

FY 1996 OCRWM QA Management Assessment

Preliminary Report for the SNL Segment

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**FY 1996 OCRWM Quality Assurance Management Assessment
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Introduction: The FY 1996 Quality Assurance Management Assessment (QAMA) is an integrated assessment of OCRWM and its major participants. The QAMA has two principal objectives: (1) evaluate the status, adequacy, and effective implementation of OCRWM's Quality Assurance Program, and (2) identify areas where improvement is needed.

A final report summarizing the results of the integrated QAMA and conclusions drawn by the assessment team with regard to the adequacy and effectiveness of the OCRWM Quality Assurance Program will be provided to the OCRWM Director at the conclusion of all assessments. Preliminary reports consisting of an executive summary of the observations and recommendations identified during the individual assessments are also provided to the OCRWM Director after each assessment.

This preliminary report summarizes the observations and recommendations identified during the assessment of the Sandia National Laboratories (SNL), Yucca Mountain Project, QA program.

On-Site Assessment Dates: April 22-23, 1996 at the Yucca Mountain Site and in Las Vegas, Nevada; April 24-26, 1996 in Albuquerque, New Mexico.

Assessment Team: T. R. Colandrea

Conclusions: Based upon the results of this QAMA, the SNL QA program is, for the most part, considered to be adequate and effective. Improvements are needed in SNL's approach to QA training. Also, SNL should assign QA staff to work directly in task teams with the technical staff in order to facilitate quality-related progress throughout SNL.

Previous QA Management Assessment Recommendations: The results of the 1995 QAMA of SNL's QA program were documented in an excellent report by L.S. Costin dated August 14, 1995. However, several of the issues identified in this report were not adequately addressed by SNL in the interim and, as indicated below, similar problems were observed during this year's QAMA.

Executive Summary of Observations and Recommendations: The following attributes were assessed to determine Quality Assurance Program adequacy and effectiveness.

1. *Effectiveness Of Procedural Implementation:*

Observation: Section 2 ("Adequacy and Effectiveness of the QA Program") of the August 14, 1995 SNL QAMA report stated in part: "*Improvement in procedures*

continues to require attention. There is continued concern that some procedures are not structured well or flexible enough to be appropriately applied to certain activities."

Many of SNL's Quality Assurance Implementing Procedures (QAIPs) have been streamlined in recent years (excluding the signature, revision, and table of contents pages, 62% of the QAIPs are less than 10 pages in length; 27% are less than 5 pages in length). Concern was expressed by a number of people interviewed during this QAMA that the QAIPs have become oversimplified to the point that some of them no longer contain sufficient implementing detail to adequately describe how the work activities are to be performed. This concern was also the subject of an OCRWM deficiency report (YM-94-096/YMQAD-96-D-004: Inadequate Detail in SNL QAIPs¹).

In contrast, concern was also expressed during this assessment that several of the QAIPs are overly complex and difficult to understand (e.g., QAIP 17-2 entitled "Participant Data Archive").

To address QAIPs at both ends of the spectrum (i.e., simplified versus the more complex), SNL management has recognized the need to more clearly explain how the work is to be performed and to communicate the underlying intent of the QAIPs. Toward this end, SNL has the following actions² underway: (a) a senior member of the SNL staff who is particularly knowledgeable of the SNL QA program has been effectively supporting the relatively new SNL people at the Yucca Mountain Site with respect to making them more aware of the QAIP requirements and providing them with guidance on how to effectively implement the SNL QA program and (b) SNL management will have a series of training packages developed. This material will contain "how-to" examples of completed forms and other implementation guidelines that will be used in conjunction with the QAIPs. It was indicated that this training material should be available for use by the end of September 1996.

Recommendation No. 1: None.

¹ This deficiency was first issued on September 13, 1994 as CAR YM-94-096. On February 1, 1996, it was replaced by YMQAD-96-D-004. The status at the time of this QAMA was "Amended response accepted. Corrective action completion due 30 April 1996."

² It should be noted that these actions are separate and apart from the commitments made by SNL in response to YM-94-096 to include an adequate level of detail in the QAIPs.

2. *Adequacy And Effectiveness Of QA Training:*

Observation: Section 3 ("Adequacy of the Indoctrination and Training Program") of the August 14, 1995 SNL QAMA report stated in part: *"The training program continues to be a source of great frustration to staff and management. There is little perceived value in current training practices and training records are poorly developed and managed... Heavy reliance on read-and-understand provides little understanding of what is expected in terms of meeting requirements and good management practices. Numerous CARs have been issued in the past year related to training records. In addition, several other CARs for poor documentation of technical efforts can be traced to a general lack of understanding of the QA program and how to use procedures to perform work. These metrics suggest the investment in training has not been effective and significant changes in processes and methods are needed."*

Except for the action outlined above³, the SNL new employee QA training program does not appear to be particularly effective, especially for people who have not previously worked to a regulated QA program. That is, the results of this year's QAMA show that (a) the newer SNL employees typically found the intricacies of the QA program rather overwhelming and (b) the SNL Orientation Manual and other initial training given to new employees have been of little help in providing a meaningful understanding of the QA program. Furthermore, this manual, last revised in October 1994, contains outdated information which could be misleading to a new employee (e.g., it indicates that the first step in the grading process is to develop Quality Assurance Grading Reports; these reports are no longer a part of OCRWM's approach to QA grading).

With respect to refresher/other on-going training in the QA program, most of the SNL personnel contacted during this QAMA felt that the existing approach (consisting primarily of "read-and-understand" training, although supplemented recently with computer-based training for several QAIPs) was not very effective.

As outlined in the previous section of this report, SNL is in the process of taking several actions to more clearly explain how the QAIPs are to be implemented. However, QA training has been an open issue since at least the FY 93 SNL QAMA.⁴ As a result, it is felt

³ i.e., the excellent one-on-one training and guidance provided to the newer SNL employees at the Yucca Mountain Site by a senior member of the SNL staff.

⁴ A May 13, 1994 memo by L. E. Shepard entitled "SNL-YMP Management Assessment" states in part: "Although we have made some significant improvements in the training program (e.g., the SNL-YMP Orientation Manual) we have not been successful in completing the actions

that a more concerted effort is needed to ensure that this area is finally addressed in a timely and effective manner.

Recommendation No. 2: It is recommended that SNL take action to improve the effectiveness of its QA training program. Consideration should be given to the following in this regard: (a) review and address to the extent appropriate the training-related recommendations stemming from the 1993, 1994, and 1995 SNL QAMAs; (b) review LANL-YMP's approach to QA training, particularly with respect to their new employee QA orientation program; (c) to avoid duplication, contact the M&O training department to determine what they have done in this area; and (d) expand the SNL QA facilitator role (e.g., as exemplified by Joe Schelling in recent months) from the standpoint of providing one-on-one training, coaching and assistance to the staff in helping them to effectively implement the QA program.

3. *Adequacy And Effectiveness Of The Corrective Action Program:*

Observation: For the most part, SNL's approach to corrective action appears to be adequate and effective. Findings (e.g., Corrective Action Requests; CARs) identified during audits and surveillances have generally been pursued in an adequate manner. For example, SNL identified the control of Scientific Notebooks as a problem area during the first part of 1995. As a result of the emphasis placed on and the attention given to this area by SNL management (e.g., training classes and management guidelines on the control of Scientific Notebooks), improvements have been underway to upgrade the quality of the Scientific Notebooks of SNL and its contractors.

In contrast, little action was taken by SNL to address some of the recommendations contained in the August 14, 1995 SNL QAMA report. This is unfortunate since it provided several excellent suggestions regarding opportunities for improving areas that subsequently surfaced during this QAMA. For example, (a) QA training and (b) the assignment of QA staff to work directly in task teams with the technical staff are both issues identified in the 1995 QAMA report that are still impacting the effectiveness of SNL's QA program. Whereas it is important to take action on deficiencies such as CARs, SNL should also follow up on recommendations offered as a result of audits, QAMAs,

identified last year in the FY 1993 Management Assessment. Further, we have not implemented a 'Just-in-Time' training program that requires procedure training at the time of application. For this program to be effective, the indoctrination program mentioned above must also be effective and each staff member and contractor must share responsibility for ensuring that they have the proper training at the appropriate time." (emphasis added). Accordingly, training has been an open issue for some time.

and surveillances of the SNL QA program.

The SNL TPO closely monitors the status of deficiencies such as CARs and is aware of those that have been open for some time. Delays in closing CARs have typically been due to awaiting the verification of corrective action.

SNL employs a useful practice whereby a member of the QA staff interacts with recipients of audit and surveillance findings in order to provide a "face-to-face" delivery and explanation of each deficiency. In this manner, the SNL staff is (a) given a clear explanation of the nature and extent of the deficiency and (b) provided informal suggestions as to how to address the deficiency (including suggested wording that might be used in the response). In general, this technique appears to be appreciated by the SNL staff.

Recommendation No. 3: It is recommended that SNL address and follow up on recommendations resulting from audits, QAMAs, and surveillances of the SNL QA program.

4. ***Effectiveness Of QA Program Application To OCRWM Program Elements Considered Critical To Mission Success:***

Observation: (SNL Surveillances) In general, the SNL surveillances reviewed during this QAMA appeared to be meaningful in terms of evaluating the adequacy and effectiveness of QA program implementation. They frequently addressed key aspects of SNL's QA program (e.g., the control of Scientific Notebooks and the adequacy of work agreements) and appeared to identify substantive issues requiring improvement. A total of twelve surveillances were conducted during 1995. One surveillance has been performed in 1996 and three additional surveillances are scheduled to be performed during the first half of 1996. Manpower shortages within the QA department may impact SNL's ability to conduct these surveillances on schedule.

Recommendation No. 4: (SNL Surveillances) None.

Observation: (Records Submittal and Retrieval) SNL has identified instances where records packages have not been processed or submitted to the Local Record Center in a timely manner. For example, when contractors were cut from the program due to budget reductions, it was determined that there were a number of Scientific Notebooks that had not been kept current, closed out, or submitted to the records center. Aggressive action has been underway to (a) ensure that these documents are checked, corrected, and processed without further delay and (b) prevent a recurrence of the problem (e.g., reduce the scope of Work Agreements - and, in the process, the size of the resulting records packages - to where they can be closed out in a short time frame).

In a manner similar to what other affected organizations have experienced on the OCRWM program, SNL has not always been able to retrieve records from the OCRWM Records Processing Facility in a timely or effective manner (e.g., SNL's records staff recently spent three hours without success attempting to find a certification and training record that is somewhere in the Records Processing Center in Las Vegas). This issue is beyond the immediate scope of this SNL QAMA and will be pursued separately during a subsequent phase of the integrated OCRWM QAMA program.

Recommendation No. 5: (Records Submittal and Retrieval) None at this time, pending the results of further investigation of this issue.

5. *Adequacy Of Resources And Personnel Provided To Achieve And Assure Quality:*

Observation: In FY95, the budget for the SNL Quality Assurance Department was approximately \$1,000,000. In comparison, the current budget for the SNL QA Department has been reduced by 52% to approximately \$480,000⁵. Concern was expressed during this QAMA regarding the extent to which these funds will be sufficient to adequately implement the QA program.

Section 1 ("Adequacy of Organizational Structure and Staffing to Implement the QA Program") of the August 14, 1995 SNL QAMA report stated in part: *"The QA organization and staffing needs some adjustments to accomplish their three prime functions ... assist the task leaders and principal investigators in meeting QA requirements throughout the work process, from planning to final documentation.... QA engineers need to be assigned directly to the teams doing the work in order to provide the benefit of building in QA from the initial planning stages and maintaining an active, day to day involvement in the work."*

The report recommended that, as resources allow, QA staff should be assigned to work directly in task teams to provide the QA expertise needed to assure QA is a fundamental part of the work process. The intent of this recommendation was implemented in part by SNL in recent months through Joe Schelling's role as a "QA facilitator." As such, he provides QA support to the SNL staff in Las Vegas and at the Yucca Mountain Site in terms of helping them implement the QA program in an effective manner.

⁵ In fact, however, the budget available to QA at this point in time is less than this amount since the rate of spending by the SNL QA department at the start of FY96 was greater than budgeted.

Comments expressed during this QAMA from a wide cross section of SNL's technical and management staff indicated that the SNL QA department personnel should be similarly involved on a more extensive basis in helping others with the day-to-day implementation of the QA program. This is particularly important at this point in time since, with the recent budget cuts, it (a) represents one of the best uses of the SNL QA Department's limited resources and (b) would help the SNL technical and management staff make better use of their limited resources (e.g., SNL's Principal Investigators would be able to spend more of their time on science because QA's proactive support and involvement would help them fulfill their QA program responsibilities more efficiently).

Recommendation No. 6: It is recommended that the following actions be considered in order to adapt to the recent reductions in SNL QA Department's budget: (a) focus available resources on those areas with the greatest value; (b) encourage the QA staff to work more closely with and provide guidance to the staff performing the work; and (c) achieve enhanced teamwork and integration between the QA and technical staff. Toward this end, SNL QA Department personnel should take a more active involvement in working side-by-side (i.e., co-located) with SNL technical and management staff to facilitate QA-related progress. Their goal in this regard should be to help the staff apply the QA program in a more efficient and effective manner and, in the process, achieve a better balance between the technical adequacy and procedural compliance for the work that is done. The Quality Assurance Lead (QAL) approach implemented by LANL-YMP serves as an excellent role model in this regard.

Programmatic/Hardware Deficiencies: No programmatic or hardware deficiencies were identified during this assessment.