



Defense Threat Reduction Agency

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AUG 23 2006

James A. Zimble, M.D.
Chairman, Veterans' Advisory Board on Dose Reconstruction
7910 Woodmont Avenue, Suite 400
Bethesda, MD 20814-3095

Dear Dr. Zimble:

Thank you for your letter regarding the recommendations that were approved at the Board's June 2006 meeting. The Defense Threat Reduction Agency (DTRA) concurs with these recommendations, and is taking action to aggressively implement them. Our current plans and how the Board can further assist us are described below.

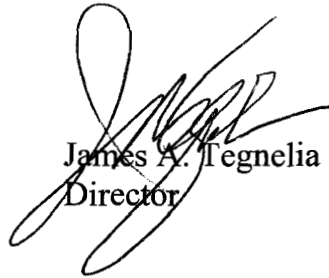
To develop expedited processing procedures for skin cancer cases (Recommendation 1), we are working to publish a DTRA technical report on screening doses calculated with the Interactive Radioepidemiological Program. On the related recommendation that the Nuclear Test Personnel Review (NTPR) Program undertake a comprehensive analysis of uncertainties for all beta dose exposure scenarios (Recommendation 3), another pending technical report on skin doses from dermal contamination will provide the foundation for this analysis. We hope the Board will assist us by providing peer review of these reports. We anticipate staging skin cancer cases for expedited processing as early as November 2006.

In response to the Board's recommendation that the NTPR Program develop screening and expedited processing procedures for prostate cancer cases (Recommendation 2), we initiated work on this recommendation, and are currently staging cases for impending action. We will keep the Board apprised of our progress and plans to begin expediting cases by the end of August 2006.

Concerning the Board's final recommendation (Recommendation 4) to develop and implement a quality assurance (QA) program that can be integrated into current and future contracts involving the dose reconstruction process, hire a consultant to write a QA plan, and develop a comprehensive manual of standard operating procedures (SOP) that addresses the necessary QA elements, the NTPR Program has been developing a comprehensive SOP manual since February 2006, and will ensure that it addresses the appropriate QA elements. Additionally, we have hired a consultant to create a QA plan to meet the needs of the present NTPR support contracts as well as future contract requirements. We anticipate providing the Board with our draft QA plan prior to the next public meeting in November 2006.

On behalf of the Defense Threat Reduction Agency and the NTPR Program, I wish to thank the Board for its hard work and valued assistance.

Sincerely,



James A. Tegnalia
Director

cc:
Under Secretary for Benefits, VA

VBDR

Veterans' Advisory Board on Dose Reconstruction

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July 5, 2006

Dr. James Tegnalia
Director, Defense Threat Reduction Agency
8725 John J. Kingman Rd., Stop 6201
Fort Belvoir, VA 22060-6201

Dear Dr. Tegnalia:

The Veterans' Advisory Board on Dose Reconstruction met in Austin, Texas, on June 8-9, 2006. At that meeting, the Board approved a number of recommendations that, if implemented, should improve the NTPR dose reconstruction process and the VA compensation program for atomic veterans. The Board's findings and recommendations represent its efforts to distill almost twelve months of audits, reviews of NTPR radiation dose assessments and VA claim procedures, and information and testimony presented at VBDR meetings.

I have enclosed the recommendations which have been approved by the Board, along with a suggested brochure for your consideration as a means of distributing essential information to those veterans who participated in the post-World War II occupation of Hiroshima and Nagasaki, or were prisoners of war there, and to service members who took part in atmospheric nuclear tests between 1945 and 1962. The brochure offers answers to questions related to the purpose and process of dose reconstruction, the information required to conduct dose reconstruction, and an explanation of VA claims processing.

Also enclosed are drafts of two model letters, designed to offer reasonable expectations with regard to the length of the process and the historical outcomes of similar claims to those veterans with non-presumptive conditions related to ionizing radiation.

Please contact me if you require any additional information concerning these recommendations.

Very respectfully,



James A. Zimble, M.D.
Vice Admiral, US Navy, Retired
Chairman

Enclosures: 1) Formal VBDR recommendations
2) Model VA brochure
3) Suggested letters to veteran claimants

cc: Ms. Shari Durand (DFO)

VETERANS' ADVISORY BOARD ON DOSE RECONSTRUCTION

RECOMMENDATIONS

On the basis of the Veterans' Advisory Board's (VBDR) audits and assessments of Nuclear Test Personnel Review Program (NTPR) radiation dose assessments (RDAs) and the Department of Veterans Affairs (VA) claim procedures, and facts presented at VBDR meetings, the Board offers a number of recommendations that it believes would, if implemented, improve NTPR dose reconstruction process and the VA compensation program for atomic veterans. The Board's recommendations follow with selected explanatory text from the VBDR deliberations at the June 2006 meeting held in Austin, Texas.

For the Defense Threat Reduction Agency (DTRA):

Recommendation 1: The VBDR recommends that NTPR develop a screening procedure for skin radiation dose assessments that would allow expedited processing of those cases for which the doses are well below or well above the level likely to result in a successful claim. Worst case upper bounds should be used in this screening procedure to provide the veteran the maximum benefit of the doubt.

The Board notes that the National Institute for Occupational Safety and Health (NIOSH) provides an abbreviated RDA when doses are considered either well below or well above the level required for a successful claim. It is not cost-effective for the government to perform detailed RDAs when the dose can be quickly shown to be clearly well below or well above the level that would result in a successful claim. Adopting an abbreviated RDA for these cases, based on a preliminary screening procedure that provides the veteran the maximum benefit of the doubt, will not only be cost effective and scientifically justifiable, but will significantly reduce the backlog of current claims and result in more expedited handling of future claims.

Recommendation 2: The VBDR recommends that NTPR also develop a screening procedure for prostate cancer cases that would allow expedited processing of those cases for which the doses are well below the level likely to result in a successful claim.

The lowest dose likely to result in a favorable outcome for a prostate cancer claim, ~20 rem, is far above the dose received by almost all test participants. Again, adopting an abbreviated RDA, based on a preliminary screening procedure that provides the veteran the maximum benefit of the doubt, will not only be cost effective and scientifically justifiable, but will significantly reduce the backlog of current claims and result in more expedited handling of future claims.

Recommendation 3: The VBDR recommends that NTPR undertake a comprehensive analysis of uncertainties for all beta dose exposure scenarios.

At present, the Board believes that some of the sources of uncertainty in beta dosimetry have not been fully addressed. Examples are non-uniform deposition on skin, manual redistribution of contaminants, differing beta-gamma ratios due to variations in body orientation, the extent of decontamination accomplished by brushing clothes, and efficiency of removal by showering. Upper bound skin doses currently assigned by NTPR dose analysts might or might not exceed the 95th percentile of dose for that individual. It is important to estimate the uncertainties in doses received by particular individuals, as opposed to the uncertainty in the dose to a population. This analysis, besides being necessary to carry out detailed RDAs for those cases that do not qualify for an expedited RDA, will also provide the justification for the worst case upper bound used for screening (see recommendation #1)

Recommendation 4: The VBDR recommends that NTPR hire a consultant to write a quality assurance (QA) plan. The VBDR further recommends that NTPR develop and implement a QA program on a schedule that allows it to be integrated into the contracting process now ongoing, and the development of a comprehensive manual of standard operating procedures (SOPs) that address the necessary QA elements, including metrics.

NTPR's overall quality management system spanning its multiple contractors and addressing SOPs and all key quality requirements is under development. However,

- The draft QA plan, as currently provided to the Board, focuses solely on process control and is not, in fact, a QA plan. A QA plan needs to be integrated from NTPR all the way through the organizational structure to the RDA contractor. A plan should be produced by September 30, 2006, so that it can be reviewed by VBDR prior to its next meeting.
- VBDR's audit findings indicated that SOPs and documentation do not meet overall requirements for a quality management system.
- Although well-defined SOPs are not yet spelled out, it appears that NTPR dose reconstructions apply the principle of *benefit of the doubt* in favor of the veteran. However, application of the *benefit of the doubt* principle needs to be made more consistent, especially with regard to upper bound estimates and ease of quality assessment.
- Final SOPs, quality metrics, quality assessment and NTPR participant responsibilities depend upon case handling strategy. It is not yet clear that an optimum strategy is guiding case handling and SOPs development.

For the Department of Veterans Affairs (VA):

Recommendation 1: The VBDR recommends that VA provide the adjudicated case outcomes to NTPR.

VA and the Department of Defense (DoD) Report to Congress of June 2004 states: “. . . VA will break out the presumptive and non-presumptive radiation claims information with an indication of whether they had been granted or not.” At present, VA does not provide information to NTPR regarding the resolution of claims for which RDA was provided to VA. This information would be useful to NTPR and to the Board in improving the planning and processing of RDAs in a timely and efficient manner.

Recommendation 2: The VBDR recommends that VA grant service connection without regard to dose for those atomic veterans whose basal cell skin cancers and melanomas are claimed to be as a result of participation in aboveground nuclear test and service in Hiroshima and Nagasaki, and whose participation in these activities has been verified by DoD.

Service connection for basal cell skin cancer and melanoma should be afforded to atomic veterans confirmed as participants in atmospheric nuclear tests and service in Hiroshima and Nagasaki for the following compelling reasons:

- The uncertainties in the development of the dose estimates and the probability of causation for these particular cancers are significantly higher than those for other conditions covered by 38 CFR 3.311.
- These cases are 53% (789 cases as of May 1, 2006) of all pending claims for reconstructed dose. The average age of these claims is 708 days and the longest is in excess of 1200 days.
- The current cost associated with the reconstructed dose and claims processing incurred by the government is estimated to be between \$9,000 and \$15,000 per dose estimate.
- The vast majority of these claimants are elderly.
- The costs being incurred by the government when taken together with the level of uncertainty in calculations far exceed the benefit.
- The average compensation benefit payable in these claims is \$1,296 annually.

Recommendation 3: The VBDR recommends that VA centralize claims with radiation issues to a single site staffed with trained and experienced personnel, and that the Veterans Benefits Administration (VBA) should establish a centralized database to track radiation issues with both input and output information readily available. The VBDR further recommends that VA provides the Board with a timetable and status for the development of a QA plan and program, including metrics, in the radiation exposure claims adjudication process.

The Board found many reasons for the delay in the claims process. Many of the claims were complex, with multiple diagnoses which made separating out radiation exposure difficult and time-consuming. In several cases, there were delays in initiating claim development at the VA regional offices (VAROs), and in at least one instance, a claim was sent for dose reconstruction for a presumptive condition, thus delaying the granting of disability. Some delays occurred because of the changes instituted by NTPR, although that does not explain entirely the time it took for dose reconstruction to be done and reported. Notably, the response from the Veterans Health Administration (VHA) concerning eligibility for disability using the probability of causation/assigned share criteria was almost immediate.

The Board also found that the VA claims processing management includes a broadly defined quality indicator system. The indicators are used in quality assessment, training, and improvement. However, claims from atomic veterans related to radiation exposure comprise a very small fraction of VA's overall case load, especially for many of VA regional offices. As a result, difficulties in case handling associated with radiation exposure are not likely to be detected among the far more numerous other claims being tracked by the quality indicator system.

Recommendation 4: The VBDR recommends that VA recognize and automatically place all validated radiation issues claimants into the Ionizing Radiation Registry (IRR).

Many of the atomic veterans, as well as many VARO staff personnel, are unaware of the IRR and the benefits which are available to the registrants. By placing such claimants automatically into the IRR and informing them of the resulting benefits, VA would enhance its service to the veteran.

Recommendation 5: The VBDR recommends that VA award service connection retroactively to the date of the initial claim for all current and future radiation risk activity conditions held to be presumptively service connected under 38 CFR 3.309 which previously required a RDA under 38 CFR 3.311

The Board believes that all current and future presumptive conditions, held to be service connected as a result of exposure to ionizing radiation, should be retroactive to the date of the initial claim. This is an appropriate response in equity and fairness for the following reasons:

- Atomic veterans with presumptive disabilities are currently receiving disparate treatment compared to all other veterans who qualify for service connection under other presumption rules. In all other cases where a veteran has a qualifying presumptive condition at the time the presumption is created and has previously filed a claim, the veteran is entitled to service connection back to the initial claim or one-year prior to the creation of the presumption, whichever is

less. This disparate treatment, without justification, creates an inequity for atomic veterans.

- Requiring a dose reconstruction for the sole purpose of establishing an effective date:
 - is administratively burdensome and costly, and
 - is an artificial distinction not understood by atomic veterans or their survivors, and
 - is inconsistent with the intended purpose of a compensation scheme.

Recommendation 6: The VBDR recommends that VA improve interaction and communication with the atomic veterans. More effective approaches should be established to communicate the general meaning of information on radiation risk. In addition to presenting general information on radiation risk, information should be communicated to claimants about the significance of their doses in relation to their diseases.

VBDR is providing a model informational brochure to VA and DTRA to review, edit, print and distribute to atomic veterans. The objectives of the brochure are to provide atomic veterans, who participated in the post-World War II occupation of Hiroshima and Nagasaki, Japan, or were prisoners of war there, or a service member who took part in atmospheric nuclear tests between 1945 and 1962 in the United States, with answers to questions related to the purpose of dose reconstruction, how radiation doses are reconstructed, information used to conduct dose reconstructions, and how the VA processes claims.

Specific topics discussed in the brochure include:

- dose reconstruction,
- presumptive conditions,
- probability of causation, and
- compensation regulations.

VBDR is also providing VA with two model letters to be used in the claims process associated with the non-presumptive conditions. The letters are designed to set reasonable expectations with regard to the length of the process and the historical outcomes of similar claims.