

April 10, 2003

Joseph D. Ziegler, Acting Director
Office of License Application and Strategy
U.S. Department of Energy
Office of Repository Development
P.O. Box 364629 M/S 523
North Las Vegas, NV 89036-8629

SUBJECT: NRC REVIEW OF THE U.S. DEPARTMENT OF ENERGY'S "POSITION
PAPER ON USE OF SENSITIVITY STUDIES TO SUPPORT RESPONSES TO
KEY TECHNICAL ISSUES AGREEMENTS"

Dear Mr. Ziegler:

This letter provides the U.S. Nuclear Regulatory Commission (NRC) staff's response to your December 24, 2002, letter which enclosed a U.S. Department of Energy (DOE) report titled "Position Paper on Use of Sensitivity Studies to Support Responses to Key Technical Issues [KTI] Agreements." In the Position Paper, DOE proposed using data not qualified, software not verified, and models not validated in accordance with the requirements of Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, to provide insight into a risk-informed, performance-based foundation for closure of some KTI agreements. The staff's position described in this letter, should also be considered within the context of the staff's review and comments on the DOE Risk Prioritization Report, as described in a letter to DOE dated January 27, 2003.

NRC has a policy of risk-informed, performance-based regulatory decision-making that encourages the use of risk assessments and sensitivity analyses to help to identify data, models, and barriers that are most important to repository performance and to focus available resources on those items. Consistent with this policy, staff reviewed the information provided by DOE in the Position Paper. It is our opinion that DOE will be able to successfully address various KTI agreements by using risk information. Where the risk assessments and sensitivity analyses, in combination with other available information, are considered to provide the information that NRC staff believes will be necessary to support DOE's conclusions, then NRC staff can consider the relevant KTI agreements to have been satisfied for the purposes of pre-licensing issue resolution.

The quality of DOE's collection of data, verification and validation of software and models, and the various analyses performed supporting the possible license application are important process elements that impact all of the KTIs. It must be emphasized that DOE has stated on several occasions that all data, software, and models supporting the license application will be qualified, verified, and validated in accordance with the requirements of the QARD. This statement is consistent with NRC's expectations. In this regard, DOE should recognize the inherent risk of using data, software, or models that do not meet the requirements of the QARD in sensitivity studies that support risk-prioritization of KTIs. Using such data, software, or models to support risk-prioritization analyses may lead to erroneous assumptions about the importance of certain KTIs. Specifically, DOE should consider how it will assure that the

outcome of the sensitivity analyses would not significantly change if data, software, or models that meet the requirements of the QARD were used in those sensitivity analysis.

When sensitivity studies are proposed as a basis for closure of KTIs, DOE needs to provide sufficient supporting information to NRC staff when submitting information to NRC to address specific agreements. The supporting information must be adequate to allow NRC staff to evaluate whether the risk arguments acceptably address NRC staff's questions such that no information beyond that provided, or agreed to, will likely be required at the time of initial license application.

If you have any specific questions regarding this letter, please contact Thomas Matula of my staff at 301-415-6700.

Sincerely,

/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

J. Ziegler

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Letter to J. Ziegler from J. Schlueter, dated: April 10, 2003

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