PRELIMINARY

10-7-88

WBS 1.2.9.3
QA Level I

Lawrence D. Ramspott
Technical Project Officer for YMP
Lawrence Livermore National Laboratory
Mail Stop L-204
P.O. Box 808
Livermore, CA 94550

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 88-05 OF LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) SUPPORT OF THE YUCCA MOUNTAIN PROJECT

Please be advised that a team from the Project Office will conduct a QA audit of the LLNL QA Program Plan and quality related activities from October 24-28, 1988. Current plans call for the audit team to hold a preaudit Conference on October 24, 1988, beginning at 10:00 a.m. in Livermore, CA. Please arrange for the appropriate LLNL personnel to attend the meetings. The postaudit conference is scheduled for October 28, 1988. The arrangement for locations of the preaudit and postaudit conferences are the responsibility of LLNL.

The audit will be conducted in accordance with the enclosed audit plan.

The audit team will consist of the following members:

John C. Friend, Lead Auditor, SAIC, Las Vegas, NV
Stephen P. Hans, Audit Team Leader, SAIC, Las Vegas, NV
James E. Clark, Auditor, SAIC, Las Vegas, NV
James A. Ulseth, Auditor, SAIC, Las Vegas, NV
Keith E. Schwartztrauber, Auditor, SAIC, Las Vegas, NV
Catherine M. Thompson, Auditor, SAIC, Las Vegas, NV
Mae D. Cotter, Auditor, SAIC, Las Vegas, NV
Larry Ramirez, Auditor, DOE/SAN, Oakland, CA
Paul Cloke, Lead Technical Specialist, SAIC, Las Vegas, NV
U-Sun Park, Technical Specialist, SAIC, Las Vegas, NV
Martha J. Mitchell, Technical Specialist, SAIC, Las Vegas, NV
Keith Kersch, Technical Specialist, SAIC, Las Vegas, NV
Dave Stahl, Technical Specialist, SAIC, Las Vegas, NV

Additionally, observers from the State of Nevada, U.S. Nuclear Regulatory Commission, U.S. Department of Energy/Headquarters, or other interested parties may accompany the audit team.

If you have any questions, please contact Royce E. Monks of my staff at FTS 544-7974.

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-

Enclosure:
Audit Plan

cc w/encl:
Ralph Stein, HQ (RW-30) FORS
L. H. Barrett, HQ (RW-40) FORS
J. J. Dronkers, LLNL, Livermore, CA
D. W. Short, LLNL, Livermore, CA
S. H. Klein, SAIC, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
E. P. Ripley, SAIC, Las Vegas, NV
J. C. Friend, SAIC, Las Vegas, NV
S. H. Hans, SAIC, Las Vegas, NV
J. E. Clark, SAIC, Las Vegas, NV
K. E. Schwartztrauber, SAIC, Las Vegas, NV
Paul Cloke, SAIC, Las Vegas, NV
U. S. Park, SAIC, Las Vegas, NV
M. J. Mitchell, SAIC, Las Vegas, NV
K. M. Kersch, SAIC, Las Vegas, NV
B. A. Tabaka, SAIC, Las Vegas, NV
P. T. Prestholt, NRC, Las Vegas, NV
J. J. Holonich, NRC, Washington, D.C.
S. W. Zimmerman, State of Nevada, Reno, NV
F. L. Ramirez, SAN
R. W. Gray, MED, NV
V. F. Witherill, NTSO, NV
A. R. Veloso, NTSO, NV
C. P. Gertz, YMP, NV
L. P. Skousen, YMP, NV
M. B. Blanchard, YMP, NV
W. R. Dixon, YMP, NV
R. E. Monks, YMP, NV
E. L. Wilmot, YMP, NV

YMP QA AUDIT PLAN

AUDIT 88-05

OCTOBER 21-28, 1988

## 1.0 Purpose and Scope

The purpose of this audit is to evaluate the effectiveness of implementation of the Lawrence Livermore National Laboratory (LLNL) Quality Assurance Program Plan (QAPP), Rev. 22.

## 2.0 Organization to be Audited

Lawrence Livermore National Laboratory at Livermore

Package Environment
Container Design
Release Rate
Geochemical Modeling
Performance Assessment

## 3.0 Audit Schedule

| | |
|---|---|
| Preaudit Team Meeting | 9:00 a.m., 10/17/88, Las Vegas, NV |
| Preaudit Team Meeting/Observers | 8:00 a.m., 10/24/88, Pleasanton, CA |
| Preaudit Conference | 10:00 a.m., 10/24/88, Livermore, CA |
| Audit Activities | 8:30 a.m. - 4:00 p.m., 10/25-28/88, Livermore, CA |
| Postaudit Conference | 2:00 p.m. - 10/28/88, Livermore, CA |

## 4.0 Requirements to be Audited and Applicable References

The requirements to be evaluated through the audit process are contained in the programmatic technical checklist. These checklists were developed from the following documents:

- LLNL QAPP and Implementing Procedures (QA and Technical)
- SIPs
- SCP/CD, Chapter 8.0

The conduct of the audit will be guided by the referenced documents listed below:

- QMP-18-01, "Audit System for the Waste Management Project Office," Rev. 3

4.0 Requirements to be Audited and Applicable References (cont'd)

- o QMP-16-03, "Standard Deficiency Reporting System," Rev. 0
- o Project Office QA Audit Task Organization
- o Project Office Observer Inquiry
- o Policy for Participation of State, Tribal, and NRC Representatives as Observers on DOE Audits Date July 14, 1987
- o HLW Division Procedure of Conducting Observation Audits of DOE HLWR Program QA Audits
- o Headquarters Observation of Project Office QA Audits

5.0 Activities to be Audited or Evaluated

The activities to be evaluated during the audit process include but are not limited to:

Programmatic Elements:

| Criteria | Activities |
|---|---|
| 1.0 | Organization (LLNL Matrix Management) |
| 2.0 | QA Program |
| 3.0 | Scientific Investigation/Design Controls |
| 4.0 | Procurement Process |
| 5.0 | Instruction Procedures and Drawings |
| 6.0 | Document Control |
| 7.0 | Control of Purchased Items |
| 8.0 | Identification and Control of Samples and Items |
| 9.0 | Control of Processes and Special Processes |
| 10.0 | Inspection |
| 11.0 | Test and Data Collection Control |
| 12.0 | Control of Measuring and Test Equipment |
| 13.0 | Storage Controls |
| 14.0 | Inspection and Test Status |
| 15.0 | Nonconformances |
| 16.0 | Corrective Action |
| 17.0 | Control of QA Records |
| 18.0 | Audits |

5.0 Activities to be Audited or Evaluated (cont'd)

The scope of this audit is scheduled to include the following technical activities:

| SIP No. | Activity No. |
|---|---|
| B-2.2.2 - Package Environment | B-20-1 - Two Fluid Phase Flow<br>B-20-2 - Single Fluid Phase: Dehydration-Rehydration of Tpt in a Temperature Gradient |
| D-2.2.3.1 - Waste Form Testing | D-20-27 - Conduct Unsaturated Testing of WVDP and DWPF Glass (WB)<br>D-20-32 - Studies of Geochemical Interactions (WB)<br>D-20-37 - Generate Models for Release from Glass (WB)<br>D-20-42 - Saturated, Semi-Static Dissolution Tests of Spent Fuel and Uranium Oxide (HS)<br>D-20-44 - Oxidation Tests of Spent Fuel and Uranium Oxide Using TGA (HS)<br>D-20-45 - Oven Oxidation Tests of Spent Fuel and Uranium Oxide (HS) |
| E-2.2.3.2 - Metal Barrier Testing | E-20-13 - Degradation Mode Surveys<br>E-20-14 - Coordination with Package Design<br>E-20-15 - Establishment of Criteria for Metal Barrier Selection |
| G-2.2.3.4 - Integrated Testing | G-20-2 - Determination of Elements Profile in Rocks, Minerals and Glass |
| H-2.2.4 - Design, Fabrication, and Prototype Testing | H-20-2 - Development of Waste Package Requirements<br>H-20-4 - Container Fabrication Process Development<br>H-20-5 - Container Closure Process Development<br>H-20-6 - Container Closure Nondestructive Evaluation Process Development<br>H-20-7 - Materials Acquisition |
| I-2.2.5 - Performance Assessment | I-20-1 - Development of Detailed Near-Field Flow and Transport Model (AT)<br>I-20-2 - Verification and Validation of Detailed Flow and Transport Model (AT) |

5.0 Activities to be Audited or Evaluated (cont'd)

| | |
|---|---|
| | I-20-3 - Sensitivity Analysis of Near-Field Flow and Transport Model (AT)<br>I-20-4 - Analysis of Source Term Attenuation in Near-Field Host Rock (AT)<br>I-20-5 - Development of Version I of System Model<br>I-20-6 - Verification and Validation of System Model Version I<br>I-20-7 - Testing of System Model Using Waste Package Design Concepts<br>I-20-14 - Development of Uncertainty Analysis Methodologies for Testing with the System Model |
| J-2.3.8 - Geochemical Modeling Code | J-20-7 - EQ3/6 Model Development<br>J-20-8 - EQ3/6 Data Base Development<br>J-20-9 - EQ3/6 Documentation and Code Release<br>J-20-10 - EQ3/6 Code Maintenance |
| S-2.6.9.2.5 - Engineered Barrier Design Testing | S-20-1 - Evaluate Test Components in Support of Component Selection Previously S-20-12<br>S-20-2 - Perform Scoping Calculations in Support of Test Plan Development Previously S-20-13 |

6.0 Audit Team Members

| | | |
|---|---|---|
| Stephen Hans | Audit Team Leader | SAIC, Las Vegas, NV |
| John Friend | Lead Auditor | SAIC, Las Vegas, NV |
| Catherine Thompson | Auditor | SAIC, Las Vegas, NV |
| James Clark | Auditor | SAIC, Las Vegas, NV |
| James Ulseth | Auditor | SAIC, Las Vegas, NV |
| Mae Cotter | Auditor | SAIC, Las Vegas, NV |
| Larry Ramirez | Auditor | DOE/SAN, Oakland, CA |
| Paul Cloke | Lead Technical Specialist | SAIC, Las Vegas, NV |
| David Stahl | Technical Specialist | SAIC, Las Vegas, NV |
| U Sun Park | Technical Specialist | SAIC, Las Vegas, NV |
| Keith Kersch | Technical Specialist | SAIC, Las Vegas, NV |
| Keith Schwartztrauber | Technical Specialist | SAIC, Las Vegas, NV |
| Martha Mitchell | Technical Specialist | SAIC, Las Vegas, NV |
| Thomas Devine | Observer | State of Nevada, Carson City, NV |
| Susan W. Zimmerman | Observer | State of Nevada, Carson City, NV |
| Don Shettel | Observer | State of Nevada, Carson City, NV |

6.0 Audit Team Members (cont'd)

| | | |
|---|---|---|
| Joseph Holonich | Observer | NRC, Washington, DC |
| Linda Riddle | Observer | NRC, Washington, DC |
| Kien Chang | Observer | NRC, Washington, DC |
| Tin Mo | Observer | NRC, Washington, DC |
| Robert Englehardt | Observer | NRC, Washington, DC |
| Carl Sommer | Observer | DOE/HQ, Washington, DC |
| Thomas Gutmann | Observer | DOE/HQ, Washington, DC |
| Norman Franks | Observer | DOE/HQ, Washington, DC |
| Catherine E. Hampton | Observer | YMP, Las Vegas, NV |
| Nancy Voltura | Observer | YMP, Las Vegas, NV |
| Chris Pflum | Observer | SAIC, Las Vegas, NV |

7.0 Audit Checklists, Annexes, and Attachments

88-05-01 - Programmatic Audit Checklist

88-05-02 - Technical Audit Checklist

Annex A - DOE Procedure on Observer Protocol (July 1987)

Annex B - NRC Draft QA Procedure for Observing DOE/OGR HLWR Program Audits

Annex C - DOE/HQ/OGR Observation of YMP QA Audits (Draft)

Attachment 1 - YMP Audit Observer Inquiry, Rev. 0, May 1988

Prepared By: J Friend & P. Clark Date: 10/4/88
Lead Auditor/Lead Tech Specialist

Approved By: R A Caldwell Date: 4 Oct 88
Manager, Audit Division

Approved By: Nancy Voltura for Jim Blaylock Date: Oct. 5, 1988
Project Quality Manager

Department of Energy
Washington, DC 20585

JUL 14 1987

SAIC/T&MSS

JUL 20 1987

CCF RECEIVED



State and Tribal Representatives (List Attached)

At the last Quality Assurance Coordinating Group meeting DOE, State, Tribal and NRC representatives discussed the policy that should be used with regard to the participation of State, Tribal and NRC representatives on DOE audits. It appears that a general consensus was reached among the meeting participants on a procedure for participating in the DOE QA auditing process. Details are in the attached draft policy statement.

We are pleased to invite your review of the enclosed draft policy statement and would appreciate knowing of any remaining concerns you may have.

Sincerely,

S. H. Kale

Stephen H. Kale
Associate Director for
Geologic Repositories, Office of
Civilian Radioactive Waste Management

Enclosure

# POLICY FOR PARTICIPATION OF STATE, TRIBAL AND NRC REPRESENTATIVES AS OBSERVERS ON DOE AUDITS

1. The QA Manager of OGR will furnish to the State, Tribal and NRC representatives a schedule of audits planned by DOE-HQ (OGR) and by the DOE project offices. Because of frequent changes to the schedule, the schedule will be updated at approximately monthly intervals and copies furnished to the State, Tribal and NRC representatives.

2. OGR and the project offices will make every effort to send an audit notification at least 30 days prior to each QA audit. The audit notification will, whenever possible, include an audit plan and a description of the scope of the audit. Copies of OGR audit notifications will be furnished to NRC and to all State and Tribal representatives; copies of project audit notifications will be furnished to NRC and to the affected State and Tribal representatives.

3. State, Tribal and NRC representatives may request to participate in any audit. Requests need not be in writing. Telephone contacts to request participation are:

   OGR - Carl Newton - (202) 586-5059
   BWIP - Pierre Saget - (509) 942-7250
   WMPO - Jim Blaylock - (702) 295-1125
   SRPO - Jerry Reese - (806) 374-2320

   State, Tribal and NRC representatives who wish to participate will make every effort to contact the DOE representative at least two weeks prior to the audit so that arrangements for their participation can be made.

4. When a request to participate is received by DOE from a State, Tribal or NRC representative, it is DOE's policy to make every reasonable effort to honor the request. When small audit teams are used by DOE, and requests for many observers are received, it may be necessary for DOE to limit participation (but in no event to less than one observer per organizational entity, i.e., one from the affected State, one from each affected Tribe, and one from NRC), so that the auditing process will not be hampered by an excessive number of observers. In instances where the limit of one observer per affected party will still result in an excessive observer to auditor ratio, DOE will contact the affected parties and seek voluntary reductions. It is expected the parties will make every reasonable attempt to accommodate DOE's requests.

5. Observers on DOE audits will be under the authority of the audit team leader (or sub-team leader if the team is divided during the audit). Observers are encouraged to participate fully by furnishing their questions, observations and recommendations to the audit team leader (or sub-team leader). Direct interactions between observers and auditee personnel will generally be discouraged and it may be necessary to exempt observers from certain portions of an audit (such as procurement actions that are in-process, classified material, or sensitive personnel records). The DOE policy is that every effort is to be made to limit such exemptions and to include observers as full participants in all aspects of the audit possible.

6. The State, Tribal and NRC representatives who will be participating in a QA audit are to be furnished a copy of the audit checklist as soon as it is available. A target date of ten days prior to the audit will be attempted. The State, Tribal and NRC representatives who receive audit checklists are, of course, to keep their contents confidential and to not, under any circumstances, divulge its contents to representatives of the organization to be audited.

7. DOE encourages observers to receive formal QA auditor training and QA lead auditor training. Every effort to accommodate State, Tribal and NRC representatives in DOE sponsored training courses is to be made. There are, however, no DOE requirements for observers to have had such training.

8. DOE invites observers to express concerns and recommendations on the auditee's QA program to the audit team leader for his consideration in preparing the audit report. DOE also invites observations on the conduct of the audit and solicits recommendations on how we might improve our audit process. Observers will be afforded an opportunity to speak at exit meetings following each audit. Regular opportunities are to be provided to observers during the course of the audit and at the quarterly QACG meeting for State, Tribal and NRC representatives to discuss their comments and recommendations.

## State and Tribal Representatives to QACG

Mr. Allan V. Pinkham, Chairman
Nez Perce Tribal Executive Committee
Box 350, Main Street
Lapwai, ID 83540

Mr. Elwood Patawa, Chairman
Board of Trustees
Umatilla Confederated Tribes
P. O. Box 638
Pendleton, OR 97801

Mr. Melvin R. Sampson, Chairman
Yakima Tribal Council
Yakima Indian Nation
P. O. Box 151
Toppenish, WA 98948

Mr. Terry Husseman
Program Director
Office of High-Level Nuclear
Waste Management
Washington State Department
of Ecology, MS PV-11
Olympia, WA 98504

Mr. Max S. Power
Washington State Institute for
Public Policy
Science and Technology Project
The Evergreen State College
4111 Seminar Building TA-00
Olympia, WA 98505

Mr. Steve Frishman, Director
Nuclear Waste Program Office
Office of the Governor
201 E. 14th Street, Room 205
Austin, TX 78711

Ms. Ruth Ann Storey
High-Level Nuclear Waste Office
355 West North Temple
Suite 330
Salt Lake City, Utah 84180-1203

Mr. Robert Loux, Jr.
Director
Nuclear Waste Project Office
Office of the Governor
Capitol Complex
Carson City, NV 89710

Mr. Hall Bohlinger
Assistant Administator Nuclear
Energy Division
P. O. Box 14690
Baton Rouge, LA 70898

Mr. John W. Green, Jr.
Executive Director
Department of Energy &
Transportation
214 Watkins Building
510 George Street
Jackson, MS 39202

Ms. Susan Zimmerman, Geologist
Nuclear Waste Program Office
Office of the Governor
P. O. Box 12428
Austin, TX 78711

Mr. James Reed
Advisory Committee on Institutional
Government Relations
P. O. Box 13206
Austin, TX 78711

Ms. Cheryl Runyon
National Conference of State Legislatures
1050 17th Street
Suite 2100
Denver, CO 80265

Mr. Carl Johnson
Nevada Nuclear Waste Storage
Investigation
State of Nevada
Capitol Complex
Carson City, NV 89710

Mr. Don Provost
Ofc. of High Level Nuclear Waste
Management
Department of Ecology
Mail Stop P.V. -11
5820 Pacific Avenue
Olympia, WA 98504

Mr. Stephen S. Hart
Council of Energy Resource Tribes
1580 Logan Street, Suite 400
Denver, CO 80203

Mr. Hal Aronson
Nuclear Waste Program
Yakima Indian Nation
5041 West Fair Avenue
Littleton, CO 80123

Mr. Robert Mooney
State of Washington
Dept. of Social & Health Services
Office of Radiation Protection
MS LE-13
Olympia, WA 98504

Mr. William Burke
Nuclear Waste Project Director
Umatilla Confederated Tribes
P. O. Box 638
Pendleton, OR 97801

Mr. Ronald T. Halfmoon
Nez Perce Nuclear Waste Program Manager
Nez Perce Indian Tribe
P. O. Box 350, Main Street
Lapwai, ID 83540

Dennis Bechtel, Planning Coordinator
Clark County, Nevada
225 Bridger Street
Las Vegas, NV 89155

Robert Palm
Clark County, Nevada
225 Bridger Street
Las Vegas, NV 89155

Russel Jim
Yakima Tribal Council
Yakima Indian Nation
P. O. Box 151
Toppenish, WQ 98948

Bim Oliver
355 W. North Temple
#3 Triad Center, Suite 300
Salt Lake City, Utah 84180-1203

# QACG Members

Pierre Saget
BWIP Project Office
DOE Richland
710 Jadwin Ave.
P. O. Box 550
Richland, WA 99352

Rodger Johnson
Rockwell Hanford Operations
Energy Systems Group
Rockwell International
P. O. Box 800
Richland, WA 99352

Jake Lefman
Battelle
Project Management Division
505 King Avenue
Columbus, OH 43201

John Rinaldi
U.S. Dept. of Energy
2753 S. Highland Dr.
Las Vegas, NV 89109

E. A. Patzer
Battelle
Project Management Division
7000 South Adams Street
Willowbrook, Il 60521

[redacted]
The Valley Bank Ctr.
101 Convention Ctr. Drive
Suite 407
Las Vegas, NV 89109

Bud Kehew
Quality Assurance Manager
Repository Technology and
Transportation Division
9800 S. Cass Ave.
Argonne, IL 60439

Jim Blaylock
U.S. Dept. of Energy
Waste Management Project Ofc.
U. S. Dept. of Energy
2753 S. Highland Drive
Las Vegas, NV 89109

Jerry Reese
U. S. Dept. of Energy
SRPO
110 North 25 Mile Avenue
Hereford, TX 79045

Clarence Williams
Battelle
Project Management Division
505 King Avenue
Columbus, OH 43201

Mike Flannigan
Project Manager and Energy Division
U.S. Dept. of Energy
9800 S. Cass Avenue
Argonne, IL 60439

Gary Faust
Roy F. Weston
955 L'Enfant Plaza
8th Floor
Washington, D.C. 20024

RECORD OF CORRESPONDENCE CONCURRENCE AND DISTRIBUTION

SUBJECT: Role of Observers on DOE audits

FROM: S.Kale, RW-20

TO: States & Tribes (List attached)

PC CODE: CN 150 (MARIE ADAMS' IBM)

DISTRIBUTION

QA FILE # L5
OCRWM CCRU, RW-13 (5)
OCRWM ARCHIVES (2)
ORIGINATOR'S CHRON: NEWTON
OGR READING FILE
S,L,& QA DIV CHRON

K. Sommer, RW-24
J. Knight, RW-24
M. E. Langston, RW-40
H. Steinberg, RW-33
S. Echols GC-11

L. Barrett, RW-33

D. Siefken, Weston
L. Skoblar, Weston
G. Faust, Weston
J. Kennedy, NRC

CONCURRENCES:

C. Newton 7/13/87
C. Newton, RW-24

J. Knight 7/13/87
J. Knight, RW-24

S. Kale, RW-20 / /

# QUALITY ASSURANCE PROCEDURE FOR AUDITING DOE HIGH LEVEL WASTE REPOSITORY PROGRAM QA AUDITS

## 1.0 PURPOSE

This guidance describes the HLW Operations Branch QA Section methodology for auditing quality assurance (QA) audits performed by the Department of Energy (DOE) of their contractors and subcontractors. The DOE audits may be performed on the DOE, DOE contractors and subcontractors, or any other participating organization. This may include contractors auditing other contractors.

The objective of the QA audit observation program is to assess the quality of DOE's QA audit program for the geologic repository program. Where necessary, recommendations for improving the DOE audit program will be made by the staff. Audit observations by the staff will enable them to give guidance to DOE on QA programs that are being developed and should help to provide confidence that DOE is meeting NRC's QA program requirements.

## 2.0 OBJECTIVE

The objective of this procedure is to provide guidance on the following areas:

(a) Responsibilities.
(b) Criteria for selection of audits for observation.
(c) Areas to be observed.
(d) Qualifications required for the observers.
(e) Reporting requirements.
(f) Protocol during the audit.

## 3.0 RESPONSIBILITIES

NMSS Management - The appropriate NMSS management has the following responsibilities:

(a) Preparation of an audit schedule. (Branch Chief)
(b) Selection of one or more observer(s). (Section Leader)
(c) Evaluating the training needs of the observers. (Section Leader)
(d) Assuring that the observers are adequately prepared. (Section Leader)
(e) Transmitting the final observation report to DOE. (Branch Chief)

Observers - The observers have the following responsibilities:

(a) Notification of the DOE audit team leader.
(b) Reviewing all pertinent background documents including audit plan, audit checklist, and QA Plan. (Within constraints of lead time provided by audit team leader)

(c) Preparation of audit report.
(d) Presentation of observations to auditors.

## 4.0 CRITERIA FOR SELECTION OF AUDITS FOR OBSERVATION

The selection of audits for observation should be based on the following:

(a) The importance of the activity being audited (for example, data collection activities important to safety or waste isolation).
(b) The time since the last audit (NRC, DOE, WHPO, etc).
(c) The results of previous audits or observations.
(d) The identification of potential problems by the onsite representatives or other NRC staff.
(e) Availability of qualified observers.
(f) OGR Consolidated Audit Schedule.

## 5.0 AREAS TO BE OBSERVED

The following areas should be addressed before or during the audit to the extent practicable:

### 5.1 Qualification of the auditors

(a) Nuclear licensing experience (if any)
(b) Nuclear QA experience (if any)
(c) Years of experience
(d) Communication skills
(e) Training in auditing techniques
(f) Technical expertise

### 5.2 Audit team preparation

(a) Content of audit plan and checklist
(b) Knowledge of audited organization
(c) Knowledge of audited organization procedures, policies, standards, etc. (b and c can only be evaluated by observing the auditors during the audit and interviewing the auditors)

### 5.3 Selection of areas to be audited

(a) Technical versus programmatic based on subject matter
(b) Known problem areas including followup from previous audits

### 5.4 Conduct of entrance/exit interviews

(a) Was the scope of the audit clearly discussed?
(b) Are the audit results clearly communicated to the auditee?
(c) Did the auditor obtain commitments from the audited organizations to correct noted discrepancies.

5.5 Coverage of the audit

(a) If applicable, have all 18 criteria been covered?
(b) What is the purpose or objective of the audit?
(c) Were the auditors knowledgeable about the regulations and standards they were auditing to?
(d) What was the nature of the findings (i.e., significant, trivial, etc.)?
(e) Did the auditor reach a conclusion on a solid foundation of facts?
(f) Did the auditor research any findings or deficiencies to attempt to determine the root cause?
(g) Is the audit plan/checklist adequate?

5.6 Examination of technical products - extent and depth of review.

5.7 Involvement of audit team members, use of technical team members.

(a) Are the technical specialists knowledgeable in the areas being audited (i.e., geochemists for geochemistry)?

5.8 Audit team coordination

(a) Does the technical specialist complement the audit team?
(b) Does the lead auditor take charge and run the audit?
(c) Does the audit report reflect what was discussed by the audit team?
(d) Were daily or appropriate frequency of caucuses held?

6.0 QUALIFICATIONS OF THE OBSERVERS

Personnel selected for observations shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. The observers should be selected based on the following qualifications: auditing and technical experience, education, auditor training, communication skills, and knowledge of QA, technical, and regulatory requirements. The audit observers will be selected by the High-Level Waste Operations Branch QA Section Leader. When technical specialists are utilized, the selection will be coordinated with the Technical Review Branch. All QA section observers shall meet the requirements of ASME/ANSI NQA-1 for auditor qualifications. Technical observers may also be utilized and shall be selected based on their education and experience in the technical area being audited. If they do not meet the requirements above for QA observers they will not be expected to comment on the QA aspects of the audit.

7.0 REPORTING REQUIREMENTS

A report shall be written upon completion of the audit and will be sent to the Director of Siting, Licensing, and Quality Assurance Division, Office of Civilian Radioactive Waste Management, Department of Energy. The report shall address each area covered in Section 5.0 to the extent that each was observed. In addition, each report shall address the audit results. The [illegible]

The following is a sample format for the report:

7.1 Purpose of audit - state the objective of the audit and observations of the audit.

7.2 Summary

(a) Areas audited - brief listing of general areas that were audited, date of audit and agenda
(b) Observations - brief summary of general observations

7.3 Scope of audit

7.4 Observations/conclusions, effectiveness of audit with supporting facts.

7.5 Auditors - list of auditors, observers, titles, and affiliations

All concerns raised will be tracked and followed up.

8.0 PROTOCOL DURING AUDIT

Observers should coordinate with the audit team leader to assure that the effectiveness of the audit team is not disrupted. Observers are encouraged to participate fully by furnishing their questions, observations, and recommendations to the DOE audit team leader. Efforts should be made by the observer to minimize direct questions of the audited organization. It may be necessary to exclude observers from certain portions of the audit (such as procurement actions that are in-process, or sensitive personnel records). Observers should obtain a copy of the audit checklist as soon as it is available and should prevent predisclosure of the list from the audited organization.

Observers shall indicate the acceptable areas of the audit program as well as express concerns, or recommendations to the DOE audit team leader prior to leaving the site. Every attempt should be made to express their concerns daily to the DOE audit team leader. Whenever possible, the observers should attend the entrance and exit meetings and audit team caucuses. The observers should also express their concerns about the auditee's QA program at the auditor caucus prior to the exit meeting. Observer concerns about the conduct of the audit should be addressed only to the audit team. The audit team should be given the opportunity to respond to staff concerns. The staff should consider any new information provided to determine if concerns are still valid. Efforts should be made to reach agreement on the nature of the concern and where necessary the appropriate corrective action will be taken.

All observations should be based on facts and personal opinions should be avoided.

ANN

# HQ OBSERVATION OF WMPO QUALITY ASSURANCE AUDITS

Audit No. _____

Audited Organization and Location _____

Date of Audit _____

Observer _____

## General Observation Areas

1. Was the content of the Audit Plan and Checklist adequate?

2. Did the audit team have adequate knowledge of the audited organization (i.e., scope of work, procedures, policies, etc.)?

3. a) If appropriate, were technical areas as well as QA programmatic areas audited? b) Was the extent and depth of review of the technical areas adequate? c) Were the technical specialists knowledgeable in the areas being audited?

4. Were known problem areas identified from previous audits investigated?

5. Was the scope of the audit clearly presented to the audited organization?

6. Were the audit results clearly communicated to the audited organization?

7. Did the auditor obtain commitments from the audited organization to correct noted discrepancies?

8. If applicable, were all 18 criteria of 10CFR50, Appendix B covered?

## 9.0 REFERENCES

ASME/ANSI NQA-1-1986
10 CFR Part 50 Appendix B
DOE Procedure on Observer Protocol (July 19, 1987)
OGR Consolidated Audit Schedule

## Requirements of WMPO QMP-16-01, Revision 1

| | | |
|---|---|---|
| 1. | Sect. 3.4 | Is the audit team leader certified to develop and perfor an audit, report audit findings, and to follow-up and evaluate corrective actions? |
| 2. | Sect. 4.1.6 | Are conditions adverse to quality evaluated and reported on Standard Deficiency Reports (SDRs) per QMP-16-03? |
| 3. | Sect. 5.2.2 | Are the requirements of this section met? |
| 4. | Sect. 5.3.1 | Was a pre-audit conference held per this section? |
| 5. | Sect. 5.4.1 | Were pre-prepared audit checklists used in the conduct of the audit? |
| 6. | Sect. 5.4.1 | Is objective evidence examined and documented for compliance with the checklist requirements? |
| 7. | Sect. 5.4.1.1 | Is each "not applicable" or "not audited" entry on the checklist explained? |
| 8. | Sect. 5.4.1.2 | Is reference to specific deficiencies noted on the checklist by documenting the sequential number of the SDR rough draft (or number of the observation)? |

Attachment 1

# WMPO AUDIT OBSERVER INQUIRY

**Audit No.** _____

**Log No.** _____

**Name** _____ **Organization** _____

**NNWSI Requirement Reference** _____

**Question/Concern** _____

**Response** _____

_____
Observers Acknowledgement

**Cleared for Submittal to NNWSI Participant**

_____
Lead Auditor / Lead Technical Specialist

☐ **Incorporated in WMPO Audit Checklist...Ref** _____

_____
Audit Team Leader