. He felt this was accomplished.

Ms. Munn commented on the effort to gather and analyze as much information as possible about exposures of the workers in the proposed class. The detail and availability of the data clearly shows concern for the workers' safety and welfare by both the contractor and governmental agency overseeing work at Mallinckrodt site. There should be no reason why a subcommittee couldn't provide direction on priorities, and why SC&A and NIOSH couldn't come to some agreement on the major issues to resolve while at the same time moving forward with resolution on the outstanding cases.

Ms. Munn wanted to know if her understanding was correct that nothing could be done on outstanding cases until a decision with respect to the SEC was made. **Dr. Ziemer** stated there is nothing in the law that requires dose reconstruction be halted while the petition is in process. **Dr. Wade** asked **Dr. Neton** if there is a subset of the 107 that you could begin to work on now and **Dr. Neton** responded that, yes, there is.

Dr. Ziemer pointed out to the Board that a delay has the same effect as denying the petition. **Ms. Munn** commented that she was prepared to make a motion. **Dr. Ziemer** said that before a motion was put on the floor he asked if there were additional discussion. **Mr. Espinosa** wanted to know if adjudicated claims could be discussed by the Board in executive session. **Ms. Homoki-Titus** remarked to the Board that they are an advisory board not an appeals board for individual claims.

Dr. Melius made a comment that the Board still must decide on issues related to contractor doing SEC evaluations. The Board must come up with a better process. He stated preference for postponement on a decision on the Mallinckrodt petition until NIOSH has had time to evaluate the SC&A report. This will also provide time for the petitioners to evaluate the SC&A report.

Dr. Ziemer inquired if building 6 workers are being viewed as a possible subset of the cohort that might contain eligibility status on its own. **Dr. Melius** commented his belief that once NIOSH had a chance to comment on the SC&A evaluation of the site profile they would be able to come to a conclusion on building 6 issues. **Ms. Brock** interjected that she has not had an opportunity to take in all the information. She asked for clarification on the issue if halting the decision will also not halt the dose reconstruction.

Mr. Elliott clarified that work on the Mallinckrodt claims had been suspended for the Destrehan facility unless there was a claim that allowed us to move forward using the efficiency process. **Dr. Melius** commented that certain aspects of individual dose reconstruction should move forward except for when particular issues have not been resolved for the dose reconstruction. **Mr. Elliott** concurred.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Mr. Elliott reiterated that they could move forward on dose reconstruction of specific claims where SC&A site profile comments have been resolved. Claims with outstanding site profile issues will have to wait for dose reconstruction until issues are resolved.

Dr. Anderson concurred and dialogue continued between **Mr. Elliott** and **Dr. Anderson**. **Ms. Munn** commented that there was no need for a Special Exposure Cohort since NIOSH has committed that they can do the dose reconstruction. **Ms. Brock** commented that if the dose reconstructions can be done, why have they not already been done.

Mr. Elliott remarked that two things have happened to put the Mallinckrodt claims on hold that were not reconstructable using efficiency approaches: review of the revision for the site profile and the petition. He added that the 75 claims completed were all lung and prostate cancer claims.

Dr. Ziemer announced a break and that upon reconvening motions would be accepted.

Dr. Wade proceeded to remind the Board of the requirements of the SEC legislation by reciting appropriate parts of the *Federal Register*.

Dr. Ziemer recognized **Ms. Munn** for making a motion.

A motion was made and seconded that the SEC petition for the 1949 through 1957 time period at the Mallinckrodt Destrehan facility be denied. Motion is on the floor for discussion.

Dr. Anderson moved to table the motion and this was seconded by Mr. Gibson. **Dr. Ziemer** stated that a vote must be taken on tabling a motion and requires a two-thirds vote. The vote carries for tabling motion.

A motion was made and seconded for the Board to consider formulating a letter of apology or regret for delaying SEC petition. Motion passed.

Dr. Ziemer proposed postponement until tomorrow on the SEC policy issue discussion so that working group may get underway. The Board proceeded with a future meeting logistics discussion before **Dr. Ziemer** formally recessed the meeting.

* * * * *

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Thursday, July 7, 2005

Dr. Ziemer opened the third day by repeating some of the previous announcements related to registration and availability of handouts.

* * * * *

SC&A Task III/Workbook Issues

Hans Behling, Sanford Cohen & Associates

Dr. Behling opened the presentation by providing background dealing with Task III. He defined Task III as being procedures and methods used by NIOSH to do dose reconstruction and outlined Task III subject matters as follows:

- Procedures that deal with external dosimetry,
- Procedures that deal with internal dosimetry,
- Procedures that deal with CATI interviews, quality assurance, documentation and record management.

Dr. Behling stated that the federal regulations mandate that the Advisory Board will conduct an independent review of the methods and procedures used by NIOSH for dose reconstruction. NIOSH identified 33 procedures for this review. **Dr. Behling** commented in regard to the documents reviewed, the details, specificity and nonspecificity when reviewing the 33 procedures.

As directed by the Board SC&A was tasked to develop a method to conduct a review of the 33 procedures. He decided to break down Task III into two phases:

- Phase I -- develop method to systematically review and standardize the review process that was presented to the Board September 2004.
- Phase II -- review of the NIOSH and ORAU procedures that was presented to the Board in January of 2005.

In addition, SC&A was asked to evaluate a list of issues from a technical as well as a non-technical viewpoint. He identified for the Board seven basic objectives followed for Task III work:

- Timelines issue.
- Is procedure written in an effective and efficient manner.
- Is the procedure as written complete or standalone document.
- Is the procedure fairly consistent among different DOE sites.
- Is the procedure fair and will it provide benefit of the doubt to claimant.
- Uncertainty of procedure.
- Does the procedure have a proper balance between technical precision and process efficiency.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Dr. Behling presented information on the development of a checklist comprised of secondary questions and rating system for evaluating the procedures based on the previously presented seven objectives. The ratings scheme is 1 through 5, 1 represents "never" and five represents "perfect." Rating scheme also provided for "NA" determination.

Dr. Behling referenced for the Board SC&A's nearly 300-page report which contained the application of the checklist and rating system of the seven objectives for the 33 dose reconstruction procedures reviewed. The remaining presentation to the Board provided detailed examples of the checklist and rating system results.

* * * * *

Questions/Discussion from Board

The Board raised the following questions with regard to the presentation:

- ▶ Does anything actually have to be done with deficiency side of the procedures, are the deficiencies being corrected by later procedures.
- ▶ Response was that subcommittee is trying to rank or develop a matrix for the more technical issues they're trying to address and questioned the higher number (525) of "NA" in matrix; are we using the right matrix.

* * * * *

Report on the Review of the First 20 Dose Reconstructions

Dr. Ziemer explained to the Board the matrix details; such as, the finding number, ranking, case rank, external, et cetera. He pointed out to the Board in the matrix the proposed Board actions categorized as 1 through 7 are the ones on which action will have to be taken.

Dr. Ziemer and **Mr. Griffon** presented the definitions of the 7 categories:

- NIOSH agrees and accepts findings.
- NIOSH disagrees but will comply.
- NIOSH disagrees and will not implement unless Board recommends action through HHS.
- NIOSH disagrees and the Board and NIOSH reach a compromise.
- NIOSH disagrees and the Board concurs.
- Issue is deferred to a site profile, TBD or procedure review process.
- SC&A concurs with NIOSH's view.

The Advisory Board then proceeded on with the task of categorizing the first 20 procedures. The Board produced a modified matrix.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

A motion was made and seconded to accept the summary of findings matrix as part of the Board's report on the first 20 cases. With no discussion, the motion carried unanimously.

* * * * *

Board Discussion

The Board then proceeded to discuss the modified summary of findings matrix. **Dr. Ziemer** noted the Board also has to consider the narrative wording to the Secretary of Health and Human Services report on dose reconstruction findings. The only wording change to the latest report version as reported by Mr. Griffon dealt with case ranking and site/program-wide ranking totals.

A motion was made and seconded to approve the modified report document, along with the modified summary of findings matrix document as the report to the Secretary.

The motion was open for discussion. **Mr. Griffon** referenced a summarizing table as not being included in the report but will be added. Board members discussed placeholders to be filled in and wording changes.

As a result a friendly amendment was filed to the motion for a slight change in the report wording to include all the pertinent attachments together with the table that NIOSH will supply and the matrix be included in the report. The motion was amended and passed without opposition.

Dr. Ziemer next identified for the Board recommended changes in a document entitled "Priority Issues for Demonstrating Feasibility of Dose Reconstruction for MCW Destrehan Street Workers for the Time Period 1949 to 1947, List of Tasks."

Dr. Ziemer proceeded to outline the modifications recommended by the subcommittee.

Timetable recommendation:

- July 26 -- work group conference call for status report and task clarification;
- July 31 -- NIOSH will provide a draft report on the following tasks, in consultation with SC&A;
- August 7 -- NIOSH completes the tasks with the SC&A;
- July 31 through August 7 -- schedule work group meeting within this time frame;
- August 16 -- SCA to review NIOSH response;
- August 16 through August 22 -- schedule work group conference call during this time frame;
- August 25 & 26 -- scheduled board meeting.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

He further recommended specific wording changes for the list of tasks within the document report.

After discussion and a few amendments the Board unanimously approved the amended document.

With that **Dr. Wade** cited to the Board how the engagement process should proceed. He indicated that any workgroup telephone conference participants keep records of their calls. Workgroup meetings will be noticed in the *Federal Register*, opened to the public and transcripts officially recorded.

Ms. Munn commented on the requirement that subcommittee meetings be noticed in the *Federal Register*. **Dr. Wade** commented that they are not required, but proposed that workgroup meetings be noticed in the *Federal Register*. **Dr. Ziemer** identified the workgroup participants as Mark Griffon, Wanda Munn, Jim Neton, Mike Gibson, with Rich Espinosa as an alternate.

Dr. Melius proposed a motion dealing with the provisions governing communication and program direction with the Board's audit contractor.

A motion was made and seconded that the Advisory Board on Radiation and Worker Health adopt the following provisions governing communication and program direction with the Board's audit contractor. Number one, all communications initiated or received by the Chair, NIOSH and/or the audit contractor regarding the scope, performance or activities of the audit contractor will be copied to the entire Board. The audit contractor shall prepare and disseminate to the Board a written summary of all telephone calls and meetings with NIOSH regarding issues related to contracting scope or performance. Number two, no approvals, changes or directives related to task orders or procedures may be provided by the Chair and/or NIOSH to the audit contractor without first securing concurrence from the Board for these approvals, changes and directives in advance to the entire Board. If three or more Board members raise concerns or objections about the proposed changes, then the Chair shall convene a meeting of the Board forthwith to review the proposed changes. Number three, all working groups and subcommittee meetings, including conference calls, involving NIOSH and the audit contractor to review findings of the audit contractor will include the participation of at least two Board members. All Board members will be notified about the meetings at least two weeks prior to the meeting, and the Chair will ensure that adequate Board representation will be present at the meeting. Such meeting shall be noticed in advance to the public through the e-mail list and on the NIOSH web site and open to the public, consistent with the Open Governments Act. Such meetings, including those by teleconference, shall be transcribed.

The motion consisted of three distinct wording parts and was read to the Board. The motion was seconded by Mr. Gibson and put on the floor for

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

discussion. **Ms. Munn** strongly protested the motion and would not vote on it unless it was a vote to table the motion. At which time **Ms. Munn** put forth a motion to table and it was seconded by **Dr. DeHart**.

Dr. Ziemer informed the Board the motion to table is not debatable and requires an immediate vote. Two-thirds vote is required for tabling. **Ms. Homoki-Titus** stated that only one-half is required for tabling a motion. The vote on motion by Board to table motion failed, therefore the original motion is put back on the floor for discussion.

Dr. DeHart commented that he had concerns about the lack of flexibility in the drafted document. **Ms. Homoki-Titus** wanted to double check the written motion to make sure there was no violation of FACA regarding board approvals. **Dr. Melius** thought that the Board needed to be more transparent or open regarding dealings with contractor.

Mr. Gibson noted that the Board members accepted an obligation with their Presidential appointment and felt that all Board members should be sent all the correspondences to review, not just certain members on the list.

A written copy of the motion was distributed to all Board members and **Dr. Ziemer** presented each item of the motion. Items 1 and 2 as read were commented on and slightly modified.

At this time Item 3 as read was commented on and slightly modified through friendly amendments. **Dr. Ziemer** relayed to the Board an issue regarding the time the contractor spends briefing people on the Hill when requested. He noted that this work was outside the scope of the contract, however, the existing contract funds were being utilized for this task. He has previously approved this work by the contractor, but suggests a formal policy regarding this matter. The Board just wanted this action as it occurs to be notified or communicated about it.

Board voted on amended motion and was unanimously passed except **Ms. Munn** who abstained.

A motion was made and seconded that the Board recognize Cori Homer for her superior administrative support and assistance to individuals and the Board. The motion passed overwhelmingly.

Ms. Homer indicated she will miss everyone and thanked the Board for the last three years. She informed the Board that her duties would now be in the capable hands of **LaShawn Shields**.

The Board continued the meeting. **Dr. Melius** commented on the conflict of interest issue brought up in the public comment period. He felt that the Board should consider having their own conflict of interest statement on the web site for public view.

Dr. Mauro of SC&A commented that their conflict of interest planned procedures and forms have been completed and signed by project members

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

and are on file in hard copy at corporate headquarters. He can provide to the Board conflict of interest documents in any form the Board requests for the purpose of posting on web site. **Dr. Toohey** informed the Board that all ORAU forms are posted on their project web site at www.oraucoc.org.

Dr. Wade reminded the Board about the SC&A SEC task order developed by the Board. The task order has been submitted to the contractor, SC&A, for approval. The Board will consider the proposal in closed session when received.

* * * * *

**Report on Review of the Second Round,
18 Dose Reconstructions**

Kathy Behling, SC&A

Ms. Behling started the presentation by outlining three key elements of SC&A's approach to doing dose reconstruction review.

- Review all the collected data for completeness and adequacy for use in estimating doses.
- Look at internal and external doses and attempt to reproduce all the doses assigned by the dose reconstructor.
- Review the CATI and evaluate whether NIOSH has addressed all information regarding the claimant.

Ms. Behling reviewed for the Board the NIOSH/ORAU approach to the dose reconstruction process. She presented various examples to the Board of maximizing external dose cases, maximizing internal dose estimates, and best estimate external dose. She stated that the overwhelming majority of cases fell into the external dose category.

Ms. Behling presented a chart detailing how the 18 cases and the 113 findings broke down by category. The categories consisted of the following:

- reviewer could not reproduce assigned dose,
- procedure used to estimate dose was not referenced,
- procedural errors and inconsistencies,
- unresolved CATI issues,
- data collection issues,
- procedural noncompliance or misinterpretation of procedures,
- use of inappropriate procedure method or assumption, model or model assumptions selection is not scientifically sound,
- all potential sources of exposure were not considered or the exposure was not accounted for.

Ms. Behling then presented a chart of the breakdown of the findings for all 30 cases reviewed. She summarized for the Board the majority causes of the 113 findings were due to procedural issues with choices made by

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

the dose reconstructor. She pointed out to the Board that the dose reconstruction audits so far have not impacted the changes in compensability.

* * * * *

Board Comments/Questions on Presentation

The Board raised the following questions with regard to the presentation:

- Future pie chart should be consistent with color and location.
- Procedure used, audit summary of the dose reconstruction, was very effective.
- What will have to be done with advanced dose reconstructions.
- Indication was that these advanced dose reconstructions will require more extensive data review.
- Audit of the internal doses will be required for the advanced cases and that this will be a major challenge for both dose reconstructor and auditor.
- Question to the subcommittee members regarding future dose reconstruction issue in terms of resources and priorities.
- What is the status on the next round of reviews.
- A better understanding of the use of workbooks, especially for the Savannah River Site, will be required for the next round of dose reconstruction reviews.

Dr. Ziemer, before closing out the Board discussion, commented that the contractor and NIOSH should proceed on the development of the matrix for the 18 cases just as was presented earlier for the first 20 cases.

* * * * *

SC&A Contract Issues

John Mauro, SC&A

Dr. Mauro updated the Board relative to the four tasks performed by the contractor over the past year and a half. He stated that the work has been performed on the 22 additional cases and work on the three site profiles, the first four tasks would be completed. He felt that based on the fact that NIOSH was moving more toward doing realistic dose reconstruction and away from the minimum/maximum procedure, this has resulted in more sophisticated TIBs and workbooks produced for best estimate dose reconstruction.

Dr. Mauro felt that Task I scope of work had to be modified to capture a more detailed effort NIOSH is now using and that to actually have dose reconstruction cases completed by the contractor is now part of Task I. He felt that Task IV needed to be modified to include more best-estimate case selections for dose reconstruction rather than minimum/maximum reconstruction.

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

Dr. Mauro further stated that he felt minimum/maximum cases reviewed so far were showing the same conclusions and weren't adding any real value.

He recommended site profile reviews conducted under Task I include workbooks and cases which have used best estimate methods; for Task IV they should select more realistic cases for testing.

* * * * *

Board Questions and Comments

Questions raised and observations made included the following:

- ▶ Is there some procedure (sorting tool) that can be utilized to provide information as to whether the case is a best estimate case or a minimum/maximum case.
- ▶ Response was that dose reconstructor makes the choice at the time he approves the dose reconstruction.
- ▶ Comment provided that in principal you should be able to make the procedure to use on the basis of POC, but presented a case as to why this has not been successful.
- ▶ Task I needed to be modified to have the contractor review the workbooks and include several specific best estimate cases when they review a site profile.
- ▶ For Task IV, selection of the next 20 cases by the subcommittee include more realistic cases would suffice.
- ▶ Concern about including actual cases in the procedural review for Task I, actual cases selected is part of Task IV.
- ▶ Comment provided as to why including actual cases selected should be under Task I.
- ▶ Workbook review should already be included in Task I.
- ▶ Workbook review as part of Task I is with contracting officer.
- ▶ Concern that the subcommittee choosing the next 20 cases for review was not the process that had been used previously.
- ▶ Clarification that the Board and subcommittee use the same procedures utilized in the past, but for the next 20 consider the criteria of using realistic cases for case selection.

A quorum was not available for the Board to act on issues discussed, so the Board halted the discussion. **Dr. Wade** concluded that Board members should continue this discussion via a phone conference.

* * * * *

Public Comment Period

Dr. Ziemer introduced **Colonel Ed Taylor** from the newly formed advisory board administered through the National Council on Radiation Protection and Measurements. This will be a parallel group handling the veteran's cases. Colonel Taylor thanked the Board for allowing him to sit in all week and learn.

The following is a list of the members of the public who spoke. A full

Executive Summary/Minutes: July 5-7, 2005
NIOSH/CDC Advisory Board on Radiation and Worker Health

transcript of their comments is available on the OCAS web site,
www.cdc.gov/niosh/ocas.

Mr. Dan McKeel, Missouri Coalition for the Environment; Mr. Larry Gassei; Ms. Denise Brock, UNWW/Mallinckrodt; Mr. Roni Steger, Mallinckrodt.

* * * * *

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

End of Summary Minutes

◆ ◆ ◆ ◆ ◆

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

Paul L. Ziemer, Ph.D., Chair

Date