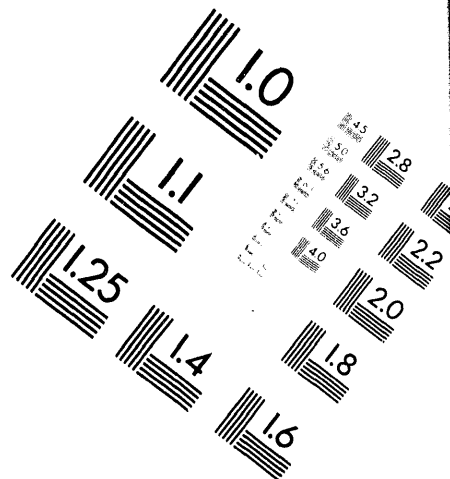


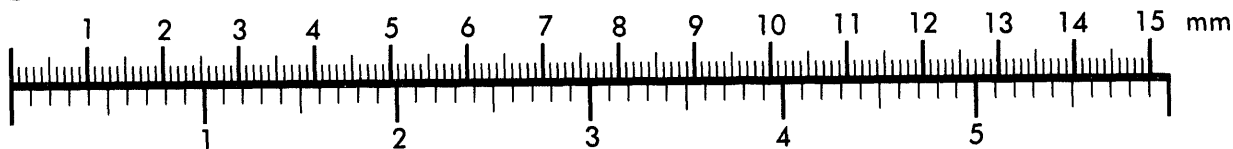
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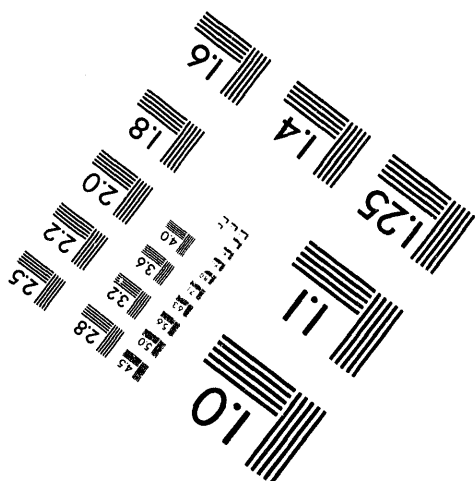
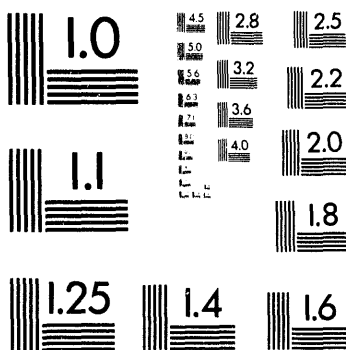
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Silver Spring, Maryland 20910
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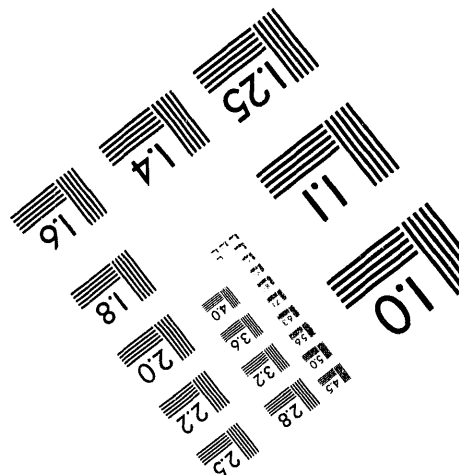
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IMPROVING THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE PROGRAM FOR SCIENTIFIC INVESTIGATIONS-
TAILORING QUALITY REQUIREMENTS TO FIT THE NEED

ZEROING IN ON REQUIREMENTS:
SANDIA NATIONAL LABORATORIES' APPROACH TO
MEANINGFUL PROGRAM IMPROVEMENT

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by

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ABSTRACT

The necessity to evaluate our participant Quality Assurance (QA) Program for the Yucca Mountain Site Characterization Project (YMP) against the Office of Civilian Radioactive Waste Management (OCRWM) (1) Quality Assurance Requirements and Description (QARD) issued December 1992, presented an opportunity to improve the QA Program. The process resulted in a number of lessons-learned for Sandia National Laboratories (SNL) as a participant organization and for the Project as a whole.

For some time, the SNL YMP technical staff had complained that the QA requirements imposed on their work were cumbersome and inhibited their ability to perform investigations using scientific methods. There was some truth to this, since SNL had over the years developed some procedures with many detailed controls that were far beyond what was required by project QA requirements. This had occurred either as a result of responding to numerous audit findings with a "make the auditor happy" attitude or with an attempt to cover every contingency. Procedures affecting scientific work were authored by the technical staff in an effort to provide them with ownership of the process; unfortunately, there were problems. Procedures were inconsistent because of the varied writing styles and differing perceptions of the degree of QA controls required to implement the Program. It was extremely difficult to get all of the technical staff to accept the QA Program as it was intended. These issues were endemic to the program and resulted in the QARD, the actual requirements, being written by a team of QA professionals.

Once new QARD requirements were issued, an opportunity to evaluate the QA Program and to revise it not only to meet the QARD, but also to make it more plausible and meaningful to the technical staff, was presented. The discussion that follows will describe how the program was changed, will present both the positive and negative experiences observed by SNL personnel during the QARD transition, and will provide some recommendations.

(1) Office of Civilian Radioactive Waste Management, "Quality Assurance Requirements and Description," DOE/RW-0333P, DOE Washington, DC, Revision O; December 18, 1992.



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BACKGROUND

The SNL scope of work for YMP involves scientific investigations, modeling, performance assessment analyses, and design verification analysis activities. SNL's work does not include "items" that affect the safety or waste isolation of the potential repository. The SNL YMP QA Program must, therefore, be structured accordingly with this mission in mind.

In December 1992 when the QARD was issued, SNL YMP's QA Program consisted of a Quality Assurance Program Description (QAPD) and approximately 55 implementing procedures. Some of these procedures were extremely long, complicated, and highly prescriptive (e.g., the procedure for software QA was more than 50 pages) and, in general, were difficult to follow. SNL YMP at that time decided to streamline its implementation of the QA Program while revising the program to meet the new QARD requirements.

TRANSITION PROCESS

Two individuals were assigned to the transition process, a QA staff member and a data-entry individual. The QA staff member began development of a transition plan: coordinating the revision of implementing procedures and developing a "draft" matrix on paper to show where QARD requirements were implemented, where they were not applicable, or where exceptions could be taken. The data-entry individual was responsible for data input into the Requirements Traceability Network (RTN). This electronic matrix formed the "draft" matrix, which made the link with QARD requirements.

The process began in late 1992 by comparing the old procedures against the QARD to see if there might be any major omissions in our program. At this point, we realized that significant changes were not possible if we could not isolate those requirements which were actually applicable to SNL YMP, as well as identifying those requirements with which exception could be taken. (Nonapplicability means that a requirement would never be invoked or applied, based on the nature and scope of SNL work. Exceptions were taken for cases in which alternative means of meeting requirements would be utilized.) Even though acceptance of the non-applicable requirements was not called for until much later in the transition process, as envisioned by the Yucca Mountain QA Division (YMQAD), a preliminary list of requirements that were not applicable to our scope of work was submitted to the YMQAD in February 1993. We received a tentative response to this list, which allowed us to continue the revision process without having to worry about dealing with unnecessary requirements. This one step made our revision process much more efficient.



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Since most of the new or revised procedures consist of improvements and/or simplifications, the decision was made to implement each procedure or revision as it was developed, thereby implementing QARD requirements prior to YMQAD acceptance of SNL's QARD matrix. Our program now consists of 37 implementing procedures. We were able to develop procedures that were easier to use, less prescriptive, and much smaller in size with (a) the use of the playscript format, (b) input from the technical staff, and (c) determination of which QARD requirements were specifically applicable to SNL. As a result, acceptance by the technical staff appears, for the most part, to be positive and procedure usage has increased.

With the exception of a few procedures, the revision process was completed by September 1993. We encountered problems with the revision of some of the technically related procedures, for example the one concerning software QA. This procedure was assigned to a group of individuals who took 12 months to come to agreement and complete their task. There were two factors that contributed to that delay: (a) the group never actually became a "team," that is, individuals strongly maintained and defended their own personal concerns, without striving for an acceptable consensus outcome; and (b) the key individual in the group, who had been on the Project Software Advisory Group, was also deeply involved in another YMP effort at SNL, the 1993 Total-System Performance Assessment (TSPA-93). Management prioritized his support to TSPA-93 above his support to completion of the Software QA procedure. Because of these factors, we were forced to request several extensions to our transition plan completion schedule.

Our data-entry individual received necessary training in October and started matrix input and linking in November. We completed our final verification of the input and submitted the matrix to the YMQAD for review in December 1993.

DISCUSSION ITEMS

A synopsis of the positive and negative experiences or outcomes for the QARD transition process follows, as well as several recommendations.

POSITIVE EXPERIENCES

- The QARD in general is now a much more applicable document for YMP work.
- Each participant was allowed to develop their own timelines.
- Revisions to the transition plan schedules were allowed with no hassle, "just document them."



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- YMQAD did not "pester" us during the process.
- The YMQAD transition plan and instructions were useful tools when developed and disseminated.
- The process served to identify weaknesses/omissions in our program.
- The focus of the QARD on YMP activities allowed us to "streamline" our program.
- RTN system training at the YMQAD was helpful.
- After the procedure revisions were thought to be completed, the verification processes served to identify some remaining implementation gaps that we had missed.
- The electronic matrix is easy to revise.
- To avoid developing a program around a "cloudy" system, the use of an early, tentative exception/not applicable list was helpful.

NEGATIVE EXPERIENCES

- The representation that the "QARD wasn't changed much, so procedures won't need many changes," wasn't borne out in our experience, which resulted in the transition taking longer than originally estimated.
- Communications with YMQAD on "conventions" for the matrix (the specific format and method to indicate N/A, exceptions, not requirements, and the numbering scheme) were difficult telephonically, necessitating travel to resolve.
- The network/INGRES support from the YMQAD to SNL via telephone, mail, and electronic means was less-than-effective. The only effective interaction for help was face-to-face visits with Project Office experts, including getting user passwords to sign on the system.
- Estimates with regard to time specified in the transition plan were unrealistic and did not factor in that we also had other things to do.
- It was difficult showing specific "implementation" of broad policy requirements, e.g., "measures shall be established , develop a system which"



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- We awaited clarification on some things (e.g., lifetime/nonpermanent records) throughout the transition. Therefore, this meant some requirements could not be addressed and we finally had to take an exception during the draft comment cycle, pending clarification.
- The process, especially the last few actions dealing with software QA, were not treated as a priority by SNL management on the same level as technical activities, milestones, and deliverables.

RECOMMENDATIONS

Such a transition process should provide for preliminary exception/not applicable lists being submitted and feedback provided prior to initiating large-scale program changes.

YMQAD needs to provide specific guidance to participant organizations on how the matrix is to be maintained. Specific guidance should be provided on changes, approval, reverification, and how this system is to be monitored. An administrative procedure is needed.

We recommend that this database be maintained by a QA staff member rather than a data-entry person. We believe, from personal experience, that a complete understanding of the QA program is necessary to make this system work.

It would have been a valuable learning tool for SNL to submit one typical procedure (e.g., procurement) and the associated matrix input early in the process for prototyping purposes. In this way, there would have been a guide, model, or successful process in hand prior to attempting matrix input for all procedures. Without such prototyping, input for all procedures at once created repetitive discrepancies in matrix entries. Interaction between participant personnel and matrix reviewers concerning one "example" set of matrix input would have effectively addressed any misunderstandings in (a) how to identify difficult passages, (b) network/software operations, and (c) how to address large policy statements. We later found that this was done by some organizations who gained from the benefits stated above.

YMQAD comment sheets should be provided on diskettes to allow for ease in responding to comments.

CONCLUSION

Deployment of the current QARD has been of benefit to all organizations in the Yucca Mountain Site Characterization Project. It provides for a QA Program that is more appropriate for scientific and analysis work, placing the QA staff in a more credible situation. Execution of the



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YMQAD-guided QARD transition at SNL provided a structured method of implementing the new or changed requirements, as well as offering the opportunity to streamline and improve our QA implementing documents. Experiences of the SNL YMP QA staff in carrying out the transition have provided suggestions, presented above, for improvement to the process for any future such transitions in Project requirements.

ACKNOWLEDGMENTS

This report was prepared under the Yucca Mountain Site Characterization Project WBS number 1.2.11.2, QA Grading Report # 1.2.11.2. Work Agreement, WA-047, was the planning document that guided the work activity. The information documented in this report is not qualified and will not be used for licensing.

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