

Department of Energy

Washington, DC 20585

QA: QA

FEB 03 2004

Nancy H. Williams
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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.




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Enclosure 4

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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.


R. 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
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QA: QA

RECEIVED BY BSC CCU
DATE: 02/12/2004

R. Dennis Brown, Director
Office of Quality Assurance
U.S. Department of Energy
Office of Repository Development
1551 Hillshire Drive
Las Vegas, NV 89134-6321

CONTRACT NO. DE-AC28-01RW12101 – RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION REGARDING “USE OF OUTPUT FROM SOFTWARE UNDER DEVELOPMENT FOR PRELIMINARY ANALYSIS MODEL REPORT (AMR) FEEDS”


Reference: Ltr, Brown to Williams, dtd 02/3/04, BSC log #0203040329

Thank you for your clarification of the Quality Assurance and Description document (QARD) language relative to the use of software not fully qualified during the development of a model or analysis. We have reviewed the issues discussed in your letter and have initiated some procedural clarifications to ensure that adequate controls are in place to ensure that no completed analyses are based on software yet to be qualified.

Based on our review, we have concluded that adequate controls are currently in effect relative to the submittal of preliminary data to the Technical Data Management System (TDMS). The controlling procedures are: *Submittal and Incorporation of Data/Technical Information to the Technical Data Management System (AP-SIII.3Q)*, *Document Review (AP-2.14Q)*, *Managing Technical Product Inputs (AP-3.15Q)*. Therefore, no changes to these procedures appear necessary.

Changes will be made to the implementing procedures for models (AP-SIII.10Q) and analyses (AP-SIII.9Q) on the use of output from software yet to be qualified (preliminary output). The changes will include documentation and traceability of such preliminary output, including documentation of the comparison between preliminary output and the final output from baselined software. Preliminary and final output will be submitted to the TDMS in accordance with the procedure on submittal of data to the TDMS (AP-SIII.3Q). The responsibilities of the originator will be clarified to provide clear accountability to ensure that only “final” software output, as defined in the referenced letter, will be used in approved AMRs. The controls on technical review will be clarified relative to preliminary output to allow technical review of products developed using preliminary output. The Interim Change Notices (ICNs) to the implementing procedures for analyses and models will be issued by 05 March, 2004.

Please contact myself or William Watson at (702) 295-5550 for any additional information you may require.


Nancy H. Williams
Repository Development Manager

2-11-04
Date Signed

WWW:cs - 0211040421

cc:

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FEB 13 2004


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REVISION TO POSITION ON USE OF OUTPUT FROM SOFTWARE UNDER
DEVELOPMENT FOR PRELIMINARY ANALYSIS MODEL REPORT FEEDS

In my letter dated February 3, 2004, on the use of output from software, the third paragraph presented two points. The second point, second sentence began with "The nuclear industry emphasizes ...". The sentence is not relevant to the point and should be disregarded.

Also, please consider your responses to Condition Reports 1804, 1805, and 1806 in your response.

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


R. Dennis Brown, Director
Office of Quality Assurance

OQA:RDB-0734

cc:

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