



Department of Energy
Washington, DC 20585

JAN - 8 1987

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JAN 13 P12:56

Mr. Robert R. Loux, Executive Director
Agency for Nuclear Projects
Nuclear Waste Project Office
Capitol Complex
Carson City, Nevada 89710

Dear Mr. Loux:

Thank you for your review of our Quality Assurance Plan and for the comments in your letter of December 4, 1986. We appreciate your careful review and your interest in our program. We are currently evaluating your comments to see what changes we can make to our QA program to strengthen and improve it.

At the Quality Assurance Coordinating Group Meeting, which is being held on January 29, 1987 in Las Vegas, we plan to address verbally the major comments you and the other States have made. We will also be happy to answer any questions you or your representatives may have and to discuss our response. A written response for each of the comments in your letter of December 4, 1986 will also be provided to you.

We have enclosed, for your information, a copy of the comments we received from the State of Texas and those from the State of Washington. We have not yet received comments from the Nuclear Regulatory Commission (NRC), but will supply you with a copy when we receive them. The NRC comments are expected shortly.

Thanks again for your review and comments. I look forward to seeing you at the QACG meeting.

Sincerely,

S. H. Kale

Stephen H. Kale
Associate Director for
Geologic Repositories

Enclosures:

WM Record File

WM Project 11

Docket No. _____

PDR

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OFFICE OF THE GOVERNOR
STATE CAPITOL
AUSTIN, TEXAS 78711-2428
November 21, 1986

MARK WHITE
GOVERNOR

Mr. Carl Newton, RW-24
OGR QA Manager
U.S. Department of Energy
Washington, D.C. 20585

Dear Carl:

Attached are the State of Texas comments on the OGR QA Plan and its supplements. Thank you for the opportunity to review and comment on this document. Please give these comments serious consideration in any revision of the QA Plan.

Sincerely,

A handwritten signature in cursive script that reads "Susan W. Zimmerman".

Susan W. Zimmerman, Geologist
Nuclear Waste Programs Office

SWZ:dp
attachments

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State of Texas Comments on OGR QA Plan for
High-Level Waste Repositories

Comment 1

On page viii, the Revision/Change Board refers to CCBD/BCP numbers B-119 and B-126. How do these documents relate to OGR/B-3 and DOE/RW-0095?

Page 2, Section 1.4: This section states that NQA-1-1983 definitions apply. It is our understanding that NQA-1-1986 will be invoked in the new QA specifications. How will this new version of NQA-1-1986 affect the OGR QA plan?

Comment 2

Figure 3.1: The organizational position of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Manager is not in direct line to the Director of OCRWM. The fact that the QA Manager answers to the Director of Policy and Outreach (who answers to the Director of OCRWM) does not provide adequate access to top management.

Figure 3.2: The same inadequate organizational structure exists in the Office of Geologic Repositories (OGR) matrix. The OGR QA Manager answers to the Chief of Licensing and QA Branch, who reports to the Director of Siting, Licensing, and Quality Assurance, who reports to the Associate Director of OGR. This structure does not provide adequate access to top management.

What is the relationship between the OGR QA Manager and the OCRWM QA Manager, i.e., who is in charge of what?

Comment 3

Page 7: OGR Associate Director responsibilities should include ensuring adequate staffing of QA personnel in all areas of the OCRWM QA program.

Comment 4

On page 12, Section 3.2.6.2(a)(ii) should read "Coordinating the QA programs of the project offices and providing interface with federal regulatory agencies and appropriate agencies of affected States and Tribes."

Comment 5

Page 13, Section 3.3: The Project Manager does not have the degree of independence necessary to be responsible for the QA program and at the same time be responsible for the implementation and execution of the project. The PM may have the responsibility for establishing the program, however, its implementation must be carried out with a proper level of independence.

Comment 6

Section 3.5.2 should be expanded to include notice to and participation by affected States and Tribes.

Comment 7

Page 17, Section 4.2: The development of different QA programs by the various divisions and projects could result in substantial inconsistencies in QA application. This could affect the implementation or decisions in the future when similar activities are being carried out by different organizations with OCRWM.

Page 21, Section 4.4: This section needs more elaboration, detail. How will management perform these assessments? Will additional guidance be issued for the objectives and implementation of the assessments?

Comment 8

Page 21, Section 4.3.2: Who is responsible for verifying the QA programs for the various subcontractors?

Page 21, Section 4.5: The affected States and Indian tribes should be included in the list of those receiving information, along with POs, contractors, and OCRWM.

Page 24, Section 5.3.2(b): The affected states and Indian tribes should be included in recipients of this information.

Comment 9

QIP 2.0, Section 6.2.2: This section states that "The procedures may be: Approved, Approved with comment, or Disapproved". Section 6.1.2 states the status of the QA Plan will be approved, approved with comment, or disapproved. Why is the wording different?

Section 7 states that records of Headquarters reviews of Projects' plans and procedures are nonpermanent. This means they must be retained for only five years. These records may provide valuable insight for future revisions to plans and procedures and should be kept for a longer period of time.

The Quality Assurance manual Evaluation Checklist does not require the reviewers to be identified.

Comment 10

QIP 2.1, Section 7.1: Records of training activities are considered to be nonpermanent (minimum five year retention). This retention period is inadequate, considering the time scale of the project.

All handouts and copies of visual aids used in training sessions should be included in the records.

- 11 -

- 3 -

QIP 5.0, Section 4.1.1: This section has a typographical error. The word has been omitted.

Records of reviews of QIPs and Activity Plans and subsequent resolution of comments are considered nonpermanent. The five-year minimum retention period is not adequate, considering the project timetable.

Comment 12

QIP 16.0: The record retention time of five years (minimum) is inadequate. The Corrective Action Report form does not require a schedule for the completion of the corrective action. The procedure in Section 6.5 does require a schedule.

Comment 13

QIP 17.0: This procedure requires the review of nonpermanent records prior to the removal from the system. This addresses some of the previous comments that a five-year retention period is inadequate. The review process is defined as one that confirms whether or not the continued retention record is required at the time that could lead to the destruction of some documents that are not required at the five-year period but could possibly be needed at some later time in the project.

Comment 14

QIP 18.0: Records of audits are required to be maintained for a minimum of five years. This is an inadequate time span. Same comment for QIP 18.1 and 18.2.

Comment 15

QIP 18.3: This procedure states that the Technical Specialist must be a trained auditor. A provision should be made to allow technical personnel not qualified as auditors to assist and observe the audit team. The term "technical observer" would probably satisfy this need.

Is the term Audit Team Leader synonymous with the term Lead Auditor for this QA program?

Does the Lead Auditor examination, as administered by DOE, fulfill the requirements of Section 6.1.5 for auditor qualification?

Comment 16

Supplement 2, Section 5.4: The first sentence lacks a verb.

Comment 17

Supplement 3, page 1: The first sentence of the first quote in the middle of the page reads "...important to safety not waste isolation". This should probably read "important to safety nor waste isolation. This entire document should maintain consistent statement referencing the definition in 10 CFR 60 and other NRC regulations.

Page 5: A truly conservative approach at the SCP design stage would be to include all site characterization activities on the Q-list.

Page 6: Retrieval of the waste cannot be considered to be just the reversal of the emplacement procedure. If the waste needs to be retrieved then that could imply that the repository is not functioning properly and there is the possibility of contamination. In this case, which is a very viable scenario, the items and activities needed for retrieval would be far different than the ones needed for the emplacement. Therefore, items and activities necessary for retrieval should be on the Q-list separately from the items and activities for waste emplacement.

Comment 18

Supplement 4: The list of records for lifetime storage should be expanded to include the records commented on previously regarding the five year retention limit.

Section 5.5 and 5.6: Since no licensed repository has ever been designed or constructed, it is improper to refer to "typical" records. In addition, the presented lists should not be considered limiting, and a statement to that effect should be included. The recognition of nonpermanent records "and still available" points up earlier comments about records retention time.

Comment 19

Supplement 5: Research is often a combined effort by several people. This supplement implies that only one project notebook would be generated. This would not be the case where several groups develop input into a single report. The Activity Plans developed and approved for each activity will satisfy many of the requirements of this supplement, and perhaps the Activity Plans should be referenced in the document.

Comment 20

Supplement 6: Section 4.1: The term "adverse impact" needs clarification and "a quality problem that possesses generic traits ..." needs better definition.

Section 4.2: Define the "various participants".

Section 5.2: Does the Project QA Manager of each office have sufficient knowledge of the overall program to be able to determine quality problems generic to all offices? The OGR QA Manager should be responsible for issuing generic QAs.

Define "fast relaying". Is there a specific length of time that correlates to this term?

Section 6.1: How will deteriorating quality conditions be identified by the project personnel?

In condition (d), define the term "remarkable experience/innovations".

Section 6.2.2(a): If "other means of communication" are used for the "fast relaying" of QAAs, then there should be a requirement that formal written transmittal of the QAA should follow the initial communication within some definite time span, such as 3 days.

Section 6.2.2(d): Who assigns the unique tracking/identification number to the QAA and, if it is done at the Project Office level, how will the different Project Offices keep track of the numbers used by the different offices?

Comment 21

Supplement 7, page 2, Section 5.2: Peer review panels should require the inclusion of at least one person independent of DOE and its contractors.

Comment 22

Supplement 8, page 1, Section 3: Define how the term "economic considerations" is used in this section.

Supplement 8: Assignment of Quality Levels by the different projects could lead to inconsistencies between projects and affect the decision process.

Attachment B indicates that all records that support licensing activities are Quality Level 1. Records such as qualification of personnel, audit findings, and corrective actions might be part of the licensing activities. Therefore, taking the conservative approach, these documents should have a considerable retention period, if not lifetime.

Page 5, Section 5.3.1.2: The statement that "Activities covered under Quality Level 1 include: ... site characterization." implies that all aspects of site characterization are covered under this level. Is this true?

Page 6, Section 5.3.2.2: Definition is needed for which field and laboratory investigations are covered under Quality Level 2. If these investigations have to do with site characterization, shouldn't Quality Level 1 apply?

Why are items and activities with potential impact on public and occupational health and safety only Quality Level 2?

Comment 23

Supplement 9, page 2, Section 5.2: Independent review panels should require at least one reviewer not associated with DOE or its contractors.

Section 7 states that records of Headquarters reviews of Projects' plans and procedures are nonpermanent. This means they must be retained for only five years. These records may provide valuable insight for future revisions to plans and procedures and should be kept for a longer period of time.

The Quality Assurance manual Evaluation Checklist does not require the reviewers to be identified.

Comment 24

Supplement 11, Section 1.0: For waste that is to be accepted in the repository, the waste must have been processed under a QA program that complies with 10 CFR 60, Subpart G, not the OGR QA Plan.

Section 5.1.1: The QA Program must comply with 10 CFR 60, Subpart G, not to 10 CFR 60.2 which does not even address any requirements.

Section 5.2(a): If the DOE HQ-OGR does not intend to review the technical procedures for processing the waste, will audits of the program include audits of the technical procedures and, if the procedures are determined to preclude the waste from being accepted by the repository, how will this be resolved?

Comment 24

Section 5.4: The NRC must be able to determine that the waste form from the defense facilities will be acceptable by and compatible with the repository. This can only be achieved by active NRC QA oversight of the defense waste facilities, not by depending on the DOE to overview themselves. This section states that the DOE HQ-OGR will advise the NRC about the adequacy and implementation of the QA programs at the defense waste facilities, but it does not mention how often this will be done. Will there be only one report to cover the entire length of the program? This is unacceptable.

If this report is issued, affected States and Tribes should be allowed review and comment on the report.

Comment 25

Supplement 12: This supplement does not belong in the QA Plan. It is more of a policy statement.

Section 3.0: Does the one observer allowed mean one observer from each interested affected State and Tribe, or one observer to be picked by DOE if more than one affected State and Tribe are interested in observing the audit?

Section 4.0: Define "certified auditor". To our knowledge, there is no defined requirements for certification of auditors, only the requirements for certification of Lead Auditors. Have there been changes in the QA training of

auditors as required by NOA-1 or is this just a requirement of DOE for State and Tribe observers? If auditors are now required to be certified, does DOE plan to require their own auditors to be re-trained in accordance with these unknown requirements?

Does the DOE Lead Auditor training course qualify as training, qualification and certification of an auditor?

Section 5.1: Since this section requires 21 day written notice for observer participation in a DOE audit, we would like the requirement that 30 days written notice of scheduling of audits be given the affected States and Tribes.

This section also states that the observer be trained, qualified, and certified in accordance with QIP 18.3. We would like the statement changed to state "in accordance with ... QIP 18.3 or its equivalent .

Section 5.2: The documents sent to the audit observer should also include a list of the audit team members.

Section 6.2.2: How will possibly conflicting comments of the audit observer be resolved and who will be responsible for the resolution?

ANDREA BEATTY RINKER
Director



STATE OF WASHINGTON
DEPARTMENT OF ECOLOGY

Mail Stop PV-11 • Olympia, Washington 98504-8711 • (206) 459-6000

November 20, 1986

Ben Rusche, Director
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy
1000 Independence Avenue
Washington, D.C. 20585

Dear Mr. Rusche:

The state of Washington appreciates the opportunity to comment on the Office of Civilian Radioactive Waste Management (OCRWM), Office of Geologic Repositories (OGR) "Quality Assurance Plan for High-Level Radioactive Waste Repositories". Earlier state of Washington comments on quality assurance issues were included as a part of our submittals on the Site Characterization Report, the General Guidelines for the Recommendation of Sites for Nuclear Repositories, the Mission Plan, and the Environmental Assessment. In each submittal we expressed concerns about the quality assurance function within the U.S. Department of Energy organization. In each submittal we expressed a concern about the lack of an adequate quality assurance program. Recent stop work orders at Hanford and Yucca Mountain again illustrated the need for a strong, independent, and accountable quality assurance programs.

It appears the writers of the currently issued version of the OGR Quality Assurance Plan were not aware of our earlier comments and comments made during Quality Assurance Coordinating Group (QAG) meetings. In our opinion, the current version must be revised to reflect our positions on several significant areas.

Our comments are divided into general comments on organization, accountability, independence, and matrix management, plus detailed comments on specific sections of the plan.

Previous state of Washington comments have emphasized the need for organizationally recognizing the importance of quality assurance. As a minimum, the OCRWM Quality Assurance Manager should report directly to the OCRWM Director, the OGR Quality Assurance Manager should report directly to the OGR Associate Director, and the each field site quality assurance manager should report directly to the field site project manager. Each quality assurance manager must be fully accountable for appropriate functions, be independent of project cost and schedule considerations, and report directly to one boss.

The OCRWM organization chart indicates the OCRWM QA Manager reporting directly (solid line) to the Office of Policy and Outreach Director, with an unexplained dotted line to the OCRWM Director. The OGR organization chart indicates the OGR QA Manager reports directly to the Licensing and QA Branch Chief, who reports to the Siting,

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Licensing and Quality Assurance Division Director, who reports to the OGR Associate Director, who reports to the OGR Associate Director. The chart shows unexplained dotted lines from the QA Manager to the OGR Associate Director and the OCRWM QA Manager. This leads one to conclude that the OGR QA Manager has three bosses. This is the classic case of matrix management, where the QA Manager does not report to one boss and cannot be accountable for the QA function. The person reporting directly to the OGR Associate Director has responsibility for siting and licensing, plus the quality assurance function. This person is, therefore, not independent of projects and costs and schedule.

Figure 3-3 shows the Basalt Site Richland Operations Office (BWIP) with program/project responsibilities and reporting directly to the Office of Geologic Repositories (headquarters). The Department of Energy Richland Operations Office shows the BWIP Project Manager reporting directly to the Richland Operations Manager. This is another example of the project manager working for two bosses. In the past, the BWIP Project Manager has been on extended "special assignments" for the Operations Office. On several occasions, the QA Manager temporarily sat in for the project manager while the project manager was on special assignment. During this period, the QA Manager was clearly responsible for BWIP costs and schedules. The Quality Assurance Plan must address this issue in more detail.

The OGR QA plan does not address the issues of how many USDOE QA persons should be on staff to oversee contractors. At Hanford there has been an unacceptable ratio of USDOE QA persons to contractor QA persons. USDOE is accountable for the quality of work and must provide an adequate number of USDOE quality assurance persons to ensure quality. Recent Hanford QA problems and the resulting stop work orders at Hanford illustrate the problem. The OGR QA plan should discuss this issue and the plan should specify an appropriate ratio.

Specific comments are as follows:

- 2.3.1 The Mission Plan should provide an informational basis sufficient to permit informed decisions, but recent USDOE decisions regarding a second repository have severely reduced the value of the document.
- 3.1 The statement that the "QA management functions responsibilities and authorities for OGR have been assigned by the Director, OCRWM to the Associate Director OGR" seems inconsistent with figure 3.1.
- 4.3.2.d The OGR QA Manager "overview" funding for QA activities and identified insufficient resources through the Licensing and QA Branch Chief through the SLQA Division Director to the Associate Director OGR. This appears to illustrate our concern about the level of QA personnel within the USDOE organization.
- 4.3.2.e.1 Project office QA plans and procedures should be submitted to the appropriate states and affected Indian tribes for their review and comment.
- 4.3.2.e.3 The appropriate state and affected Indian tribes should be invited to participate in project readiness reviews. The invitation should include early access to data.

- 4.3.2.f.6 Results of surveillance performed should also be reported to the appropriate states and affected Indian tribes.
- 4.6 OGR QA Supplement #6 should be changed to indicate that states and affected Indian tribes will be notified at the time significant quality problems are identified and again when resolved. Significant problem reporting and corrective action records are a significant part of the record for NRC licensing and as such should become permanent records.
- 5.3.1 The project QA plan and/or applicable QA administrative procedures should describe a process for review and comment by appropriate states and affected Indian tribes.

Appendix A - Quality Assurance Manual Evaluation-Handling, Storage and Shipping -- Requirements for control of samples from collection of the sample analysis should be established and documentation for control of each sample must be provided.

Supplemental QA Requirements - Supplement No. 11

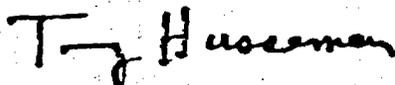
- 1.0 Appropriations have been approved to begin preliminary design work on the Hanford Waste Vitrification Plant and criteria are being developed to determine which wastes should be vitrified. Both activities require an adequate QA program. The supplement should be amended at this time to include Hanford wastes.

Supplemental QA Requirements - Supplement No. 12

We question whether this supplement is appropriate. Arbitrarily limiting non-DOE observers to one observer during each audit cycle is contrary to the NWPA because the states, tribes and NRC have a statutory role which allows participation. USDOE should substitute a process whereby states, tribes and NRC are encouraged to cooperate on audits and the audit team is made up of the most highly qualified personnel.

Please contact me or Don Provost if you have questions.

Sincerely,



Terry Husseman, Director
Office of Nuclear Waste Management.

TH:ht

cc: Jim Knight
Carl Newton

United States Government

C. Newton
Department of Energy

memorandum

12.1.2

DATE: November 13, 1986

REPLY TO
ATTN OF: RW-40

SUBJECT: OCRWM Quality Assurance Management Appraisal of the
Headquarters Office of Geologic Repositories

TO: Stephen H. Kale
Associate Director
Office of Geologic Repositories

In accordance with the quality assurance management policies and requirements for the civilian radioactive waste management program, and on the behalf of the Director, the first quality assurance management appraisal of the Headquarters Office of Geologic Repositories (HQ-OGR) was conducted during the period from September 8 to 24, 1986.

The appraisal was designed to determine the status, adequacy and effectiveness of HQ-OGR quality management systems, including the direction, control, and overview of project-level quality assurance activities. HQ-OGR organizational structure and staffing for managing for quality were assessed, also, as were actions to enhance proper quality attitudes and improve quality management systems.

The appraisal focused on five quality assurance management concerns:

- Organization and staffing
- Indoctrination and training
- Planning and direction
- Problem management
- Management overview

The attached report summarizes the observations of the appraisal team and contains my recommendations for your consideration. Your response to these recommendations, including a brief description with schedules for initiation and completion of appropriate actions, would be appreciated within 45 days. Please indicate, also, any additional actions that are being taken or planned by your office to further strengthen the HQ-OGR quality assurance management function.

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At your convenience I would like to discuss plans for future OCRWM quality assurance management appraisals which would encompass project-level activities and would be coordinated with and supported by your staff.

Merritt E. Langston

Merritt E. Langston
Manager, Quality Assurance
Office of Civilian Radioactive
Waste Management

Attachment

CC:

B. Rusche, RW-1
C. Kay, RW-2
J. Knight, RW-24

**REPORT ON THE
QUALITY ASSURANCE MANAGEMENT APPRAISAL OF THE
OFFICE OF GEOLOGIC REPOSITORIES**

NOVEMBER 7, 1986

EXECUTIVE SUMMARY

The appraisal confirmed that HQ-OGR quality management systems were in an varying stages of evolution. In many areas, HQ-OGR managers were consistently implementing, or making satisfactory progress toward developing, sound management systems as the foundation for a strong QA program. Most importantly, quality management systems were derived primarily from frequent interactions among HQ-OGR and waste repository projects managers.

In some areas, such as technical management control and tracking, technical assessments, and problem management, quality management systems appeared to be either inadequate or indeterminate in their development and implementation status, due primarily to the lack of documentation and promulgation of these systems among HQ-OGR divisions. Quality management systems development was oriented primarily toward procedural aspects, without sufficient attention to the promotion of the OCRWM concepts of managing for quality at the HQ-OGR and project levels, to the enhancement of proper quality attitudes, and to the improvement of quality management systems.

INTRODUCTION

In accordance with the quality assurance (QA) management policies and requirements for the Office of Civilian Radioactive Waste Management (OCRWM), and on the behalf of the Director, the first QA management appraisal of the Headquarters Office of Geologic Repositories (HQ-OGR) was performed during the period from September 8 to 24, 1986.

The appraisal assessed the status, adequacy and effectiveness of HQ-OGR quality management systems, including HQ-OGR management direction, control, and overview of waste repository project offices, for ongoing and near-term activities. HQ-OGR organizational structure and staffing for managing for quality were assessed, also, as were actions to enhance proper quality attitudes and improve quality management systems.

The appraisal focused on five quality assurance management concerns:

- Organization and staffing
- Indoctrination and training
- Planning and direction
- Problem management
- Management overview

The following OCRWM and HQ-OGR quality management systems documents constituted the basis for the appraisal:

- OCRWM Program Management System (PMS) Manual (DOE/RW-0043)
- OCRWM QA Management Policies and Requirements (QAMPR) (DOE/RW-0032)
- HQ-OGR Systems Engineering Management Plan (SEMP) (OGR/B-7)
- HQ-OGR QA Plan (DOE/RW-0095, OGR/B-3)

The appraisal was performed by the OCRWM Assurance Manager, with the assistance of several independent quality assurance management professionals. The observations of the appraisal team and the recommendations of the team leader are summarized in the following sections.

DISCUSSION

1. ORGANIZATION AND STAFFING

Consistent with OCRWM concepts of managing for quality, as defined in the documents referenced above, lead responsibility for development and implementation of the HQ-OGR quality management systems was vested by the Director, OCRWM, in the HQ-OGR Associate Director; division directors, branch chiefs and professional staff were responsible for QA program implementation in their assigned line functions.

Responsibility for coordinating and overseeing the HQ-OGR and waste repository project offices QA programs was assigned to the Director of the HQ-OGR Siting, Licensing and Quality Assurance Division (SLQAD). This function was delegated to the HQ-OGR QA Manager, who was located in the Licensing and QA Branch. The HQ-OGR QA Manager was: (1) independent from the HQ-OGR line technical divisions, (2) had the right of direct access ("dotted line" authority) to the HQ-OGR Associate Director and to the OCRWM QA Manager, and (3) obligated to report on significant quality problems and issues and cause their resolution. While this functional arrangement was workable, it was perceivable that the HQ-OGR QA Manager had been relegated to a position too far down in HQ-OGR and, as licensing activities increased, the HQ-OGR QA function could become buried in branch. A rationale for maintaining or changing the location of the HQ-OGR QA Manager, in response to an Nuclear Regulatory Commission (NRC) issue on QA organization for site characterization activities, had not been developed by HQ-OGR.

Regarding staffing levels, HQ-OGR management indicated that needs for additional staffing for FY1987 had been identified, and that recruiting of qualified and experienced personnel was in progress. Consistent with long standing DOE management practices, HQ-OGR relied on competent contractors for technical and QA assistance to the HQ-OGR professional staff.

Regarding organizational interfaces, HQ-OGR QA interactions with other DOE program offices, the NRC, first repository states, and affected Indian tribes had increased significantly during FY1986. HQ-OGR was developing positions on a number of QA interface issues, such as HQ-OGR overview of West Valley and defense waste QA activities.

RECOMMENDATION

1. Develop and provide to the Director, OCRWM, an action plan with rationale for establishing a strong and independent HQ-OGR quality assurance management function with adequate staffing and at an appropriate organizational level for coordination and overview of ongoing and near-term HQ-OGR and project-level activities.

2. INDOCTRINATION AND TRAINING

HQ-OGR had not implemented a comprehensive QA indoctrination and training program:

- (1) to promote an understanding of the OCRWM concepts of managing for quality among management and professional staff at all levels of program,
- (2) to enhance proper quality attitudes, and
- (3) to cause improvement in quality management systems.

HQ-OGR training consisted of QA Auditor courses only. In May 1986 a broader QA indoctrination and training program had been proposed for HQ-OGR professional staff but was postponed indefinitely due to other priority activities.

OCRWM concepts of managing for quality were relatively new to HQ-OGR management and were significantly different from traditional approaches which had been applied to the licensing of nuclear power plants and which were reflected in the NRC QA review plan. In the traditional approach, QA was generally regarded as the responsibility of the QA organization. Contrary to this approach, the OCRWM concepts strived to integrate QA into the program and systems engineering management plans and procedural controls, and to hold line management, rather than the QA organization, primarily accountable for QA. Understandably, perhaps, the OCRWM managing for quality concepts were only beginning to be understood and implemented by HQ-OGR program managers. HQ-OGR had not yet established or endorsed an indoctrination program that promoted the OCRWM concepts of managing for quality.

As a means for increasing quality awareness, HQ-OGR managers were receptive to including measurable standards/elements for quality in performance appraisal plans for HQ-OGR professional staff.

Consistent with the QAMPR, HQ-OGR required that all QA auditors be qualified to standards for education, training and experience along the lines prescribed by ANSI/ASME NQA-1, and that lead auditors be qualified and certified. Several HQ-OGR technical personnel had received auditor training in 1984 and had participated in audits. It was not evident that HQ-OGR professional personnel would be trained in the principles and process of technical assessments prior to undertaking this planned activity.

HQ-OGR was informed about but had not taken the lead in coordinating and overseeing project-level QA indoctrination and training activities. As a result, HQ-OGR was not in a position to determine the adequacy, consistency and completeness of these activities.

RECOMMENDATION

- 2A. Establish a comprehensive and coordinated HQ-OGR plan for indoctrination and training of HQ-OGR and project-level professionals who perform activities affecting quality.
- 2B. Assume a more active leadership role in overseeing project-level QA indoctrination and training activities.
- 2C. Develop measurable standards/elements for quality achievement and quality management systems improvement in appraisal plans for HQ-OGR technical managers and professionals.

3. PLANNING AND DIRECTION

According to HQ-OGR managers, HQ-OGR QA management direction was provided in various ways and at three management levels. At the top level were the bimonthly project managers' meetings at which key generic QA management issues were discussed. The second level consisted of numerous coordinating groups which met periodically to discuss a variety of topical issues, such as a common approach to the application of graded QA. At the third

level were task and working groups and committees which worked in specific areas of assignment for HQ-OGR, such as waste acceptance QA. This tiered structure had the potential for effective QA management direction, provided that QA was a regular, high priority agenda topic in project managers' meetings, that resolution of generic issues was documented and traceable, and that QA coordination occurred consistently among the second and third tiers.

HQ-OGR responsibilities for technical review and approval of project activities were defined generally in the SEMP. Specific responsibilities relative to HQ-OGR controlled milestone activities and documentation were redefined periodically in program direction memoranda and in functional design requirements documents. Thus, HQ-OGR was developing potentially effective mechanisms for technical management control and tracking but had not documented and promulgated these mechanisms as quality management systems.

In July 1986 HQ-OGR had developed a list of quality-related technical management activities and documents for which HQ-OGR was responsible for initiation, review or approval, and for which technical management procedures were to be developed. The goal was to have the procedures issued by September 30 and have HQ-OGR professionals trained in their use by October 30, 1986; this activity had not been fully implemented.

At the time of the assessment it was difficult to determine the status and adequacy of the overall HQ-OGR QA program. Perhaps because the technical requirements and activities, which were the basis for the QA program, were still evolving, there was no master plan or listing of tasks to be completed at specific program milestones which would indicate whether a fully acceptable and auditable HQ-OGR QA program was in place for ongoing and near-term program activities.

In July 1986 the HQ-OGR QA Plan was extensively revised and reissued, to comply with the QAMPR, address comments of the NRC and waste repository projects, and describe more fully the responsibilities of line managers for quality; the revised plan had been provided to the NRC, first repository states and affected Indian tribes for comment. Included in the revised HQ-OGR QA Plan were supplemental QA requirements for 8 of 11 identified topics: two of the more complex topics having licensing significance and OCRWM-wide impact were concerned with the "Q List" methodology and a three-level system for the application of graded QA. Also included in the HQ-OGR QA Plan were Quality Implementing Procedures (QIP'S) for 11 of 17 identified topics. Consistent with the QAMPR, HQ-OGR was

proceeding with the review and approval of project-level QIP's. Issue dates had not been established for the remaining HQ-OGR supplementary requirements and QIP's. HQ-OGR had not followed up to determine that the baselined HQ-OGR and project-level QA documents were being implemented effectively. HQ-OGR had not implemented the graded QA approach on technical activities and contracts that were managed directly by HQ-OGR.

Quarterly QA Coordinating Group (QACG) meetings, chaired by the HQ-OGR QA Manager and attended by projects QA managers and their principal contractors, served as the principal forum for the exchange of QA information, for obtaining consensus on common requirements and procedures, and for presenting the status of project-level QA program implementation. In July 1986 the QACG meeting was expanded to include invited representatives of the NRC, first repository states and affected Indian tribes, who were provided for an opportunity to present their viewpoints. The effectiveness of the QACG for providing technical direction was weak because the HQ-OGR QA Manager did not have the authority to make QA management decisions.

RECOMMENDATION

- 3A. Reestablish dates for timely issuance of identified technical management procedures and for training of personnel in their use.
- 3B. Complete the documentation and coordination of quality management systems, including review and tracking of HQ-OGR controlled milestone activities.
- 3C. Develop a master plan and schedule for determining the readiness status of the HQ-OGR and project-level QA programs, including a listing of tasks to be completed, and issue dates for remaining supplementary requirements and implementing procedures.
- 3D. Implement graded QA approach on activities and contracts managed directly by HQ-OGR.
- 3E. Define the authority of the HQ-OGR QA Manager relative to decision making and direction at QACG meetings.

4. PROBLEM MANAGEMENT

HQ-OGR management appreciated the importance of timely and accurate reporting of significant quality problems and their resolution. This appreciation was heightened by a series of stop-work orders that had been issued in 1986 by the projects to a number of contractors when adequate QA programs had not been implemented for programmatically important activities.

During the assessment, it was learned that significant quality problems and issues were included in HQ-OGR weekly printouts as part of a computerized action system and were tracked to closure by the HQ-OGR QA Manager. This quality management system had not been documented for general HQ-OGR usage, thus reducing its effectiveness. In a similar vein, the HQ-OGR Engineering and Technology Division Director had worked out a logical process for the lifting of stop-work orders on one project, whereby the project was responsible for lifting the stop-work order after HQ-OGR review and concurrence; this process had not been documented and issued as a quality management system for general usage.

In August 1986 the NRC and HQ-OGR agreed to develop a quality management system that would track NRC QA issues and their resolution; subsequently, HQ-OGR requested the NRC to identify existing or new issues. At the time of the assessment a system had not been developed nor had the NRC provided a list of issues.

HQ-OGR had reviewed the NRC Ford Amendment Study (NUREG 1055) of existing and alternative methods for improving quality and the assurance of quality in the design and construction of nuclear power plants. A primary focus of the study was to determine the underlying causes of major quality-related problems in the construction of some nuclear power plants and the untimely detection and correction of these problems. The study concluded that the root cause for major quality-related problems was the failure or inability of some utility managements to effectively implement a quality management system that ensured adequate control over all important aspects of the project. The study recommended a number of improvements in quality management systems, including self-imposed rising standards of excellence, improved diagnostic and trending capabilities, and an ordering of hardware and related QA activities commensurate with their importance to safety.

RECOMMENDATION

- 4A. Develop and promulgate HQ-OGR quality management systems for identifying and tracking significant quality problems and NRC issues, and for lifting stop-work orders.
- 4B. Re-evaluate the Ford Amendment Study and take appropriate actions to ensure implementation of applicable lessons to be learned for waste repositories.

5. MANAGEMENT OVERVIEW

HQ-OGR had not implemented an aggressive, comprehensive QA management overview function. HQ-OGR overview consisted of annual quality systems compliance audits of waste repository projects. While compliance audits were appropriate, they did not provide for a technical assessment of the adequacy of project quality-related activities and products. Notwithstanding the good communication among HQ-OGR and waste repository project offices, HQ-OGR overview had not confirmed by frequent, documented surveillance and followup whether adequate and effective project quality management systems were being implemented and would be in place prior to the submittal of site characterization plans and prior to NRC audits.

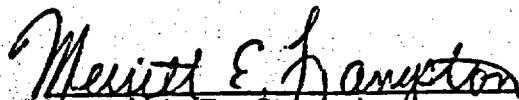
No internal QA audits of HQ-OGR had been conducted. An internal QA audit of HQ-OGR had been rescheduled from February to November 1986, at which time the HQ-OGR supplemental requirements, QIP's, and technical management procedures mentioned above were expected to be in place.

HQ-OGR technical assessments of selected waste repository project activities and products were in an early planning stage. In May 1986 an approach for HQ-OGR technical assessments was developed but implementation was postponed until the second quarter of FY1987.

A QA management appraisal of HQ-OGR was performed by the technical support contractor in February 1986. HQ-OGR management was unaware of the results because an appraisal report had not been issued. At the request of the Director, OCRWM, the HQ-OGR QA plan was revised to require HQ-OGR QA management appraisals to be performed at least annually and reported to senior OCRWM management.

RECOMMENDATION

5. Plan and implement a strong, comprehensive HQ-OGR QA management overview activity which will provide for the performance of management appraisals, technical assessments and audits on a timely basis commensurate with major program milestone events.


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