Department of Energy
Office of Civilian Radioactive Waste Management
Office of Repository Development
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QA: N/A
Project No. WM-00011

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OVERNIGHT MAIL

ATTN: Document Control Desk
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RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) AUDIT OBSERVATION INQUIRIES (AOI) FOR AUDIT OQAP-BSC-03-07

During NRC's observation of the Office of Civilian Radioactive Waste Management audit, OQAP-BSC-03-07, Performance Based Audit of Software, three AOIs were identified. The response to AOI #1 was provided during the audit. The responses to AOIs #2 and #3 are detailed in the Enclosures 1 and 2.

If you have any questions, please contact Neal K. Hunemuller of my staff at (702) 794-5081.

Joseph D. Ziegler, Director
Office of License Application and Strategy

OQA:KMG-1884

Enclosures:
As stated

NMSS07
WM11

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AOI #2 states:

> *Software is categorized as either Level A or Level B (current procedures) or Level 1, Level 2, or Level 3 (previously). Different procedures are used to qualify Level A and Level B software. This represents a graded approach to the quality assurance for software qualification, which is not provided for in the QARD. DOE stated in the QA meeting summary dated April 29, 2003 that DOE will not be implementing a graded QA approach. Please provide a justification for the graded approach used for software qualification which does not appear to be in accordance with the provisions in the QARD.*

Response

As stated in the inquiry, the project has elected to not implement a graded approach to Quality Assurance (QA) at this time. A graded approach to QA relates to the QA controls, e.g., inspections, audits, reviews, corrective actions, training, verifications, etc., which are placed on various activities.

The Quality Assurance Requirements and Description (QARD) document identifies four development life cycle phases (Requirements, Design, Implementation, and Testing) for software. The QARD in section I.2.1.A.1 also states that the number of phases and relative emphasis placed on each phase of the software life cycle will depend on the nature and complexity of the software.

Procedure AP-SI.1Q, *Software Management*, divides the software into two levels, Level A and Level B, based on the nature and complexity of the software with Level A software being the more complex software. Because Level A software is the more complex, the applicable procedures describe the four phases as separate and distinct activities with the appropriate documentation for each phase. For the less complex Level B software, the phases, and the associated documentation, are consolidated into one phase.

This approach is fully supportive of the QARD and does not represent a graded approach to QA since all requirements must be met for both Level A and Level B software. The differences in the two levels are the timing of the activities and the documentation required, i.e., multiple packages versus one.

To summarize:

- The designation of software as Level A and Level B is a classification process based on the nature of complexity of the software.

- The classification of software results in a different number of life cycle phases and different documentation (multiple versus single packages and different format.) The QA controls placed on the software does not differ, i.e.; there is not a graded approach to QA controls.

AOI #3 states:

Approximately 90 DRs and CARs have been identified in the last four years. Based on the initial review of these DRs/CARs by the observers, a potential pattern of ineffective corrective actions along with examples of failure to follow procedures was identified. Although the audit team was aware of these issues, the overall significance of these recurring deficiencies was not integrated into the OQAP-BSC-03-07 audit. Therefore, it is requested that DOE provide within 30 days a detailed review and evaluation of the cumulative significance and impact of these deficiencies and an assessment of the adequacy of the associated corrective actions and human performance considerations.

Response

Please note that an informal response was provided to this inquiry during the audit.

DOE recognizes there has been a potential pattern of ineffective corrective actions and procedural compliance issues not only in the software processes but also within the project. DOE management has initiated several actions to address these issues on a project wide basis. Examples of the actions being taken to address these issues include the Management Improvement Initiatives (MII) and the Quality Focus Meetings. Specific to the software processes, Corrective Action Report (CAR) BSC-01-C-002 was initiated on May 31, 2001. This CAR identifies inadequate implementation of software quality assurance controls.

Because this CAR is all encompassing for the software process, any DRs or CARs initiated prior to the CAR initiation date of May 31, 2001 would be addressed within the response of CAR BSC-01-C-002. In addition, any conditions adverse to quality (CAQs) that occurred prior to the initiation of CAR BSC-01-C-002 but were identified after the CAR initiation would also be addressed within the response to the CAR. A final subset that should be considered is CAQs that occurred after the initiation of the CAR but before the corrective actions from the CAR were put in place. These CAQs also would be addressed by the CAR corrective actions.

DOE identified 38 DRs/CARs/QOs that were initiated after May 31, 2001. Note that this does not include the CAQs identified by the recent software audit. These 38 documents were reviewed to categorize the documents based on the previously described criteria. Other information that would focus the analysis was also identified. The review results were as follows:

- CAQ occurred prior to initiation of CAR – 4
- CAQ occurred prior to implementation of CAR corrective actions – 11
- Original analysis identified issue was not a CAQ – 5
- Document was closed with corrective action to be taken by the CAR or another listed document – 6
- Issue was related to software but not a software process issue, e.g., improper review of software procedures, software records not submitted – 3

As was previously discussed, these issues would be addressed by the CAR corrective action or would not contribute to identifying a pattern of ineffective corrective action or procedure non-compliance. Therefore, further analysis of these 29 documents is not considered necessary.

An analysis of the nine remaining documents resulted in the following:

- The issue, while a procedure non-compliance, was administrative in nature with no consequence, e.g., failure to use the right form to obtain a number, inconsistent names on forms – 4
- Procedural non-compliance – 3
- Human error – 1
- Inadequate controls – 1

Based on this analysis, no pattern of ineffective corrective actions or procedural non-compliance could be established specific to the software processes. The software audit did identify additional CAQs, some of which may, when the causal analysis is complete, identify ineffective corrective actions or procedural non-compliances as the cause(s). In the future the trending program would identify any pattern, i.e. trend.