

**SEC Petition Evaluation Report Supplement
SEC Petition SEC-00020**

Report Rev # 0

Supplement Submittal Date: 01-18-2006

Petition Administrative Summary											
Petition Under Evaluation											
Petition #		Petition Type		Submittal Date			DOE/AWE Facility Name				
SEC-00020		83.13		01-03-2005			Pacific Proving Ground (PPG)				
Feasible to Estimate Doses with Sufficient Accuracy?											
Single Class				Multiple Classes				Determination Established for All Classes			
Yes		No	X	Yes		No		Yes	X	No	

Initial Class Definition
All scientists and scientific couriers employed at Enewetak Atoll during Operation HARDTACK I, from July 1, 1958 through August 31, 1958.

Proposed Class Definition
All employees of DOE, DOE contractors, or subcontractors employed at the PPG from 1946 through 1962 who were monitored or should have been monitored for exposure to ionizing radiation as a result of nuclear weapons testing at the PPG.

Related Petition Summary Information			
SEC Petition Tracking #(s)	Petition Type	DOE/AWE Facility Name	Petition Status
None			

Related Evaluation Report Information	
Report Title	DOE/AWE Facility Name
None	

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SEC-0020, Pacific Proving Ground Supplement to SEC Evaluation Report

Discussion of comments received from the Defense Threat Reduction Agency

In a letter dated December 22, 2005, the Defense Threat Reduction Agency (DTRA) provided comments to NIOSH on Special Exposure Cohort (SEC) Petition Evaluation Report-0020. The proposed class definition for this petition included all Department of Energy (DOE) employees and DOE contractors or subcontractors employed at the Pacific Proving Ground (PPG) from 1946 through 1962¹. In their letter, DTRA expressed concern that NIOSH's decision to add this class of workers to the SEC was based on "serious misconceptions" about the operating status of the Nuclear Test Personnel Review (NTPR) program which DTRA administers under the Department of Defense (DOD). In addition, DTRA expressed concern that NIOSH's SEC Petition Evaluation Report-0020 contained "several misrepresentations" of a National Research Council (NRC) report that presented the results of a Congressionally mandated review of the NTPR program (NRC 2003). A copy of the letter is provided in Attachment A.

The "serious misconceptions" that NIOSH has of the operating status of the NTPR program are believed by DTRA to unfairly cast doubt on the credibility of the NTPR's dose reconstruction process and also might errantly influence NIOSH's conclusion that internal doses for the defined class could not be estimated with sufficient accuracy. NIOSH regrets any negative inference to the credibility of the DTRA program that might be implicitly drawn from this conclusion. SEC Petition Evaluation Report-0020 was not intended to cast doubt on the integrity of the DTRA process for reconstructing doses under the framework of their governing regulations. Rather, it was written solely for the purpose of deciding if NIOSH could reconstruct doses to civilian participants employed at the Pacific Proving Ground (PPG) in accordance with EEOICPA and with sufficient accuracy as specified in the requirements of NIOSH's governing regulation. As indicated in SEC Petition Evaluation Report-0020, the procedures governing this decision are outlined in 42 C.F.R. pt. 83, which states in part that a dose reconstruction can be estimated with sufficient accuracy if:

NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class...

As described in SEC Petition Evaluation Report-0020, NIOSH's judgment was that it could not estimate the maximum internal radiation dose for every type of cancer that

¹ To ensure that only those participants who were actually exposed to radiation are covered under this class, NIOSH has modified the definition to read: *All employees of DOE, DOE contractors, or subcontractors employed at the PPG from 1946 through 1962 who were monitored or should have been monitored for exposure to ionizing radiation (see discussion below).*

could have been incurred by civilian employees at the PPG. This conclusion was reached after a careful evaluation of the available monitoring data and a comparison of these data against the dose reconstruction process outlined in the dose reconstruction regulation, 42 C.F.R. pt. 82. The rule describes a hierarchical approach to the use of existing data sources to reconstruct doses. These are, in order of decreasing preference: individual monitoring data; 2) area monitoring data; and 3) process and source-term information. As indicated in the evaluation report, NIOSH did not find bioassay data suitable for reconstructing internal doses to civilian employees at the PPG. Further, there were insufficient sources of air monitoring data to put credible upper bounds on the internal doses experienced by this class of workers.

Given that individual bioassay and area monitoring data were determined to be inadequate, NIOSH reviewed the source-term technique that DTRA employs to reconstruct internal doses for claimants under the NTPR program. This review was conducted with the intent of determining the applicability of this technique to dose reconstructions under the EEOICPA. After an on-site visit with DTRA contractor personnel, and the review of several example dose reconstructions, NIOSH learned that internal doses reconstructed under the NTPR program were based on a computer model that relates a measured external dose to an intake of radioactive material². This is, in effect, a source-term model in which a measured external dose is used to estimate the activity and composition of the radioactive material deposited in the vicinity of the test participant. Once the activity and the composition of the material in the air or on the ground are estimated, the inhalation intake can be estimated by applying appropriate factors. The individual's fifty year committed internal dose is then estimated using the methodology contained in ICRP publication 30.

While this model appears to be based on reasonable scientific principles, a number of the factors used in this model were brought into question during the NRC review of DTRA's methodology. One of the most significant issues raised in the NRC review was that the:

Sources and uncertainty in the methods of estimating radionuclide concentrations in deposited fallout based on measured external photon exposures have not been evaluated, and reliability of methods is not known.

Although the case is made by DTRA that the NRC report concluded that the uncertainties associated with this method are likely to have the greatest impact on participants at the Nevada Test Site, the report does not suggest that this uncertainty be ignored for participants at the Pacific Proving Ground.

In SEC Petition Evaluation Report-0020, NIOSH chose to highlight the issues identified by the NRC that tended to result in potential underestimates of the internal dose to individuals. Although SEC Petition Evaluation Report-0020 acknowledged that there were also a number of issues identified in the NRC report that could potentially result in

² Although DTRA's letter indicated that some bioassay and air monitoring are known to exist, NIOSH was informed by DTRA contractor personnel that all internal doses under the NTPR program are estimated using algorithms that relate the external dose to internal dose.

overestimates of the internal dose, they were not specifically identified in the report. NIOSH's SEC regulation, 42 C.F.R. pt. 83, requires that it evaluate the ability to estimate the maximum radiation dose for each type of cancer under plausible conditions. Because the NRC report provided little or no quantitative judgment regarding the relative magnitude of the countervailing effects of the factors that either underestimated or overestimated doses, NIOSH did not believe it important to specifically cite every issue raised by the NRC. While it might be the case that these effects have a tendency to compensate for each other, NIOSH has no quantitative ability to determine this at this time. As stated in DTRA's letter to NIOSH:

It is important to note that the NRC committee did not question the ability to establish credible upper bounds, but rather the credibility of the upper bounds that were being estimated at the time of the review.

Until such time as DTRA completes the research necessary to address the magnitude of the effect for each issue, NIOSH does not believe that it can independently establish the magnitude of the maximum internal dose to each organ that develops cancer under plausible conditions.

At the time the SEC evaluation report was written, NIOSH was unaware that DTRA established interim guidelines for processing of dose reconstructions while the issues raised by NRC are researched. These interim guidelines, which were published in letter format on July 16, 2003, contain the following (excerpted in part) direction from DTRA to their dose reconstruction contractor:

The following rules of thumb should be applied to upper bound results:

- *apply a factor of 10 times to the internal dose estimate for scenarios not identified in the NAS/NRC report as highly uncertain*
- *refer internal dose upper bound estimates for highly uncertain scenarios to an independent contractor chosen by DTRA*

These rules of thumb, based on our review of the results in the NAS/NRC report, are intended to facilitate the processing of VA claims while ensuring upper bound estimates are not underestimated.

NIOSH has not seen any scientific evaluation of the "rules of thumb" put in place by DTRA for reconstructing internal dose. While these guidelines may be appropriate for making compensation decisions under the NTPR program, NIOSH can not utilize guidelines that call for increasing internal doses by a factor of 10, without a detailed justification of the scientific basis, which would constitute sufficient accuracy under the NIOSH SEC regulation. Under EEOICPA, the establishment of a credible upper bound is critical because the decision for compensation is based on a Monte Carlo analysis of the distribution of probabilities of causation (PC). The law requires that, of the distribution of possible PCs, the 99th percentile be used to determine if the worker's cancer was "at least as likely as not" caused by his/her exposure. As such, any upper

bound dose selected for input to the Interactive Radioepidemiology Program (IREP) will directly affect the PC at the 99th percentile.

Based on the above discussion, NIOSH continues to support its position that internal doses for civilian employees at the PPG can not be reconstructed at this time with sufficient accuracy under the requirements established by the EEOICPA and evaluated under 42 C.F.R. pt. 83.

Change in proposed class definition

The proposed class definition currently contained in SEC Petition Evaluation Report-0020 covers all employees of DOE, DOE contractors or subcontractors employed at the PPG from 1946 through 1962. After some discussion with Department of Labor representatives, and internal deliberation within the Office of Compensation Analysis and Support, NIOSH now believes that this definition is too broad in that it potentially includes civilians who worked on activities at the PPG, but were not necessarily present in the vicinity of radiation and/or contamination generated by a nuclear test. Because of this, NIOSH has modified the proposed class definition to read:

All employees of DOE, DOE contractors or subcontractors employed at the PPG from 1946 through 1962 who were monitored or should have been monitored for exposure to ionizing radiation as a result of nuclear weapons testing at the PPG.

Reference

NRC 2003

National Research Council, "A Review of the Dose Reconstruction Program of the Defense Threat Reduction Agency" 2003

ATTACHMENT A

Letter from Paul Blake to James Neton, dated December 22, 2005