

Attachment 4

Response to Concerns Raised in the Memorandum Dated February 13, 2004

1. The safety concerns identified in the NRC's Revised Draft Safety Evaluation Report (RDSER), including inconsistencies with other limits and frequent changes, have not been addressed.

This question was addressed by the Reference 1 policy review on this issue and by the Reference 2 majority staff position. Following is an excerpt from Reference 1.

"The original intention of the TEEL was to provide temporary guidance until ERPG or AEGL values can be developed. However, there are a number of chemicals for which a TEEL value, ERPG value, and an AEGL (or interim AEGL value) exists. Review indicates that when both values exist, the TEEL value and the ERPG value are identical. During the FCSS review process since the initial MOX application, several additional ERPG values have been put in place, and the TEEL value had be adjusted to match the ERPG value. For several of the chemicals of interest in the MOX application, this has resulted in larger concentration values for one or more of the consequence levels. The TEEL values have undergone several revisions since the beginning of the review period. Although not "peer reviewed" in the consensus standard definition of the term, the review and revision of TEEL values is a structured formulaic derivation process involving a large group of experts drawn from across the DOE complex."

2. Normal NRC procedures for changing established NRC practice for multiple facilities (e.g., staff interactions and rulemaking) were not followed in management acceptance of the use of TEELS. Specifically, management relied on the view of a single individual, who is not an expert on chemical toxicology and consequence limits.

As stated in Reference 1, the Division of Fuel Cycle Safety and Safeguards (FCSS) requested an independent policy review of the use of TEELS for the Mixed Oxide Fabrication Facility (MOX). This review was conducted to provide an independent perspective of the background material developed by the FCSS chemical safety staff, and the relative merits of positions which FCSS could take in the review of the application for MFFF construction authorization request. The individual who performed this review, while not an expert in chemical consequence analysis, is an expert on applying similar standards for radiation protection and radiological consequence analysis.

3. TEELs are, by definition, temporary and do not incorporate safety margins that are usually included in other chemical exposure limits.

This question was addressed by the Reference 1 review, which states:

"In general, it would appear that the ERPG/TEEL values tend to be higher values when multiple guidance documents exist. This could be due to a more recent reflection of available data, since the ERPG/TEEL values are subject to more periodic revisions. It may also be the result of differences in the underlying methodology and approach used to derive the values. The actual rationale for specific changes is not available. As

with any situation, there is a body of scientific evidence that is subject to data availability, interpretation, uncertainty, and debate. The establishment of values for acute exposure effects from chemicals is no exception. This results in a range of values, some of which may have more conservatism and margin built into their derivation."

4. TEELs also do not have clear linkage to toxicological effects, and were established for emergency preparedness—not design bases for safety controls.

Reference 3 describes how the TEELs are developed using a methodology that is based on the results of statistical analyses of existing ERPGs and human-equivalent concentrations calculated from toxicity parameters. Reference 3 also states that the exposure limits are required for emergency planning, for the performance of hazard assessments, and for safety analysis.

5. There is insufficient rationale to accept chemical concentration levels that are higher than other consequence levels from other agencies.

This issue is discussed in Reference 1. The reason for developing TEELs is to provide a temporary limit when there aren't well established standards developed by other agencies. As stated in the independent analysis, TEEL values are identical to ERPG values where they both exist. In addition, a comparison was made between immediately dangerous to life and health (IDLH) values and TEEL values. In some cases IDLH values are less than the TEEL 3 values, while in other cases they are greater than the TEEL 3 level. There were two instances where IDLH is lower than TEEL3 for chemicals used at the MFFF; chlorine is a factor of 2 different, and nitric acid is a factor of between 3 and 4 different. The independent analysis describes why there is a difference between the TEEL value and the IDLH value for nitric acid, as follows:

The ERPG was established for nitric acid in 2001, and the TEEL 3 value was correspondingly adjusted in revision 18 of the TEELs. The ERPG sheet for nitric acid⁸ cites several animal and human studies to support a 78 ppm TEEL 3 value, including LC₅₀ animal data and human data from accidental silage gas poisoning. The IDLH value for nitric acid was revised from 100 ppm to 25 ppm in 1997. According to the data sheet for nitric acid IDLH⁸:

"The revised IDLH for nitric acid is 25 ppm based on acute toxicity data in humans [Gekkan 1980] and animals [Diggle and Gage 1954]. This may be a conservative value due to the lack of relevant acute inhalation toxicity data for workers."

There do not appear to be any recent references or studies that were used to support the reduction of the IDLH. Thus, the differences between the IDLH value and the ERPG value may be seen as a measure of conservatism used in the derivation.

6. The NRC staff have been directed not to review latency effects even though the applicants Construction Authorization Request and the MFFF SRP both mention latency effects.

The applicants revised Construction Authorization Request (in section 8.4.2) states that latency impacts would be addressed in the possession and use license application. The Standard Review Plan (SRP) states that the applicant's consequence analysis, which is encompassed by the ISA, should evaluate latent impacts. The SRP (Section 5.5.1) explicitly states that the possession and use license application should address the ISA. The lead chemical safety reviewer proposed adding a section on latent impacts to the draft SER less than 3 weeks before the draft SER was scheduled to be issued. The section was removed based on OGC's recommendation because it was contrary to the SRP.

References:

1. **Policy Review for Chemical Consequence Criteria, Dr. Donald Cool. September 29, 2003.**
2. **Memorandum to Joseph G. Giitter from Brian Smith, Safety Evaluation and Staff Positions on the Closure of Remaining Chemical Safety Open Item CS-5b Pertaining to the Applicants Use of Temporary Exposure Limits. November 25, 2003.**
2. **The Methodology for Deriving Temporary Emergency Exposure Limits (TEELS), Douglas K. Craig and C. Ray Lux, Westinghouse Safety Management Solutions**