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ATTACHMENT H

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

SUPPLEMENT No. 12

PROTOCOL FOR NON-DOE OBSERVERS ON DOE QUALITY ASSURANCE AUDITS

December, 1986

U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Office of Geologic Repositories

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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

PROTOCOL FOR NON-DOE OBSERVERS ON DOE QUALITY ASSURANCE AUDITS

1.0 GENERAL

This supplement provides guidance for the participation of non-DOE observers on QA Audits of DOE/OGR repository program activities. It supplements the OGR QA Plan. The requirements in this supplement are to be used in conjunction with the requirements embodied in the OGR QA Plan.

2.0 PURPOSE

The purpose of this Supplement is to describe the requirements, responsibilities, and limits of authority on non-DOE observers participating in OGR Audits of the repository program.

3.0 SCOPE

This Supplement applies to audits conducted by HQ-OGR, OGR Project Offices and their contractors.

4.0 DEFINITIONS

4.1 Non-DOE Observer - An individual who is not employed or hired by DOE or an OGR project contractor, who is allowed to participate in an OGR audit as an observer.

4.2 OGR Project Contractor - An individual or organization under contract with DOE to perform work or provide services to HQ/OGR or an OGR project.

5.0 RESPONSIBILITIES

5.1 Number of Non-DOE Observers - This supplement limits non-DOE observers to one (1) observer during each audit unless approval for additional non-DOE observers is granted by the OGR QA Manager.

5.2 Requesting Organization - The organization requesting that a non-DOE observer be allowed to participate in a particular audit shall send a written request to the attention of the OGR QA Manager at least twenty-one (21) days prior to the start of the audit. If the audit is an audit of the Project Office, or Project Office contractors, the OGR QA Manager will consult with the Project Manager prior to granting observer approval.

5.3 Training - The observer shall be trained on the principles of auditing. The formal training shall include training in the requirements of 10CFR50, Appendix B, NQA-1, NRC Review Plan: Quality Assurance Programs for Site Characterization for High Level Nuclear Waste Repositories and general training in areas of fundamentals, objectives, characteristics, organization, performance, and results of auditing. A copy of the observers training records shall be sent to the OGR QA Manager at least seven (7) days prior to the start of the audit.

5.4 Audit Team Leader - The audit team leader shall forward to the HQ-OGR-approved observer, at least fourteen (14) days prior to the start of the audit, the following documents:

(a) Audit Scope and Schedule
(b) Audit Plans and Checklists
(c) Copies of Relevant QA Reference Documents
(d) Action Items/Closeout information from any previous audit of the organization being audited.
(e) Other information that is relevant to the audit.

5.5 Observer - The Observer shall be responsible for reviewing all pertinent information prior to the start of the audit. If there are any questions regarding the contents of the pre-audit documents, the observer should contact the audit team leader for clarification. The observer is to inform the audit team leader at least seven (7) days prior to the start of the audit, those audit activities the observer is interested in observing.

5.6 Conduct and Participation

During the audit, the observer's conduct shall be limited to the following activities:

(a) Attend and participate in the audit team caucus prior to the start of the audit.
(b) Attend the pre-audit meeting with audit team members and the audited organization's representatives.
(c) Attend various portions of the audit as an observer. The observer must direct any questions, comments, or concerns to the audit team leader.
(d) Attend and participate in audit team caucus and meetings during the audit.
(e) Attend the post-audit meeting with audit team members and the audited organization's representatives.

5.7 Submission of Report

The observer shall submit a written summary report, to the attention of the audit team leader, with a copy to the OGR QA Manager, no later than five (5) days upon completion of the audit. The purpose of this summary report is to provide an opportunity for the observer to document any observations or concerns about the conduct of the audit and to transmit them to the OGR QA Manager.

5.7.1 The report, as a minimum, shall address the following:

(a) Describe the portions of the audit observed.
(b) List date(s) of audit participation.
(c) Provide comments on the effectiveness of the QA Plan and procedures audited.
(d) Provide comments on the quality of technical work elements audited.
(e) Provide comments regarding observations, with appropriate recommendations, that could enhance both audit and program activities.

5.7.2 The observer's report format may follow the format used by his/her organization, but shall address the above noted report requirements (Section 5.7.1).

SUPPLEMENT ON ISSUING AND LIFTING OF STOP WORK ORDERS

NO SUPPLEMENT NEEDED

- PROJECT QA PLANS/PROCEDURES ALREADY INCLUDE REQUIREMENTS FOR STOP WORK - APPROVED BY DOE-HQ
- SUBJECT CAN ONLY BE ADDRESSED IN VERY GENERAL TERMS EVEN AT PROJECT QA PLAN LEVEL
- FURTHER DEFINITION OR DETAILS WOULD BE CONSTRAINING TO PROJECTS
- READINESS REVIEW PROCESS MAY BE USED IN PREPARATION FOR LIFTING MAJOR STOP WORK ORDERS
- DO NOT RECOMMEND A SPECIFIC SUPPLEMENT FOR ISSUING AND LIFTING OF STOP WORK ORDERS

Draft Revision D April 1987

Supplemental Quality Assurance Requirements

READINESS REVIEW

1.0 GENERAL

This Supplement provides amplified requirements for the conduct of Readiness Reviews. It supplements the OGR-QA Plan. The requirements in this Supplement are to be used in conjunction with the requirements specified or referenced in the governing QA plans and procedures.

2.0 PURPOSE

This Supplement establishes the requirements and responsibilities for the conduct of Readiness Reviews during the life of mined geologic disposal systems.

3.0 SCOPE

This Supplement identifies the requirements and responsibilities for the Readiness Review process used to determine that critical work activities related to site characterization, design, procurement, construction, test and operations, permanent closure and decommissioning are ready to proceed.

The Readiness Review process is to assure that items or elements of critical work activities such as, but not limited to, plans, costs, schedules, procedures, work site controls, modules, hold points, equipment, safety, hygiene, traffic, security, emergency procedures,

critical safety radiation protection, environmental protection, hardware, personnel training, testing, certification and qualification have been adequately addressed and may be released for use on the project. The Readiness Review process shall be in addition to other reviews, shall be at a senior level in the organization, and shall be limited to critical project activities.

4.0 DEFINITIONS

Readiness Review - A systematic documented review of the readiness for startup and/or continued intended use of a facility, process, or activity.

5.0 REQUIREMENTS

The requirements specified in this Supplement are applicable to all project entities (DOE project offices, construction managers, Integrating Contractors, Contractors, as applicable) and shall be used in conjunction with the requirements embodied in the governing documents identified in the OGR QA Plan.

5.1 The Readiness Review process shall be defined in a series of documents:

1. A programmatic procedure shall be developed by each entity required to perform readiness reviews.

2. Individual readiness review instructions, supported by checklists, shall be developed for each critical work activity to which the process is being applied.

5.2 The process shall be implemented by:

1. A Readiness Review Board

2. Readiness Review Teams

5.3 The Readiness Review procedure shall define the duties and responsibilities of the project's participants. The document shall define when the process is to be used, approval requirements, involvement of others (DOE-HQ, NRC, States, and Affected Indian Tribes), development of readiness review instructions and checklists for specific activities, creation of a readiness review board and readiness review teams, and documentation requirements.

5.4 Readiness Review Instructions shall be prepared to identify and assess the status of work items or elements that are necessary prerequisites to the transition of a project from one phase to the next. These instructions shall include the identification of hold points which must be satisfied including the criteria to release the hold. Items or elements of critical work activities shall be identified within the instruction. These items or elements shall include, but not be limited to, design process, reviews, system identification, facilities, structures, hardware, documents, equipment, procedures, personnel training, records, services, inspection, testing, construction, manufacturing, purchasing, or analysis.

5.4.1 Checklists shall be developed prior to performing readiness reviews, shall be approved by the readiness review board, shall be implemented by the readiness review teams. Completed checklists shall serve as evidence of the reviews and readiness to perform an activity.

5.5 The project shall appoint a Readiness Review Board (RRB) to include a chairperson and appropriate members. The Board will make recommendations to the senior official of the organization (i.e., Project Manager, Program Director) as to the readiness to proceed based on the evaluation and recommendations of the Readiness Review Teams. Each RRB shall consist of senior level management representatives including representatives responsible for QA, technical work, licensing, safety, etc. as applicable. The expertise of independent parties may be used as appropriate. The main support to the Board shall be provided through readiness review teams appointed by the RRB.

5.6 The Readiness Review Team shall be sufficiently multidisciplined to identify and assess the status of and coordinate implementation of prerequisite activities. The team shall consist of individuals from the disciplines of science, engineering, safety, quality assurance, management and construction, as appropriate, under the direction of a team chairperson. Each member shall have the authority to act independently of their technical discipline for readiness review tasks. This group will initiate the preparation, review, approval, use and control of readiness review instructions, schedules, analytical methods, checklist, logic networks and personnel training records, as applicable.

5.7 The project Quality Assurance organization shall assess the implementation and effectiveness of readiness reviews against applicable quality assurance requirements.

5.8 The readiness review process may be utilized in special instances (i.e., lifting of major stop work orders, managerial requests) as determined by the project office or OGR.

ATTACHMENT K

Supplement No. ____

SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

AUDIT OF PROGRAM EFFECTIVENESS

1.0 GENERAL

This supplement provides requirements for and guidance in auditing the effectiveness of mined geologic repository quality assurance programs.

2.0 PURPOSE

The purpose of this supplement is to establish a standard methodology for conducting, and reporting results of, audits of QA program effectiveness in order (1) to ensure valid, objective measurement of program effectiveness, and (2) to ensure that reported effectiveness results are comparable across the mined geologic repository program.

3.0 SCOPE

This supplement applies to all entities within the scope of the Office Geologic Repositories (OGR) Quality Assurance (QA) program who conduct QA audits.

4.0 DEFINITIONS

4.1 QA Program Element

A set of related institutional provisions or a management control system established to reduce the likelihood that a recognized project risk will materialize, or to detect and correct the effects of risks that do materialize.

4.2 Project Risk

The possibility of occurrence of an event or condition which, if it were to occur, (1) could render the output of a project activity unusable without rework or performance of unplanned additional work, or (2) could compromise project licensability.

4.3 Institutional Provision

An aspect of the framework within which project activities take place (e.g., organization, facilities, working conditions, training, management philosophy, equipment and tools, personnel practices, etc.).

4.4 Management Control System

An organized set of decision points, actions and feedback mechanisms for ensuring the correct (valid) outcome of a process - ordinarily an integrated set of individual controls.

4.5 Attribute

A characteristic or feature.

4.6 Effectiveness

For a QA program element, the attribute of accomplishing, or of having accomplished, its intended purpose. Its purpose is judged to have been accomplished if the output of the controlled activity has not suffered the effects of risks the control is intended to prevent or detect.

4.7 Significant Deficiency

a. With respect to effectiveness audit, failure of a QA program element to satisfy its intended purpose such that, had the resulting discrepancy(ies) in completed output of the affected activity(ies) not been detected, the validity of characterization or design of one or more repository systems would have been compromised in an aspect affecting safety or waste isolation.

b. With respect to effectiveness audit, lack of or incorrect performance of a feature of a QA program element such that the program element could not achieve its intended purpose if challenged.

4.8 Administrative Deficiency

With respect to effectiveness audit, lack of or incorrect performance of an administrative feature of a QA program element such that the discrepancy does not constitute a significant deficiency as defined above.

5.0 RESPONSIBILITIES (LATER)

6.0 REQUIREMENTS

6.1 QA Program Elements

To facilitate interpretation and focus corrective action efforts, QA program effectiveness shall be audited, and audit results shall be reported, in terms of the QA program elements listed in Appendix A to this supplement.

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a. The program elements of Appendix A correspond to subsections within the supplements to ANSI/ASME NQA-1 or, in the absence of NQA-1 supplements, to discrete and distinct measures specified within individual criteria of 10CFR50 Appendix B.

b. Each QA program element shall be interpreted as embodying all of the requirements contained in the matching NQA-1 subsection or 10CFR50 Appendix B requirement.

c. It is not required that auditee procedures (QA administrative, implementing, or technical) be organized by QA program element. For example, the management control system designed to provide a required control will often involve decisions and actions across several of the auditee's organizational units, whereas procedures may be organized to address responsibilities by individual units; again, an auditee may find it desirable to use a single procedure to cover an organizational unit's responsibilities for several related QA program elements.

6.2 <u>Effectiveness Checklist</u>

It is recommended, but is not mandatory, that checklists intended for auditing the effectiveness of all or part of a QA program be organized by QA program element.

a. Checklist organization by QA program element should help focus the attention both of the auditor and the auditee on the control provision at issue and on its purpose, rather than on isolated bits of the system.

b. Organization of the checklist by QA program element shall not be construed as inhibiting the technique of following a particular item (study, report, design, component, sample, etc.) through a sequence of applicable QA program elements.

c. The effectiveness checklist shall include provisions (i.e., questions or instructions) for evaluating the end product of the audited activity for evidence that the QA program element is accomplishing its intended purpose (see Effectiveness definition).

d. The effectiveness checklist shall also include provisions for verifying that critical features of the QA program element at issue are in place.

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6.3 Effectiveness Indicators

Verification of QA program element effectiveness shall be based on objective evidence. For the sake of clarity, this supplement uses the expression "effectiveness indicator" to signify any attribute of an activity's output whose presence or absence would constitute definitive evidence that the control was or was not accomplishing its intended purpose.

For example, presence of an unauthorized or incorrect input among the bases for a design calculation would be compelling evidence that the system for control of design inputs was not, or had not been, effective. Absence of any instances of unauthorized or incorrect inputs in an appropriate sample of calculations would constitute evidence that the control system was working effectively.

Appendix A contains generic effectiveness indicators (labelled "indicators of system deficiency") for each QA program element. Normally, the auditor should express those indicators in terms of specific outputs of the activities to be audited.

6.4 Critical Features

In any QA program element, one or more of its features are critical to its operation; their absence or failure would make it impossible for the control system to accomplish its purpose if challenged. Most of the system's features, however, are simply preferred or agreed-upon auxiliary steps supporting those critical features; their absence, or presence of alternate steps, would not necessarily prevent the critical features from working.

In auditing QA program element effectiveness, the audit shall be designed to the extent feasible to distinguish between deficiencies that do not disable the control and those which do.

6.5 Reporting

Effectiveness audit results shall be reported in terms of the effectiveness of the audited QA program elements. The report shall, as a minimum, indicated which program elements were audited and which, if any, were found to be ineffective. It shall be permissible to report a QA program element as marginal or at risk because of noncritical deficiencies.

Individual effectiveness audit findings (adverse) shall be reported against the affected QA program element, rather than as isolated discrepancies. If a number of discrepancies within a single QA program element are discovered during the audit, they shall be cited as supporting evidence, not as separate findings.

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6.5.2 Determination of significance

a. Management of the audited organization shall determine the significance of the reported QA program element deficiency, making use of technical expertise as appropriate. Results of the determination and the rationale upon which it is based shall be documented and reported to the auditing agency.

b. The audit team leader and responsible management of the auditing agency shall evaluate the significance determination, in consultation with appropriate technical expertise if technical issues are involved.

c. In the event of disagreement between the audited and auditing organizations over assignment of significance level, an independent board representing the appropriate disciplines and including a senior member of QA management shall adjudicate the dispute.

6.5 Corrective Action

Corrective actions for a finding of QA program element ineffectiveness shall proceed as follows:

6.5.1 Observed discrepancies -- The discrepancies upon which the finding was based shall be corrected. If correction includes changes to previously approved and issued data or analytical results, the correction(s) shall be transmitted to all recipients of the original document, including parties receiving the information through the accessions list.

6.5.2 Impact -- For any finding determined to be significant, the audited organization shall investigate, document, and report implications of the system deficiency with respect both to ongoing and completed work. Impact assessment shall include the following considerations:

a. What activities other than those in which the deficiency was diagnosed fall within the scope of the deficient control system.

b. What work (data, analytical results, design, etc.), either ongoing or completed, should be put in question because of the system deficiency.

6.5.3 Preventive action - The audited organization shall establish a plan of action to accomplish the following:

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a. Review or otherwise evaluate work placed in question because of the system deficiency to determine whether or not it is technically acceptable for its intended use.

b. Take the necessary action to make affected work acceptable, or remove it from further use.

c. Take the necessary action to qualify any subsequent work based on work found to be defective or incapable of being pedigreed.

d. Determine the root cause(s) of the QA program element (system) deficiency.

e. Take action to eliminate the root cause(s) or render them incapable of adversely affecting QA program elements in the future.

f. Correct the design and/or implementation of the deficient QA program element to make it effective.

6.6 Corrective Action Evaluation

The auditing agency shall evaluate the response, including the plan of action. In the event of disagreement over response adequacy or appropriateness, the process described under significance determination shall be employed to resolve the issue.

FROM DOE COM CTR RICHLAND (MON)04.13.'87 14:09 NO.19 PAGE 7

SRPO COMMENTS ON "AUDIT OF PROGRAM EFFECTIVENESS"

I. General.

A. This is an example of what I think is the wrong path for use of OGR supplements. We all should beware of adding additional requirements, unless they are clearly needed. The Ford study concluded that written requirements were adequate--it was implementation of requirements that failed. Are present QA audits so poor that we need a new requirement? I suggest a "guidance document" to aid in meeting the present requirements.

B. What are the limitations of the proposed supplement? All audits? Only when selected? Every third audit?

C. Has anyone in the program used this method and found it acceptable? Are all the "words" in use now, e.g., "institutional provisions," "recognized project risk," "effectiveness," "significant deficiency," "administrative deficiency," "critical features of the QA program element"?

II. Specific Comments

A. Page 2, Section 4.7. This section limits the definition in S-1 of NQA-1, unless 4.7b is intended to mean "operability."

B. Page 2, Section 6.1. There is no Appendix A attached.

C. Page 3, Section 6.1 a and b. These sections cannot be evaluated without Appendix A.

D. Page 3, Section 6.1 c. What is the purpose of this section? No requirements are given.

E. Page 3, Section 6.2. Since this section is recommended, no "shalls" should be included; "should" is the word to use.

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F. Page 3, Section 6.2 d. This section is not clear as to its intent.

G. Page 4, Section 6.4, 2nd paragraph. How could this section be demonstrated to NRC?

H. Page 4, 5, 6. The numbers for sections are scrambled.

I. Page 4, Section 6.5, 1st paragraph, last sentence. What actions would be required by the audited organization?

J. Page 5, Section 6.5.2. This section does not appear to be necessary. If a proposed corrective action is adequate, why would it be necessary for an agreement as to significance?

K. Page 5, Section 6.5.1. What is an "accessions list"?

L. Page 5, Section 6.5.1., 1st sentence. This should be done for all adverse findings, not just for significant ones.

M. Page 5, Section 6.5.3. Is preventive action apply to significant findings or all adverse findings?

N. Page 6, Section 6.5.3c. What is meant by "incapable of being pedigreed"?

O. Page 6, Section 6.5.3 d, e, f. These are already required in NQA-1.

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COMMENTS ON DRAFT SUPPLEMENT CONCERNING AUDITING OF QA PROGRAME EFFECTIVENESS

BY: R.J. Oberle, CER Corp.

PARA 6.1

For clarity, this section should be reworded to make it clear to the reader/user that the intent of the audit is to assess and measure the effectiveness of the control system in facilitating acceptable end product.

PARA 6.2.

The instruction/guidance provided in this section are not adequate. Development of an checklist oriented toward evaluating effectiveness should follow the following steps. These steps should be included in Para. 6.2.

1. Identify the end product to be examined.

2. Identify the various processing steps or actions necessary to produce the end product.

3. Identify the QA Program elements applicable to the process.

4. Select an appropriate sample of end product for evaluation.

5. For each sample product, work backwards through the production process and control system to assure that QA Program elements were appropriately applied. Emphasis should be placed on identification of QA Program element deficiencies that are not manifested by obvious problems in complete ~~from~~ products.

6. For products identified as deficient upon inspection or evaluation at the completion. Focus on identification

specific QA Program elements that may have contributed to the deficient condition.

7. For all deficient conditions, the audit should focus on identification of the root cause of the deficiency. This should then be related to a QA Program element.

Para 6.2.c

How are "critical features" to be identified? What criteria are to be used? Perhaps a definition is in order.

Para 6.3 and 6.5

"Effectiveness Indicator" is not adequately defined. Some sort of ~~quantitation~~ quantitative scale needs to be identified. Absolutes (Yes/No or Go/No-go) are not well received by audited organizations.

1.0 GENERAL

This supplement amplifies the requirements for the conduct of a management assessment. It supplements the OGR QA Plan and ANSI/ASME NQA-1-1986. The requirements in these supplements are to be used in conjunction with the requirement embodied or referenced in the governing QA plans and procedures.

2.0 PURPOSE

The purpose of this supplement is to specify requirements for the documents and control of management assessments.

3.0 SCOPE

The requirements of this supplement are applicable to the OGR Project Offices.

4.0 DEFINITIONS

4.1 Management Assessment: A detailed evaluation conducted to determine the effectiveness of the Quality Systems and management controls that are established to achieve and assure quality. This includes the adequacy of resources and personnel dedicated to the implementation of the Quality Assurance Program.

4.2 Management Level (within the major Project Participants): That level of official management reporting directly to the Project Manager and other levels of management within the organization that may report to the Project Manager's support group, e.g., Personnel, Engineering, or Finance.

4.3 Line Organization: The level within the structure of an organization that has the responsibility for technical direction of one or more tasks.

5.0 RESPONSIBILITIES

5.1 The ultimate responsibility for compliance with QA requirements, even though delegated to subordinate Project Organizations, rests with the delegating organization.

5.2 Each major organization participating in the Project shall develop internal procedures for planning, organizing, performing and documenting Quality Assurance management assessment programs. These procedures shall implement the general requirements of this supplement and shall include appropriate analyses, reporting of results, and the tracking of recommendations to their intended conclusions.

5.3 Management of each major Project Participant shall verify that their Quality Assurance Program is being effectively implemented and that personnel performing quality affecting activities are correctly trained/certified in accordance with their approved Quality Assurance Program.

5.4 The Project Office Project Manager shall develop annual schedule for completion of the management assessment. The schedule shall include, as a minimum, the milestone dates for completion of the Level I, II, and III management assessment inputs.

6.0 PROCEDURE

6.1 The management assessment activities shall be conducted at three distinct levels as follows:

6.1.1 Level 1: The line organization level consisting of the Quality Assurance Deputy (or second in command, whatever the title), the Quality Assurance Staff and the Principal Investigator and/or Technical Principal(s) for each major work activity.

6.1.2 Level 2: The management organizational level consisting of the Quality Assurance Manager, Project Manager Deputy (or second in command, whatever the title), and selected management as designated by the Project Manager.

6.1.3 Level 3: The Project Office Project Manager Deputy, the Project Manager of each major participating organization, and the Project Quality Manager.

6.2 The Level 1 management assessment process shall proceed as follows:

6.2.1 The committee shall be formed and chaired by the designee selected by the Project Manager. The committee meeting(s) shall be planned and scheduled to be flexible for all members to insure that all management assessment activities are completed in a timely manner.

6.2.2 The QA Staff will provide Quality Assurance documents necessary to provide detailed information regarding the activities falling within the purview of the QA program when requested by the committee. This will include Nonconformance Reports, Surveillance Reports, personnel activities such as document reviews, indoctrination and training results, statistics, trend analyses or other documents identified during the course of the assessment.

6.2.3 Each Principal Investigator (or Technical Principal as identified by the Project Manager) shall prepare an independent assessment of the activities related to their work scope. Recommended outlines of assessment content is provided in Attachment 1 to this procedure. The primary purpose is to assess the effectiveness of the implementation of the QA Program and identify improvement actions where needed. This assessment must demonstrate an understanding of the quality requirements, resource allocations, technical task goals and objectives. The assessment should identify deficiencies related to the Assurance Program implementation and recommend improvement actions.

6.2.4 The committee shall meet as necessary to prepare their assessment of the QA Program implementation. The final report, including minority positions, shall be presented to the Project Manager's Deputy.

6.3 Level 2 management assessment process shall proceed as follows:

6.3.1 The committee shall be formed and chaired by the Project Manager's Deputy or his designee. The meeting(s) shall be planned and scheduled to be completed by the Project Scheduler for completion of the management assessment. The final report, including minority positions considered of major import by the committee, shall be presented to the Project Manager. The final report shall contain the essential elements shown in Attachment 1 plus any data deemed pertinent by the committee.

6.3.2 The Level 1 management assessment report and minority positions shall be used as information for the Level 2 assessment. Also data such as Management reports, staffing level(s) obtained from the appropriate personnel departments, and any other relative information shall be used.

6.3.3 The Level 2 management assessment report should be a consensus document, however, minority positions believed to have major programmatic impact by a member of the committee shall be included. The final report shall include, as a minimum, the following:

6.3.3.1 Implementing Procedures adequacy.

6.3.3.2 Personnel Statistics; including numbers of personnel (both QI and technical staffs), types, adequacy, training and certification status.

6.3.3.3 Summary information regarding Quality Assessments performed by Principal Investigators and Technical Contacts.

6.3.3.3 Procedure Implementation effectiveness assessment, including the identification of conditions indicating effectiveness in achieving objectives, and procedure/implementation adequacy.

6.3.3.4 Quality Assurance Audit Report Summary(ies), Trend Analyses and/or Annual Reports generated by the QA organization.

6.4 The Level 3 management assessment process shall proceed as follows:

6.4.1 The committee will be chaired by the Project Office Project Manager Deputy.

6.4.2 The purpose of the committee is to prepare a detailed management assessment of the overall Project Quality Assurance Program. The final report form shall be at the discretion of the committee; however, as a minimum the following aspects shall be addressed:

6.4.2.1 Quality Assurance Program requirements and the effectiveness of their implementation.

6.4.2.2 Personnel Statistics

6.4.2.3 Summary of task analyses, schedules, projections of future work under the QA Programs.

6.4.2.4 Summary information of Quality Assessments conducted by each of the major Project participants.

6.4.3 This committee shall plan and schedule the necessary meeting(s) to comply with the management assessment schedule. The committee shall complete a final report which will include any minority reports deemed necessary by the committee. Majority opinion shall rule. The final report shall be forwarded to the Project Office Project Manager by the committee chair.

6.4.4 The Project Office Project Manager shall review the report and require any clarification necessary. Any further requirements identified by the Project Office Project Manager to conduct further analysis, track recommendations, and/or conduct further investigative management action shall be identified and conducted.

6.4.5 The Project Office Project Manager, after satisfying himself that the management assessment report fairly represents the state of affairs of the Quality Assurance Program, shall issue the report to the Associate Director, OGR, and QA Manager, OCRWM.

Attachment 1 to ~~Administrative Procedure~~ Supplement # _____

MANAGEMENT ASSESSMENT OF QUALITY ASSURANCE PROGRAM IMPLEMENTATION EFFECTIVENESS

CONDUCTING ASSESSMENTS

The assessments are conducted to review the adequacy of the QA Program implementation procedures, training/instruction on the implementing procedures, procedure implementation effectiveness and resources. The primary purpose is to assess effectiveness and take improvement action where the need is indicated.

In making an assessment, the following questions should be answered:

1. Implementing Procedures

   Are they needed?
   Have they been properly reviewed and approved?
   Are they in need of revision?

2. Training/Instruction on Implementing Procedures

   What methods are being used? Are they effective?
   How is training effectiveness determined?
   Is timing/frequency adequate for:
   - orientation of new employees?
   - training on procedure additions or revisions?
   - refresher training?

3. Procedure Implementation Effectiveness

   What conditions indicate whether implementation is effective or not?
   Where ineffectiveness is indicated, is the cause due to procedure inadequacy or implementation inadequacy?
   Is implementation inadequacy due to lack of knowledge, lack of time, or other causes?

4. Resource Evaluation

   Are there adequate numbers of personnel to accomplish the task(s)?
   Do the personnel have the correct skills? Are they properly trained?

REPORTING ASSESSMENT RESULTS

The management assessments will be a written report intended to provide an accurate picture of quality management at the level the report is written. It should allow each level to gain ideas from the planned improvement actions that are developed. These reports typically detail the specific shortcomings that were noted and include responsibilities and schedules for their correction.

POST-ASSESSMENT FOLLOWUP

The QA organization of the Participants and NTS Subcontractors conduct post-assessment followup to verify that improvement actions have been accomplished as planned. This is intended to be a reminder service, where needed, and less formal that the corrective action followup for audit or surveillance findings.

The management assessments do not replace audits or surveillances by the QA organization.

MANAGEMENT ASSESSMENT

IMPLEMENTING PROCEDURE

QA Program Element _____

Document Name & Paragraph _____

Reviewed and Approved _____

Needs Revision _____

TRAINING ON PROCEDURES

Method of Training/Instruction _____

_____

_____

Method of Determining Effectiveness _____

_____

_____

Training/Timing:

New Employees _____

Procedure Revisions _____

Refresher Training _____

PROCEDURE IMPLEMENTATION EFFECTIVENESS

Conditions Indicating Effectiveness/Ineffectiveness in Achieving Objectives _____

_____

_____

Objectives not achieved because:

Procedures Inadequate (Explain) _____

_____

_____

Implementation Inadequate (Explain) _____

_____

_____

RESOURCES

Adequate numbers of Personnel _____

_____

_____

Skills correct for task(s) _____

_____

_____

Are they properly trained? _____

_____

Assessment by: _____

Date: _____

Approved by: _____

IMPROVEMENT ACTION	EFFECTED ORGANIZATION	ACTION DATE

ATTACHMENT M

NRC MINI AUDIT STATUS

NRC MINI AUDITS

- DURING JULY 1986 THE DOE IDENTIFIED THE POSSIBILITY OF NRC CONDUCTING AUDITS OF DISCRETE AREAS OF THE NNWSI PROJECT TECHNICAL PROGRAM. THESE AUDITS WERE TO BE CONDUCTED PRIOR TO THE MAJOR NRC AUDIT OF THE PROJECT PRIOR TO THE START OF THE SINKING OF THE EXPLORATORY SHAFT.

- IN NOVEMBER 1986 THE NNWSI PROJECT IDENTIFIED FIVE (5) PERTINENT SUBJECT AREAS FOR NRC TO CONDUCT MINI AUDITS ON.

- AT A MEETING WITH THE NRC, OGR, AND NNWSI PROJECT QA IN JANUARY 1987, IT WAS AGREED THAT THE NRC WOULD CONDUCT THE FIRST MINI AUDIT ON THE MINERALOGY AND PETROLOGY WORK BEING PERFORMED BY LANL.

- NRC AND OGR HELD A MANAGEMENT MEETING IN MARCH 1986 TO DISCUSS THE PROTOCOL FOR THE MINI AUDIT. THE MAJOR OUTCOMES WERE AS FOLLOWS:

  - NRC WOULD CONDUCT A SCOPING VISIT TO LANL PRIOR TO THE MINI AUDIT.

  - DOE IS TO PROVIDE NRC A COPY OF THE MINERALOGY/PETROLOGY TECHNICAL PROCEDURES IN ORDER FOR NRC TO DEVELOP A CHECKLIST.

  - NRC WOULD PROVIDE DOE WITH A COPY OF THE CHECKLIST OF THE AUDIT DURING THE AUDIT.

  - DOE WILL PROVIDE NRC JUSTIFICATION ON WHICH THE DOE FEELS THEY ARE READY FOR AN AUDIT BY THE NRC.

- THE SCOPING MEETING WAS HELD BETWEEN WMPO, NRC, AND LANL ON APRIL 15, 1987, AT LANL. THE MAJOR OUTCOMES WERE AS FOLLOWS:

  - NRC MINI AUDITS ARE NOT CONSIDERED AN APPENDIX 7 MEETING.

  - THE AUDIT TEAM WILL CONSIST OF 8 NRC REPRESENTATIVES - 3 NRC QA, 1 NRC QA CONSULTANT, 1 NRC SITE REPRESENTATIVE, 2 NRC TECHNICAL, AND 1 NRC TECHNICAL CONSULTANT.

- OBSERVERS WOULD BE LIMITED TO 1 STATE, 1 OGR, AND 2 WMPO REPRESENTATIVES.
- INTERACTION WITH STATE OBSERVERS WOULD BE AN NRC RESPONSIBILITY.
- THE PROGRAMMATIC AUDIT SCOPE WOULD INCLUDE ALL 18 CRITERIA EXCEPT THE FOLLOWING: RECORDS, FIELD COLLECTION OF SAMPLES, AND QA SOFTWARE.
- THE TECHNICAL SCOPE WOULD INCLUDE DISCUSSION ON WHY ONE METHOD/TEST/EQUIPMENT WAS BEING USED VERSUS ANOTHER IN ADDITION TO IMPLEMENTATION/ANALYSIS/EVALUATIONS ASSOCIATED WITH THE IDENTIFIED METHOD/TEST/EQUIPMENT.
- COPIES OF 12 TECHNICAL PROCEDURES UNDER DEVELOPMENT WERE GIVEN TO THE NRC. THIS IS IN ADDITION TO 8 THAT HAVE BEEN ISSUED.
- COPIES OF LANL INTERNAL AUDIT 8704 AND THE SDRS FROM THE WMPO 87-1 AUDIT WERE GIVEN TO THE NRC. A BLANK COPY OF THE WMPO CHECKLIST WILL BE PROVIDED TO NRC.
- FORMAT OF THE OUTPUT (REPORT) WAS NOT TOTALLY AGREED UPON.

o THE NRC MINI AUDIT IS BEYOND THE SCOPE OF THE EXISTING MANAGEMENT AGREEMENTS BETWEEN NV AND THE OTHER FIELD OFFICES.

ATTACHMENT N

CONSOLIDATED/COMMON TRAINING

HISTORY

- 'TRAINING WORK GROUP' ESTABLISHED WITH R.P. SAGET AS CHAIRPERSON - 1/28/87
- MEMBERS:

- TERESA HENNIG	BWIP
- CARL NEWTON	DOE/HQ
- RON OBERLE	SRPO
- ~~NANCY VOLTURA~~ WENDY DIXON	NNWSI

PURPOSE

- ESTABLISH A UNIFORM APPROACH TO TRAINING FOR THE REPOSITORY PROGRAM
- FACILITATE THE EXCHANGE OF INFORMATION AND MATERIALS

GOALS

- PROVIDE POLICY GUIDANCE
- IDENTIFY COMMON TRAINING NEEDS
- ESTABLISH A SYSTEM/METHOD FOR PROVIDING COMMON TRAINING
- SUGGEST TOPICS OF CORE COURSES

ACCOMPLISHMENTS

- IDENTIFIED AND CONTACTED GROUP MEMBERS
- ESTABLISHED GOALS AND OBJECTIVES
- PROVIDED POLICY GUIDANCE BY:
  - ENDORSING A 'SYSTEMS APPROACH TO TRAINING'
    PROPOSED REVISION TO SUPPLEMENT 1 OF QGR-B3 'SELECTION INDOCTRINATION AND TRAINING OF PERSONNEL'
  - IDENTIFYING AREAS FOR STANDARDIZATION:
    APPROACH, COURSE WORK, PERFORMANCE, EVALUATION

SUGGESTED TOPICS OF CORE COURSES

- SUGGESTED TOPICS OF COURSES

  - ORIENTATION
    - PROGRAM: HISTORY, GENERAL SITE, SPECIFIC COMPANY
    - QUALITY-RELATED CODES, STANDARDS AND REQUIREMENTS
    - NRC'S ROLE: INTERFACING ACTIVITIES, LICENSING PROCESS
  - AUDITING:
    - LEAD AUDITOR
    - AUDITOR
    - TECHNICAL AUDITOR
    - AUDITING FOR EFFECTIVENESS
    - SURVEILLANCES
  - TECHNICAL AREAS
  - INSTRUCTOR TRAINING

ON-GOING ACTIVITIES

STATUS PRESENTED AT QUARTERLY AQCG MEETING

- IDENTIFICATION OF PROJECT TRAINING NEEDS
- IDENTIFICATION OF AVAILABLE TRAINING MATERIALS
- IDENTIFICATION OF SPECIFIC CORE COURSES AND RESPONSIBILITY FOR DEVELOPMENT
- SELECTION OF METHODS FOR PROVIDING COMMON TRAINING
- DEVELOPMENT OF SYSTEMS FOR SHARING TRAINING MATERIALS ON BOTH THE PROGRAM AND PROJECT LEVEL
- ESTABLISH A MILESTONE SCHEDULE FOR THE ACCOMPLISHMENT OF GROUP ACTIVITIES

PROPOSED CHANGES TO OGR/B-3 SUPPLEMENT ONE

SELECTION, INDOCTRINATION AND TRAINING OF PERSONNEL

LEGEND: *Italics - Material added*
Regular Type - Unchanged
~~Overstrike~~ - Word Deleted
The proposed changes incorporate the systems approach to training

5.6 *TRAINING PROGRAMS*

Programs for accomplishing the required training shall meet the following requirements for the systems approach to training:

5.6.1 *Program Definition*

a) The goals and objectives of the training program shall be defined in policies, plans or procedures.

b) Jobs shall be analyzed to identify the quality-related tasks or functions performed.

c) The courses and other training increments to be used shall be identified.

d) When necessary for effective instruction, the sequencing of courses and other training increments shall be determined.

e) The training organization, lines of authority, and specific responsibilities for meeting training program requirements shall be identified. Managers shall be held responsible for assuring that their personnel receive their required training.

PROPOSED CHANGES TO OGR/B-3 SUPPLEMENT ONE

SELECTION, INDOCTRINATION AND TRAINING OF PERSONNEL (CONT'D)

5.6.2 *Course and Lesson Development*

a) Objectives for courses shall be identified.

b) When courses must be subdivided into lessons, the lessons, their sequence and their individual objectives shall be determined.

c) Resources required to implement the courses shall be determined and acquired.

5.6.3 *Course and Lesson Delivery*

a) Requirements for the selection, training, and qualification of instructors shall be established.

b) Training environments that are conducive to learning shall be provided.

c) Courses and lessons shall be scheduled, and the persons who are to attend them shall be designated. Management shall assure that their personnel attend the designated courses and lessons.

d) Courses and lessons shall be conducted by trained instructors using the established course and lesson plans, and environments.

PROPOSED CHANGES TO OGR/B-3 SUPPLEMENT ONE

SELECTION, INDOCTRINATION AND TRAINING OF PERSONNEL (CONT'D)

5.6.4 *Program Assessment*

a) As necessary and appropriate, individuals who have completed courses, lessons, or other training, shall be evaluated to assure that they have met the learning objectives.

b) The effectiveness of the training program and its resources shall be periodically assessed. Changes shall be made if appropriate.

c) Periodic audits of the training program shall be performed.

5.7 PROFICIENCY EVALUATION

The job proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with other supervisory performance evaluations. Proficiency evaluations shall be performed by managers or supervisors who have assigned responsibility for the activities being performed or verified.

PROPOSED CHANGES TO OGR/B-3 SUPPLEMENT ONE

SELECTION, INDOCTRINATION AND TRAINING OF PERSONNEL (CONT'D)

5.8 RECORDS

Records of personnel qualificaton evaluations, indoctrination, training, training *program implementation*, and proficiency evaluations shall be retained as lifetime QA records. These records shall include the following, as a minimum:

5.8.1 Personnel Qualification Evaluation Records

Records of the evaluation of a candidate's education, experience and training compared to those required for the position.

5.8.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date(s) of indoctrination, and other applicable information.

PROPOSED CHANGES TO OGR/B-3 SUPPLEMENT ONE

SELECTION, INDOCTRINATION AND TRAINING OF PERSONNEL (CONT'D)

5.8.3 Training *Program Implementation* Records

Records of training ~~which~~ *shall include:*

a) *Training program definitions.*

b) *Course and lesson development.*

c) *Course and lesson delivery.* This shall include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

d) *The training received by each individual.*

e) *Program assessments and resulting actions.*

5.8.4 Proficiency Evaluation Records

Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evluation.

ATTACHMENT O

DRAFT

PROPOSAL FOR ESTABLISHMENT OF OCRWM SOFTWARE QUALITY ASSURANCE PROGRAMS

DRAFT

Introduction

OCRWM has identified a need for documentation that establishes a consistent set of requirements for the development of computer software by Program Participants. To achieve this desired effect, the following activities are proposed. First, preparation of documentation that establishes the requirements for a Software Quality Assurance (SQA) program specific to OCRWM. This document would specify the systematic activities that would be required to achieve the desired level of software quality. Second, preparation of a guidance document and training program for how OCRWM Program Participants are to meet these requirements in establishing their respective SQA programs. These proposed documents and training program will serve as a basis for the OCRWM Program Participants so that each individual program will be compatible with and meet the requirements of the DOE-HQ SQA program.

The documents to be prepared will be made compatible with the needs and, where possible, the constraints of each of OCRWM's organizational components. These documents, at a minimum, will encompass the information and guidance contained in the following: OCRWM QAMPR, the OSTS QAD, and OGR's Quality Assurance Plan for High Level Radioactive Waste Repositories. Although the proposed SQA Requirements document will explicitly address software which is safety-related or important-to-safety (Level-I), it will allow for three Quality-Level (Q-Level) classes and a graded SQA methodology.

Task Descriptions

Five separate tasks have been defined for the generation and integration of consistent Software Quality Assurance (SQA) requirements within OCRWM. These tasks consist of: 1) Preparation of a draft SQA Program requirements document for adoption by OCRWM; 2) Preparation of a guidelines document to assist OCRWM contractor QA personnel in the preparation of contractor specific SQA procedures; 3) the generation of an inspection checklist and guidance for

OCRWM in the auditing of contractor SQA procedures for compliance with OCRWM's SQA requirements; 4) the preparation of a training program for OCRWM contractor QA department staff to assist them in implementing OCRWM's SQA requirements; and 5) the scheduling and execution of the training courses described in 4) above. Of the five tasks outlined here, only the first task is expected to be implemented in FY87; the remaining tasks would be implemented in FY88. Estimated funding levels for this work are: $100K for FY 87; $270K for FY 88, and $90K for FY 89. A more detailed description of each of the proposed tasks is given below.

Task 1: Preparation of Software Quality Assurance Program Requirements ($70K PNL, $30K BPMD)

The objective of this task is to prepare a "strawman" document that delineates the SQA Program requirements for OCRWM work. The work has been divided into four subtasks; 1) A review and preparation of an annotated bibliography which summarizes the relevant documents pertaining to the content of QA requirements, 2) Generation of a "strawman" SQA requirements document, suitable for adoption by OCRWM, 3) definition of an OCRWM SQA requirements committee and review process, 4) convening of the above SQA requirements committee. Each of these sub-tasks is described in more detail below.

Task 1.1 Review Relevant Background Information

- Various QA, SQA, and other relevant documents will be reviewed to gather essential information to perform the remainder of Task 1. This subtask will rely on previously gathered information as well as, supported by more recent references, facts, and information.

- An annotated bibliography of material reviewed within this subtask will be produced. (June 1987)

Task 1.2 Generation of "Strawman" SQA Program Requirements Documentation

- From the information gathered in Task 1.1, the essential requirements for an adequate SQA Program will be generated.

- A "Strawman" Requirements Document will be prepared to specify and document the specific needs of OCRWM. This Requirements document will encompass material contained in existing guidance (OCRWM QAMPR, the OSTS QAD, and OGR's Quality Assurance Plan for High Level Radioactive Waste Repositories), as well as other applicable industry standards. (July 1987)

Task 1.3 Definition of Review Process for Strawman Documentation

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- This subtask will make recommendations regarding the structure necessary to obtain adequate review of, and additional input for, the "strawman" documentation to be produced within Task 1. This subtask will address two major issues: 1) Composition, size, structure, and convening of an OCRWM Strawman Documentation Review Committee; and 2) Methods to obtain additional review/input by a larger set of non-committee individuals.

- Specific recommendations from this subtask will be incorporated into a letter report to DOE/HQ. (May 1987)

It is proposed that this subtask be started in parallel to Task 1.1 to allow for the necessary interactions and concurrences from DOE on the structural and procedural aspects of convening an OCRWM SQA Review Committee.

Task 1.4 Convening OCRWM Strawman Review Committee

- The OCRWM Strawman Review Committee will be convened according to the approved plan from Task 1.3. A PNL staff member will function as Chairman and implementor for the Committee. The Committee will include a recording documentationist to accurately transcribe the information provided by the participants.

- Comments will be solicited from both committee members and other individuals and organizations who will be affected by the document.

- Comments received on the strawman will be gathered and reviewed by the Committee during its meeting(s). This task will coordinate comments from the Committee; as well as others; on the strawman and generate a 2nd draft of the documentation for committee concurrence.

- A second convening of the Committee may be necessary to finalize the comment stage. Should a second Committee meeting be convened, additional funding will be necessary for Task 1.4; estimates given do not include a second convening, nor subsequent iterations.

- The revised documentation will be delivered to DOE for consideration by OCRWM as either guidance, orders, Program Requirements, or Contractor Requirements/ guidance. (October 1987)

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Task 2: Preparation of Guidelines for Contractor SQA Program Implementation ($180K - FY 88)

- The objective of this Task is preparation of detailed guidance to DOE Contractors for how to implement the requirements set forth by the SQA documentation produced in Task 1. For each of the SQA Program requirements defined in Task 1, detailed implementation methods will be suggested.

- A guidance handbook will be prepared to assist OCRWM Participants in preparing individual SQA Programs specific to their particular environments. (June 1988)

- Written comments on the Handbook will be solicited from OCRWM participant representatives.

Task 3: Inspection Checklist/Guidance ($90K - FY 88)

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- The objective of this task is to provide information to DOE/OCRWM for use in audits of Contractors for compliance with the SQA program requirements. This guidance/checklist may also be used by contractors to evaluate their own existing programs for responsiveness to the Task 1 requirements document. Those areas identified as being deficient can then be updated and improved using the detailed guidance to Contractors provided in the documentation produced in Task 2.

Task 4: Preparation of OCRWM Training Program for SQA ($90K - FY 89)

- The objective of this task is preparation of materials (i.e., viewgraphs/outlines/handouts/etc.) to be used in structuring and presenting a cohesive training program for OCRWM and Contractor QA staffs in the area of SQA Program implementation.

Task 5: Presentation of Training Materials to OCRWM Program Participants (Funding to be determined; Estimated $10-15K per presentation - FY 89)

- The objective of this task is the actual presentation of the Training Program developed in Task 4 to Contractor QA Personnel on an as-needed basis.

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Staffing

Resumes of key staff involved in the initial requirements development and committee support are attached. It is proposed that Sid Ailes (BPMD) participate in the development of the requirements and in the review committee process. His involvement can either be funded as a sub-contract through PNL, or, perhaps more simply, by a formal request to SRPO for their support in making his time available to support these activities. No funding is included for committee member participation. It is anticipated that reviewers and committee members time and expenses will be covered by direct project office funding at the request of DOE/HQ.

OCRWM SOFTWARE QUALITY ASSURANCE SUPPORT
(Reference: Memo 3 February 1987 Steinberg to Goranson)

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SCOPE OF EFFORT

- Need for OCRWM SQA Plan
  - Relevant set of requirements
  - Responsive to governing documents
    - NQA-1
    - *NUREG-4640*
- Need for set of SQA Implementing Procedures, based on:
  - *NUREG-4640*
  - *IEEE-Guide to Software Configuration Management (P1042)*
  - *IEEE-Guide for Software Quality Assurance Plans (P983)*
  - *N.Wilburn-Guidelines--Software Verification (HEDL-TC-2425)*
- Guides to be Compatible with and reflect:
  - Needs and constraints of OCRWM Organizational Components
  - Guidance of:
    - OCRWM QAMPR
    - OSTS QAD
    - OCR "QA Plan for High Level Radioactive Waste Repositories"
    - Provisions for 3 Q-Level Classes with graded QA Methodology

MAJOR ACTIVITIES

[1] Preparation of Software Quality Assurance Requirements

- Review of Governing Documents
  - OCRWM
  - NRC
  - DOE

  (*NOT COMPLETED*)
- Review of relevant SQA Documents
  - NRC (*yes*)
  - IEEE (*yes-but must be updated continually*)
  - NBS (*no-several more have been issued*)
  - *Open Literature/Tutorials* (*no*)
  - *DOD* (*no*)

- Preparation of Strawman SQA Plan
  - Review for comments/concurrence by OCRWM participants

[2] Preparation of SQA Implementation Guidelines/Handbook
  - Review for comments/concurrence by OCRWM participants
  - SQA Plan and Implementation Guidelines Issued by OPO

[3] *Preparation of Inspection Procedures*

[4] *Preparation of Training Materials and Procedures*

[5] *Presentations of Training Courses to OCRWM Participants*

[6] Preparation of:
  - Estimated manpower, time, cost for activities
  - Identification of qualified available staff
  - Proposed schedule of milestones and deliverables

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