

January 14, 1997

Mr. Ronald A. Milner, Director  
for Program Management and Integration  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy, RW 30  
1000 Independence Avenue, S.W.  
Washington, D.C. 20585

SUBJECT: MINUTES OF THE DECEMBER 5, 1996, QUALITY ASSURANCE MEETING

Dear Mr. Milner:

Enclosed are the minutes of the December 5, 1996, quality assurance meeting between the staff of the U. S. Nuclear Regulatory Commission, representatives of the U.S. Department of Energy (DOE), and Office of Civilian Waste Management. The purpose of the meeting was to discuss items of mutual interest with regard to quality assurance (QA). The meeting was held by videoconference between the DOE Offices in Las Vegas, Nevada, and the NRC Offices in Washington, D.C. Other attendees included representatives of the State of Nevada, the Nuclear Waste Technical Review Board, and various contractors supporting DOE.

If you have any questions regarding this letter, please contact Sandra L. Wastler of my staff. Ms. Wastler can be reached at (301) 415-6724.

Sincerely,

/s

John H. Austin, Chief  
Performance Assessment and HLW  
Integration Branch  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards

cc: See attached list

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PUBLIC LSS ACNW CNWRA JAustin MBell  
OSR RJohnson w/o Encl.: JSurmeier MFederline

\* See previous concurrence

DOCUMENT NAME: S:\DWM\PAHB\SLW\QAMTG.126

OFC	PAHL*		PAHL*		PAHL				
NAME	Swastler/wd		JThoma		JAustin				
DATE	01/13/97		01/13/97		01/14/97				

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OFC	PAHL	PAHL	PAHL					
NAME	SWastler/wd	JThoma	JAustin					
DATE	01/13/97	01/13/97	01/ /97					

OFFICIAL RECORD COPY

**LIST FOR LETTER TO R. MILNER DATED January 14, 1997**

cc: R. Loux, State of Nevada  
B. Price, Nevada Legislative Committee  
J. Meder, Nevada Legislative Counsel Bureau  
W. Barnes, YMPO  
C. Einberg, DOE/Washington, DC  
M. Murphy, Nye County, NV  
M. Baughman, Lincoln County, NV  
D. Bechtel, Clark County, NV  
D. Weigel, GAO  
P. Niedzielski-Eichner, Nye County, NV  
B. Mettam, Inyo County, CA  
V. Poe, Mineral County, NV  
W. Cameron, White Pine County, NV  
R. Williams, Lander County, NV  
L. Fiorenzi, Eureka County, NV  
J. Hoffman, Esmeralda County, NV  
C. Schank, Churchill County, NV  
L. Bradshaw, Nye County, NV  
W. Barnard, NWTRB  
R. Holden, NCAI  
A. Melendez, NIEC  
S. Brocoum, YMPO  
R. Arnold, Pahrump, NV  
M. Stellavato, Nye County, NV  
J. Lyznicki, AMA

## MINUTES OF THE DECEMBER 5, 1996, QUALITY ASSURANCE MEETING

A meeting of the staff of the U.S. Nuclear Regulatory Commission, representatives of the U.S. Department of Energy (DOE), and Office of Civilian Waste Management (OCRWM) was held on December 5, 1996, to discuss items of mutual interest with regard to quality assurance (QA). The meeting was held by videoconference between the DOE Offices in Las Vegas, Nevada, and the NRC Offices in Washington, D.C. Other attendees included representatives of the State of Nevada, the Nuclear Waste Technical Review Board, and various contractors supporting DOE. Enclosure 1 provides the attendance list.

Enclosure 2 contains the meeting agenda and the topic areas discussed. NRC opened the meeting with an announcement that Jack Spraul was being transferred to another Division. Correspondence containing Jack Spraul on distribution should now be distributed to John Thoma. John Thoma will be the main NRC Headquarters contact concerning QA. Questions concerning QA may also be directed to Bill Belke, the NRC Senior On-Site Licensing Representative for Yucca Mountain.

DOE presented a brief informational presentation of the recent reorganization of the Yucca Mountain Site Characterization Office (YMSCO) and OCRWM QA. The slides for this presentation are contained in Enclosure 3 and there were no significant discussions or questions.

DOE then presented a summary of its 1996 QA Management Assessment, which is contained in Enclosure 4. The primary focus of this assessment was to evaluate the adequacy and effectiveness of the OCRWM QA program and identifying areas for potential improvement. The assessment concluded that the QA program was well planned, well conducted, and produced meaningful results; but there was room for improvement in some areas. NRC questioned if the management assessment group considered the performance of the United States Geological Survey (USGS) over the last year in reaching its conclusions and why this was not noted in the Management Assessment report. NRC has identified QA/technical concerns with the USGS in several On-Site Licensing Representative Reports. Likewise, DOE identified similar concerns during several of its audits and surveillances. However, the author of the section of the Management Assessment Report addressing USGS was not present at the meeting and NRC will pursue the question at a later time. The assessment made ten specific recommendations and some of those recommendations are discussed in the Enclosure. Concerning the effectiveness of self-study training, the assessment team concluded that self-study training, as used in this specific program, was marginally effective. The team based this conclusion not on any actual problem observed but based on the potential for problems to exist. The team recommended "just-in-time" training. No objection to the principal of "just-in-time" training was raised at the meeting but several concerns were expressed for DOE to consider if it chooses to implement this recommendation. Another issue discussed was the recommendation to implement an electronic training verification system as opposed to hard copies of records. Again, the manner in which DOE implements this recommendation will decide the acceptability of this approach.

Enclosure 5 contains recent changes to DOE's 1997 Audit Schedule and some instructions for obtaining up-to-date information on scheduled audits through the Internet.

The next topic discussed was the capture of records by DOE from discontinued activities. This agenda item was added at the request of the State of Nevada. Basically, the State was concerned because, at a recent DOE audit of the Los Alamos National Laboratory, it was found that a Principal Investigator (PI) had left the project and there were no funds to enter that PI's records into the records center. The State wanted to be sure the problem was being addressed from a programmatic point of view. This was an open discussion, and there are no "hand-outs" for this portion of the meeting. DOE responded by saying that the particular issue in question is contained in an open deficiency report (DR). The response to the DR should address the programmatic aspects. However, DOE does not believe it is a generic problem because a program already exists to generically address this issue. In addition, although it may have been said during the audit, the funds for resolving the specific example provided were not terminated and there are funds to get the PI's records properly recorded.

The status of DOE's data qualification efforts were then discussed and the "hand-outs" for this presentation are contained in Enclosure 6. In addition, DOE indicated that it had formed a committee, which includes a QA representative, to address data qualification issues. NRC indicated that its letter on data qualification of August 19, 1996 (J. Austin to S. Brocoun) should be addressed by this committee. In addition, NRC would be willing to discuss issues with the committee by teleconference or videoconference when the committee is ready for such discussions.

Enclosure 7 contains DOE's presentation on performance-based audit changes. NRC noted that recent performance-based audits by DOE are focusing more on the technical aspects and less on the compliance aspects than previous performance-based audits. Both DOE and NRC acknowledged that performance-based audits should focus more on the technical aspects and the final product. DOE is committed to conduct a compliance based audit of all 18 criteria of each program participant on a yearly basis. DOE did indicate that it may use the results of surveillances and performance-based audits to document achieving some of the compliance criteria. In concept, NRC does not object to the approach proposed by DOE. However, NRC staff indicated that whatever approach is used by DOE to satisfy the compliance commitment should be clearly documented and submitted to NRC. If NRC has concerns about how DOE addressed a specific compliance criteria, they will be raised at the appropriate time.

NRC staff then discussed NRC QA plans for FY97 and beyond. There were no "hand-outs" for this presentation. NRC management is firmly committed to QA. Without a responsible QA program, a license application will not succeed. However, with the budget cuts in FY96 and FY97, NRC has reduced somewhat its QA oversight of DOE. A partial justification of this reduction is that over the years the DOE QA program has shown improvement and NRC expects DOE QA to continue at a high level. NRC will continue to audit the DOE QA program and if expectations are not met, recommendations will be made to senior management to adjust NRC resources accordingly. By letter (J. Greeves to R. Milner)

dated November 12, 1996, NRC informed DOE of some of the impacts of the budget cuts on NRC activities and that NRC would focus on its Key Technical Issues (KTIs). In FY96, NRC had already implemented a change in its QA observation activities. The QA observation audits NRC conducted in FY96 were directly related to one of NRC KTIs. The only DOE audits observed were performance-based audits. Performance-based audits place more of an emphasis on the input of the technical representative. NRC observation teams consisted of a QA representative and one or more technical representatives. In FY97, NRC will continue to observe DOE QA audits that relate to the criteria in NRC's November 12, 1996, letter. However, on a number of these audits, NRC may only send a technical representative. For example, there is an audit starting December 9, 1996, where NRC will only send a technical representative. Oversight of the compliance portion of the audits may be accomplished at NRC headquarters with a debriefing of the technical representative and by communications with the DOE QA organization. When resources are available, NRC will send a QA team leader to lead a specific audit observation. Based on the results of these observations, NRC will evaluate the need for future changes in its level of staffing in the area of HLW QA. NRC is producing for publication an Annual Progress Report for FY 96 on NRC activities concerning KTIs. Eventually this document will be published as a NUREG/CR. This document will provide DOE a more clear indication of where NRC is focusing its efforts in the near term.

Susan Zimmerman responded that the State is concerned, disillusioned, and dismayed with the change in NRC's HLW QA staff. She recognized that budget cuts have real effects and acknowledged that NRC said it believes that QA is important. But the perception from the State is that NRC no longer considers QA important in HLW. The State will document its concerns in a letter to NRC. DOE also expressed some concerns in the loss of experienced personnel in the HLW QA program at NRC. NRC indicated that there is still a desire to conduct periodic QA meetings to discuss the overall DOE QA program.

Enclosure 8 contains DOE's presentation on trend analysis from recent audit findings. Enclosure 9 contains the status of NRC open QA issues. Bill Belke will now assume the lead for tracking these issues to closure at NRC.

Neither NRC or DOE had closing remarks. The State had closing comments in three areas. First, at a recent audit of Los Alamos, the PI did not appear to recognize the importance of using qualified data to meet the milestone. The State indicated it is disappointed to learn that some DOE contractor personnel do not recognize the importance of QA this late in the program. Second, the State will be interested in the response to the deficiency report concerning the capture of records from discontinued activities. Third, the State wants QA meetings to continue to be held periodically.

  
John O. Thoma, Section Leader  
Performance Assessment and  
Integration Branch  
Office of Nuclear Material, Safety,  
and Safeguards  
U.S. Nuclear Regulatory Commission

  
Frederick C. Rodgers  
Regulatory Integration Division  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy

ATTENDEES  
 DOE/NRC PERIODIC MEETING ON QUALITY ASSURANCE  
 VIDEOCONFERENCE  
 December ~~July~~ 5, 1996

NRC HEADQUARTERS, WASHINGTON D.C.

<u>NAME</u>	<u>ORGANIZATION</u>	<u>PHONE NUMBER</u>
John Thoma	NRC	301-415-7293
Jack Spraul	NRC	301-415-7293
Ram Murthy	DOE-RW3	202-586-1239
James R. Cassidy	OCRWMS M&O	703-204-8824
Tom Colandrea	DOE- QAMA TEAM	619-487-7510
Fred Rogers	DOE-RW-52 (Reg. Cord.)	202-586-9313
Sidney Crawford	SAIC	703-235-4473
Frank Randal	NWTRB	703-235-4473

DOE BUILDING LAS VEGAS, NEVADA

<u>NAME</u>	<u>ORGANIZATION</u>	<u>PHONE NUMBER</u>
Bill Belke	NRC - OR	702-388-6125
Susan Zimmerman	State of Nevada	702-687-3744
Carl Hamlin	DOE-YMSCO-AML	702-794-1304
April Gill	DOE-YMSCO-AML	702-794-5578
John Therien	OQA-QATSS	702-794-5408
Tom Bjerstedt	VA&SP/YMSCO	702-794-1362
J. Blaylock	OQA	702-794-1920
Mario R. Diaz	OQA	702-794-1489
Hank Greene	OQA/OATSS	702-794-1498
Jim Schmit	OQA/OATSS	702-794-1472
Richard Peck	OQA/QATSS	702-794-5556
Steve Bodnar	TRW/M&O	702-295-4844
Charlie Warren	OQA/QATSS	702-794-1487
Steve Dunn	OQA/QATSS	702-794-1496
Bob Clark	OQA	202-586-1238
Donald Horton	OQA	702-794-5568
Dennis Threatt	OQA/QATSS	702-794-1400

**NRC-DOE MEETING AGENDA  
HIGH-LEVEL WASTE QUALITY ASSURANCE**

**- VIDEO CONFERENCE -**

DOE Facility, 1551 Hillshire Drive, Las Vegas, Nevada  
NRC Facility, 11545 Rockville Pike, Rockville, Maryland

December 5, 1996

**OBJECTIVE** - *Technical meeting leading toward issue resolution for items listed below.*

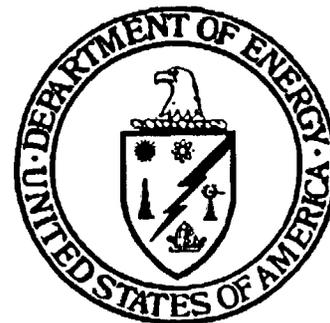
1:00 EST (10:00 PST)	Opening Remarks . . . . .	DOE, NRC, NV, AULG
1:10 EST	Reorganization of YMSCO and OCRWM QA . . . . .	DOE
1:20 EST	DOE's 1996 Management Assessment . . . . .	DOE
1:40 EST	1997 Audit Schedule . . . . .	DOE
1:50 EST	Capture of records from discontinued activities . . .	DOE
2:10 EST	- Break -	
2:20 EST	Status of DOE Data Qualification Efforts . . . . .	DOE
2:35 EST	Performance Based Audit Changes . . . . .	DOE
2:50 EST	NRC QA Plans for FY97 and beyond . . . . .	NRC
3:00 EST	Trend Analyses (Recent Audit Findings) . . . . .	DOE
3:20 EST	Status of NRC Open Issues . . . . .	NRC
3:50 EST	Closing Remarks and Discussion . . . . .	DOE, NRC, NV, AULG
4:00 EST	Adjourn	

**ATTACHMENT**

**DOE/NRC  
HIGH-LEVEL WASTE  
QUALITY ASSURANCE MEETING**

**DECEMBER 5, 1996**

**(DOE QA DISCUSSION ITEMS)**



)

**REORGANIZATION OF  
YMSCO AND OCRWM QA**

)

**Project Manager**  
**W. Barnes**

**Deputy Project Manager**  
**R. Dyer**

**Associate Deputy Project Managers**  
**W. White/S. Jones**

**Chief Counsel**  
**S. Rives**

**YMSCO**  
**HQ Representative**  
**L. Desell**

**Office of**  
**Institutional Affairs**  
**A. Benson**

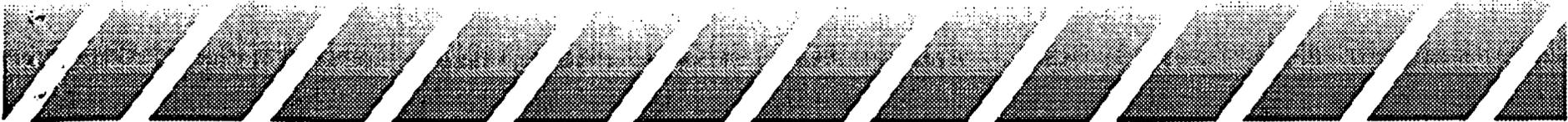
**Project Control**  
**R. Spence**

**Administration**  
**and Asset**  
**Management**  
**J. Adams**

**License Application**  
**and Site**  
**Recommendation**  
**S. Brocoum**

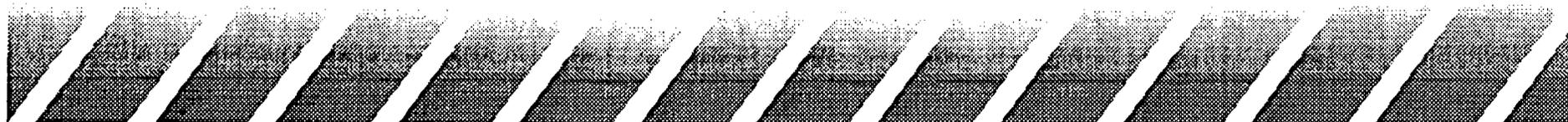
**Viability**  
**Assessment**  
**R. Craun**

**Environment**  
**Safety and Health**  
**W. Dixon**



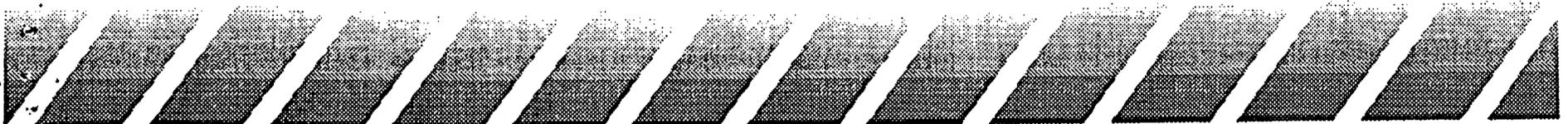
# ADMINISTRATION AND ASSET MANAGEMENT

- ◆ Resource Management
- ◆ Information Management
- ◆ Contract Management
- ◆ Site Management



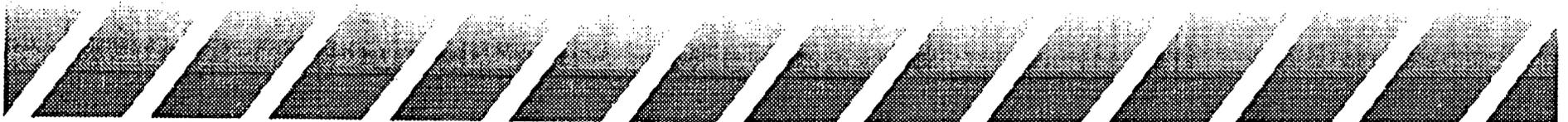
## LICENSING

- ◆ **Viability Assessment**
- ◆ **Site Recommendation**
- ◆ **Licence Application**
- ◆ **Performance Confirmation**



**VIABILITY ASSESSMENT  
AND  
SPECIAL PROJECTS**

◆ **Special Projects and TBM**

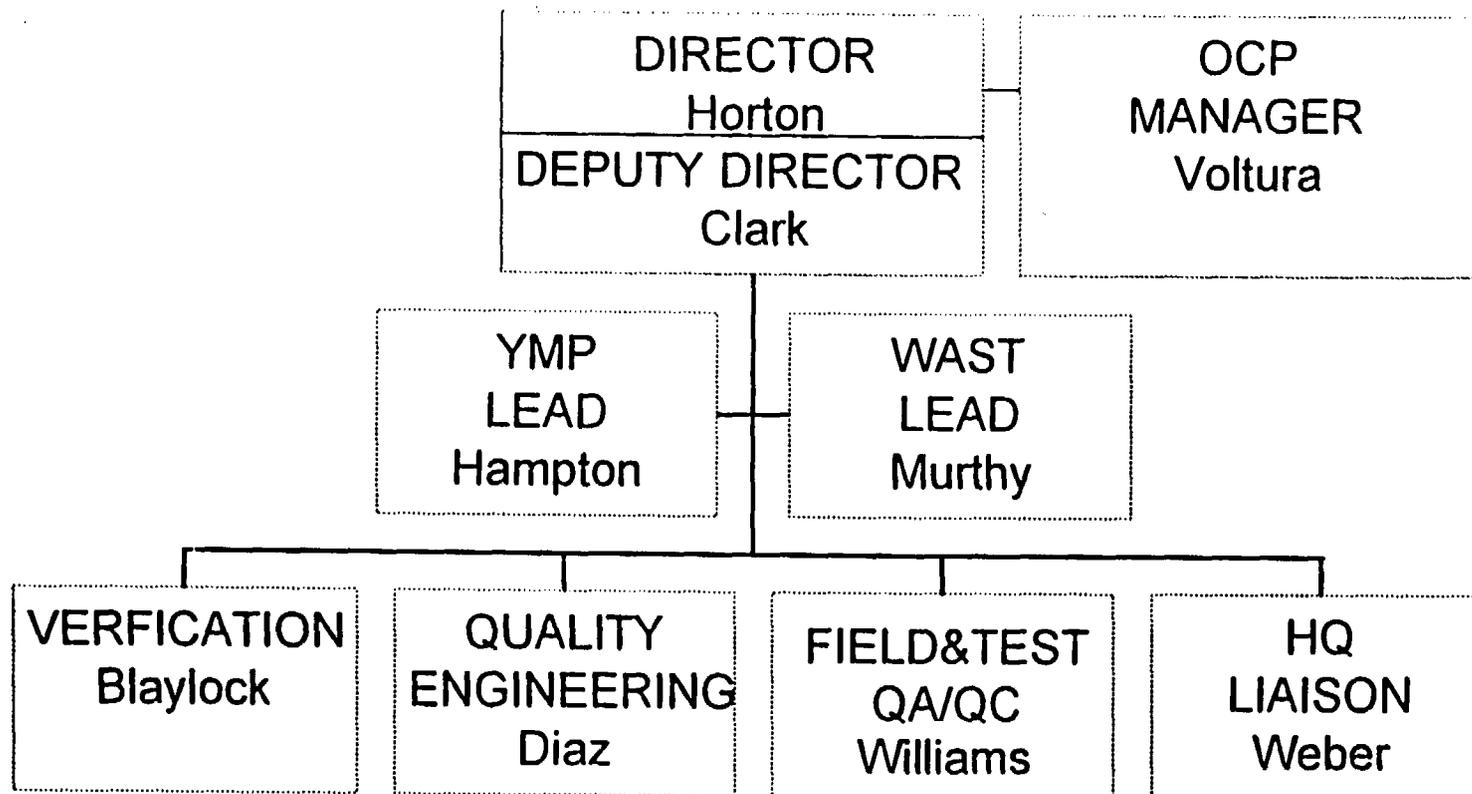


# **ENVIRONMENTAL, SAFETY, AND HEALTH**

- ◆ **Safety and Health**
- ◆ **Environmental Impact Statement**
- ◆ **Environmental**



# OFFICE OF QUALITY ASSURANCE ORGANIZATION



FY 1996

QA Management Assessment

Key Highlights

and

Recommendations

## Goals of the Integrated QA Management Assessment Approach

- Provide an overview of the adequacy and effectiveness of the entire OCRWM QA program
- Improve consistency of QA program implementation
- Help reduce QA program costs
- Identify issues crucial to success of the OCRWM QA program

## Objectives of the QA Management Assessment

- Evaluate OCRWM QA Program adequacy and effectiveness
- Identify areas where improvement is needed

## Assessment Results

- OCRWM QA Program adequate for licensing
- Implementation is effective
- Still room for improvement in some areas
- QA audit program is particularly effective

# Self-Study Training

## Effectiveness of Self-Study Training:

- Marginal in achieving training objectives
- Reading procedures does not explain how work is to be done
- Recommendations provided for revising self-study approach

## Timeliness of Self-Study Training:

- Self-study process not linked to when the work is performed
- Procedures are read months before work takes place
- Investigate the merits of a “just-in-time” training system

## Self-Study Training - Continued

### ) Documentation of Self-Study Training:

- Hard-copy approach to training verification form
- Represents very costly burden to OCRWM program
- Labor-intensive for each of many organizations to create, transmit, track, file, maintain, and monitor this form
- )
- Implement an electronic training verification system

# Technical Data Management System

- No systematic method to ensure data needed to support licensing are entered into database in a timely, complete manner
- Some users find system cumbersome, difficult to enter data
- Upgrade underway
- OCRWM management needs to ensure upgrade:
  - is completed in a timely manner
  - effectively supports the licensing process (data must be identified, entered in a timely manner, and retrievable)
  - is coordinated among users

## System Level Design Interfaces

- Existing design interface control procedure inadequate
- Controls not addressed in configuration management plan
- No “system” to ensure physical interfaces are:
  - identified
  - controlled
- Need to upgrade design interface control procedure
- Need to create system level interface drawings

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**1997 AUDIT SCHEDULE  
(AND CHANGES)**

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2

# **FY 1997 INTERNAL AUDIT SCHEDULE, REVISION 1**

- **29 Total Audits**
  
- **12 Compliance Audits**
  
- **17 Performance Based Audits**
  
- **4 Audits Have Been Completed**
  - **3 Performance Based**
  - **1 Compliance**

## **CHANGES TO FY 1997 INTERNAL AUDIT SCHEDULE, REVISION 1**

- M&O-ARP-97-004**    **Change in Team Leader and  
dates of audit from 11/6-14/96 to  
11/11-22/96.**
- LBNL-ARC-97-007**    **Dates of audit changed from  
12/9-13/96 to 1/6-10/97.**
- SNL-ARP-97-008**    **Dates of audit changed from  
1/13-17/97 to 2/3-7/97.**

# Audit and Surveillance

## Audit and Surveillance Schedules

These schedules are updated nightly. The portrait reports are designed to fit on a typical monitor without scrolling to see the full document and print without having to adjust font size. *Landscape reports may require scrolling to view and may need the font size reduced to 8 to fit on a full 8.5 by 11 piece of paper.* To reduce your font size, look for the title bar called **OPTIONS** or **PREFERENCES**. The ability to change your font should be in there under a submenu.

Audit Schedules		
Schedule	FY 96	FY 97
Internal Approved		
Internal Current		
Supplier Current		

Surveillance Schedules		
Document	FY 96	FY 97
Schedule		
Requests		



[Index of Audit and Surveillance Reports](#)



**STATUS OF DOE  
QUALIFICATION EFFORTS**

## **STATUS OF DOE DATA QUALIFICATION EFFORTS**

### **FY 97 QED ACTIVITIES**

- \* Resurveying all necessary Borehole, Pit, and Trench locations using a Global Positioning System procedural process currently under development.**
  
- \* Qualifying off-the-shelf database development and storage software through a Verification & Validation (V&V) procedural process.**
  
- \* Identifying necessary technical data for qualification in support of the License Application development process.**
  
- \* Evaluating current QED options described in NUREG 1298 and the QARD Document.**

**CHANGES TO  
PERFORMANCE BASED AUDIT**

# **CHANGES TO PERFORMANCE-BASED AUDIT (PBA) PROCESS AS A RESULT OF PBA TRAINING**

- PBA PROCESS STAYED THE SAME
- BENEFITS OF PBA TRAINING
  - A COMMON UNDERSTANDING OF PROCESS AND ITS APPLICATION
  - A VEHICLE TO ASSURE PROCESS IS CONSISTENTLY IMPLEMENTED
  - FORUM FOR STUDENTS TO SHARE IDEAS
  - ENHANCES THE OVERALL AUDIT PROCESS
- NRC ATTENDED 10/31 PBA WORKSHOP SESSION
  - FEEDBACK WAS VERY POSITIVE

**TREND ANALYSIS RESULTS  
OF RECENT AUDIT FINDINGS**

## **CURRENT TRENDING ACTIONS AT SNL**

- As a result of FY96 audit deficiencies, an evaluation was made using the trend database.
- This database flagged a potential negative trend in Implementing Documents.
- Suspected Trend Investigation Report (STIR SNL-97-T001) was issued.
- Further evaluation indicated the negative trend was legitimate (SNL implementing documents consistently lacked sufficient quantitative and qualitative acceptance criteria).
- The STIR is being closed and a CAR is being initiated.

## **CURRENT TRENDING ACTIONS AT LANL**

- FY96 audit activities revealed several deficiencies.
- Deficiencies were not determined to be a trend, based on evaluations using the trend database.
- Determination based on evaluations indicating deficiencies were not similar in nature (i.e., same program element).
- This area will continue to be evaluated during future audits as deficient areas are re-examined.

## **CURRENT TRENDING ACTIONS AT USGS**

- FY96 audit activities revealed several procurement deficiencies.
- These multiple deficiencies resulted in initiation of CAR-YM-96-C004.
- Other audit deficiencies resulted in other potential trends being identified in the area of corrective action.
- Suspected Trend Investigation Report (STIR YM-96-T001) was issued and is being evaluated in conjunction with the verification of the corrective action for CAR YM-96-C004.

# **STATUS OF NRC OPEN ISSUES**

# NRC OPEN ITEMS STATUS REPORT

11/12/96

Item #	Issue Item	Reference	Responsible (OCRWM) Individual	Responsible (QATSS) Individual	Comments	Status
1	M&O design control program.	Bernero to Dryfus ltr, 10/13/94			Dreyfus to Bernero ltr, 11/14/94	Open
2	ESF design and construction phasing.				Holonich to Milner ltr, 03/09/95, closes Item 2	CLOSED
3	Potential of construction work to impact site characterization or the waste isolation capability of the site.	Bernero to Dryfus ltr, 10/13/94			Dreyfus to Bernero ltr, 11/14/94	Open
4	Request for more details regarding QA concerns as well as the design of the ESF.	Bernero to Dryfus ltr, 10/13/94			Dreyfus to Bernero ltr, 11/14/94	Open
5	Validation of acquired software.				Austin to Milner ltr, 03/06/96, closes Item 5	CLOSED
6	Electronic Scientific Notebooks.				Holonich to Milner ltr, 01/27/95, closes Item 6	CLOSED
7	License Application Annotated Outline (LAAO) incomplete and editorially poor.	Holonich to Milner ltr, 08/15/95				DOE resubmitting
8	LAAO Chapter 10 headings do not reflect NRC guidance.	Holonich to Milner ltr, 08/15/95				Open
9	Quality controls applied to the LAAO.	Holonich to Milner ltr, 08/15/95				Open
10	USGS technical review process effectiveness.	Holonich to Milner ltr, 11/02/95				Open
11	Lack of QARD requirements for the qualification of scientific investigation methods.	Austin to Milner ltr, 04/08/96			Horton to Austin ltr, 04/25/96, closes Item 11 (w/ draft ltr Milner to Austin)	CLOSED
12	Quality of the 1996 Volcanism Synthesis Report	YM-ARP-96-14, 10/28/96 NRC Observation Audit Report of LANL, 10/24/96				Open