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August 11, 2006

C. William Reamer, Esq., Director
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: DOE's Misuse of Expert Elicitation in the Yucca Mountain Licensing Process

Dear Mr. Reamer,

Now that the U.S. Department of Energy ("DOE") has announced that an application for a construction authorization for its proposed geologic repository at Yucca Mountain, Nevada, will not be filed until mid-2008, at the earliest, and that a "design" for the application is not even developed, it may be inferred that DOE's earlier efforts to perform an adequate safety evaluation and to draft a suitable application were unsuccessful, and that major portions of the draft application are now being redone. Given this substantial delay, and DOE's apparent recognition that much of its prior work must be redone, the time is ripe for the NRC to address some outstanding critical issues that will affect DOE's schedule and ongoing efforts. One important issue, addressed by this letter, is the relation between expert elicitation and quality assurance ("QA"). As explained below, it appears that DOE has taken advantage of ambiguities in current NRC guidance and engaged in a program to "launder" unqualified safety data through expert elicitations so that elicitation results are considered QA-qualified even though most or all of the data used by the experts were not qualified. Nevada requests NRC to advise DOE that this practice is not acceptable.

The problem may be traced to Revision 8 of DOE's "Quality Assurance Requirements and Description," or "QARD," developed by DOE in 1998. This revision (the eighth of over fifteen DOE revisions of the QARD spanning more than two decades) added new provisions (a new section C.2) for conducting expert elicitations that, among other things, purported to take account of NRC Staff guidance in NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." The new provisions, which were acknowledged to reflect a reduction in commitments to the NRC, allowed DOE to supply elicitation experts with unqualified

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data and software. DOE explained that, “the scope of expert elicitation is to consider all relevant data and interpretations, not just those collected or developed under a Quality Assurance Program.” Moreover, “[m]uch of the existing data to be used may have been developed using software that was not controlled under a Quality Assurance Program.” However, according to DOE, this did not pose any problem since the experts “are expected to provide their own judgments concerning the merits of the data sets and to decide what data to use.” Also, “the expert elicitation process is roughly equivalent to a peer review and provides a method for the qualification of the results.” *See* NRC000006768.

This last suggestion, that an expert elicitation can somehow be used to produce qualified data from unqualified data, purported to rely on NRC Staff guidance in NUREG-1298, “Qualification of Existing Data for High-Level Nuclear Waste Repositories.” NUREG-1298 suggests that unqualified data may be qualified by a peer review of the data consisting of a “documented, critical review performed by peers who are independent of the work being reviewed.” The peer review must include “an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and adequacy of work.” DOE apparently recognized, however, that its QARD revision was not in accord with this NRC guidance. Rather than assert that its new expert elicitation procedures satisfied the data qualification (peer review) requirements in NUREG-1298, DOE claimed instead that its new procedures were “roughly equivalent” of what NRC had recommended.

Accordingly, DOE has assumed that its expert elicitation results will always be qualified regardless of whether the data or software relied upon by the experts was qualified or unqualified. *See, e.g.*, DEN000769556 (“output data and conclusions resulting from an expert elicitation process are considered qualified.... [t]he qualification status of the input data (relative to our QA program) doesn’t matter”); DEN001189221 (“you do not TBV [to be verified] data that is from expert elicitation...since it is considered qualified if from EE (I don’t understand what you mean since you cannot have unqualified data from EE!”).

DOE’s training and internal guidance on expert elicitation was consistent with QARD Revision 8. *See, e.g.*, DEN001140155 (“[s]oftware, and unqualified data may be used in the expert elicitation process. The results of the expert elicitation process are considered qualified.”).

Not surprisingly, the infection of unqualified data from expert elicitation therefore spread easily throughout DOE’s performance assessment since there apparently was no requirement to “TBV” data in an Analyses and Model Report (“AMR”) if the data were taken from another AMR. *See* DEN001189221. So, once unqualified data was “laundered” through an expert elicitation and used (in the form of quantitative elicitation

results) in an AMR, the data (elicitation results) proliferated throughout the performance assessment with no marking or tagging to suggest any qualification problem.

Not only was Revision 8 of the QARD a reduction in commitments to the NRC, and inconsistent with NRC guidance, but it was also apparently adopted by DOE management over the objections of its own QA organization. An internal DOE memo objected that an expert elicitation was not the same as a peer review of data, and it stated that, "it is our position that the results of any expert elicitation be considered unqualified until interpretations and associated data undergo a peer review." See DEN000745598.

In 2004, Revision 17 of the QARD was adopted, superseding prior revisions. See NRC000027264. Revision 17 was a complete rewrite of the QARD. Revision 17 provides simply that "expert elicitation shall be conducted in accordance with the requirements and recommendations of NUREG-1563," and Supplement III.2.4 of Revision 17 appears to require that data be qualified. There is no indication that expert elicitation results are deemed qualified, but neither is there any indication that such results are not deemed qualified, and none of the accompanying justification documents specifically address the expert elicitation QA issue. However, it appears that DOE's implementing procedure AP-AC.1Q, "Expert Elicitation Procedure," is still in effect, and this procedure specifically calls for DOE to "[p]rovide the expert panel with background data, including qualified and unqualified data...." Thus, despite the QARD revision, the "data laundering" practice apparently continues.

NUREG-1563 carefully distinguishes between expert elicitation and peer review. See NUREG-1563 at pp. 5, A-1, E-1 ("language in [DOE's] *Principles and Guidelines*, in many places, appears to confuse the concepts of 'expert judgment,' expert elicitation,' and 'peer review,' concepts that, in the Staff's judgment, are distinct."). NUREG-1563 also carefully states, "external *peer reviews* may be used as a part of the QA actions necessary to provide confidence in the data submitted." NUREG-1563 at p. 12 (emphasis added). This is consistent with NUREG-1298, and clearly implies that expert elicitation, as distinguished from peer review, cannot be used to add confidence in results that rely on unqualified data or to qualify unqualified data. On the other hand, NUREG-1563 also states that information sponsors supply to the elicitation team should be "all-inclusive." NUREG-1563 at p. 26. This suggests that both qualified and unqualified data are to be used. Thus, DOE apparently took advantage of ambiguities in NRC Staff guidance to develop its position.

The distinction between qualifying unqualified data by a peer review of the data, and "laundering" unqualified data through an elicitation process, is critically important. DOE's argument that its expert elicitation procedures were "roughly equivalent" to a peer review of the data hid a key defect. NRC's guidance on expert elicitation (NUREG-1563) does not recommend that the experts devote any special attention to the qualification status of the data supplied to them by the elicitation sponsor (DOE). Thus, critical elements of a peer review focused specifically on data qualification may be entirely missing from the expert elicitation. As a result, the elicitation results may suffer from the "garbage in, garbage out" syndrome. For example, DOE claimed that the results

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of the 1995 Probabilistic Volcanic Hazard Analysis ("PVHA") for Yucca Mountain, arrived at through an expert elicitation process, were fully qualified simply because they were determined through an expert elicitation, even though the elicitation used various data sets regardless of their qualification. *See* NRC000025931 at section 4.3.1.9. In fact, the PVHA elicitation report states (at Appendix H) that, "it is unnecessary to discriminate between qualified and unqualified data in this report." *See* NRC000023427. Further, although DOE took some efforts to distinguish between elicitation results (deemed qualified) and the data supplied to the elicitation experts (not qualified just because of the elicitation), *see* DEN001140155, this distinction was easily forgotten or misunderstood and was meaningless in any event. *See* DEN000427163 (a "Data Qualification Report" indicating that unqualified data on water chemistry had been "qualified under process validation and engineering (PVAR) procedure or expert elicitation. No data verification required.").

Nevada requests NRC to inform DOE now that its "data laundering" practice is wholly unacceptable. NRC must clarify to DOE that the results of an expert elicitation are not suitable to support safety conclusions in the license application unless the data used and relied on by the experts were generated under a compliant QA program or the data were qualified by some other suitable means, for example by a careful and focused peer review of the data that, among other things, examined traceability, instrument calibration, qualifications of investigators, and reliability. The results of an expert elicitation should not be deemed qualified just because the elicitation was conducted in accordance with the QARD and NUREG-1563. Nevada does not object to elicitation experts considering and relying on a broad range of data of intrinsic reliability, such as generally accepted scientific facts and facts from peer-reviewed scientific journals (not so-called "gray literature"). Nevada supports the concept that experts should consider a wide range of relevant and reliable data, not just data generated specifically in the Yucca Mountain Project. However, in recognition of the "garbage in, garbage out" syndrome, an elicitation should not rely on unqualified and unreliable data.

This issue is especially critical now that DOE's new PVHA expert elicitation is progressing. Nevada believes that NRC Staff may support its view of the "data laundering" matter because it has advised DOE with regard to the new PVHA that "[i]f the requested data was generated within the Yucca Mountain Project, however, the NRC Staff expects that all applicable DOE Quality Assurance procedures were followed in the creation, analysis, and reporting of the data." *See* letter from NRC to Mark Williams, DOE, July 27, 2006 (ML062010317). However, it is not clear to Nevada that DOE's broader problem has been addressed. *See* NUREG-1762, Rev.1, "Issue Resolution Status Report," at section 7.4.

Nevada respectfully requests an appropriate response from NRC on this key issue before further work in this area is undertaken by DOE and its contractors.

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Sincerely,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

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