Executive Summary

The Third Meeting of the Veterans' Advisory Board on Dose Reconstruction (VBDR or the Board) was held at the Omni Austin Hotel Downtown in Austin, Texas on June 8 and 9, 2006. Members in attendance were Dr. James A. Zimble, VADM, USN (Ret.), Chairman; Mr. Harold L. Beck; Dr. Paul K. Blake, CAPT, MSC, USN (Ret.); Dr. Ronald R. Blanck, LTG, USA (Ret.); Dr. Patricia A. Fleming; Mr. Kenneth L. Groves, CDR, MSC, USN (Ret.); Dr. John Lathrop; Dr. David E. McCurdy; Mr. Thomas J. Pamperin, LTC, USAR (Ret.); Dr. Curt W. Reimann; Dr. Kristin Swenson, Lt Col, USAF (Ret.); Mr. George Edwin Taylor, COL, USA (Ret.); Mr. Paul G. Voillequé; and Dr. Gary H. Zeman, CDR, MSC, USN (Ret.) (via telephone). Unable to attend were Dr. Elaine Vaughan and Dr. John Boice, CAPT, USPHS (Ret.). Others in attendance included staff of various Federal agencies, as well as members of the public.

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THE VETERANS' ADVISORY BOARD ON DOSE RECONSTRUCTION
DEPARTMENT OF DEFENSE AND DEPARTMENT OF VETERANS AFFAIRS

Summary Minutes of the Third Meeting
June 8 and 9, 2006

The Third Meeting of the Veterans' Advisory Board on Dose Reconstruction (VBDR or the Board) was held at the Omni Austin Hotel Downtown, 700 San Jacinto Street; Austin, Texas 78701 on June 8 and 9, 2006. The meeting was called by the Defense Threat Reduction Agency (DTRA) of the Department of Defense (DoD) and the Department of Veterans Affairs (VA). These summary minutes, as well as a verbatim transcript certified by a court reporter, are available on the internet on the VBDR web site located at www.vbdr.org. Those present included the following:

VBDR Members: Dr. James A. Zimble, Chair; Mr. Harold L. Beck, Dr. Paul K. Blake, Dr. Ronald R. Blanck, Dr. Patricia A. Fleming, Mr. Kenneth L. Groves, Dr. John Lathrop, Dr. David E. McCurdy, Dr. Curt W. Reimann, Mr. Thomas J. Pamperin, Dr Kristin Swenson, Mr. Paul G. Voillequé, Mr. George E. "Ed" Taylor, and Dr. Gary H. Zeman (via telephone).

Designated Federal Officer: Ms. Shari Durand, Deputy Director of the Business Directorate, DTRA.

Federal Agency Attendees: Mrs. Sandra Brackett, DTRA; Mr. James Delduco, DTRA; Mrs. Dee Marquardt, Waco, TX VARO; Mr. Kyle Reybitz; DTRA; Ms. Irene Smith, DTRA; Mr. Rainer Stachowitz, DTRA; Mr. Eric Wright, DTRA.

National Council on Radiation Protection and Measurements Staff: Dr. Isaf Al-Nabulsi, Ms. Melanie Heister, Mrs. Carlotta Teague, and Dr. Thomas Tenforde.

Members of the Public: See Registration

Thursday, June 8, 2006

Opening Remarks

Dr. James A. Zimble, Chair of the Veterans' Advisory Board on Dose Reconstruction, called the meeting to order and introduced Ms. Shari Durand as the Designated Federal Officer (DFO).

Ms. Shari Durand welcomed all members to the third meeting of the Board. She explained her role as DFO, and asked that cell phones and pagers be turned off during the progress of the meeting. She asked members of the Board and the public to use the microphones when speaking, and welcomed Dr. Gary Zeman who was unable to be present, but would be listening to the discussions and participating by telephone.

Dr. Zimble then recognized Mr. Carl Lowe, Veterans Administration Regional Office, Waco, Texas, who welcomed the Board to his state and reminded attendees that he requests questions from veterans with claims of any sort, from any region.

Dr. Zimble welcomed the newest member of the Board, Dr. Patricia Fleming, and then called upon the Board members to introduce themselves.

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Briefing on BEIR VII: Epidemiology and Models for Estimating Cancer Risks

Dr. Ethel S. Gilbert
Radiation Epidemiology Branch, National Cancer Institute

Dr. Gilbert began by providing an outline of her presentation, emphasizing that new data had appeared since the BEIR V (Biological Effects of Ionizing Radiation report number 5) report was published in 1990. She noted BEIR VII includes a comprehensive review of studies in four areas: Japanese atomic-bomb survivors, medical radiation, occupational Radiation; and environmental radiation.

Beginning with the Japanese atomic-bomb survivors study, Dr. Gilbert noted that this cohort included 87,000 Hiroshima/Nagasaki survivors with individual dose estimates and has been the primary data source for radiation health risk assessments. She went on to say that the studies of disease in the Japanese atomic-bomb survivors have provided the most reliable information for risk assessments for several reasons: 1) large numbers of subjects, 2) well-defined cohorts involving all ages and both sexes, 3) long term follow-up for mortality and cancer incidence, 4) whole body exposure, 5) well-characterized dose estimates

for each member of the cohort as a result of in-depth dosimetry studies, and 6) the population received a wide range of doses.

Dr. Gilbert noted that following publication of the BEIR V report, a major international effort was made to reassess and improve dose estimates; however, the impact of improved dose estimates has had a minor effect on risk estimates. She went on to say that parallel analyses using the new DS02 (Dosimetry System of 2002) doses and the older DS86 (Dosimetry System of 1986) dose estimates found that the new dose estimates (DS02) reduced the risk estimates for solid cancer and leukemia by about eight percent.

Dr. Gilbert pointed out that the cancer incidence data obtained from Hiroshima/Nagasaki was the most important development, especially for estimating site-specific risks. These incidence data include cancers not resulting in death. She went on to say that for cancers that have a fairly good prognosis of recovery such as colon, female breast, and bladder cancers, the number of cases is far greater than the number of deaths, thus providing a much stronger basis for risk assessments.

Dr. Gilbert also mentioned that a large number of medical studies involving radiotherapy for a myriad of diseases (benign and malignant) have marginal value for estimating risks at low doses because they lack individual dose estimates. However, the data from atomic-bomb survivors and several relevant medical studies on thyroid and breast cancers are of interest because these studies have individual dose estimates and in a useful dose range, and provide models for estimating risks for thyroid and breast cancers.

Regarding occupational studies, Dr. Gilbert indicated that she would address only the nuclear industry workers because the strength of these studies is that dose estimates are available from dosimeters worn by the workers. She went on to say that there have been many studies of workers at various facilities and combined analyses have been conducted on a national and international scale. Two of the most important studies were the International Agency for Research on Cancer (IARC) 3-country study, covering about 100,000 workers in the United States, the United Kingdom and Canada; and the National Registry of Radiation Workers study covering over 100,000 workers in the United Kingdom.

She also noted that the largest worker study ever conducted was the IARC 15-country study, which was released about the time of the BEIR VII report and was incorporated in the BEIR VII appendix. That study involved about 400,000 workers, among whom there were 6,500 cancer deaths. Dr. Gilbert provided details on the countries involved and the number of cancer deaths from each country. She went on to say that some of the smaller countries had relatively small nuclear industries,

and relatively young workers, which accounted for some of the differences in deaths among the countries.

Dr. Gilbert explained that the IARC 15-country study gave extensive attention to dosimetry to develop factors for converting recorded doses to organ doses, and to record the uncertainties in these factors. She presented the results for leukemia for the three studies, and the comparable estimates based on the atomic-bomb survivors.

Dr. Lathrop inquired about the confidence levels of the study outcomes. Dr. Gilbert replied that they were at the 95 percent confidence intervals.

Continuing, Dr. Gilbert showed that the 15-country study led to a higher risk estimate that was statistically significant. However, the confidence limits are very wide. These estimates are adjusted for socioeconomic status aimed at taking into account lifestyle factors such as smoking.

Dr. Gilbert also described various categories of cancer to the extent they are related to smoking, suggesting there is some bias related to smoking. These findings indicate a confounding effect of smoking that may be partly responsible for the estimated increase in risk of death from all cancers other than leukemia as a function of radiation exposure.

Dr. McCurdy inquired if the data referred strictly to photon exposures. Dr. Gilbert explained that was the case. Workers with internal or neutron exposures were excluded to avoid including doses that could not be quantified.

Continuing, Dr. Gilbert stated that although these studies have advantages of providing a direct assessment at low doses and low dose rates, they are subject to limitations. Even with large studies, small risk estimates cannot be estimated with great precision. Those studies also have a great potential for confounding and are subject to a high percentage of bias; consequently it is difficult to estimate risks at the two or three percent level.

In discussing environmental studies, Dr. Gilbert noted that these studies are of limited usefulness for quantitative risk assessment because they lack dose estimates, and most of the doses would be very low. Studies showing promise are radiation exposures from the Chernobyl accident and the releases from the Mayak facility.

Quoting from BEIR VII report, Dr. Gilbert described the primary objective is developing the best possible risk estimates for exposure to low dose, low-linear energy transfer radiation in human subjects.

The BEIR VII committee defined low dose as below one tenth of a gray.

Dr. Lathrop requested quantification of a gray as compared to natural background exposure. After some discussion it was concluded that a gray was significantly larger than the annual natural background exposure of the average American.

Continuing, Dr. Gilbert stated that the objective was to estimate the lifetime risk of developing cancer, considering variables such as dose, sex, and age at exposure. Data are generally inadequate to quantify other factors. She also noted that the BEIR VII report gave equal attention to cancer incidence and mortality, and provided separate estimates for leukemia, solid cancers, and cancers of specific sites. Dr. Gilbert went on to say that uterine and prostate cancers were included as separate categories to get them out of the "all solid cancer" category. However, skin cancer was not included as a separate category of solid cancers.

The methodology for developing lifetime risk estimates was explained by Dr. Gilbert and outlined on a series of slides. In developing risk models for breast and thyroid cancers, data from the atomic-bomb survivors and relevant medical studies were used. For solid cancers, risk was expressed as a linear function of dose. Applying the models to estimate lifetime risks to the U.S. population involves two significant issues: 1) the use of the model to estimate risk at low doses and low dose rates, and 2) transport risk from Japanese atomic-bomb survivors to the U.S. population.

Dr. Gilbert also noted that two approaches have been used regarding the issue of transporting risks from Japanese to U.S. populations. First, absolute risk transport assumes that radiation risks are independent of the baseline rates with regard to country. Second, relative risk transport assumes that the radiation risks are proportional to the baseline risks. Intermediate approaches have also been used. Although none provides a definitive answer, it is thought there is slightly more support for relative risk transport than for absolute risk transport.

In response to Dr. Lathrop's suggestion that this difference in risk estimates is a significant source of uncertainty, Dr. Gilbert replied it is when looking at specific cancers, but not so much when looking at all cancers. To address the issue, estimates were provided based on both approaches for cancers other than breast or thyroid. For the point estimates, a weighted mean of the two estimates was used.

Dr. Gilbert illustrated the BEIR VII approach to developing transport models for stomach cancer in males. She illustrated lifetime risks were expressed as number of cases per 100,000 persons exposed to a tenth of a gray. She mentioned that the BEIR VII report contains this

kind of information for all the risk estimates presented.

Noting that the lung cancer estimates used a slightly different approach than other cancers because of the effect of smoking, Dr. Gilbert presented a slide to illustrate an example of a risk estimate, showing that if 100 people were exposed to a tenth of a gray, one cancer from the exposure and 42 cancers from other causes would be expected. She explained a tenth of a gray is the upper limit of the low dose range.

Dr. Gilbert noted that statistics in her remaining illustrations would be accompanied by 95 percent confidence intervals. In conducting their uncertainty assessments the BEIR VII committee evaluated statistical and dose and dose rate effectiveness factor (DDREF) uncertainties, and uncertainty in transporting risks from the atomic-bomb survivors to the U.S. population.

Dr. Gilbert also presented estimates for solid cancer and leukemia, noting that the incidence rate of cancer is about twice the mortality rate. She illustrated lifetime risk estimates for cancer incidence and mortality in females. Dr. Gilbert explained that the data presented had been for people exposed at specific ages for one exposure of one milligray per year to reflect an environmental exposure, or ten milligray per year to reflect an occupational exposure. She then discussed a comparison of BEIR VII estimates with those of earlier studies, explaining that the latest estimates use the DDREF developed for BEIR VII report.

Dr. Gilbert went on to say that since all the estimates have an uncertainty factor of at least 2, there is not a great deal of difference among them. Those differences that do appear can be accounted for by differences in DDREF and a different approach to risk transport. She also discussed uncertainties associated with various types of cancer. She summarized her report by pointing out the major features of BEIR VII and contrasting it with BEIR V.

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A Briefing on Summary of Findings on Beta Dosimetry and Uncertainty From the Academy's Report on Dose Reconstruction for Atomic Veterans

Dr. Thomas Gesell
Professor, Health Physics
Idaho State University; Pocatello, Idaho

Dr. Gesell began by explaining that his talk would be in two parts: 1)

beta dosimetry, and 2) quality assurance and procedures. He explained his presentation was about the observations and findings of the National Research Council's (NRC) review of the dose reconstruction program of the Defense Threat Reduction Agency, and he recognized that the program has changed since that review.

He noted that before 1998 skin doses were not routinely estimated by the Nuclear Test Personnel Review (NTPR). The methods used in 1998 and 1999 are documented in the 2000 Barss report, and methods used from 2000 forward to the time of the NRC report are presented. Pathways of exposure included: 1) standing on a contaminated surface, 2) being in contaminated air, 3) being in contaminated water, and 4) contaminated skin.

Dr. Gesell explained that external beta doses from contaminated surfaces were calculated by applying a beta-to-gamma ratio to an estimated upper-bound gamma dose, measured either by film badge or by dose reconstruction. Different ratios were used for fallout and activation products. Variables affecting ratios were location of the test (Pacific or Nevada), time after detonation, and the height of detonation above ground. Dose to skin would be the sum of the beta and gamma doses. This is the relevant quantity for estimating probability of causation for skin cancer.

Using a graph, Dr. Gesell illustrated that the beta dose coefficient changes as a function of time after detonation. He also noted that the approach for contaminated water dosimetry is similar to that used for air, but must account for the difference in density between water and air. He went on to say that the gamma dose from skin contamination is not an indicator of beta dose skin contamination. Consequently, film badge data are not applicable. Rather, dose coefficients are based on radionuclides on or near the skin.

Discussing the beta dose received from standing on contaminated ground, Dr. Gesell pointed out that the beta dose is a product of the beta-to-gamma ratio. Consequently, if there are uncertainties in the gamma dose, there must be uncertainty in the beta dose.

In response to a query from Dr. Lathrop as to how the cases were selected by the NRC committee, Dr. Gesell replied they were selected in a stratified random way.

Though uncertainties of beta-to-gamma ratios were not estimated, there are a number of other variables upon which the beta-to-gamma ratios depend -- time since detonation, distance from source, and height above ground -- where errors would be intrinsic to the estimates of beta-to-gamma ratios. Therefore the NRC review raised two concerns: 1) that the gamma doses may have been underestimated in some cases, and 2) that

uncertainties were not explicitly recognized in the beta-to-gamma ratios. These concerns led the committee to conclude that the beta components of skin doses are questionable.

Dr. Gesell presented findings of the NRC committee with respect to beta-dose skin contamination. He noted that direct skin or clothing contamination was not considered a pathway for skin dose. However, some participants took multiple showers; contaminated dirt was brushed from participants; a report indicated that contamination was found frequently on clothing and bodies of persons aboard ships; minor radiation burns were seen on personnel below deck on the USS Phillip when vents were opened during a period of fallout; contamination estimates were not made for troops potentially contaminated while marching or working, yet published articles on the subject exist in the literature. On the basis of its findings, the NRC committee concluded that neglect of skin contamination was important with respect to skin cancer claims.

Moving to the uncertainty phase of the NRC review, Dr. Gesell noted that NTPR did not perform uncertainty calculations for beta-particle dosimetry. It was thought such calculations would require enormous resources to quantify the uncertainties in model parameters and propagate the uncertainty of each parameter to the model to obtain an overall uncertainty. It was assumed the measurements were, at worst, overestimated by a factor of 2 to 3 in favor of the participants. There was generally no discussion of uncertainty. Dr. Gesell observed that there have been many changes, improvements and updates since the NRC committee's review.

Shifting to procedures and quality assurance, Dr. Gesell explained that the Standard Operating Procedures (SOPs) were more a statement of approach and general principles than a manual of procedures that were used to reconstruct dose. They were incomplete and out of date. SOPs reviewed by the NRC committee contained provisions for review and updating, but in 2003 no reviews had been performed since 1997. Quality assurance (QA) was not discussed in detail in any of the SOPs.

Discussing QA, Dr. Gesell stated the NRC committee was never provided a QA manual. It was explained that the QA procedures were a proprietary part of the contractor's proposal and were not publicly available. Little evidence of a QA program surfaced in looking at the 99 cases reviewed. As a result, dose calculations were not signed, dated or initialed by the analyst, so there was no way to check on the sources of the calculations. Lack of dates made it difficult to determine the latest calculations. There were errors in calculating and reporting dose. There was no documentation to show that reviews had occurred prior to sending findings to the VA or to the veteran. There was no evidence of an effective peer review.

Dr. Gesell explained that the overall conclusion of the NRC committee was that, because of the foregoing findings, there were inconsistencies in the dose reconstructions.

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Public Comment Period

Prior to opening the meeting for public comments, Dr. Zimble reminded attendees that the Board had two objectives. The first is oversight of dose reconstruction and the filing and processing of veterans' claims dealing with ionizing radiation. The second is to assist DTRA, specifically NTPR, and the VA in communicating with the veteran and keeping the veteran informed.

Dr. Zimble then emphasized there are issues for which the Board is not responsible. They include individual dose reconstruction cases; the Board is not an appeals board; if the system is not working, the Board needs to know, but the Board has no legislative power.

For those interested in what the Board is doing, Dr. Zimble suggested that a visit to the web site at www.vbdr.org is the easiest way to keep up with Board activity.

The meeting was then opened to the public for comments. Comment was received from **Mr. Carlos R. Contreras**, president of newly-formed Atomic Veterans of America, Inc.; **Mr. Joe Faulkner**, Colonel, U.S. Air Force (Ret.); **Mr. Caffarello**; **Mr. Bernard Tschoerner**, **Mr. Joe Terry**, retired Navy chief radarman, and **Mr. Clyde Wyant**. A verbatim transcript of their remarks is available at the VBDR web site, noted above.

The veterans spoke about the new organization headed by Mr. Contreras. They related conditions they felt were a result of past exposures, including kidney problems, skin cancers, diabetes, prostate cancers, leukemia, and ear problems. They expressed their frustration in dealing with issues such as lost records and inability to get a response or clarification from government agencies.

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**A Briefing on Nuclear Test Personnel Review (NTPR)
Dose Reconstruction Program**

**Dr. Paul Blake,
Program Manager, NTPR**

Dr. Blake announced that he would be addressing two items as

recommended from the last VBDR meeting in Los Angeles. The first item was an update on the June 2004 report to Congress. The second item was discussion of a point paper on skin cancer. This cancer comprises more than 50 percent of the cases being reviewed by NTPR.

As background Dr. Blake reminded everyone that in May 2003 NRC published its report on the dose reconstruction program. It had a major impact on the NTPR program, resulting in procedural changes and a halt to dose reconstructions for six months while those changes were made. Additionally, the VA returned over 1,200 cases to be reevaluated. Thus, a tremendous backlog was created. Following the study Congress passed Public Law 108-183, Section 601, requiring the establishment of the Veterans' Advisory Board on Dose Reconstruction.

Discussing the current status of the NTPR program, Dr. Blake presented a graph outlining the impact of the NRC study. In an effort to bring the backlog down, NTPR committed to spending an additional $6 million. It was predicted the backlog would be reduced by September 2006. However, with new requirements of the NRC 2003 review and the number of new cases, it is now predicted that the backlog will not be reduced until 2008.

Dr. Blake acknowledged the veterans' frustration as a result of this situation, but explained that it is a tedious and expensive process. NTPR has brought additional contractors on board and allocated an additional $4 million. In addition, they support two other agencies, one of which is the Department of Justice (DOJ). Those cases are relatively easy in that they only request information on where the veteran was located. Also a number of the cases from the VA are presumptive cancers that do not require dose reconstruction and can be handled quickly.

Explaining that a dose reconstruction can be both time-consuming and expensive, Dr. Blake noted the cost ranged from $9,000 to $15,000 each. New cases are coming in at the rate of about 35 per month. More than 50 percent of dose reconstruction cases deal with skin cancer or a skin-related disease.

Turning to the report to Congress, Dr. Blake pointed out that there were 23 findings and a number of action plans. He indicated that some action plans have been completed and they hoped to have all of them completed in two years. Findings 5 through 14 related to DTRA actions to improve NTPR program procedures. These were highlighted by Dr. Blake and he discussed each briefly.

Finding 5: *Inadequate and inconsistent application of benefit of the doubt in favor of the veteran*. DTRA's response was development of the Scenario of Participation and Radiation Exposure (SPARE).

Finding 6: *Several pathways were frequently neglected in exposure scenarios; specifically 1) contamination resuspended by shock wave; 2) dermal exposure from skin contamination; 3) exposure from ingestion of contaminated materials*. DTRA's response was to revise procedures to ensure these pathways are considered.

Finding 7: *External gamma dose upper bounds were often underestimated*. DTRA's response was to issue interim guidance and revised procedures for calculating the dose. This procedure needs a follow-up and further scientific review.

Finding 8: *Estimates of internal dose may not always be high-sided as intended*. DTRA has since issued an interim adjustment factor of 10.

Finding 9: *Upper bound on neutron dose component was always underestimated*. DTRA has produced a draft report that should address this problem effectively (pending peer review and publication).

Finding 10: *VA adds upper bound estimate of the external dose to reported high-sided inhalation dose and/or beta skin dose*. The VA has minimized this issue by using the Interactive RadioEpidemiological Program (IREP) exclusively. A report will be forthcoming at a future VBDR meeting.

Finding 11: *Correlations are often not properly accounted for by combining various doses to arrive at a total organ dose*. NTPR has initiated an investigation of correlations between different exposure pathways, such as between: 1) prompt neutron and gamma doses; 2) residual gamma and beta doses; 3) internal doses from different radionuclides.

Finding 12: *DTRA's documentation of specific methodology for reconstructing doses was criticized*. A four-tiered approach has been developed and work continues on SOPs and quality assurance. This activity is ongoing and will require considerable investment of time and money.

Finding 13: *Suggested DTRA needs to develop, implement and maintain an auditable documentation system*. DTRA is implementing controls for different templates and manuals, some of which are still being developed.

Finding 14: *Recommended DTRA develop a comprehensive quality management system that covers all aspects of the dose reconstruction program*. A draft manual has been provided to VBDR Subcommittee 3 and feedback is expected soon.

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Dr. Blake then discussed the DTRA Skin Cancer Point Paper entitled "An Analysis of Service Connection for Radiation-Induced Skin Cancer in Veteran Compensation Claims", prepared in response to a request from the Board at the January 2006 meeting. The paper introduces background and discussion material, concluding with three recommendations for the Board's consideration.

Dr. Blake noted that DTRA currently has a backlog of 789 skin radiation dose assessments (RDAs), with 160 new cases projected per year. Uncertainty associated with DTRA's skin RDAs is potentially significant. Beta dosimetry is the biggest challenge as to how well the reconstructions are done. Upper bounds are compared to a screening dose generated through IREP. For some scenarios, basal cell carcinoma and malignant melanoma screening doses are smaller than 20 to 30 percent of DTRA's RDA upper-bound doses. For the overall population of veterans, it is 20 percent. If the Hiroshima/Nagasaki population of veterans is excluded, it is about 30 percent.

In response to Dr. Lathrop's request for clarification, Dr. Blake explained that physicians from the Veterans Health Administration (VHA) calculate probability of causation, using software similar to what is used for screening doses, and provide opinions as to what dose is considered greater than 50 percent probability that the cancer was radiation-induced.

The Hiroshima/Nagasaki detonations were unique, Dr. Blake explained, in that they were detonated some 500 meters above ground, thereby producing little radioactive fallout. Test detonations closer to the ground did produce significant fallout; therefore it is more difficult to make a case for skin cancers developed from radiation in the Hiroshima/Nagasaki scenario.

Reiterating that dose reconstructions for skin cancer cost between $9,000 and $15,000 per case, Dr. Blake observed that this cost is often greater than the compensation obtained by the veteran. Thus Recommendation 1 is the elimination of the requirement for non-Hiroshima/Nagasaki basal cell carcinoma and malignant melanoma RDAs as a matter of policy; grant service-connected compensation without calculating a skin dose.

Recommendation 2 presented by Dr. Blake is to eliminate the requirement to perform all non-Hiroshima/Nagasaki squamous cell carcinoma RDAs by establishing internal VA policy to grant service connection without calculating a skin dose.

Dr. Lathrop, Dr. Blake, Mr. Beck, Mr. Pamperin, Dr. Zimble and Dr. Fleming discussed the various implications of the recommendations, specifically the semantics of the recommendation and the determination

of fiscal ramifications.

Dr. Blake noted that Recommendation 3 does not depend on the VA. It can be acted on by the VBDR in that it is a recommendation to "Implement various efficiency measures that enable DTRA to perform expedited processing, provide worst-case skin doses to VA, and discontinue central dose estimates for skin RDAs." He suggested that this recommendation would expedite certain cases.

Dr. Blake concluded by requesting that VBDR and VA endorse the recommendations in the DTRA Point Paper.

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A Briefing on VA Radiation Claims Compensation Program for Veterans

Mr. Thomas Pamperin,
Assistant Director for Policy
Compensation and Pension Service
Department of Veterans Affairs

Mr. Pamperin began by discussing the interface between VA disability compensation for radiation activities and the award of benefits under the Radiation Employees Compensation Act. He cited the governing regulations, 38 CFR 3.309 and 3.311. The former provides for the 21 presumptive disabilities and was amended four years ago to come in line with the Radiation Employees Act and added four more presumptive disabilities, the most important of which are lung cancer and colon cancer.

This change has created a bizarre situation, observed Mr. Pamperin. By changing the category of these disabilities, it is possible to begin compensation at once. But to see if an earlier effective date for compensation can be established, it is necessary to go back to NTPR and ask for a dose reconstruction. All other cancers and macular degeneration are covered by 38 CFR 3.311 and do require dose reconstruction.

Dr. Lathrop requested clarification on the requirements of 38 CFR 3.311 and the recommendations of Dr. Blake regarding skin cancer. Mr. Pamperin replied that he could not speculate on what the final decision might be concerning the recommendations presented by Dr. Blake.

There are three kinds of claims, Mr. Pamperin said. They are presumptive (38 CFR 3.309) claims, the reconstructed dose (38 CFR 3.311) claims, and occupational claims. He then explained the process by which these claims is considered. In discussing the need for dose

reconstruction for certain claims, Mr. Pamperin received a question from Mr. Beck regarding the presumptive classification of, say, colon cancer and the need for a dose reconstruction where the finding might be, for other diseases, disqualifying.

Dr. Zimble elaborated on this anomaly by pointing out that because the disease is in the presumptive category, the veteran should be compensated, while the dose reconstruction clearly indicates he/she should not be compensated. Mr. Groves inquired if the VA could use its flexibility to address such an issue. Mr. Pamperin replied he would have to defer an answer to that question, noting that part of the problem lies with the need to coordinate with the Radiation Employees Compensation Act.

Continuing his update on readjudication, Mr. Pamperin said that the 2003 NRC report estimated 50 additional veterans would be granted service-connected status. Some 1,251 cases were referred by VA to DTRA for reevaluation of dose reconstruction. Service-connected status has been granted thus far to 136 veterans, 124 of whom fall into the category of the four cancers that had previously required dose reconstruction. Twelve cases, all skin cancer, have been granted compensation under 38 CFR 3.311.

Mr. Pamperin pointed out that there are about 1,400 claims pending at DTRA. They are the oldest cases in the VA inventory, some of much are now three years old. Typically they are in the 700-day range. Add about another nine months to develop the case, and they are typically three years old.

Mr. Pamperin provided figures from surveys that have been conducted by the VA. They surveyed 11,843 records from DTRA and identified 39.2 percent of veterans that were still living. Of those, 44.8 percent receive compensation. Of the deceased veterans, 1,667 surviving spouses are receiving Dependency and Indemnity Compensation (25.7 percent). He also provided comparative figures for the entire veteran population, adding that atomic veterans receive compensation at a significantly higher rate than the veteran population in general.

Regarding dose reconstruction, Mr. Pamperin noted that skin cancer and prostate cancer make up the vast majority of requests. He added that cost estimates have been reviewed anticipating that basal cell carcinoma will be classified presumptive, with similar estimates being developed for squamous cell carcinoma and melanoma.

According to Mr. Pamperin, an outreach effort to atomic veterans will be made with an article to be included in the atomic veterans' flyer that goes out to all on the registration list. The VA is continuing

efforts to locate additional atomic veterans through the various service organizations, Veterans Health hotlines and other outreach activities.

Dr. McCurdy asked about the seeming conflict of financial implications if skin cancer is made a presumptive disability. Mr. Pamperin explained the complexity this decision brings to the financial management of the VA, noting that the implications are far-reaching.

Dr. Lathrop questioned whether any money saved would be retained by agencies involved with veterans' issues. Dr. Swenson mentioned that what might be saved in one department could very well be spent by another department. Overall savings are questionable, at best.

Dr. Zimble noted that perhaps using the term "service-connected" instead of "presumptive" might keep the focus on the veteran and avoid issues with the Department of Labor and the Department of Justice.

Dr. Fleming reminded the Board of other populations such as the downwinders, uranium miners and millers and onsite participants, noting these people might flood the Department of Justice with claims if skin cancer is made presumptive.

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Having concluded the day's business, an adjournment was taken until Friday, June 9, 2006 at 9:00 a.m.

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Friday, June 9, 2006

Dr. Zimble reconvened the third meeting of the Veterans' Advisory Board on Dose Reconstruction, observing that the previous day's meeting had been something of an educational session. Today will be a working session with reports from the four subcommittees, assessing recommendations, and then voting on these recommendations.

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Reports of the Subcommittees

Mr. Harold Beck, Chairman
Subcommittee 1 on DTRA Dose Reconstruction Procedures

Mr. Beck began by reviewing the two tasks of subcommittee 1: 1) to

assess the dose reconstruction procedures, and 2) to audit a random sample of NTPR dose reconstructions. He announced that an additional six cases had been chosen for assessment from a stratified random sample to emphasize skin and prostate cancers. Additionally, fairly recent cases were chosen to compare the recent procedural changes of DTRA/NTPR relative to earlier cases. He also noted that Board members were provided draft reports of the initial six audits.

Mr. Beck explained that the audit process being followed was that after the subcommittee analysis of the cases, subcommittee 1 has interviewed the analyst who prepared RDAs of each case to be sure the subcommittee understands his reasoning, methodology and conclusions. This has proved useful to both the subcommittee and the contractor. As a result of such interviews, changes have often been initiated before a subcommittee recommendation was made to the Board.

A number of topics have been discussed in these interview meetings. They include methods for expediting skin dose assessments, uncertainty analysis, uncertainties in assessing skin doses, and a need for NTPR to perform technical analyses to validate or replace interim upper-bound dose uncertainty factors established in 2003.

Mr. Beck announced that the review of the six new cases is not complete, but Board members can expect draft audits within the next month.

The preliminary findings from all 12 cases were outlined by Mr. Beck as follows:.

Finding 1: NTPR is generally providing benefit of the doubt to the veteran in development of the SPARE; however, this is not always done in a consistent manner.

Finding 2: The prime contractor has a great depth of personal knowledge of the issues, an excellent library, and access to background data.

Finding 3: The documentation of dose assessment procedures and consistency of dose reconstruction methodology can be improved.

Finding 4: Case file documentation can be improved, even though improvement was evident from a comparison of the first six cases to the second six.

Finding 5: The RDA memorandum sent to the VA and to the veteran often contains technical information and/or references not available to the veteran.

Finding 6: The Subcommittee recognizes that contractors are developing new templates to perform dose assessments more rapidly for certain veterans.

Finding 7: The Subcommittee audits confirm that skin dose calculations are complicated and the analyses are not consistent. There is a major concern with respect to skin dose uncertainty factors. Some calculations may be wrong, and it is not possible to evaluate the calculations because NTPR has not formalized the methodology. Some doses may be unquantifiable.

Finding 8: NTPR still has not issued a formal technical analysis demonstrating the NTPR upper-bound factors recommended in the NRC report are at the 95th percentile.

Finding 9: The Subcommittee has confirmed that some of the findings of the 2004 report to Congress have yet to be implemented and some have not been addressed.

Finding 10: Though there are inconsistencies in methodology and documentation, in only one case was an error found that might have affected he VA decision on how to adjudicate a veteran's claim. In that case, the error benefited the veteran.

Finding 11: NTPR is not being informed by VA of the outcome of each claim; therefore, no statistical data is available at NTPR to evaluate the percentage of successful non-presumptive claims.

Mr. Beck described future plans for subcommittee 1, including six new cases to be analyzed prior to the November meeting. They will be recent cases and one or two will be from the new NTPR contractor in order to evaluate consistency between contractors. Meetings with analysts will continue. Technical reports will be prepared by NTPR and subcommittee 1 has been asked to review them. Subcommittee 1 will continue assessments of methods, both established and new, especially the SPAREs and templates developed by NTPR.

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Suggested Issues for Discussion by VBDR and Recommendations

1. Outcome of Dose Reconstructions: The 2004 Report to Congress stated VA will break out presumptive and non-presumptive radiation claims information with an indication whether they had been granted or not. There is no indication this has been done as there is no information in the NTPR files regarding resolution of claims for which an RDA was provided to VA. Subcommittee 1 recommends that a procedure be established and implemented to provide case

outcomes to NTPR.

2. Uncertainty Analysis of Beta Dosimetry: The variety of individual situations brings into question the practice of assessing an individual case using uncertainties based on a population. SC1 recommends that NTPR undertake a realistic analysis of uncertainties for all beta dose exposure scenarios.

3. Proposal for Expedited Beta Skin Dose Assessment: When it can be clearly shown the dose is below the level that would result in a successful claim, adopting expedited radiation dose assessment that provides the veteran with maximum benefit of the doubt would be cost effective and scientifically justifiable. SC1 recommends that the VBDR endorse Dr. Blake's proposal to develop an expedited screening procedure for certain dose assessments. The assessment of uncertainties in beta dosimetry must be accomplished first to determine worst case upper bounds to be used in this screening procedure.

4. Screening for Prostate Cancer Claims: The lowest screening dose is 20 rem, which is far greater than that received by almost all participants. SC1 recommends that NTPR develop a screening procedure for prostate cancer cases that would allow expedited processing of those cases for which the doses are well below 20 rem.

Mr. Beck explained that Dr. Blake, as the NTPR representative, does not take positions on the subcommittee's findings. However, he is a valuable member of the subcommittee.

A motion was made and seconded to accept the report of subcommittee 1. There being no objection, the report was accepted.

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Dr. Ronald Blanck, Chairman
Subcommittee 2 on VA Claims Adjudication Procedures

Dr. Blanck stated that the purpose of subcommittee 2 is to provide audits of the procedures and policies used by the VA and the decisions made on claims. Toward that end, 12 cases were reviewed. Dr. Blanck stressed the complexity of the cases, often dealing with multiple diagnoses and varied conditions. The reviews were complicated and time-consuming.

While subcommittee 2 noted some errors and delays in various areas, Dr.

Blanck opined that the complexity of the cases was the cause of most of the delays, amounting to months and even years. He noted that the VHA made timely decisions, once they were provided with the DTRA dose reconstructions.

Dr. Blanck pointed out that the process in place at the VA could be shortened with a centralized claims processing location. This was a recommendation from previous meetings. He emphasized that it takes such a long time to obtain reasonably predictable results for the vast majority of cases, new models should be sought that would shorten the process of making decisions on claims for many of the veterans.

Subcommittee 2 concluded that "service-connection" should be awarded for basal cell skin cancer and melanomas to veterans who are confirmed as participants in nuclear testing or the occupation of Hiroshima and Nagasaki. Detailed reasons for this conclusion are provided in the subcommittee 2 report.

Dr. Blanck reported that subcommittee 2 found conditions which were originally non-presumptive and later became presumptive should be compensated on the basis of the date of initiation of the claim. Again, rationale is provided in the subcommittee 2 report.

The recommendations from subcommittee 2 were outlined by Dr. Blanck as follows:

1. VA should select out radiation issues of claims and centralize those issues to a single site staffed with trained and experienced personnel.

2. VA should establish a centralized database to track radiation issues with both input and output information readily available.

3. VA should automatically place all validated radiation issues claimants into the Ionizing Radiation Registry.

4. Basal cell skin cancer and melanoma, as conditions claimed to be a result of participation in aboveground nuclear tests and occupation of Hiroshima and Nagasaki, should be granted service connection for veterans whose participation in these activities has been verified by DoD.

5. All current and future radiation risk activity conditions held to be presumptively service connected under 38 CFR 3.309 that previously required a reconstructed dose estimate under 38 CFR 3.311 should be awarded service connection retroactive to the date of the initial claim that now requires a reconstructed dose estimate.

Dr. Blanck pointed out that the key recommendations are the last two. He noted that Mr. Pamperin, the VA liaison to subcommittee 2, took no position on the recommendations.

A motion was made and seconded to accept the report of subcommittee 2. There being no objection, the report was accepted.

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Dr. Curt W. Reimann, Chairman
Subcommittee 3 on Quality Management and
VA Process Integration with DTRA NTPR Program

Dr. Reimann, after an introduction covering subcommittee 3's approach, goals and previous activities, listed their observations.

First, the NTPR's overall quality management system is not adequate. Though work on it is proceeding, the draft plan provided to subcommittee 3 focuses on the narrower and partial aspects of the overall plan, and is not a full QA plan.

Second, subcommittee 3 studied subcommittee 1’s audit findings and generally agreed with them, especially with the need for greater consistency in operating procedures. In four of the six cases SC1 noted that there were modifications in the calculated dose. This reflects uncertainty and lack of clarity in procedures.

It is evident that analysts apply the principle of benefit of the doubt in favor of the veteran. However, the lack of consistency in application of this principle when there are so many factors to consider in its application makes quality assurance difficult to conduct in a routine way.

Final SOPs, quality metrics, and quality assessments need to be built upon a clear and efficient case handling strategy.

Referring to earlier remarks by Dr. David Kocher, Dr. Reimann pointed out that whatever approach is adopted to expedite cases, it should ensure that there are no disadvantages to the veteran. He noted that all the steps in the process are high-sided and this reduces errors which would penalize the veteran. However, it is important to ensure that money and time are used to maximum benefit.

Dr. Reimann observed that NTPR is using a metrics report. However, the report deals more with case types and case throughput than specific quality indicators. This fact is important to subcommittee 3 because

in order to make needed improvements, it is important to measure a number of performance dimensions, such as accuracy, response time, and costs. Such quality indicators are important to ensure the work is carried out properly and to indicate the specific processes that need to be improved. With multiple contractors, this issue is more critical than it would be if everything were accomplished by one organization.

Dr. Reimann also stated that subcommittee 3 supports the subcommittee 2 recommendation to direct all radiation-related claims to one VA office. This should improve accuracy, timeliness, and provide a better quality assessment within VA's overall quality assurance program.

Detailed observations are enumerated in the subcommittee 3 report.

Dr. Reimann outlined the following subcommittee 3 recommendations:

1. NTPR should move quickly to complete the QA plan. This is especially important to ensure that each contractors use the same procedures.

2. NTPR should hire a consultant to write a QA plan. The present plan is insufficient. The revised plan should be completed by September 30, 2006.

3. In accord with that QA plan, NTPR should develop a QA implementation plan.

4. The QA plan implementation should be included in the Statement of Work for NTPR Program Support as an evaluation criterion to be used in the Award Fee Plan for the RDA contractor; this will assure continued quality in the RDAs.

5. VA should provide subcommittee 3 a timetable and status of development of the broader QA plan that is to be prepared.

A motion was made and seconded to accept the report of subcommittee 3. There being no objection, the report was accepted.

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Mr. Kenneth Groves, Chairman
Subcommittee 4 on Communication and Outreach

Mr. Groves began by describing the purposes of subcommittee 4, details of which are found in the subcommittee's report. He continued by

updating the Board on their activities since the previous Board meeting, including joining subcommittee 3 in their meeting with the VA. A number of conference calls were made among committee members to discuss issues. Mr. Groves said one of those issues was the location of the next Board meeting, to be held in Hampton, Virginia. They continue to work with support staff in the selection of future meeting sites.

Actions proposed by subcommittee 4 included the following:

1. Meet with other subcommittees to identify issues related to communication that subcommittee 4 can help resolve or improve.

2. Provide a final draft of the brochure prepared by Subcommittee 4 to VA and DTRA to complete with intent of distributing the final product at VA facilities.

3. Complete the list of Frequently Asked Questions (FAQ) for the web site for final review by VBDR.

4. Work with the other subcommittees to ensure consistent messages are sent to the stakeholder community.

5. Analyze the calls made to the VBDR and "hits" on the web site to better understand veteran issues and how to effectively answer their questions.

6. Continue public meetings with stakeholders to assess and collect information needed by VA and NTPR to better serve the veteran community.

7. Identify steps to be taken to improve communications with individual claimants and veterans' groups.

8. Provide VA with a proposed letter to be included with the veteran's claim package that places the process in perspective and helps to establish reasonable expectations relative to processing time and historical results of similar claims.

9. With establishment of a central review office for radiation-related claims, the VA would become the sole source of information exchange with the veteran on these claims.

A detailed listing is provided in the subcommittee 4 report.

Dr. Zimble noted that items 1-8 of the report are essentially internal to the Board and recommended they be accepted without comment by the Board. Without objection, they were accepted.

A motion was made and seconded to accept the report of subcommittee 4. There being no objection, the report was accepted.

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Board Discussion of Subcommittee Reports and Possible Recommendations

Dr. Zimble suggested that the Board move on to vote on the subcommittees' recommendations. He further suggested that the VBDR staff, under the guidance of Dr. Isaf Al-Nabulsi, develop the precise wording of these recommendations.

Following some discussion related to internal Board procedures, each subcommittee's recommendations were considered in turn individually, and the following actions were taken:

Subcommittee 1:

Recommendation 1 was accepted with the understanding that it was to be accomplished by the VA.

Recommendation 2 was accepted following a thorough discussion of cost, scientific specificity and other implications. It was agreed that it would be carefully worded, and Board members would have ample opportunity to provide further comments upon receiving the staff's proposed wording of the recommendation.

Recommendation 3 was accepted following a thorough discussion.

Recommendation 4 was accepted without objection.

Subcommittee 2:

Recommendation 1 was accepted without discussion or objection.

Recommendation 2 was accepted without discussion or objection.

Recommendation 3 was accepted, with comment from Mr. Beck, but without objection.

Recommendation 4 was accepted, noting that it had already been discussed.

Recommendation 5 was accepted with clarification from Dr. Blanck.

Subcommittee 3:

Recommendation 1 was accepted following discussion between Dr. Blake and Dr. Lathrop.

Recommendation 2 was accepted with some clarification recommended by Dr. Lathrop.

Recommendation 3 was accepted without discussion or objection.

Recommendation 4 was accepted, with a comment concerning the possibility of subcommittee 4 having access to the statement of work. Dr. Blake agreed to support that request to the extent possible.

Recommendation 5 was accepted, with comments by Dr. Lathrop.

Subcommittee 4:

After considerable discussion, it was agreed the only recommendations needing acceptance were related to transmitting the final brochure draft to VA and DTRA, and providing a letter to be used by VA in the veterans' claims package. These recommendations were accepted without objection.

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Board Discussion Session

Future Meeting Dates and Invited Speakers:

Dr. Zimble announced that a series of proposed meeting dates had been developed in accordance with availability of Board members taken from their previously submitted calendars. Those dates are March 5-9, 2007; June 11-15, 2007; September 17-21, 2007; and December 3-7, 2007. With a quorum being assured for those dates, they were approved.

At Mr. Groves' request, Dr. Zimble reminded the Board they would next meet on November 8-9, 2006 in Hampton, Virginia. The subcommittees would meet there on November 7.

After discussion, Las Vegas, Nevada was agreed upon as the site for the March, 2007 meeting. Mr. Groves suggested Board members make recommendations for future meeting sites by e-mail.

Mr. Beck recommended the Board consider speakers for future meetings. He observed that some of the guest speakers have presented highly technical information that, while interesting, has not been easily

understood by some of the attendees, as well as some of the Board members.

Dr. Lathrop remarked he has been discussing a speaker to address acceptable risks and societal attitudes toward risk, noting that a talk on this subject might contain less professional jargon than some of the talk in the past.

Dr. Al-Nabulsi announced two speakers she had approached for the November meeting were not available, but might be for future meetings. She indicated that Dr. Henry Royal will speak in November. Other recommendations for speakers included Mr. R. J. Ritter of the National Association of Atomic Veterans, and Mr. Jerry Fisher, who could address RECA and DOJ issues.

* * *

Dr. Zimble addressed the statement of work issue raised earlier in the subcommittee 3 report. Dr. Reimann assured the Board that it had been accomplished. Thus, he suggested that recommendation 4 should be deleted from the subcommittee formal recommendations.

Responding to Mr.Taylor's query about the Board report, Dr. Zimble assured him that the Board activities are continually made known to agency heads and to the House and Senate Veterans Affairs committee.

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Public Comment Period

Veterans gave public testimony indicating they perceived that the Board is recommending elimination of dose reconstruction. They also expressed concerns about possible radiation exposure during ABC training; atomic veterans compensation; advertising to raise attendance at meetings; and difficulty adjudicating claims. They raised issues related to skin cancer, and squamous cell cancer; disabled children of atomic veterans; and correcting service records. VA medical facilities were lauded for excellent care.

Mr. R. J. Ritter discussed the National Association of Atomic Veterans web site and mentioned the large number of visits it gets each month. The Board thanked Mr. Ritter for his assistance.

In addition to Mr. Ritter, others who gave public testimony included **Mr. Carlos R. Contreras**; **Mr. Ray Mullins**, who served aboard the USS Bellegrove during Operation HARDTACK in 1958; **Mr. Herschel McFarland**, who witnessed two atomic blasts in 1946; **Mr. James Piersol**, who served

aboard the USS Curtiss; and **Captain Will K. Brown**, President of the Austin Service Coalition.

A transcript of the public comments in their entirety is available on the VBDR web site at www.vbdr.org.

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Dr. Zimble recognized the VBDR support staff, the audio-visual support, the hotel staff, all the Board members and the atomic veterans.

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With no further business to come before the Board, the meeting was adjourned at 2:27 p.m.

End of Summary Minutes

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

/s/

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James A. Zimble, M.D., Chair
VADM, USN (Ret.)

August 4, 2006

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Date