



QA: QA
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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

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