
Attachment 1



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 25, 2003

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MEMORANDUM TO: Joseph G. Glitter, Chief
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

FROM: Brian Smith, Chief
Special Projects Section
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards, NMSS

A handwritten signature in black ink, appearing to be "BS", is written over the name "Brian Smith" in the "FROM:" field.

SUBJECT: SAFETY EVALUATION AND STAFF POSITIONS ON THE CLOSURE
OF REMAINING CHEMICAL SAFETY OPEN ITEM CS-5b PERTAINING
TO THE APPLICANT'S USE OF TEMPORARY EMERGENCY
EXPOSURE LIMITS

The purpose of this memorandum is to communicate the views of the staff on chemical safety open item CS-5b, regarding the use of Temporary Emergency Exposure Limits (TEELs) where Emergency Response Planning Guides (ERPGs) and Acute Exposure Guideline Levels (AEGs) are not available. This open item was documented in the April 30, 2003, Draft Safety Evaluation Report (DSER) for the Mixed Oxide Fuel Fabrication Facility (MFFF).

Since April 2003, staff have conducted several in-office reviews at DCS facilities and held many open meetings with DCS to discuss and resolve the open items. Additional information that the staff have considered in its review include DCS presentations and written commitments at open meetings, letters, phone call summaries, and page changes to the revised CAR.

The Attachment to this memorandum provides the staff's safety evaluation of the applicant's proposal to use TEELs. A consensus staff position is presented as "Staff Position 1 - Acceptable", which supports closure of the item. A dissenting view from the Lead Chemical Safety Reviewer, "Staff Position 2 - Unacceptable", is also presented.

I recommend including the consensus staff position as the staff's position in the Final Safety Evaluation Report.

Attachment: Staff Evaluation of Applicant's Proposal to Use TEELs (CS-5b)

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Use of TEELs when ERPGs and AEGLs are not available (Open Item CS-5b)

Background

The Division of Fuel Cycle Safety and Safeguards (FCSS) requested an independent policy review of selection of chemical consequence criteria for use in the designation of high, intermediate, and low consequence events at 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 construction. Background materials included the Standard Review Plan for Fuel Cycle Facilities, draft Safety Evaluation Report, and various references related to development of industry standards.¹ The question posed by FCSS is the appropriate values to be used in designating high and intermediate consequence concentrations. A tremendous amount of work has gone into the analysis and identification of concerns, and the efforts are to be commended.

The question of acceptable methods for designating chemical consequence criteria is addressed in NUREG-1520, Fuel Cycle Facility Standard Review Plan, Chapter 6, Chemical Process Safety. The standard review plan for the MOX facility indicates that Emergency Response Planning Guidelines (ERPG) values and Acute Exposure Guidance Levels (AEGL) are recognized acceptable values for consideration. Temporary Emergency Exposure Limits (TEEL) are not identified in the SRP. However, there are some chemicals that will be used in the MOX facility for which neither an ERPG or AEGL is available. Hence the question of appropriate values.

Applicants are to demonstrate that they meet the criteria of § 70.61 for Performance Requirements. For chemical safety, applicants are to designate and limit the risk of credible high consequence events and intermediate consequence events as defined in §70.61(b) and §70.61(c), respectively.

The applicant has proposed the use of the TEEL² values for low, intermediate, and high consequence concentrations of chemicals. The TEEL values would be used to designate systems and components for which additional protection and controls are needed. This methodology is used by the Department of Energy for chemical hazard criteria, particularly in situations where other criteria, such as ERPG or AEGL values are not available. The applicant has proposed that the risk must be reduced if the chemical concentration from a intermediate consequence event exceeds the TEEL 2 level. Thus, TEEL 2 is the lower boundary for action. TEEL 3, in a corresponding way, forms the lower boundary for high consequence events, and would require further actions, above those proposed for TEEL 2 levels, to reduce the risk.

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FCSS, in the draft Safety Evaluation Report, Revision 1, dated April 30, 2003, reached the following position:

"The values proposed by the applicant are temporary limits are not from a regulatory based and revised document, not based on a peer-review process, and have high numerical values as compared to other standards. Thus, they do not provide adequate margin and conservatism for assessing chemical risks and identifying PSSCs to meet the performance requirements of 10 CFR 70.61. Therefore, the NRC does not find the applicants proposed values in Table 8-11 acceptable. These concerns about consequence levels are identifies as part of Open Item CS-5b."

FCSS has indicated that the primary concern is the applicant's proposal for the high consequence level. There is a greater degree of agreement with the values at the intermediate and low consequence level. Staff has suggested a possible algorithm for selecting among different values, including AEGL's, ERPG's, TEEL's and other indices in order to specify the concentrations for high and intermediate consequence. This algorithm would effectively select the minimum concentration value from among a variety of possible sources, some of which are based on acute effects, and some of which also include consideration of long-term carcinogenic effects.

Staff Review and Observations

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 has 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.

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.

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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.

To understand the potential for a substantial safety concern if the TEEL methodology is used, a comparison has been made with the concentrations considered to be immediately dangerous to life and health (IDLH). In every case reviewed, the IDLH is greater than the TEEL 2 value. Thus events would be identified as at least of intermediate consequence at concentrations less than that considered to be IDLH. In some cases IDLH values are less than the TEEL 3 values, while in other cases they are greater than the TEEL 3 level. In the two cases where IDLH is lower than TEEL3, chlorine is a factor of 2 different, and nitric acid is a factor of between 3 and 4 different. Thus it would appear that the only value of potential concern would be the TEEL3 value for nitric acid.

Nitric acid is unique in that the difference between TEEL 2 and TEEL 3 is more than an order of magnitude, an unusually large difference. 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 acid³ 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 IDLH⁴:

"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.

Staff Positions

Staff Position 1

In a risk informed and performance based regulatory approach, it is not necessarily appropriate to derive a process whereby all of the values are the most conservative of the possible range of outcomes available. Likewise, it may not be appropriate to select values which are the least conservative. The standard review plan indicates that ERPG values are one of the recognized acceptable values for consideration. Thus it would be reasonable to accept these values as a consistent methodological system for specifying

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high consequence and intermediate consequence levels. Given the derivation approach used for TEELs, it also appears reasonable to accept TEELs when ERPG values do not exist.

NRC would be on generally less firm ground to pick and choose between different sets of numbers on the basis of desired conservatism or margin.

Selection of values from different methodologies would appear to result in an inconsistent basis for regulatory action, and one which would not promote regulatory stability or clear understanding and communication. The FCSS proposal for an algorithm to select each chemical based upon the most conservative values available would constitute creation of a government specific standard when industry standards exist, and would be subject to the same criticisms of not having a regulatory basis and not being based on a peer-review process. Unless there is a safety concern, the preferred approach would be for a consistent methodology. This review has not identified a safety concern, given the degree of variance between values, and the stated conservative nature of the key chemical in question. Further, no rationale has been presented for invalidating the previously published staff determination that ERPG values were an acceptable approach.

From a policy perspective, the use of the TEEL values, as proposed by the applicant, would appear to be a reasonable and consistent approach which provides for adequate protection of worker and public health and safety. This methodology will result in consistent designation of systems and components at levels for workers below that considered to be immediately dangerous to health and safety. While it is true that lower numbers could be advocated, this would not appear to be necessary to protect health and safety, and would lead to incoherence in the basis for staff decisions. The use of the TEEL values is therefore recommended. The alternative of specifying the IDLH as the high consequence definition for nitric acid, based on the difference between TEEL3 and IDLH, is not considered necessary to protect safety because of the stated conservative nature of the IDLH value.

It would be appropriate for the version and date of the TEEL values to be specified as part of the application, given the frequency with which chemical consequence criteria are revised. The applicant may wish to request a change to the application to reflect the revisions that have taken place since the original application.

References

1. Memo from Andrew Persinko to Donald Cool, June 23, 2003, with attachments.
2. Derivation of Temporary Emergency Exposure Limits (TEEL). Journal of Applied Toxicology, 20. 11-20 (2000).

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3. Emergency Response Planning Guidelines for Nitric Acid, 2001, AIHA Press.

4. www.cdc.gov/niosh/idlh/7697372.html

Staff Position 2 - Lead Chemical Safety Reviewer - Unacceptable

Concerns about the adequacy of the applicant's proposed use of TEELs as the chemical concentration limits come from three areas: the revised Draft Safety Evaluation Report (RDSER), the procedure used to accept TEELs, and safety issues.

Fundamentally, concerns about TEELs expressed in the RDSER have not been addressed. TEELs are not independently peer and public reviewed, and based upon clear toxicological data. The values are selected by DOE-SCAPA, a committee with DOE and DOE contractor personnel. Other peers (e.g., the NAS, universities) and the public are not involved. TEELs are by definition temporary and, per DOE-SCAPA, are not to be used in place of regulator values. TEELs are numerically equivalent to ERPGs when those values exist. ERPGs are supported by an industrial organization and generally do not involve other peers and the public. TEELs are not endorsed nor used by regulatory agencies that regulate chemicals, such as OSHA, OSHA/NIOSH, and the EPA. Often, numerical manipulations are used to define values that result in some inconsistencies, such as some chemicals having identical numerical values, some with significant spreads in the data (particularly for TEEL-2 to TEEL-3 limits), and some hazard inconsistencies (e.g., for NO₂ and N₂O₄, and the hydrazines). As noted in the RDSER, TEEL-3 limits for nitric acid, hydrazine hydrate, and N₂O₄, three important chemicals at MOX, have varied by more than 50% over the preceding two years of the review.

The potential acceptance of TEELs raises several procedural issues. The acceptance is based upon a policy decision by management, using a single senior level advisor. No committee was involved. Interactions with the staff were minimal and prior staff evaluations and concerns of TEELs going back ten years were not considered. Other regulators were not consulted and a public process (e.g., affecting several facilities) was not followed.

Chemical consequence (exposure) limits are used to define the high and intermediate consequence levels for events with chemical effects. Thus, selection of values directly impacts the potential controls for events. The use of significantly higher values may overlook the need for controls and/or reduce the affected area (the footprint of the plume). Hence, if higher values are proposed, there needs to be a clear rationale for their acceptance. Such a rationale has not been presented.

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