

July 20, 1998

Mr. Samuel Rousso, Director
Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585

SUBJECT: MINUTES OF THE MAY 6, 1998, QUALITY ASSURANCE MEETING

Dear Mr. Rousso:

Enclosed are the minutes of the May 6, 1998, Quality Assurance (QA) meeting between the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives of the U.S. Department of Energy (DOE).

The purpose of the May 6, 1998, meeting was to discuss items of mutual interest regarding QA and those areas contributing to resolution of Key Technical Issues of DOE's site characterization program for Yucca Mountain. The meeting was a video conference between the DOE office in Las Vegas, Nevada, NRC headquarters in Rockville, Maryland, and DOE headquarters in Washington, D.C..

If you have any questions regarding this letter, please contact Ted Carter of my staff. Mr. Carter can be reached at (301) 415-6684.

Sincerely,

[Original signed by:]

Michael J. Bell, Chief
Performance Assessment and HLW
Integration Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached list

NRC FILE CENTER COPY

DISTRIBUTION:

Central File PAHL r/f ACNW CGlenn WBelke EBrummett

DOCUMENT NAME: S:\DWM\PAHL\THC\QAMTG5.06b

OFC	PAHL		PAHL	PAHL			
NAME	TCarter/kv	THC	SWaste	MBel			
DATE	6/9/98		6/17/98	6/20/98			

OFFICIAL RECORD COPY

9807270321 980720
NMSS SUBJ
102.7 CF

1/1
NHLT
102.7

98147

Letter to S. Rouso from M. Bell dated: July 20, 1998

cc: R. Loux, State of Nevada
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
R. Dyer, YMPO
C. Einberg, DOE/Wash, DC
N. Slater, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
W. Cameron, White Pine County, NV
T. Manzeni, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Regan, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
S. Brocoum, YMPO
R. Arnold, Pahrump County, NV
N. Stellavato, Nye County, NV
J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski
A. Gil, YMPO
R. Anderson, NEI
C. Henkel, NEI
S. Frishman, Agency for Nuclear Projects

MINUTES OF THE MAY 6, 1998,
U.S. NUCLEAR REGULATORY COMMISSION/U.S. DEPARTMENT OF ENERGY
QUALITY ASSURANCE MEETING

On May 6, 1998, staff of the U. S. Nuclear Regulatory Commission (NRC) and U. S. Department of Energy (DOE) held a Quality Assurance (QA) video conference meeting in Washington D. C. and Las Vegas, Nevada. The purpose of the meeting was to discuss items of mutual interest regarding Quality Assurance and those areas leading toward or contributing to resolution of NRC Key Technical Issues of DOE's site characterization program for Yucca Mountain. The meeting was a video conference between the DOE office in Las Vegas, Nevada, and NRC headquarters in Rockville, Maryland. DOE headquarters in Washington, D.C., also attended the meeting.

ATTENDEES:

Attachment 1 provides the name, affiliation and telephone number of the attendees.

AGENDA:

Attachment 2 provides the agenda.

OPENING REMARKS:

The meeting opened with the introduction of attendees. The NRC's opening remarks introduced some of the deficiencies noted in the On-Site Representative's (OR's) report and stated that the results of this meeting should determine what actions will be implemented to solve these problems. The NRC stated that QA is and will remain a top priority item. The DOE program should be a mature program which prevents problems and continues to improve the corrective action process in a timely manner.

DOE stated in its opening remarks that the DOE QA program has been good but DOE will strive to do better. DOE also stated that the DOE program is capable of finding problems, but needs to be more effective in responding to problems in a timely manner. DOE presented the DOE QA organization chart and noted that auditors are being placed in locations where the work is being performed and QA should be a line responsibility in order to be effective. It was also noted that DOE QA has been able to maintain its audit schedule in spite of reduction in resources.

QA ISSUES FROM MARCH 17, 1998, OR REPORT:

Attachment 3 includes the agenda item handouts supporting DOE responses to the following issues.

Length of Time to Close Deficiencies (NRC Open Item 98-1)

The QA Director stated that although deficiencies have taken long periods to close, this has had no impact on waste isolation or radiological safety since there is no nuclear material currently on site. DOE restated its intention of closing most deficiencies within a 12 month time frame. The line organization has added resources to assist in this effort. NRC management suggested that DOE consider defining a more specific goal of closing some percentage of the open items, for example 80%, within a shorter time period with only minimal items remaining open for 12 months. DOE indicated that it will consider such a provision. The NRC will be following the changes being considered by DOE regarding the closure of future issues. In addition, DOE

indicated that they will also categorize those deficiencies open for more than one year based on their importance to safety and waste isolation and provide the results to NRC by June 15, 1998.

Increased Deficiencies in Scientific Notebooks (NRC Open Item 98-2):

DOE indicated that they are extremely concerned about the continuing QA issues regarding Scientific Notebooks (SNs). DOE indicated that they are currently reviewing all SNs for compliance with requirements. NRC management noted the repeated occurrence of errors in SNs and requested corrective action be effective to avoid future occurrences. NRC management also noted that when scientists at different organizations are writing procedures, there can be differences and perhaps inconsistent procedures. DOE replied that there is an effort underway to consolidate procedures that is planned to be in place by October 1, 1998.

Trending Program:

The NRC OR has followed the recent revisions to the trending program and has indicated that the revisions are favorable. DOE stated that this revised program could be completed and ready for implementation by June 1998. The NRC OR indicated that DOE, upon completion of the revised program, should schedule a presentation to the NRC.

DOE QARD Supplement 1 Guidance (NRC Open Item 97-1):

NRC noted that the clarification to statistical analysis in the DOE QARD was closed and no further discussion was needed.

Deficient Suppliers-Validity and Quality of Supplier Data (NRC Open Item 97-2):

The subject of the validity and quality of supplier data and products from those suppliers whose programs had been found deficient as a result of DOE audits has been documented on two DOE Corrective Action Requests (CARs). DOE is currently investigating the overall impact upon the products produced by the respective suppliers. DOE indicated its evaluation will focus first on determining the significance of data to be used for licensing.

Next, NRC management reviewed examples from the NRC OR list of deficient suppliers and requested DOE to respond as to the product and potential impact the deficient supplier may have. The supplier product was listed on the OR list, but the actual impact can not be determined until the DOE evaluation is completed. NRC requested this discussion continue at the forthcoming management meeting being planned for early summer .

Data Qualification (NRC Open Item 96-1):

NRC indicated that the agenda item on data qualification was closed for DOE purposes based on the NRC review of Revision 8 to the QARD. NRC is currently evaluating a question regarding cited literature as defined in NUREG-1298 and will be responding to DOE in the near future. DOE requested that data qualification, in general, and as it relates to the supplier issue, be discussed either at the next QA meeting or the upcoming NRC/DOE management meeting.

Level of Quality of Work Products (NRC Open Item 96-2):

Of the four Deficiency Reports (DRs) originally covered by the NRC open item, only a portion of one DR currently remains open. In the meeting, NRC stated that the report to resolve the remaining portion of this open item had recently been received and was under review by the NRC staff. The document is a DOE Level 3 report which means the report has gone through a

DOE acceptance review. DOE has accepted the report and Los Alamos National Laboratory (LANL) is expected to publish the report in the near future. However, when DOE gave NRC the report (after their acceptance review), they indicated that there were QA issues regarding some of the data sets referenced in the report. The DOE and NRC leads on volcanology have discussed the nature of these issues. DOE lead (T. Sullivan) informed NRC that DOE is working on a plan for qualifying these data sets. DOE expects this plan to be completed within the next few weeks and will make it available to the NRC as soon as it's complete. However, until such time as these QA issues are resolved, the NRC will not be in a position to close this open item.

Length of Time To Issue FY Corrective Action Requests:

DOE explained that the extended length of time to issue three FY 1998 CARs, was due to the associated issues being complex. DOE stated that they will try to improve the time period for CAR issuance in the future. NRC management suggested that DOE consider specifying a time frame in which a CAR must be issued, similar to that suggested for closure of open items.

Site Characterization Plan Question 55 and Study Plan 8.3.1.5.2.2 Comments:

NRC explained that this issue was presented to DOE in September 1997. Since part of the information necessary to resolve this issue was information regarding the adequacy of scientific notebooks, this item will need to remain open until NRC Open Item 98-2 regarding increased deficiencies in scientific notebooks is resolved.

Graded QA:

The NRC has recently issued for reactors draft Regulatory Guide DG-1064, "An Approach for Plant Specific, Risk Informed Decision Making: Graded Quality Assurance." The NRC OR is in the process of scheduling a meeting between the NRC author of the draft regulatory guidance, NRC High-Level Waste (HLW) representatives, and appropriate DOE representatives to discuss how graded QA guidance may be applied to the high-level waste program. The results of this meeting will be reported to the NRC HLW Management Board for further direction.

Unsaturated Zone Flow Vertical Slice Report Findings (NRC Open Item 98-3):

The DOE line organization performed two vertical slices reviews in September, 1997 through October, 1997, and December, 1997 through January, 1998, to assess weaknesses in the documentation and traceability of the DOE's Performance Assessment process. NRC management was pleased to see the line organization perform two vertical slices and identify deficiencies. It is important that the line organization is identifying quality problems on its own. Due to the nature and substance of the findings, NRC requested a time frame in which they can review the plans to address these findings. DOE indicated they will be available in 30 to 60 days and possibly available for discussion at the NRC/DOE July Management meeting.

In summary, as stated during the meeting, DOE's implementation of an effective QA program continues to be a top priority for NRC and, as such, we are concerned about the number and type of deficiencies that have occurred recently. The repeated deficiencies regarding scientific notebooks are especially troubling and are not an acceptable trend. We expect DOE will address these concerns expeditiously and look for ways to close deficiencies in a timely manner.

SCHEDULE QA MEETINGS:

The attendees agreed to schedule a QA meeting twice a year with the next meeting tentatively scheduled for July 1998.

CLOSING REMARKS:

DOE emphasized that they have a good QA program and will continue to strive to improve the program. DOE also wanted the NRC to recognize the cultural change such as the line organization looking in areas and applying QA without being told and doing it under budget constraints.

The NRC stated that they appreciate the openness of the program and the importance of implementing Vertical Slice. This is a healthy process. However, efforts must be improved to make sure that concerns such as Scientific Notebook deficiencies do not resurface. NRC expressed that NRC Management, the NRC Onsite Representative, and DOE QA Management should meet every six months to assure deficient items are being appropriately resolved.

The Clark County Representative requested DOE to respond to three questions:

1. Why are there increased deficiencies when the Office of QA has had a reduction in resources and the support contractor has experienced an increase in resources?

DOE Response: It is true that QA resources were reduced when the transition to one QA organization occurred. However, DOE believes there are adequate QA staff to verify implementation.

2. Are the increased deficiencies due to more reviews or parts that were overlooked before?

DOE Response: Increased deficiencies are due to a more consistent review after the QA transition. Before the QA transition, the QA organization was dispersed among several participants and reviews were inconsistent.

3. The Total System Performance Assessment has a large amount of data. Is this data suspect due to deficient suppliers and scientific notebooks?

DOE Response: DOE will get back to Clark County on this question when the investigations are completed. The results will also be furnished to the NRC.

The Nye County Representative stated that once the QA program was approved and implemented, all data acquired under the approved QA program was supposed to be qualified and all prior data was to be considered unqualified. DOE responded that they will keep Nye County informed on this issue.

The State of Nevada thanked the NRC for recognizing the problems and would like to continue be involved in the process. The State of Nevada stated that it was happy to hear of the NRC

involvement in the upcoming QA audit after a long absence and was also awaiting the response to the State's April 14, 1998, letter to the NRC.

The NRC emphasized that they disagreed with the tone of the State's letter and the response had been signed May 5, 1998, and was in the mail. The NRC also pointed out that the items listed in the State's letter were identified by the NRC. At that time, the DOE Deputy QA Management provided a copy of the response to the State of Nevada.

ADJOURN:

There were no additional issues noted by the representatives in attendance. The meeting was adjourned at 5:45 p.m. EST.



Theodore H. Carter
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission



Nancy Slater
Regulatory Coordination Division
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

ATTENDANCE
DOE/NRC Quality Assurance Meeting
NRC T2B3 Videoconference Room
May 6, 1998

Sandra Wastler	NRC	301-415-6724
Ted Carter	NRC	301-415-6684
Bill Belke	NRC	702-794-5047
John Russell	CNWRA	301-881-0289
Dave Fehringer	NWTRB	703-235-4473
Michael Bell	NRC	301-415-7286
Margaret Federline	NRC	301-415-6708
Alan Brownstein	DOE/RW	202-586-4973
Richard Spence	DOE/RW	702-794-1455
Donald G. Horton	DOE/RW	702-794-5568
King Stablein	NRC	301-415-7252
Mal Murphy	Nye County	360-945-5610
Sidney Crawford	Self	301-515-6398
Richard Goff	Booz Allen	202-626-1061
John Greeves	NRC	301-415-7437
Carl J. Paperiello	NRC	301-415-7800
Wesley Patrick	CNWRA	210-522-5158
Budhi Sagar	CNWRA	210-522-5252
Bruce Mabrito	CNWRA	210-522-5149
Ronald J. Stevens	M&O Licensing	702-295-4872
Sam Horton	OQA/QATSS	702-794-1497
Bob Clark	OQA/DOE	702-794-5583

ATTENDANCE
DOE/NRC Quality Assurance Meeting
NRC T2B3 Videoconference Room
May 6, 1998

Susan Zimmerman	State of Nevada	702-681-3744
April Gil	DOE/YMP/ANL	702-794-5578
Jim Schmit	OQA/QATSS	702-794-1472
Mary Manning	LV Sun Newspaper	702-257-4065
Tim Have	DOE	702-794-1441
Jim Smyder	Naval Reactors	702-295-0415
Nick Stellavato	Nye County	702-727-7727
E. Dow Davidson, Jr.	Contractor to Nye County	512-257-8128
E. von Tiesenhausen	Clark County	702-455-5184
Jim Linhart	DOE-EM National SNF Prog.	702-295-0366
Tim Gunter	DOE-EM/YMSCO	702-794-1343
Frank Kratzinger	MTS	702-794-5057
Phil Hammond	M&O Licensing	702-295-4876
Albert C. Williams	DOE-OQA	702-794-5580
Mary G. McDaniel	OQA/QATSS	702-794-1468
Catherine Hampton	DOE-OQA	702-794-1387
Ken Ashe	M&O Licensing	702-295-5563
Lake Barrett	DOE/RW	702-586-6850

**FINAL AGENDA
NRC/DOE QUALITY ASSURANCE MEETING**

May 6, 1998

VideoConference, Hillshire Blue Room and NRC Headquarters, T2B5

3:00 EST INTRODUCTORY REMARKS

Bell/Horton

QA ISSUES FROM MARCH 17, 1998 OR REPORT

- | | |
|---|-----|
| - Length of Time to Close Deficiencies (NRC Open Item 98-1) | DOE |
| - Increased Deficiencies in Scientific Notebooks (NRC Open Item 98-2) | DOE |
| - Trending Program | DOE |
| - DOE QARD Supplement 1 Guidance (NRC Closed Item 97-1) | NRC |
| - Deficient Suppliers - Validity and Quality of Supplier Data
And Products Questionable (NRC Open Item 97-2) | DOE |
| - Data Qualification (NRC Closed Item 96-1) | NRC |
| - Level of Quality of Work Products (NRC Open Item 96-2, since 10/24/96) | DOE |
| - Length of time to close USGS Technical Program Effectiveness
(NRC Closed Item 95-1) | DOE |

OTHER QA ITEMS OF INTEREST

- | | |
|---|-----|
| - Length of Time to Issue FY98 CARS | DOE |
| * Criterion XVII of App. B to 10 CFR Part 50 requires that deficiencies are promptly identified. Of the 7 CARS issued to date | |
| - CAR-002 - 110 DAYS TO ISSUE | |
| - CAR-003 - 79 DAYS TO ISSUE | |
| - CAR-004 - 48 DAYS TO ISSUE | |
| - September 1997, NRC requested information to close SCP Question 55 and SP 8.3.1.5.2.2 comments | DOE |
| - Graded QA | NRC |
| - UZ Flow Model Vertical Slice Report Findings (New NRC Open Item 98-3) | DOE |

SCHEDULE BI-ANNUAL QA MEETING

NRC/DOE

6:00 EST ADJOURN

Attachment 2

**U.S. Department of Energy
Office of Civilian Radioactive Waste
Management**

NRC/DOE QA MEETING

**PRESENTED TO
NRC
AND OTHER INTERESTED PARTIES**



**PRESENTED BY
DONALD G. HORTON, Director
Office of Quality Assurance**

May 6, 1998

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- LENGTH OF TIME TO CLOSE DEFICIENCIES

☐ DOE RESPONSE

- CURRENT ASSESSMENT OF CLOSED C/ACTION DOCUMENTS - FY96 TO PRESENT - SHOW 3% CLOSED IN EXCESS OF 1 YEAR (20 OF 535)
- WE RECOGNIZE NEED TO IMPROVE TIMELINESS OF CLOSURE
- THE LACK OF TIMELINESS RESULTS IN NO IMPACT TO NUCLEAR SAFETY OR WASTE ISOLATION

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- INCREASED DEFICIENCIES IN SCIENTIFIC NOTEBOOKS (SN)

☐ DOE RESPONSE

- RECENT OQA VERIFICATION ACTIVITIES HAVE INDICATED AN INCREASE IN THE NUMBER OF DEFICIENCIES WITH SNs
- CORRECTIVE ACTIONS CURRENTLY IN PROGRESS
 - REVIEWING SNs FOR COMPLIANCE TO REQUIREMENTS
 - REVISING PLANNING METHODS FOR SCIENTIFIC INVESTIGATIONS FOR PROJECT CONSISTENCY
 - CONDUCTING TRAINING CLASSES ON PROPER COMPLETION OF SNs

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- TRENDING PROGRAM MAY NOT BE TOTALLY EFFECTIVE

☐ DOE RESPONSE

- NRC STATES IN OR REPORT THAT THE PROPOSED TRENDING APPROACH WILL ASSIST IN DETECTING TRENDS IN A MORE TIMELY AND EFFECTIVE MANNER
- THE DOE INVESTIGATED THE NRC OR CONCERN AND AGREED WITH THE INADEQUACY OF THE TREND PROGRAM
- DOE WROTE A DEFICIENCY REPORT (NOVEMBER 1997)
- PERSONNEL ASSIGNED TO CORRECT AND REVISE TREND METHOD
- CORRECTIVE ACTION COMPLETION EXPECTED JUNE 1998

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- DEFICIENT SUPPLIERS - VALIDITY AND QUALITY OF SUPPLIER DATA AND PRODUCTS QUESTIONABLE

☐ DOE RESPONSE

- IDENTIFIED IN CAR LVMO-98-C-002 AND CAR VAMO-98-C-005
- BOTH CARs ISSUED IN FEBRUARY 1998 - EXTENT OF CONDITION BEING INVESTIGATED
- CARs REQUIRE IMPACT ON DATA TO BE ASSESSED
- IMPACTED DATA WILL BE QUALIFIED IN ACCORDANCE WITH QARD

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- LEVEL OF QUALITY OF WORK PRODUCTS

NOTE: At 1/21/98, NRC/DOE Meeting - DOE noted they would provide NRC information related to timeliness and reviewers of report in question

☐ DOE RESPONSE

- MISUNDERSTANDING ON PART OF DOE RELATIVE TO WHAT NRC WAS REQUESTING
- REPORT WAS DRAFT 1996 VOLCANISM REPORT - RECEIVED BY NRC ON 4/16/98
- TECHNICAL REVIEWER - FRANK PERRY
- FOUR DEFICIENCIES ISSUED FROM LANL AUDIT. ONE REMAINS OPEN (AWAIT QUALIFICATION OF DATA)
- ON 3/24/98, DOE REQUESTED THE M&O TO PROVIDE A SCHEDULE FOR DATA QUALIFICATION

QA ISSUES FROM 3/17/98 OR REPORT

☐ ISSUE

- LENGTH OF TIME TO CLOSE USGS TECHNICAL PROGRAM EFFECTIVENESS

☐ DOE RESPONSE

- MISUNDERSTANDING ON PART OF DOE IN ASCERTAINING WHAT OR WAS SEEKING
- INITIAL THREE REPORTS SELECTED FOR REVIEW - DID NOT CONTAIN CALCULATIONS, FIRST REQUESTED IN JULY 1997
- ADDITIONAL WORK TO ADDRESS NRC ITEM - CAUSED THE ISSUE TO REMAIN OPEN FOR EXTENDED PERIOD
- CONSIDERED ISOLATED CASE BASED ON MISCOMMUNICATION

QA ISSUES FROM 3/17/98 OR REPORT

❑ ISSUE

- LENGTH OF TIME TO ISSUE FY98 CARs
 - CAR-002 110 DAYS TO ISSUE
 - CAR-003 79 DAYS TO ISSUE
 - CAR-004 48 DAYS TO ISSUE

❑ DOE RESPONSE

- QARD REQUIRES C/ACTION TO BE TAKEN “AS SOON AS PRACTICAL,” UNLESS DEFICIENCY REQUIRES IMMEDIATE C/ACTION
- INITIATION DATE VS. ISSUE DATE
 - DEFICIENCY RECEIVES INDEPENDENT AND QA MANAGEMENT REVIEWS
 - NOTED CARs ARE COMPLEX; NEEDED TO ENSURE THERE WAS NO OVERLAP OF PROBLEMS
 - NEEDED TO ENSURE PROBLEMS OF SIGNIFICANCE ARE CLEARLY ARTICULATED AND WRITTEN WHERE THEY CAN BE RESOLVED
- OQA WILL BE MORE SENSITIVE TO TIMELINESS AND TRY TO IMPROVE THE OVERALL LIFE CYCLE OF DEFICIENCIES

YUCCA MOUNTAIN PROJECT

Studies

NRC/DOE QA Meeting Input

Presented to
Nuclear Regulatory Commission
NRC/DOE Quality Assurance Meeting

Presented by:
Richard E. Spence
Deputy Assistant Manager of Licensing
YMP

May 6, 1998

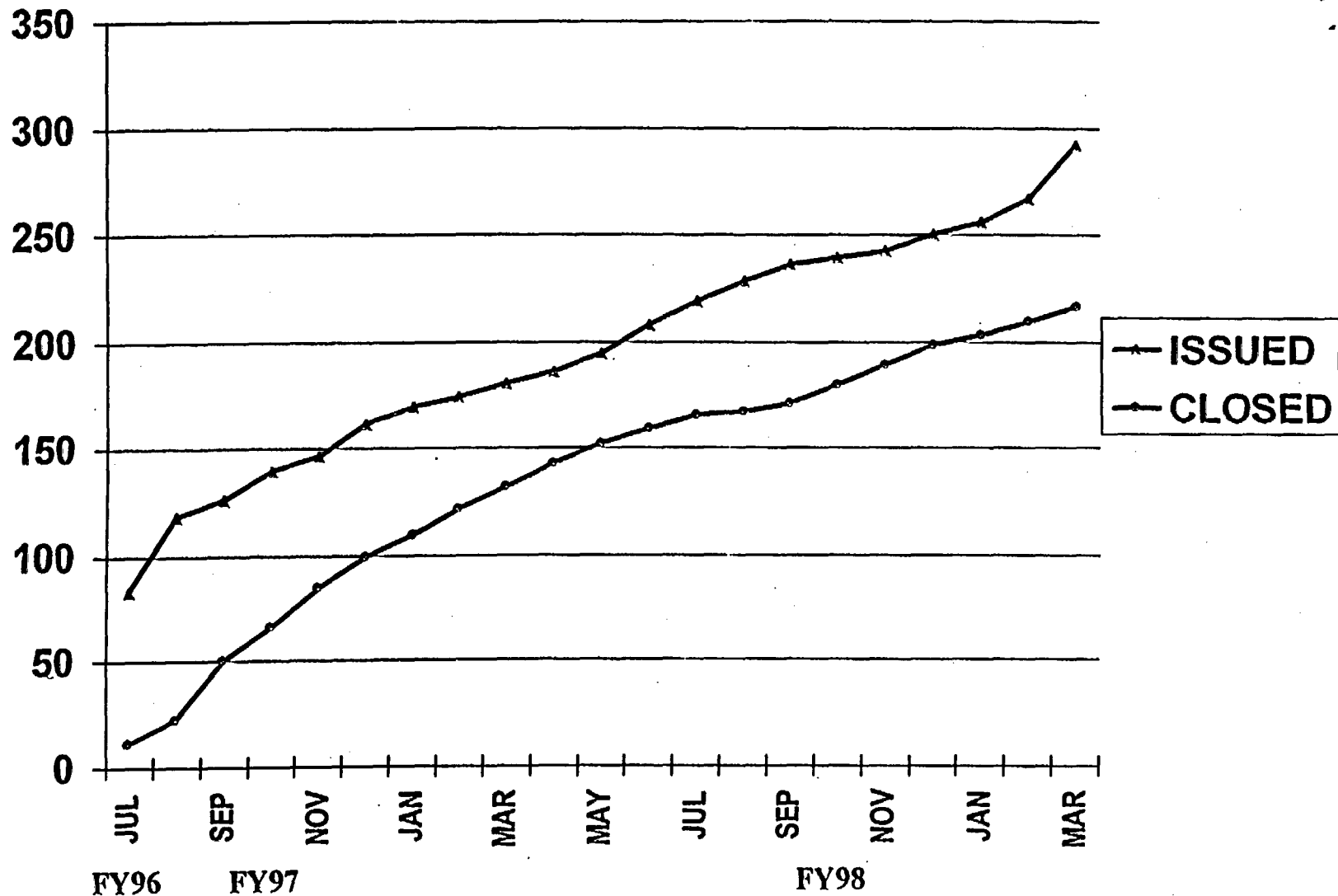


U.S. Department of Energy
Office of Civilian Radioactive
Waste Management

Increased DOE Effort To Resolve DRs/CARs

- YMP Change Request 98-016 for added USGS and M&O Engineering Assurance support to line organizations.
- MTS Task Modification YMP98-04C to expedite closure of existing DRs/CARs by reviewing, assessing, performing input analysis on related activities, prioritization and completed resource loaded schedule.

ISSUED vs CLOSED CARs/DRs



This chart shows all CARs and DRs issued to and closed for the M&O.
(Cumulative totals used for trending.)