



## Department of Energy

Washington, DC 20585

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Dr. John H. Austin, Branch Chief  
Performance Assessment and High Level Waste  
Integration Branch  
Division of High-Level Waste Management  
Office of Nuclear Material Safety  
and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Dr. Austin:

This letter is in response to the Nuclear Regulatory Commission's (NRC) letter of November 15, 1995 (Holonich to Milner). This letter addresses the open item concerning requirements to qualify scientific methods identified by the NRC at the October 25-27, 1995 Office of Civilian Radioactive Waste Management Audit of the U.S. Geological Survey. The Department of Energy agrees that justification should be required for the selection and use of any method that is not generally accepted by the technical community. A review of the Quality Assurance Requirements and Description (QARD) document has determined that requirements are imposed that adequately ensure the acceptability of scientific investigation methods. Current QARD requirements ensure that:

- proposed methodologies are planned, evaluated, justified and approved as Study Plans before their application. Further, the NRC has previously exercised its option to do an acceptance review of Study Plans in which issues such as technical adequacy have been addressed;
- resulting data and reports are subjected to documented independent reviews to confirm technical adequacy which encompass a review of the methodology used to draw conclusions; and
- the quality and effectiveness of work (including technical adequacy) are regularly assessed during performance through surveillance and audits.

In addition, the QARD provides for Peer Review in a situation where novel or beyond state-of-the art testing, plans and procedures, or analyses are utilized. This requirement can apply to methods not generally accepted by the technical community.

Implementation of these QARD provisions will accomplish the recommended "justification of methods" far in advance of the licensing process, and will verify acceptability of methodologies and the resulting data prior to use or reference in the license application.

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