



Department of Energy

Washington, DC 20585

QA: QA

FEB 03 2004

Nancy H. Williams
Repository Development Manager
Bechtel SAIC Company, LLC
1180 Town Center Drive, M/S 423
Las Vegas, NV 89144-6352

USE OF OUTPUT FROM SOFTWARE UNDER DEVELOPMENT FOR PRELIMINARY ANALYSIS MODEL REPORT (AMR) FEEDS

The Office of Quality Assurance (OQA) has reviewed your request for a change to Quality Assurance Requirements and Description (DOE/RW-0333P) (QARD) Section 1.2.4 to allow the use of Software prior to Qualification.

As you are aware, DR BSC(B)-03-D-170 (Condition Report 17) was initiated to address the "Use of Unqualified Software in a Quality Affecting Activity."

Your request of June 23, 2003, to revise the QARD Section 1.2.4 to allow the use of software not fully qualified during the development of a model or analysis has been evaluated with the following points:

1. The OQA does not believe a QARD revision is necessary since software is not considered to be "in use" until the AMR the software supports has been approved in accordance with the AMR's governing procedure(s). The software is then considered to be a "final" product. "Final" means that Bechtel SAIC Company, LLC (BSC) has formally reviewed and signed-off as complete the AMR for which the software supports.
2. Use of the terms "qualified" or "unqualified" relating to software or software output are, therefore, meaningless prior to that software becoming a final product (i.e., when the AMR the software supports is approved). The nuclear industry emphasizes the "in use" approach to whether or not an activity is quality or safety related. The OQA does not consider software to be "in use" prior to the approval of the AMR the software supports.

Additionally, BSC must demonstrate that their configuration management approach ensures that:

1. No outputs from software yet to be qualified or software under development is directly used (as use is defined above) in support of the License Application (LA).
2. Preliminary analyses using output from software that was under development has been confirmed against the output from that software when it becomes a final product. This configuration must be documented and traceable to the specific software outputs that were compared. Again, only "final" software output as defined above may be used in signed-off AMRs.
3. AMR approval occurs in a manner sufficiently timely to allow both BSC Quality Assurance and OQA to perform audit/surveillance activities required to ensure the quality of the products moving toward LA.



Nancy H. Williams

-2-

FEB 03 2004

Please inform me of the additional management controls, including procedural changes that BSC will put in place (and when) to address this issue by February 12, 2004. Also, please let us know the results of your internal assessment of all LA software codes under development and notify me if there are any codes under development that are currently not properly controlled.

Should you have any questions concerning this matter, please call me at (702) 794-1460.


K. Dennis Brown, Director
Office of Quality assurance

OQA:RDB-0665

cc:

M. E. Bennington, DOE/HQ (RW-3), Las Vegas, NV
R. A. Atkisson, BSC, Las Vegas, NV
J. T. Mitchell, Jr., BSC, Las Vegas, NV
W. J. Arthur, III, DOE/ORD (RW-2W), Las Vegas, NV
W. J. Boyle, DOE/ORD (RW-40W), Las Vegas, NV
J. D. Ziegler, DOE/ORD (RW-40W), Las Vegas, NV
Records Processing Center = "4"