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-second Meeting
August 25-26, 2005

The Thirty-second Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Westin St. Louis Hotel in St. Louis, Missouri on August 25 and 26, 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; Mr. Richard Espinosa; Mr. Mike Gibson; 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:

Department of Health and Human Services:
Mr. Fred Blosser, Ms. Chris Ellison, Mr. Stuart Hinnefeld, Ms. Liz Homoki-Titus, Ms. Emily Howell, Mr. Ted Katz, Dr. James Neton

Department of Labor:
Ms. Diane Case, Mr. Jeff Kotsch

Government Accountability Office:
Ms. Mary Nugent, Mr. Bob Sampson

Contractors:
ORAU: Dr. Richard Toohey
SC&A: Dr. Hans Behling, Mr. Joseph Fitzgerald, Dr. Joyce Lipsztein, Dr. Arjun Makhijani, Dr. John Mauro

Public Attendees: See Registration

Executive Summary

The Thirty-second Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Westin St. Louis Hotel in St. Louis, Missouri on August 25 and 26, 2005. All members were in attendance except Dr. Roy DeHart. 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.

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Thursday, August 25, 2005

Selection of Fourth Round of 20 Dose Reconstruction Reviews

The Board completed the task of selecting 20 cases to comprise the fourth round of dose reconstruction reviews. The following cases were selected:

Case No.	POC	%Cancer	Site
105	44.45	Liver	Savannah River
108	63.25	Colon	Nuclear Materials & Equipment Corporation
110	48.16	Colon	Savannah River
130	19.64	Pancreatic	Hanford
138	53.26	Colon	Bridgeport Brass
155	47.33	Male Genitalia	Savannah River
159	29.52	Stomach	Chapman Valve
176	50.29	Respiratory	West Valley Demonstration Project
201	50.81	Bladder	Oak Ridge National Laboratory, X-10
204	23.02	Colon	Oak Ridge, Y-12
216	44.74	Thyroid	Hanford
234	19.65	Bladder	Mound

253	33.80	Esophagus	Jessop Steel
256	50.00	Melanoma skin, Basal cell	Hanford
262	39.19	Acute Myeloid Leukemia	Heppenstall Company
264	27.85	Male Genitalia	Oak Ridge, Y-12
010	38.16	Nonmelanoma skin, Squamous cell	Pinellas
011	32.78	Pancreas	Feed Materials Production Center
017	50.55	Nonmelanoma skin, Basal cell	Nevada Test Site
035	26.62	Breast	Los Alamos

The Board unanimously approved the selection of the 20 cases for review. The cases were divided among six two-member review teams.

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Candidate Site Profile Selection

The Board considered a recommendation by the subcommittee of site profiles for review. Recommended as priority sites were Fernald, Los Alamos, Mound, X-10, Bridgeport Brass and Pinellas. Included for consideration as alternates were Argonne West and Lawrence Livermore.

A motion was made and seconded that the Pinellas site be replaced with Lawrence Livermore on the priority list. The motion failed.

A motion was made and seconded that the Bridgeport Brass site be replaced with the Linde Ceramics site on the priority list. After discussion the six priority sites were unanimously approved, including the substitution of Linde Ceramics for Bridgeport Brass.

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Task III Procedural Review Report

The Board unanimously approved a recommendation by the subcommittee which directed NIOSH to proceed with their comments on the SC&A Task III Procedural Review report.

Responding to a question on timing, **Dr. John Mauro** of SC&A indicated the matrix would be completed within two weeks. **Mr. Stu Hinnefeld** from NIOSH estimated their responses should be completed in four weeks.

A workgroup comprised of **Mr. Mark Griffon** as Chair, **Ms. Wanda Munn**, **Mr. Robert Presley** and **Mr. Mike Gibson** was appointed to address the completion of the Task III review issue. **Mr. Rich Espinosa** was named alternate. It was agreed the workgroup's planned October meeting would be noticed on the NIOSH web site and open to the public.

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Bethlehem Steel Site Profile

Following a report from the subcommittee on the most recent draft Bethlehem Steel site profile revision, a motion was made and seconded that SC&A review the draft, paying particular attention to those items highlighted by the Board following SC&A's previous site profile review.

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Mallinckrodt Site Profile

Dr. Jim Neton from NIOSH and **Dr. Arjun Makhijani** from SC&A presented an update on the site profile's six identified priority issues. They included raffinate ratios, radon exposure, external dose correction factors, intermediate exposure, unmonitored workers' dose reconstructions, and specific dose reconstruction examples. Following the presentations a discussion ensued among members of the Board and representatives from NIOSH and SC&A.

Discussions were suspended to accommodate a scheduled Executive Session.

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Results of Closed Executive Session

The Board met in a closed executive session to discuss future contractual issues. Upon reconvening the public session, **Dr. Paul Ziemer** reported the following decisions:

- Approval of Task I scope, site profile reviews for the upcoming year, at a cost of $1,204,948.
- Approval of Task III scope, procedural review, in the amount of $416,224.

- Task IV scope was not approved, but would be further discussed in open session at the next meeting.
- Approved Task V, contractor assistance in review of Special Exposure Cohort Petitions, in the amount of $917,341.
- Approved Task VI, project management, at a cost of $217,801.

Dr. Ziemer noted that during the closed session a conflict of interest had been discovered in one of the dose reconstruction review case assignments and had therefore been reassigned.

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The Board resumed discussion of the six Mallinckrodt site profile priority issues. The discussions primarily were directed toward concerns about illegible records and data discrepancies.

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In an effort to increase transparency in their deliberations, the Board continued discussion in open session on some of the issues surrounding the contractor's task proposals.

Task IV

The Board engaged in detailed discussion regarding the definition of a basic dose reconstruction review as compared to an advanced review. Proposals were advanced, and **Dr. Ziemer** suggested a motion could be made and acted on at tomorrow's meeting after refinement over the evening.

Task VI

Discussion was held on inclusion of SC&A trips to Washington for Congressional briefings on their work products as part of the project management task.

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Dr. Ziemer declared a recess until 7:00 p.m., at which time the public comment session would begin.

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Public Comment Period

Following is a list of 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. John Ransport, General Steel Industries; **Ms. Christine Ransport; Dr. Dan McKeel**; **Ms. Denise Brock**, Mallinckrodt SEC petitioner; **Ms. Louise McKeel**; **Father Jim Mitulski**, survivor; **Mr. Richard Miller**, Government Accountability Project.

Friday, August 26, 2005

The second day of the 32nd meeting was called to order by **Chairman Ziemer**, who reminded everyone present to register their attendance. **Dr. Lew Wade**, Designated Federal Official, stated that although NIOSH values timeliness and completeness, the time has come for the Board to make a recommendation on the Mallinckrodt SEC petition, which is on today's agenda for deliberation.

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Mallinckrodt SEC Petition

Ms. Denise Brock and **Dr. Dan McKeel** spoke on behalf of the petitioners for adding a class of Mallinckrodt employees to the Special Exposure Cohort.

Ms. Brock cited federal acts and rules she believed called for timely, uniform and adequate compensation for employees made ill from various exposures at Mallinckrodt and other sites. She provided a chronological event of meetings regarding the Mallinckrodt facility, and reviewed the feasibility issue with respect to technical, cost, and time constraints. **Ms. Brock** remarked that NIOSH has far exceeded the time contemplated by Congress for SEC petition processing, noting it has taken 24 months to assess this petition. **Ms. Brock** concluded her comments by asking the Board to approve the SEC petition for Mallinckrodt workers in the period 1949 to 1957.

Dr. McKeel declared that, based on 42 CFR 83, NIOSH lacked adequate data or information to accurately reconstruct doses. He stated the Board should recommend SEC status for the 1949 to 1957 class of Mallinckrodt uranium division workers.

Following Board discussion, a motion was made and seconded that the Board recommend that a class of Mallinckrodt workers in the period 1949 to 1957 be included as part of the Special Exposure Cohort. The motion carried.

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Conflict of Interest Disclosure Statements

Ms. Liz Homoki-Titus of the Office of General Counsel for HHS addressed the Board relative to their conflict of interest disclosure statements. **Ms. Homoki-Titus** noted that the Board had expressed a desire to have their statements posted on the OCAS web site. She reported to the Board that she had discussed the matter with others in her office and, since that is contrary to HHS policy, they would like a formal Board motion to memorialize that request.

Such a motion was made and seconded, and passed unanimously.

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Capitol Hill Policy

Dr. Ziemer referred the Board to a written motion titled "Advisory Board on Radiation and Worker Health Statement on Policy," already on the floor and preliminarily discussed at the previous day's meeting. Further discussion resulted in altering the motion to provide that presence of a Board member be requested at any meetings between Congressional staffers and SC&A, rather than that such presence be mandatory. The motion also covered proper protocol and procedures regarding notification of Congressional staff meetings. The motion carried.

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Site Profile Prioritization

Open for discussion was the issue of prioritization of the six sites previously identified for site profile review.

A motion was made and seconded that SC&A work with NIOSH to establish a priority order for review of the site profiles for Fernald, Mound, Pinellas, Linde Ceramics, Los Alamos and K-10. The motion carried unanimously.

It was agreed SC&A would report the priority list at the October meeting.

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Other Board Items

The Board approved the minutes of the Thirtieth Meeting, held April 25-27 in Cedar Rapids, Iowa.

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Dr. Wade reported to the Board on the question regarding the Department of Labor's position on non-covered cancers, should the Mallinckrodt SEC petition be approved. He stated DOL would reserve judgment on non-covered cancers pending the Secretary's determination.

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A motion was made and seconded outlining the specifics of SC&A's Task IV scope of work dealing with upcoming dose reconstruction reviews. It included the numbers of each type of review, the contents of the review reports, and a description of their participation in the extended review cycle with NIOSH and the Board in the resolution process. The motion passed without further discussion.

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Mr. Hinnefeld reviewed the process by which NIOSH informs claimants when a determination has been made that there is insufficient information available to complete a dose reconstruction. He explained how that determination is a first step for an individual petitioning for inclusion as a class in the Special Exposure Cohort.

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Dr. Ziemer concluded the meeting with a reminder that the Advisory Board will be recommending the Secretary of Health and Human Services request Congressional approval of the Mallinckrodt uranium division workers for the period 1949 to 1957 as members of the Special Exposure Cohort. He emphasized the final determination is made by Congress.

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End of Executive Summary

The Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health
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Summary Minutes of the Thirty-second Meeting
August 25-26, 2005

Thursday, August 25, 2005

Dr. Paul Ziemer called the 32nd Meeting of the Advisory Board on Radiation and Worker Health 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 announced that NIOSH personnel are available to assist individuals who may have specific problems with individual claims.

Noting the absence of **Dr. Roy DeHart**, **Dr. Ziemer** explained **Dr. DeHart** was traveling out of the country. He announced the passing of **Mr. Gibson**'s father, and expressed sympathy to the Gibson family.

Dr. Lew Wade, Designated Federal Official, reminded the Board that while there would be other business addressed, the main purpose of this meeting was to resolve issues related to the Mallinckrodt Special Exposure Cohort petition.

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Selection of Fourth Round of 20 Dose Reconstruction Reviews

Dr. Ziemer reported that the subcommittee had compiled a list of 20 dose reconstruction cases for recommendation to the Advisory Board for its fourth round of reviews. He noted 16 were chosen from the total list of completed dose estimate cases and four were from the random list. The subcommittee recommended the following cases:

Case No.	POC %	Cancer	Site
105	44.45	Liver	Savannah River
108	63.25	Colon	Nuclear Materials & Equipment Corporation

110	48.16	Colon	Savannah River
130	19.64	Pancreatic	Hanford
138	53.26	Colon	Bridgeport Brass
155	47.33	Male Genitalia	Savannah River
159	29.52	Stomach	Chapman Valve
176	50.29	Respiratory	West Valley Demonstration Project
201	50.81	Bladder	Oak Ridge National Laboratory, X-10
204	23.02	Colon	Oak Ridge, Y-12
216	44.74	Thyroid	Hanford
234	19.65	Bladder	Mound
253	33.80	Esophagus	Jessop Steel
256	50.00	Melanoma skin, Basal cell	Hanford
262	39.19	Acute Myeloid Leukemia	Heppenstall Company
264	27.85	Male Genitalia	Oak Ridge, Y-12
010	38.16	Nonmelanoma skin, Squamous cell	Pinellas
011	32.78	Pancreas	Feed Materials Production Center
017	50.55	Nonmelanoma skin, Basal cell	Nevada Test Site
035	26.62	Breast	Los Alamos

Dr. Ziemer called for comments or questions regarding the recommendation.

Mr. Leon Owens expressed concern regarding the absence of any cases

from the Lawrence Livermore Site. He reminded the Board there had been considerable interest at their meeting in the Livermore area. **Dr. Richard Toohey** from ORAU noted the Livermore site profile had not received final approval for release. Therefore the only cases that had been completed were the min/max type cases, and SC&A had specifically requested a focus on best-estimate cases.

Mr. Griffon commented that there had been two Livermore cases reviewed from the initial 60 cases, but they had indeed been min/max cases.

The Board unanimously accepted the subcommittee recommendation of the 20 cases to be included in the fourth round of dose reconstruction reviews.

Dr. Ziemer led the Board in a discussion of team members, and assigned the 20 cases among the teams as follows:

Team No.	Team Members	Case Nos. Assigned
1	Anderson and Presley	105, 108, 010
2	Gibson and Ziemer	035, 130, 138, 155
3	Roessler and DeHart	017, 159, 176, 201
4	Owens and Munn	204, 234, 253
5	Melius and Espinosa	011, 216, 256
6	Griffon and Owens	264, 110, 262

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Candidate Site Profiles

Dr. Ziemer reported that during yesterday's subcommittee meeting it was recommended the Board identify the next group of site profiles for SC&A's review. The nine site profile reviews already completed, or nearly completed, are Hanford, INEL, Nevada Test Site, Rocky Flats, Savannah River, Y-12 at Oak Ridge, Bethlehem Steel, Mallinckrodt and Iowa Army Ammunition Plant.

The subcommittee recommended six site profiles for consideration as SC&A's next reviews. They were Fernald, Los Alamos, Mound, X-10 at Oak Ridge, Bridgeport Brass and Pinellas. An additional two sites as potential alternates were Argonne West and Lawrence Livermore. **Dr. Ziemer** suggested the Board select six of the sites as priorities and, should the opportunity present itself, two more could be added later.

Mr. Richard Miller commented from the audience that consideration might be given to Linde Ceramics in place of Bridgeport Brass. He noted the Linde Ceramics plant was interesting and complex, while the Bridgeport

Brass facility was a traditional uranium processing plant.

A motion was made and seconded to move Lawrence Livermore from the alternate list to the priority list and Pinellas from the priority list to the alternate list. After discussion elaborating on the reasons the sites were positioned as they were, the motion failed.

A motion was made and seconded to replace the Bridgeport Brass facility with Linde Ceramics on the priority list. The motion was open for discussion. Interest and numbers of claimants were two additional reasons given to exchange the facilities. The motion passed.

The amended list of Fernald, Los Alamos, Mound, X-10, Linde Ceramics and Pinellas as the six priorities for site profile review, with Argonne West and Lawrence Livermore as alternates, was unanimously approved.

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Task III Procedures Review Report

Dr. Ziemer reported to the Board on the Subcommittee's discussion and subsequent recommendation related to the SC&A report on their procedures review. Over the course of time, some of the original procedures have been modified or are no longer in use. SC&A has prepared a matrix of the procedures they have reviewed. They will add to that all other procedures. That revised matrix will be delivered to NIOSH.

The subcommittee's recommendation is that NIOSH then review that total matrix and respond to SC&A's findings on those procedures still in effect, using the standard resolution process. They further recommend NIOSH identify any procedures no longer in use and report back to the Board on their plans for those procedures, either to revise them or officially cancel them.

A subcommittee recommendation coming to the Board as a motion needing no second, a vote was called for and the motion carried unanimously.

Dr. Wade inquired as to the expectations and timing of the task. **Dr. Mauro** opined the matrix would be completed in approximately two weeks. Speaking for NIOSH, **Mr. Hinnefeld** indicated their responses would be completed in roughly four weeks. Inasmuch as the Board desired participation in the resolution process, **Dr. Ziemer** appointed a

workgroup to work with SC&A and NIOSH, naming **Mr. Griffon** Chair, with **Ms. Munn**, **Mr. Presley**, and **Mr. Gibson** rounding out the group. **Mr. Espinosa** was named alternate. It was agreed their October meeting will be posted on the NIOSH web site and open to the public.

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Bethlehem Steel Site Profile Review

Dr. James Melius reviewed the subcommittee's previous discussion relative to the latest NIOSH revision of the Bethlehem Steel site profile. While this revision is still in draft form, the subcommittee recommended SC&A review the draft, with particular emphasis on those items highlighted by the Board based on SC&A's review of the previous site profile. This is to be done for the purpose of confirming that the agreed-upon resolution of those issues between NIOSH and SC&A has translated accurately to the site profile document.

A subcommittee recommendation coming to the Board as a motion needing no second, a vote was called for and the motion carried unanimously.

Dr. Mauro responded to a timing query by stating SC&A could deliver a letter report in approximately three weeks.

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Mallinckrodt Site Profile Review

Dr. Ziemer reported that the subcommittee had made no recommendations on the six items designated as priority issues in the Mallinckrodt site profile. He noted SC&A and NIOSH were prepared to make presentations on those issues, after which the Board could proceed with further discussion.

Ms. Denise Brock inquired from the audience as to whether dose reconstructions would be done on non-SEC cancers if the Mallinckrodt Special Exposure Cohort petition were approved. **Dr. Ziemer** indicated they would try to get an answer for her.

Dr. James Neton,
NIOSH

Dr. Neton reminded the Board NIOSH had been asked to evaluate six priority issues resulting from SC&A's third supplemental site profile review. Addressing each individually, **Dr. Neton** described the issue,

what SC&A had found problematic, how NIOSH had approached it, and any resolution.

The first, and perhaps the key issue, was the handling of raffinates or ore processing residues. **Dr. Neton** explained the ore processing that resulted in a different raffinate at each stage, their compositions and the ratios of various radionuclides. To address the issue NIOSH developed process-dependent ratios in which they bifurcated the processes and developed a method for looking at exposure to both radium-bearing residues and the airport case residues rich in thorium 230. He provided a written description of how NIOSH arrived at the ratios.

Dr. Neton discussed the questions raised on reliability of radon breath analyses and lost or not-analyzed data. He explained their research into the matter and the NIOSH conclusion that those data were likely lost to timing issues -- unavailability of analysts, sample shipping delays -- as a result of radon's short half-life. Their investigation revealed no indication of selective censoring.

Also discussed was consistency of the distribution of worker types and use of analytical techniques. **Dr. Neton** observed there were a number of areas prone to make the values overestimates. In showing the sampling distribution by year, it reflected little substantial change in those worker categories over the years.

Researching whether there might be additional data for those workers with missing samples, 98 percent had other samples within a year. Because the radon breath analyses measure the amount of radium in the skeleton, the picture doesn't change much within a few months or a year, so there is a way of looking at the intakes for those workers.

Dr. Neton went on to discuss the handling of radon exposures, the sufficiency of samples available and whether there is a contribution of radon inhalation to systemic organs other than the lung, a point raised in the SC&A report. NIOSH considered SC&A's analysis, re-evaluated it using their own models, and concluded there is some dose and agreed a way to account for it was needed.

A written analysis had been provided to the Board and reviewed by SC&A, and there is agreement in the way to address the radon issue.

A third matter was the external dose correction factor. SC&A's report suggested in certain job categories a lapel badge would not adequately sample exposures in some scenarios -- grinding, milling, spills -- so those were modeled using the Attila software program. Based on those analyses, NIOSH agreed there were some exposure geometries where the

film badge could underestimate the dose by about a factor of two.

NIOSH has written a Technical Information Bulletin to address this. While still in draft form, SC&A has seen it and agrees the value is appropriate, so NIOSH will be multiplying doses for workers in those exposure geometries by a factor of 2.1. **Dr. Neton** indicated it appears this will apply to about 57 percent of current cases, being based on an analysis of where the people were working and what they were doing.

The fourth priority item, assessment of intermittent exposures, resulted from SC&A's concern that the chronic exposure model NIOSH used as a default when they had bioassay data would not sufficiently bound the exposure scenarios of those workers. **Dr. Neton** reported NIOSH had gone through a number of scenarios which were discussed with SC&A during their meeting in Cincinnati. Without elaborating on details, he explained that if they fit a chronic exposure model through all the data points, it resulted in a higher intake than by inferring certain acute intakes.

Noting that SC&A had looked at the model and was convinced in general that it's true, **Dr. Neton** added there may be unique incidents to which NIOSH will need to be sensitive and make corrections as appropriate.

Priority topic number five related to dose reconstructions for unmonitored workers. Administrative workers have no exposure, but the question was raised about their environmental dose. NIOSH has agreed that unmonitored administrative workers will be assigned the full distribution of the monitored workers' environmental exposures. **Dr. Neton** remarked NIOSH has looked at the available environmental monitoring data and believes, from a routine exposure scenario, this is a claimant-favorable approach.

Unmonitored workers in Plant One and Two decommissioning area and the airport storage site will be assigned the 95th percentile of the monitored worker environmental exposure.

The final matter was a request that NIOSH present some examples of how these resolutions translate into what the doses look like. **Dr. Neton** presented examples of various scenarios using job descriptions with and without data, results for cancers to metabolic and non-metabolic organs, et cetera.

Dr. Neton indicated he had been in discussion with **Dr. Makhijani** and others from SC&A about the difference between what is in ICRP and what is in the Federal Guidance Report. They agree it is an issue that needs to be resolved. But in general **Dr. Neton** opined the patterns would hold where cancers involving metabolic organs will easily exceed

50 percent and non-metabolics will be high. Depending on the individual scenarios, they can go over.

Discussion Points:

- If a person's individual bioassay results in a lower dose than the 95th percentile of the air concentration data, the highest value will be used.
- Both will be checked in every dose reconstruction.
- Have the two-page references to Sperry cake distributed during the subcommittee meeting been shared with SC&A and have they had an opportunity to review the information prior to the meeting.
- Have the back-up calculations discussed yesterday been shared yet.
- Has there been any other analysis of the missing radon breath data.
- The site profile has had modest change.
- The site profile information is intact, though it has been refined. The processes that have evolved are becoming the Mallinckrodt workbook.
- A site profile gives you a lot of information. What you do with it when you're doing a dose reconstruction evolves over time.
- Why was there a two-month urinalysis program and then suddenly just air sampling.

Dr. Arjun Makhijani,
Sanford Cohen & Associates

Dr. Makhijani commented the Board had requested SC&A conduct their review in real time as NIOSH was responding to the priority issues. He noted this third supplemental review, and agreed with **Dr. Neton** that the question of the trace radionuclides together with uranium 238 and U-235 were seen to be significant and the focus of the review effort.

The Board had directed SC&A to keep track of how this review and resolution process was done, and it had been a fruitful and open collaboration with NIOSH. A record of communications, including the e-mail record, was available in an attachment to the report.

With the objective of tracking the six priority areas, the SC&A emphasis was on methodology. **Dr. Makhijani** noted they did not verify all the calculations. They did try to verify some of the work on ratios and radon breath and the radon dose issues, which were critical. They did not re-run IMBA. The review is also not a full SEC petition evaluation. He noted SC&A's overall conclusion is that NIOSH has developed an approach that can be applied to estimate maximum doses with plausible worst-case estimates. **Dr. Makhijani** added there is a

checklist table in the report which looks at each sub-issue and its status.

There are specific recommendations on major issues. In terms of the ratios associated with the radon breath data, **Dr. Makhijani** noted they seemed to be appropriate. They're well established, there's good measurements, and the measurements are internally consistent.

The issue of non-equilibrium radionuclide exposures in regard to thorium 230-dominated areas is more difficult because there is less information. From a broad point of view is the question of job type, and the Board did ask to whom does this information apply. NIOSH has proposed that these high non-equilibrium ratios which produce high doses would be applied to most workers. Equilibrium ratios which produce lower doses would be applied only when it's clear a uranium worker labored in areas that did not involve these residues. **Dr. Makhijani** indicated SC&A is in agreement with that, with a caveat that because of the large difference in doses and potential outcome, assumption of equilibrium exposure should be carefully made and documented.

An outstanding significant issue is the 95th percentile of air concentrations for high thorium areas. The NIOSH calculations have taken the 95th percentile of the daily weighted averages for all Plant 6 where there was uranium processing, which SC&A doesn't feel is representative of the airport cake or AM-7 areas. **Dr. Makhijani** admitted he had not reviewed the data personally, but accepting that it is double the daily weighted average of the thorium, it doesn't address the relation of the proposed number to the 95th percentile value of air concentration in the AM-7 areas. He suggested the air concentrations in the areas where thorium was dominant should be the reference point, and the 95th percentile of the value of the air concentration needs to be developed for that. SC&A believes some work needs to be done there.

Dr. Makhijani observed that though there had been much discussion about illegible data, the point he would make is that the way the calculations are now set up, workers with radon breath data may be at some disadvantage because the full distribution is being used. And while SC&A understands that's in the nature of the process, the measurement uncertainties should be assessed somewhat differently. Perhaps some method to have 95th percentile values for missing data points should be developed to make it appropriately claimant-favorable, especially for workers who have just a few radon breath data points.

On the question of Plant 7-E where thorium was extracted for parts of '55, '56 and '57, it wasn't clear how much bioassay data was available at the time the report was prepared. SC&A understands now there's

quite a bit available for the two months. The air concentration data in the TBD and associated documents was clearly inadequate. The intake in the case study is 100 times bigger than was suggested in the TBD. The new information would help carry this forward.

On the external dose issues, SC&A agrees with NIOSH regarding how they have handled the organ geometry versus the badge geometry. SC&A has reviewed the Attila results and are in agreement.

Two remaining issues regarding dose conversion factors are the angle of incidence on the badge because the shielding absorbs some of the radiation, and the dose conversion factors need to be corrected. Although these are complex-wide issues, they need to be resolved to do Mallinckrodt dose reconstruction. **Dr. Makhijani** commented SC&A had raised them in this context because if there are issues to be resolved, these should be included.

Dr. Makhijani noted there were several priority areas in which SC&A and NIOSH were in agreement such as radon exposures, unmonitored exposures, and routine environmental dose. He summarized the remaining critical issues as a need to develop ratios in the thorium areas; a need to develop air concentration measurements for the AM-7 areas; the dose correction factor for external dose needs to be completed.

There is new information available which SC&A has not reviewed, although **Dr. Makhijani** indicated he had read it. The analysis of the residues contains very significant new information about process chemistry that could result in improved ratios. The air concentration data, underlying documents, and new production data presented is significant new technical information.

Dr. Makhijani explained that between submittal of the report and coming to the meeting, he had tried to review the IMBA calculations to see if everything looked okay. That was when he had noted the discrepancy between dose conversion factors for actinium and protactinium, a significant issue which remains to be resolved as to which is appropriate.

Discussion Points:

- The discrepancy between the ICRP value and the Federal Guidance Report was on protactinium 231.
- The Federal Guidance Report documents are EPA documents providing 50-year doses.
- The ICRP models are programmed to do annual dose increments for this program.
- IMBA has programmed the most recent ICRP models, while the Federal

Guidance Report was issued around 2002.

- The question will probably be which metabolic model was used for actinium and protactinium.
- It is suspected surrogate nuclide models were used, such as thorium for one and americium for another, but the issue needs to be settled.
- The issue is whether it's a true difference in the model versus an error that's been introduced into one or the other.
- NIOSH has committed to use current ICRP models in this program and have done so. The Federal Guidance Report has taken a different tack and a different approach to the dosimetry. If theirs is the most reasonable approach, NIOSH would look into it and adopt it.

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Closed Executive Session
Review, Discussion and Finalization of Contractor Issues

Prior to adjournment for lunch and the closed session, **Dr. Ziemer** asked **Dr. Wade** to read into the record the parameters for the Executive Session scheduled from 1:00 to 3:00 p.m.

Report on Executive Session

Dr. Ziemer reported the Board had approved the scope and cost for Task I, site profile reviews for the upcoming year, in the amount of $1,203,938; Task III, procedures review, in the amount of $416,224; Task V, contractor assistance in Board review of Special Exposure Cohort petitions, in the amount of $917,341; and Task VI, contractor program management, in the amount of $217,891.

Task IV, dose reconstruction review, has not been approved. It will continue through the next four to six weeks on existing funds. There will be additional discussions on the scope of the task in open session and it is expected to be resolved at the next meeting. The discussions will revolve around the numbers of basic and advanced reviews.

Dr. Ziemer also announced a conflict had been discovered in one of the case assignments for dose reconstruction review. It had been resolved by reassigning the case to a Board member without a conflict.

Dr. Wade commented that the Board's action in closed session was based upon an assumed action on the part of Congress. It should be understood that appropriations and budgets will be factors, and if the numbers are different, adjustments may be necessary.

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Mallinckrodt Site Profile Review
Continued Discussion

Discussion Points:

- NIOSH has a team at the Office of Worker Advocacy to recapture the 451 pages of radon breath data in their possession. Those better copies will be made available to the Board and the contractor.
- Some entries appeared to be high values and it wasn't clear whether the decimal point was missing or they were actually high. NIOSH will focus on those and make sure their understanding of them is correct.
- The NIOSH team has been there for two days reviewing every image. Anything that can't be scanned properly will be captured in some form. The information gathered will be shared with SC&A.
- There were at least three or four dates in 1955 where the whole day of data is missing.
- In reviewing those dates, there were samples for 98 percent of those people at a later time. The measurements reflect a cumulative body burden, so no large intakes would have been missed.
- The individuals' names are on the data sheets so identification is not an issue.
- There are 16 or 17 data points on each of the missing days that are not in the CER database.
- NIOSH will re-code the entire 451 pages and not rely on just the CER database.
- Repeat the explanation of how the air sampling data was used and how the 95th percentile was established.
- How much of the data is clearly identifiable as AM-7 air concentration data.
- Approximately 500 air samples were collapsed into 40 or 50 job categories, approximately 11 of which were tied to an AM-7 area.
- What is the impact on the dose to an organ of a one percent error in the protactinium to thorium ratio.
- There had been an assumption that ICRP and the Federal Guidance Report were in agreement, and the discrepancy was found.

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Board Working Session

Task IV, Dose Reconstruction Reviews

Dr. Ziemer announced a carry-forward issue from the closed session is

related to Task IV, the scope discussion in terms of basic and advanced dose reconstruction reviews. Scope discussions are appropriate in the open session, so it was reserved to this time. **Dr. Ziemer** suggested discussion as to what the Board might wish from SC&A next year with respect to advanced dose reconstruction reviews versus basic reviews.

It was noted that in the task description provided by the contractor it was indicated that perhaps all of the dose reconstruction reviews to date are more advanced than basic, but less advanced than advanced.

Dr. Wade added he would like to see from the Board what it would like to have the contractor prepare and submit before the next meeting so that the decision could be made in light of that information.

Dr. Ziemer remarked closure was not reached on cost relative to this particular item because what the Board wants the contractor to do has not been defined in terms of advanced and basic reviews.

Ms. Munn suggested that, allowing some judgment on the part of the contractor, the Board might consider looking at the upcoming 22 cases and identifying a range of percentage to be identified as advanced review cases. She reminded the Board SC&A had indicated it is sometimes difficult to identify what should be an advanced review case until there's been an opportunity to look at it.

Some concern was expressed about leaving the choice to the contractor's judgment as opposed to assigning cases to receive basic or advanced reviews.

Mr. Espinosa didn't want to tie the contractor's hands and was in favor of their having the ability to decide, but was concerned the cost could get out of hand. He was more comfortable with stipulating a percentage.

Dr. Anderson questioned the purpose for doing the advanced reviews. He suggested the focus of advanced reviews might be the best-estimate cases. Conversely, an advanced review of min/max cases could show if there were any differences in the results.

Mr. Presley remarked the original intent was an audit of cases. He proposed SC&A might do the next 22 cases as basic reviews, then come back with their suggestion for which ones might be ripe for an advanced review and why. He observed that was what he considered the audit, and the Board would then decide which ones would be advanced reviewed.

Dr. Melius drew attention to SC&A's proposal in which they indicate two elements of the advanced review they have not pursued and are not

intending to pursue. The first is to evaluate other relevant sources of data and the second is the issue of an adequate effort to research co-located workers and other records to characterize the individual's work history. He observed the first issue might be included in a site profile review, if a site profile has been done. If not, some level of effort should be made to address that objective. If a site profile is in development, perhaps the case review could be deferred.

Continuing with the second element, **Dr. Melius** noted that evaluation of the effort to verify the characterization of an individual's work history should still be done on an advanced review. It was a component the Board wanted done from time to time. Survivor interviews are not going to provide much of that information. **Dr. Melius** reminded the Board that was the point of a lot of discussion about re-interviewing claimants, and this was their compromise. It's an important part of an advanced review and one he did not want to see dropped.

Noting there are some practical limits needed in that SC&A can't spend months talking to everybody at a particular site, they are doing it on a modified scale when they talk to people during a site profile review. Those interviews are not in enough depth to deal with individual cases, however.

Dr. Ziemer commented that SC&A had indicated they believe their dose reconstruction reviews are more thorough than what the Board had originally defined as basic, though not at the depth of an advanced. They used the term comprehensive. Since they've kept the Board informed all through their review process, the Board was aware they may have been a bit more thorough than anticipated, but continued along that path. For that reason, the contractor should not be faulted. But if it's the Board's desire that something less is wanted in a basic review, that should be defined. If there is uneasiness about the current level and its cost implications, that should be considered if the Board wants a sharp demarcation between basic and advanced reviews.

Observing that what SC&A refers to as comprehensive comes very close to an advanced review with only a few components missing, he noted the contractor was bidding on the basis of 60 comprehensive reviews. Since the Board has no "comprehensive" category, the Board has to decide what it wants and in what numbers.

The original breakdown was 40 basic reviews and 20 advanced, so the reviews currently underway are supposedly advanced.

Mr. Griffon asked to hear the contractor's interpretation of the difference in advanced and basic. Indicating he was happy with the product received, **Mr. Griffon** observed that if one looked over the

scope items in the original basic review definition, nothing has been added by SC&A. He acknowledged there had been a learning curve, particularly in the first 20 reviews, but felt the Board deserved some reviews done with the advanced scope in mind, with judgment reserved until they received the product.

Dr. Wade announced the first set of 62 reviews was to be 40 basic, 20 advanced and two blind. The 40 basic reviews had been delivered. The Board can tell SC&A it expects the next 22 to be advanced reviews. The Board can imagine what it would like to schedule for next year. He noted all options are open and it's a matter of deciding what to ask SC&A to do.

Dr. Hans Behling explained SC&A's difficulty in doing an advanced review on an assigned case might be in a situation where there was full dosimetry data on a claimant. An advanced review would call for verification of coworker data, a last resort when there is an absence of primary data. What would be the point in such a case? Another situation would be a min/max case where only the most simplistic reconstruction was done because it was enough to go over 50 percent. What would be accomplished by pursuing a case where even partial dose reconstruction put the claimant over 50 percent?

Dr. Melius suggested that it simply be reported as such if a particular element is not appropriate for a case. It's what SC&A bid on doing and what they're expected to do.

Ms. Munn remarked if there is a case where it is appropriate for SC&A to search other records, the Board hasn't identified it for them yet. If that is going to be incorporated into the Board's view of an advanced audit, it probably needs to be done now.

Dr. Anderson suggested the Board might want a checklist so that SC&A can say it wasn't appropriate in a particular case to look for coworker data or whatever the case may be. He added that if SC&A is saying the Board received more than what was called for in a basic review, what is that extra thing that would not be included?

Mr. Griffon proposed that one answer to **Dr. Behling**'s dilemma in pursuing coworker data might be to look at, for example, people the claimant mentioned working with to see if they had exposures much higher or lower than the claimant, or if they were monitored for something different, or any number of other things.

Dr. Wade read the language from the original task, and commented the question was whether the Board agreed with it or if they wanted something else.

Dr. Ziemer added that if **Mr. Griffon**'s suggestion were followed, it would be hoped it would confirm everything to be in order. But if not and some pattern or discrepancies were found, SC&A might come back and say the dose reconstructors need to add something to the process.

Dr. Melius discussed a proposal that would allow the reviews to continue, but still provide an opportunity for further evaluation and perhaps better decisions. He suggested the more complicated cases being reviewed in this round may raise new issues.

Dr. Ziemer acknowledged **Dr. Melius** had probably intended his proposal as a motion, but suggested he refine the wording and provide it in written form for a vote the following day. A motion clarifying scope will enable the contractor to come back with a refined or revised cost estimate, if necessary.

Mr. Gibson remarked that, regardless of how the Board defined the scope, there is nothing basic about reviewing dose reconstructions and trying to dig into all the information.

Dr. Melius offered they should also thank SC&A for being so specific in laying out their scope this time; it had been helpful to the process.

Dr. Wade reminded the Board that it had set a goal of two-and-a-half percent of dose reconstructions to be reviewed, and at some point the members should step back and evaluate what they're likely to do on that.

Speaking on behalf of SC&A, **Dr. Mauro** noted they were in the midst of completion of the last 22 cases assigned for review, which were being done as comprehensive reviews. He noted they're in a position where they have in mind what will be delivered. But there may be some cases that the two items identified in their proposal might add more value, they might gain more out of their understanding of the strengths or limitations of a given dose reconstruction. **Dr. Mauro** called for Board guidance on whether SC&A should look at this last set more aggressively, that they exceed what they had been doing in the previous reviews.

Dr. Ziemer commented that the instruction on the last set is that they are advanced reviews. He suggested SC&A might think about what it means to go into depth on something that appears to be straightforward.

Mr. Griffon added that if SC&A feels strongly there's nowhere to take a certain case, that's all that can be done, just put not applicable. But the scope has to be considered; even if it looks simple, there may

be something there.

Explaining the Board's position, **Dr. Ziemer** remarked they are not judging whether or not SC&A can do an advanced review. He cautioned SC&A should not decide that if a thing looks simple, it's not subject to an advanced review. The idea is that SC&A should at least think about whether there are other things that should be looked at to confirm the data is correct -- or whatever the issue might be.

Dr. Behling explained a question he had raised earlier with **Dr. Wade** as to what privileges SC&A is given. He noted there are certain issues that have not been addressed yet, such as who he was entitled to contact.

Noting that it may have to be done on a case-by-case basis, **Dr. Ziemer** inquired what the procedure would be if the contractor says it has to access certain information to complete the case in an advanced review. **Dr. Wade** agreed, commenting he had suggested **Dr. Behling** approach him with the particular issues and they would be handled on a case-by-case basis.

Task VI, Project Management

Dr. Ziemer announced that an issue that emerged from the scope discussions was a matter of SC&A being asked to meet with various Congressional staffers to review the contractor's work product. SC&A has been instructed to proceed and make such briefings when asked. In some cases permission for Board presence has also been requested. At a minimum, SC&A has been asked to keep a record of such visits and the items discussed so that the Board has it on record.

In the scope of the work product budget for this year those visits have been budgeted, so if Congress funds that, they will in fact be covering the cost of doing that. Nonetheless, it is not a big part of the budget.

A related issue, however, is the ground rules under which the contractor makes those visits. Some members of the Board have expressed concern that a Board member should be present. Those on the Hill don't always want Board members present, preferring a candid discussion with the contractor. **Dr. Ziemer** indicated he was seeking a sense of what the Board feels should be the ground rules, keeping in mind that in the end the people on the Hill will have the final say.

While **Ms. Munn** had drafted a written motion, **Dr. Wade** requested an opportunity to speak before the discussion begins. He commented that NIOSH very much respects the Board and looks for its advice, but is not

prepared to create the impression it surrendered its right to make the decision on Hill visits by a government contractor. NIOSH will make the final decision, guided by the Board's information. Noting that to this point it had been his agency's position that the Hill would have unfettered access to SC&A, **Dr. Wade** indicated he assumed that would remain the position.

Ms. Munn remarked the concern was not interaction with elected officials, nor the press, the public or other organizations. The concern is that the material being discussed might still be incomplete. She explained this had been the situation recently when the contractor was asked to provide a briefing on documentation that had not been through the vetting process of either NIOSH or the Board. That request had been coupled with a request that no member of the Board be present, raising a reasonable concern that misunderstanding and misinformation could derive from a draft document no one had seen.

Acknowledging it could be anticipated that any elected official would be interested in staying abreast of what was transpiring with anything that affected their district, **Ms. Munn** indicated those were the thoughts in mind when the statement of policy was drafted. She reiterated the concern is that information provided not be partial or incomplete is the sense and spirit in which the statement of policy is written.

Dr. Ziemer commented that in a majority of cases the requests are going to involve documents not yet finalized. He indicated his belief that SC&A had done a good job in making it clear that these are draft documents. In many cases the Board has not seen them yet so they don't represent the position of the Board. The other part, however, is that a Board member cannot speak for the Board. While a member may be present and hear what transpires, that member is not in a position to contradict, deny or agree on behalf of the Board. **Dr. Ziemer** suggested that should be kept in mind during this discussion.

Noting that time was running short, **Dr. Ziemer** acknowledged the statement of policy comes as a motion and called for a second in order to get it on the floor in today's session. Having been duly seconded, **Dr. Ziemer** inquired if copies were available for the public. In the absence of copies, **Dr. Ziemer** read the formal motion into the record: (Reading) As an appointed body mandated by the Energy Employees Occupational Illness Compensation Program Act, EEOICPA, the Advisory Board on Radiation and Worker Health (the Board) works with multiple Federal agencies to fulfill the requirements laid down by the statute. The business of the Board is conducted with full transparency under the Federal Sunshine laws requiring open disclosure and public access to information. The Board routinely deals with matters that are

complex, variable, frequently technical, and highly emotional. It is necessary that the Board contract for several technical or administrative services in order to completely address discrete issues within the Board's responsibilities. The resulting documents require extensive review, technical discussion and revision before the product can be released as properly vented (sic) and then authorized for distribution. Although draft documents are often widely distributed, they cannot be viewed as material yet ready for presentation or comment.

Because of the incomplete and potentially misleading nature of information contained in draft documents, it is the policy of the Board to provide briefings, interviews or other informational exchanges from Board members, our subcontractor, affiliates and associates only when the final document has been accepted by the Board. It is our further policy that at least one member of the Board be present or in telephone contact at the time such a discussion takes place.

Adopted this 26th day of August, 2005; St. Louis, Missouri.

Dr. Ziemer suggested action be deferred until the following day.

Dr. Melius remarked the Board had dealt with this issue in a slightly different form at the time of the Bethlehem Steel site profile. **Dr. Ziemer** noted the Board had taken specific action that future reports would not be withheld, with a suitable disclaimer first proposed by the late **Dr. Antonio Andrade**.

Dr. Melius expressed his opposition to the motion, noting the contractor's relationship and credibility with Congressional staffers is of benefit to the program. He commented there was a lot to lose by trying to prohibit or limit this activity in some way. He reminded the Board that, given their record in getting some documents from draft to final stage, some meetings could be delayed years.

Citing 36 years' experience in dealing with the Federal government, **Mr. Presley** agreed SC&A had done a wonderful job, but disagreed that their participation on the Hill was needed. He expressed a belief that any time there is a call for Board work on the Hill, the Board should ask to be allowed to participate.

Dr. Anderson objected to the use of the term "all draft documents". That just forces a technical issue that once something has been adopted by the Board, it's too late for the public to comment on it. He clarified that he wouldn't want SC&A to share a document that was still their internal draft, but he didn't think they were doing that.

Agreeing with **Dr. Melius**, **Mr. Owens** remarked the credibility of the Board is always on the line. He acknowledged all the Board members

realize they serve at the pleasure of the President, and that this is a political process. Describing adoption of this language as a tragic move, **Mr. Owens** suggested it would send an incorrect message to Congress and a bad message to those who watch the workings of the Board.

Dr. Melius commented there is a process in place that allows the Board to be informed about the Congressional visits, and he would have no objection to a policy that provides the Board may request permission to participate in the visit. But the Board's policy shouldn't be that they "will" attend because it is still the prerogative of the Congressional office who they want to invite into those offices. He suggested a process where the Board would be notified about the visits, members who want to participate can communicate that to appropriate staff setting up the meeting, then it's up to them to decide if they want that participation.

Dr. Ziemer observed that a policy offering the opportunity for a Board member to be present would meet NIOSH's needs in that it wasn't a requirement but an offer, and it would allow the Hill the prerogative not to make the offer. The action on the motion was postponed until tomorrow.

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The Chair declared a recess until 7:00 p.m. when public comment would be taken. He requested that any members of the public who wished to speak but had not yet signed up, do so at once.

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Public Comment Period

The following is a list of 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. John Ransport, General Steel Industries; **Ms. Christine Ransport**; **Dr. Dan McKeel**; **Ms. Denise Brock**, Mallinckrodt Special Exposure Cohort petitioner; **Ms. Louise McKeel**; **Father Jim Mitulski**, survivor; **Mr. Richard Miller**, Government Accountability Project.

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Friday, August 26, 2005

The second day of the 32nd meeting of the Advisory Board on Radiation

and Worker Health was called to order by **Dr. Paul Ziemer**, Chairman. He reminded everyone to register their attendance in the book provided.

Dr. Ziemer extended the Board's welcome to **Ms. Judith Dungan**, who was in attendance as **Senator Kit Bond**'s representative.

Dr. Lew Wade, Designated Federal Official, spoke briefly to remind the Board they will be addressing the Mallinckrodt Special Exposure Cohort petition today. He observed there will always be tension between the passage of time, the need for timeliness and the need to be complete in their scientific deliberations, a tension the Board will face in everything it does. Speaking from his perspective as DFO, **Dr. Wade** commented that he felt the Board should review the material today and move to making a decision. While the process has added value, it has been difficult for petitioners and claimants.

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Special Exposure Cohort Petition
Mallinckrodt Chemical Works

Mr. Stu Hinnefeld,
NIOSH/OCAS

Speaking on behalf of NIOSH, **Mr. Hinnefeld** indicated that his comments would be brief. Any presentations he would have made had already been made, and so he had not prepared a slide show.

He observed that a lot of people had worked very hard to get the best science available regarding the questions raised. He added that's what NIOSH expected to do, and what should be expected of them.

Mr. Hinnefeld expressed recognition of the difficulty of engaging in a site profile review at the same time as an SEC petition evaluation for that site. He proposed that NIOSH and the Board work together for a set of procedures to ensure a similar situation doesn't arise on other petitions at other times.

Ms. Denise Brock,
Petitioner

Ms. Brock cited the FY '05 Labor/HHS Appropriations Act and the Energy Employee's Compensation Act of 2000 as providing mechanisms for which timely, uniform and adequate compensation should be provided for employees made ill from radionuclide exposure.

Thanking **Senator Town**, **Congressman Akin** and their staffs for their

continued support, **Ms. Brock** also welcomed and thanked **Ms. Dungan** for her presence, and passed along **Senator Bond**'s comment that the former Mallinckrodt workers are part of an endless bureaucratic process.

Ms. Brock provided a chronology of events from past meetings regarding the Mallinckrodt facility. She reviewed the feasibility issue with respect to technical, cost, and time constraints. Remarking that NIOSH has far exceeded the time contemplated by Congress for SEC petition processing, **Ms. Brock** noted it has taken 13 months to assess this petition filed in July of 2004.

Ms. Brock concluded her comments by asking the Board to approve the SEC petition for the Mallinckrodt workers from 1949 to 1957.

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Opining that NIOSH lacked adequate data or information to accurately reconstruct doses based on his interpretation of 42 CFR 83, **Dr. Dan McKeel** offered the following reasons:

- There are 107 Mallinckrodt EEOICPA claims from the 1949 to 1957 time period awaiting dose reconstruction, providing evidence that dose reconstructions cannot be performed in a timely manner.
- The CER database is limited and biased.
- The 20 percent sample of radon breath data NIOSH proposes to use is too small a sample and thus fails to meet the 42 CFR 83 test.
- SC&A and NIOSH have significant differences with respect to the six priority Mallinckrodt issues.

Dr. McKeel concluded by stating the Board should recommend SEC status for the 1949 to 1957 class of Mallinckrodt uranium division workers.

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Dr. Arjun Makhijani from SC&A spoke briefly on a correction to be made in the Mallinckrodt site profile review report with respect to calculated values for the AM-7 area air concentrations. He explained he and **Dr. Neton** had discussed a misunderstanding of a statement in the site profile and the issue had been clarified. **Dr. Makhijani** indicated a corrected replacement page to the report will be provided.

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Board Discussion

Dr. Ziemer explained the options available to the Board relative to proceeding with the petition.

A motion was made and seconded that the Board recommend a Special Exposure Cohort be accorded to all Department of Energy employees, contractor or subcontractor employees who worked at the uranium division of the Mallinckrodt facility from 1949 to 1957 and whom were employed for a number of work days aggregating to at least 250 work days.

This motion was read by Dr. Melius: The Board respectfully recommends a Special Exposure Cohort be accorded to all Department of Energy employees or its contractor or subcontractor employees who worked at the Uranium Division of the Mallinckrodt Destrehan facility from 1949 to 1957 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 (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

The floor was opened for discussion on the motion. **Dr. Roessler** commented on defining what is meant by adequate information to do sufficient dose reconstruction, and also to be uniform in decisions for the purpose of equity.

Dr. Melius declared the Board needed to deal with the Mallinckrodt SEC petition today. To address those equity issues, however, **Dr. Melius** suggested procedures and criteria should be developed for evaluating future SEC petitions.

Ms. Munn observed NIOSH has shown that dose reconstructions can be done on this group of workers in the petition. **Mr. Griffon** argued that critical elements are missing for calculating accurate dose reconstructions.

Following extensive Board discussion, **Dr. Ziemer** put the motion to a vote. The motion carried.

Dr. Ziemer emphasized to the audience that the Board's recommendation to the Secretary, following the regular procedure of a letter to be generated for that purpose, will be to support the petitioners. This recommendation will accompany the NIOSH recommendation to the Secretary. The NIOSH recommendation is that dose reconstructions be done. The Secretary of Health and Human Services will take both recommendations into consideration as he makes his decision. **Dr. Ziemer** stressed it is the Secretary who makes the decision, not the Board. The Board simply makes a recommendation.

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Board Working Session
Conflict of Interest Disclosure Statements

Ms. Liz Homoki-Titus,
Office of General Counsel

Ms. Homoki-Titus reminded the Board that at their last meeting members had expressed an interest in having their conflict of interest statements posted on the OCAS web site. **Ms. Homoki-Titus** explained that she had reported that interest to her office where it had been discussed. However, it is not HHS policy to allow such information to be posted. The compromise is to request a formal motion from the Board and approval by consensus in order to make such posting.

Updated information for all the Board members was provided, formatted to include name, position, biographical information, the waiver statement, year issued and recusal sites. **Ms. Homoki-Titus** invited Board members to review their individual statements and report any changes needed to **Dr. Wade**, who will relay them to the Office of General Counsel.

A motion was made and seconded expressing the Board's desire to allow individual conflict of interest disclosure statements for each member to be posted on the OCAS web site. The motion passed unanimously with minimal discussion.

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Capitol Hill Policy

Dr. Ziemer referred the Board to a written motion, already on the floor and preliminarily discussed in yesterday's meeting. The floor was opened for additional discussion of the motion.

Following a discussion regarding procedural issues, **Dr. Melius** read a motion he would propose, should the current motion fail. It was as follows:

Recognizing that the credibility of the EEOICPA program and the work of this Advisory Board can be enhanced by communicating these efforts to Congressional staff, it is the policy of the Board to encourage such meetings when they are requested. The scheduling of such meetings should be communicated to all Board members. Board members who wish to participate in the

meeting should inform the Board Chair and contractor, who will then communicate with the Congressional staff to determine whether the staff would like to also invite the Board member or members to attend the meeting.

The Board also understands that our contractor must notify NIOSH about these official visits and should ensure that their staff takes appropriate precautions to properly characterize the status of the information being communicated. Further, Board members participating in such meetings will appropriately communicate any potential conflict of interest issues to the Congressional staff.

Dr. Ziemer explained the issue could be handled by a motion to substitute what he called "the Melius motion" for "the Munn motion," at which time the motion on the floor for discussion would be the Melius motion.

A motion was made and seconded that the Melius motion be substituted for the Munn motion. The motion carried.

Questions raised and issues discussed included the following:

- Congressional inquiry should be made to the Board rather than to the Board's employee, their contractor.
- The ultimate decision on how to handle Hill visits would be made by NIOSH, guided by the Board's policy.
- Who would pay for travel expenses of any Board members attending such meetings.
- Visits were not opportunities to espouse personal opinions.
- Board members might attend in a different capacity than Board member, such as site expert.
- It would have to be made clear that member was not representing the Board.

The Chair put the motion to a vote and, with grammatical corrections, it carried unanimously.

Dr. Wade reiterated that NIOSH accepts the motion and its intent and will make every effort to follow it. However, the contracting officer and the Secretary reserve the right to manage a government contractor, SC&A, as they see fit regarding Hill visits.

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Approval of Minutes

Two sets of minutes were before the Board for approval, one being the minutes for the Subcommittee meeting on April 25, 2005; the other being the minutes for the meeting of the full Board on April 25, 26 and 27, 2005, in Cedar Rapids, Iowa.

A motion was made and seconded that the minutes of the Subcommittee meeting held April 25, 2005 in Cedar Rapids, Iowa be approved. The motion passed unanimously.

A motion was made and seconded that the minutes of the Thirtieth meeting of the Advisory Board on Radiation and Worker Health, held April 25, 26 and 27, 2005 in Cedar Rapids, Iowa, be approved. The motion passed unanimously.

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Site Profile Prioritization

Opened for discussion was the issue of how to prioritize the six sites designated in yesterday's meeting as priorities for future site profile reviews. **Dr. Wade** confirmed those sites were Fernald, Los Alamos National Laboratory, Mound, X-10 at Oak Ridge, Pinellas, and Linde Ceramics, with Argonne West and Lawrence Livermore as alternative sites.

Discussion centered around whether any of the sites had SEC petitions under NIOSH evaluation; pending site closings at Fernald, Mound, Pinellas and Linde Ceramics; numbers of claimants from various sites; and potential issues relative to classified data.

A motion was made, seconded and amended that SC&A and NIOSH will review the issues surrounding the designated sites and present a proposed order of priority at the October Board meeting. The motion carried.

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Other Board Items

The question had been raised by Mallinckrodt petitioners as to what the Department of Labor's position would be on non-covered cancers should the SEC petition be approved. **Dr. Wade** reported he had spoken with a representative from DOL in an effort to find an answer. It was now his understanding DOL would reserve judgment on non-covered cancers pending the Secretary's determination. He added that the Secretary's determination could be affected by the Board's recommendation.

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A motion was made and seconded that the scope of work regarding the contractor's Task IV, individual dose reconstructions, include the following:

No. 1, 40 basic and 20 advanced dose reconstruction reviews;

No. 2, blind dose reconstruction reviews for two cases;

No. 3, prepare and deliver a report for each set of Board-assigned cases that will contain (1) findings associated with individual case audits and (2) a summary of all case findings prepared in accordance with a format acceptable to the Board;

No. 4, participate in extended review cycle, which includes working with NIOSH and the Board in resolving audit findings, and assist the Board in preparing an issues-tracking matrix which will be forwarded by the Board to the Secretary of HHS, and prepare a final audit report that reflects the results of the findings resolution process.

The motion passed unanimously without discussion.

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**NIOSH Handling of Cases
Lacking Sufficient Information
to Complete a Dose Reconstruction**

Mr. Hinnefeld announced he anticipated this issue would be on the agenda for the October meeting, but he wanted to speak to it very briefly and provide some background. He noted these are not cases for which an SEC petition has been received.

Explaining that at the inception of the program NIOSH had built the tools and procedures for doing dose reconstruction, **Mr. Hinnefeld** acknowledged that by the time those were ready to be used, a large backlog of cases had developed. First priority became getting the cases that could be done more quickly out of the way. The more difficult cases got older and remained undone.

NIOSH has focused its efforts this year on clearing out those cases. As part of that process, they are reaching determinations that there are some cases where there is not enough information to do a dose reconstruction. And furthermore, **Mr. Hinnefeld** added, there doesn't

seem to be any likelihood the information will be discovered.

The dose reconstruction regulation contained in 42 CFR Part 82 describes the steps to be taken when NIOSH reaches that conclusion. **Mr. Hinnefeld** explained the process included notification of the claimant in writing that such was the case. With that notification is a short-form SEC petition form. This is then followed by a closeout phone call in which the process is explained to the claimant. That includes a conversation about the SEC petition form and a request that they sign it and send it back. Notification is sent to DOL and DOE that the dose cannot be reconstructed, and DOL issues a regulatory denial. NIOSH is at the point now where these "test cases" are being identified.

While these petitions will be filed on behalf of the petitioner himself, the NIOSH evaluation will define the class in terms of all those cases that have similar characteristics. An example cited by **Mr. Hinnefeld** was a period of time at a particular site. NIOSH anticipates this will be a very streamlined process, but it will be presented then to the Board with a recommendation to the Board and the Secretary that the class be added because they have not located sufficient information to do dose reconstructions.

Mr. Hinnefeld indicated they hoped the Board would see this in October, but because a portion of the process is outside NIOSH's control, they can't be certain. The claimants have to choose to participate by signing the form and returning it. While NIOSH hopes to make a presentation in October, **Mr. Hinnefeld** wanted the Board to be aware of what they could expect to see very shortly.

Dr. Ziemer inquired if that meant a large number of petitions involving small numbers of individuals, or if there may be a methodology for combining groups, even from multiple facilities.

Mr. Hinnefeld indicated that initially they are looking at one-site class descriptions. **Ms. Homoki-Titus** added that they will be addressed administratively as a group, citing one *Federal Register* notice for a group of sites coming to the Board.

Mr. Owens inquired into the demographics of the relevant claimants, expressing a concern for elderly survivors who don't clearly understand the process under the best of circumstances.

Mr. Hinnefeld explained NIOSH was selecting a test case for a particular site, making every effort to choose a claimant who was able to deal well with the process, and was in fact doing the closeout interview before the letter to be sure the claimant understood what was

happening. If not, they would select another test case. In any event, once the test case was selected, that petition would bring along all the claimants who fit the class. Only that one test case would have to fill out a form and submit a petition.

Dr. Ziemer observed that seemed to suggest NIOSH was going to do everything possible to shepherd them through the process, to which **Mr. Hinnefeld** agreed.

In response to a query on potential sites, **Mr. Hinnefeld** declined, remarking that if things didn't proceed as NIOSH expected, they wouldn't want to raise expectations by discussing it prematurely.

Mr. Hinnefeld was unable to attach numbers to affected cases, noting this is in the early stages. But most of the research is done before the claimants are contacted, and the regulation intends this to be a streamlined approach for adding classes to the SEC.

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

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

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Paul L. Ziemer, Ph.D., Chair

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Date