SEP 24 1990

Mr. Ralph Stein, Associate Director
for Systems Integration and Regulations
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW-30
Washington, D.C. 20585

Dear Mr. Stein:

SUBJECT: JULY 19, 1990 QUALITY ASSURANCE MEETING

The purpose of this letter is to transmit the enclosed minutes of the July 19, 1990, quality assurance (QA) meeting. The participants included individuals from the U.S. Nuclear Regulatory Commission (NRC), U.S. Department of Energy (DOE), State of Nevada (NV), and Nye and Clark Counties, NV.

DOE indicated that a QA workshop was planned for August 7-8, 1990, in Denver, Colorado, for the Yucca Mountain Project (YMP) participants to identify problems experienced with implementing QA program requirements. Although there was no new update on the Federal Register notice pertaining to the Privacy Act issue, it was noted that the DOE System 2 for interim records should be available in the near future.

In addition, DOE discussed the proposed reorganization of the Office of Civilian Radioactive Waste Management (OCRWM), status of upcoming audits and surveillances, OCRWM and YMP internal reviews, Standard Deficiency Report program, and Trend Analysis.

Observation of the DOE May 1990 audit of Lawrence Livermore National Laboratories; review comments of DOE's Quality Assurance Requirements Document, Revision 3; and QA open items were discussed by the NRC staff.

If you have any questions regarding this letter or the enclosed meeting minutes, please contact Ken Hooks of my staff at 301/FTS 492-0447.

Sincerely,

ORIGINAL SIGNED BY
John J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

Enclosure: As stated in pocket
cc: R. Loux, State of Nevada
C. Gertz, DOE/NV
S. Bradhurst, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV.

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ENCLOSURE

MINUTES OF THE 7/19/90 QUALITY ASSURANCE MEETING

A meeting of the staff of the United States Nuclear Regulatory Commission (NRC); representatives of the United States Department of Energy (DOE); and the State of Nevada (NV) to discuss issues of mutual interest with regard to quality assurance (QA) was held on July 19, 1990 in Bethesda, MD. Representatives of the Affected Units of Local Government were notified of the meeting. Representives of both Nye and Clark Counties were present. An attendance list is included as Attachment 1.

DOE, in opening remarks, mentioned that a QA workshop to provide DOE Office of Civilian Radioactive Waste Management (OCRWM) program participants with an opportunity to identify problems with QA program implementation would be held in Denver, CO from August 7 to 8, 1990. A second meeting is planned in the September/October 1990 time-frame for resolution of the concerns raised at the previous meeting. In response to a question from the NRC staff, DOE stated that input from the DOE Technical Project Officers (TPOs) was being elicited by polling. In response to a question from a representative of the DOE Office of Environmental Management and Restoration (EM), it was stated that OCRWM, the office holding the workshop, had no objection to EM participation in it.

The first agenda topic discussed was the status of the resolution of the Privacy Act issue of availability of DOE program participant qualification and training records for QA audit and/or surveillance review. DOE reported that there was nothing new to report with regard to the Federal Register notice, but that progress on loading the DOE System 2 interim records system was complete and that the system should be available in the near future.

At the request of DOE, the next agenda topic, an update on the schedules for the integration of waste glass producers' QA programs was deferred.

The next topic discussed was the recently announced reorganization of OCRWM (see Attachment 2). This was an informal discussion of what the proposed organizational changes would be. The plan still must be approved by appropriate levels of DOE management. The reorganization is not expected to adversely affect the management of OCRWM's QA activities.

With regard to the Management Improvement Plan, DOE stated that it was not yet completed or ready for issuance. DOE will inform the NRC staff of changes to the status of this item at upcoming QA meetings.

102.7

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The status of the OCRWM and Yucca Mountain Project Office (YMPO) audits was the next agenda item. It was stated by DOE that information was not yet available on the scheduling of these events.

DOE provided the status of upcoming audits and surveillances (Attachments 3 and 4). It was announced that a close out audit of Holmes and Narver was scheduled. The audit of Sandia National Laboratories remains on schedule for August 20. The Scientific Applications International Corporation's Technical and Management Support Services are now a program participant and will not be involved in the internal YMPO audit in October.

The NRC staff discussed its recent observations of DOE audits (Attachment 5). With regard to the audit at Lawrence Livermore National Laboratories (LLNL), the NRC staff found the audit process to be good, however there was very little implementation taking place at the time of the audit. The NRC staff also provided a brief discussion on the request for LLNL program acceptance (Attachment 6). The NRC staff's believes that it had already taken a position with regard to the fact that most of the DOE program participants QA programs are acceptable for further implementation. It would seem that that is what DOE is asking for in the requests for acceptance sent to NRC by DOE for several of the program participants. DOE expressed concern about the NRC staff's use of "marginal" as a description of the adequacy of programs in which there is limited implementation. The NRC staff noted its agreement and stated that the term is no longer being used.

The NV representative expressed concern about Los Alamos National Laboratory (LANL) surveillance. Concern was expressed that better management of the program was not in evidence. The corrective action close out process was of particular concern because there has been no evidence of improvement over time in this area. DOE expressed that it is aware of the problems and that the corrective action program was a specific area being considered. The representative of the Edison Electric Institute asked the NV representative for an opinion of why the problems persisted at LANL. The NV representative stated that it appeared as if LANL was simply attempting to do the minimum amount necessary to meet the regulations.

DOE provided a brief discussion of the OCRWM and YMP internal reviews (Attachment 7). They were characterized as program reviews to assess the state of these two programs. The summary conclusion of the OCRWM review was that significant improvements in compliance and implementation are necessary before the QA program can be presented to the NRC as a qualified and acceptable for the OCRWM/HQ support of the start of new site characterization activities. The summary conclusion of the YMP review was that additional actions are required by the Project Office to ensure that sufficient controls are in-place for the overall control of its quality related activities.

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Attachment 8 was used in the discussion of the NRC staff's comments on the QARD. These comments had been previously discussed in a telephone conference. It was determined that further discussion was necessary at a later date. Subsequent to the QA meeting a telephone conference call was held at which significant progress was made in resolving the NRC comments. A discussion of the resolution will take place at the next QA meeting.

DOE next provided a discussion of its Standard Deficiency Report (SDR) program. Attachment 9 was used in this presentation. The focus was on SDRs observed at LANL, LLNL and the United States Geologic Survey (USGS). In response to a question from the NV representative, DOE indicated that it would attempt to determine the root causes of a repeated problem at LANL. The NRC staff noted that its concern was that DOE confidence in its SDR system.

Attachment 10 was used in the DOE discussion of Trend Analysis. This was related to SDR discussion. This trending program is fairly new, but it seems to show that the number of SDRs had lessened substantially, resulting in an overall decreasing trend. The first report on the system is not due until August, 1990. The NRC and DOE will discuss this further after the report is issued.

Attachment 11 was used in the NRC staff's update of the QA open items. It was noted that seven items remain open.

In closing remarks, the NRC staff requested to be notified in advance of the meeting when DOE will not be able to present an item on the agenda. A tentative date of September 18, 1990 was set for the next bimonthly QA meeting.

NV did not submit a written statement for inclusion in these minutes.

Mark S. Delligatti 9/13/90
Mark S. Delligatti, Project Manager
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission

Corinne Macaluso 9/14/90
Corinne Macaluso
Licensing Branch
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

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NRC/DOE QA MEETING

Name	Organization	Phone
Mark Delligatti	NRC	492-0430
Bill Pearson	DOE/SR	(803)557-1066
Joe W. Anderson	DOE	(615)482-9004
Jim Rusk	MacTec	(702)794-7247
Bill Belke	NRC	(301)492-0445
Susan Zimmerman	State of NV.	(702)687-3744
Donald G. Horton	DOE	(FTS)544-7504
James Blaylock	DOE	544-7913
Ken Hooks	NRC	(301)492-0447
Jim Conway	NRC	(301)492-3465
John Buckley	NRC	(301)492-0513
Teek Verma	NRC	(301)492-3465
Tom Gutmann	DOE/EM	(301)427-1605
Ray D. Walton, Jr.	DOE	(301)948-0698
Ram Murthy	DOE	(702)794-7968
Ray Wallace	USGS-HQ/DOE-HQ	(202)586-1244
Steph Echols	Bishop Cook Purcell & Reynolds	(202)371-5777
Art Spooner	WESTON	(202)646-6668
Nadine R. Karas	SAIC	(702)794-7641
Bruce D. Foster	SAIC	FTS 575-7136
Eugene H. Roseboom	USGS Dir. Office	(703)648-4423
David H. Appel	USGS	(303)236-1418
Marc Meyer	CER	(703)276-9377
E. V. Tiesenhausen	CCCP	(702)455-4181
John Gilray	NRC	(702)293-5369
Bruce Mabrito	CNWRA	(512)522-5149
Don Loosley	NRC	(301)692-0657
Tom Colandrea	EEI-UWASTE	(619)487-7510
Phillip A. Niedzielski-Eichner	NYE COUNTY	(703)818-2434
Dan Semick	GAO	(202)586-8742
Elgie Holstein	NYE COUNTY	(703)834-1173
Larry D. Vaughan	DOE/EM-30	(301)353-3137
Corinne J. Macaluso	DOE/RW-331	586-2037

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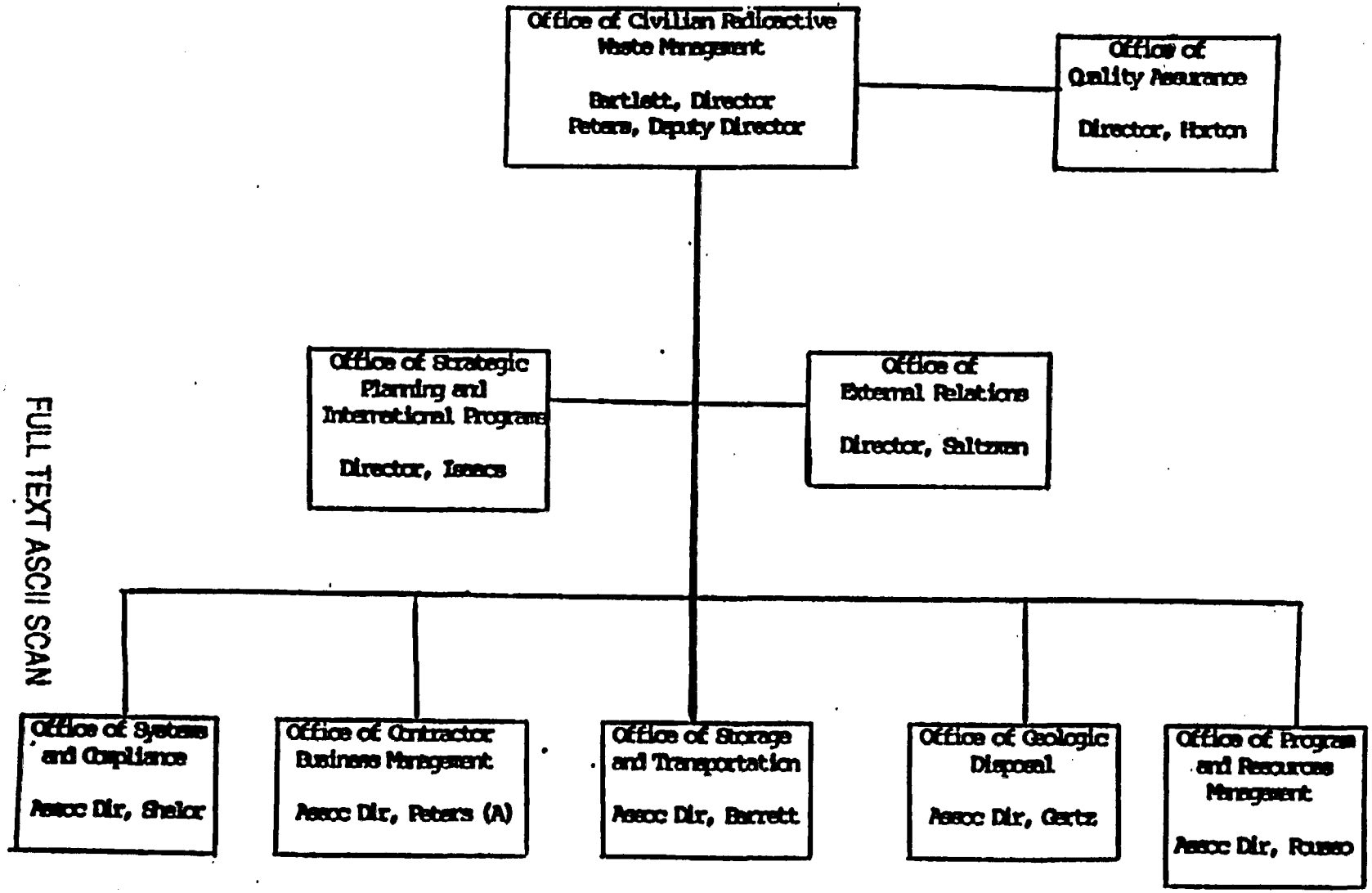
ATTACHMENT 1

(Proposed) Reorganization

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT



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ATTACHMENT 2

(PROPOSED)

OFFICE OF QUALITY ASSURANCE

Horton, D., Director
Washington, H. (Secretary)

YMPO QA Division

Director (VACANT)
Blaylock
Constable
Hampton
Diaz
Williams
Voltura
Masuda

HQS QA Division

Talboti, R., Director
Clark, B.
Arpia, J.
VACANT
VACANT
VACANT
Johnson, T. (SECRETARY)

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FY-90 AUDIT SCHEDULE *

	FEB				MAR				APR					MAY				JUN						JUL			
AUDIT#/ORG./ATL	5	12	19	26	5	12	19	26	2	9	16	23	30	7	14	21	28	4	11	18	25	2	9	16	23	30	
90-1 LANL								■	▼		●																
S.DANA																											
90-2 LLNL															■	▼		●									
J.HEANEY																											
90-3 USGS																					■	▼		●			
R.MAUDLIN																											
90-6 H&N																		□				▽		○		■	
F.KRATZINGER																											
90-5 REECO																		CANCELLED DUE TO NO WORK ACTIVITY									
R.KLEMENS																											
90-I-1 HQ	POSTPONED UNTIL FURTHER NOTICE.																										
TBD																						TIME NOW					

* ALL APPLICABLE 18 CRITERIA PLUS IMPLEMENTING PROCEDURES REV 5

DATE:

APPROVAL:

PAGE 1 OF 2

□ SCOPING VISIT

▽ TRANSMIT NOTIFICATION LETTER/PLAN

○ TRANSMIT AUDIT MANUALS

■ PERFORM AUDIT

▼ TRANSMIT SDRS

● TRANSMIT AUDIT REPORT

FULL TEXT ASCII SCAN

ATTACHMENT 3

FY-90 AUDIT SCHEDULE

AUDIT#/ORG./ATL	JUN 4	JUN 11	JUN 18	JUN 25	JUL 2	JUL 9	JUL 16	JUL 23	JUL 30	AUG 6	AUG 13	AUG 20	AUG 27	SEP 3	SEP 10	SEP 17	SEP 24	OCT 1	OCT 8	OCT 15	OCT 22	OCT 29	NOV 5	NOV 12	NOV 19	NOV 26
90-6 H&N	□				▽		○		■	▼		●														
F.KRATZINGER																										
90-5 REECO	CANCELLED DUE TO NO WORK ACTIVITY																									
R.KLEMENS																										
90-4 SNL					□			▽		○		■	▼		●											
S.DANA																										
90-7 FSN									□				▽		○		■	▼		●						
F.KRATZINGER																										
90-8 SAIC												□				▽		○		■	▼		●			
R.MAUDLIN																										
90-1-2 YMPO													□				▽		○			■	▼		●	
S. DANA																										

• ALL APPLICABLE 18 CRITERIA PLUS IMPLEMENTING PROCEDURES REV 5

DATE:

APPROVAL:

PAGE 2 OF 2

□ SCOPING VISIT

▽ TRANSMIT NOTIFICATION LETTER/PLAN

○ TRANSMIT AUDIT MANUALS

■ PERFORM AUDIT

▼ TRANSMIT SDRS

● TRANSMIT AUDIT REPORT

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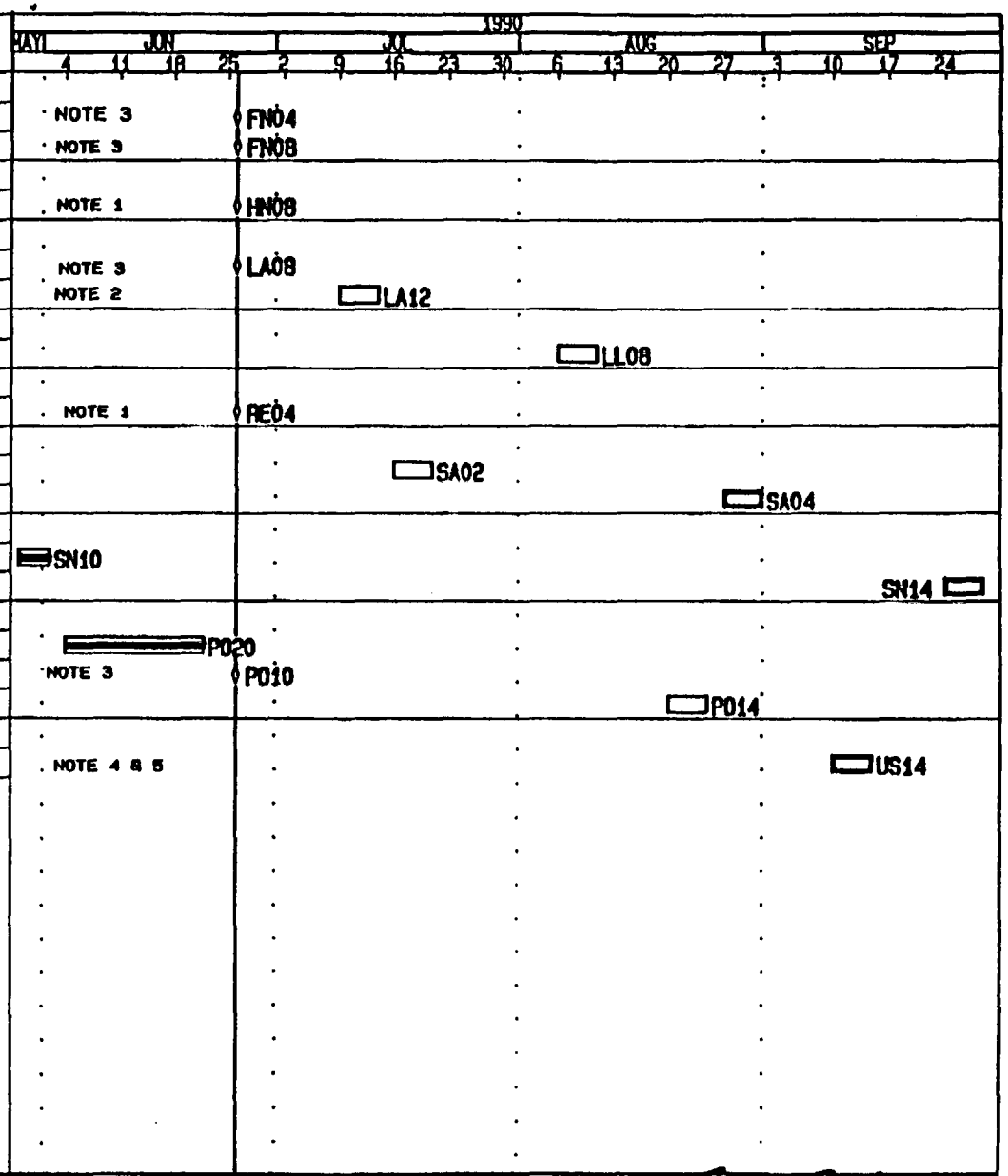
REPT	ACTIVITY DESCRIPTION	EARLY START	EARLY FINISH
➪	FENIX SCISSON NEVADA		
	SOFTWARE CONTROL	26JUN90	25JUN90
	TITLE I & II DOCUMENTATION	26JUN90	25JUN90
➪	HOLMES AND NARVER		
	SOFTWARE CONTROL	26JUN90	25JUN90
➪	LOS ALAMOS NATIONAL LABORATORY		
	SOFTWARE/CRITERIA 16, 17, 18.	26JUN90	25JUN90
	CRITERIA 2, 5, 6, 16, 17, 18	9JUL90	13JUL90
➪	LAWRENCE LIVERMORE NATIONAL LABORATORY		
	CRITERIA 2, 5, 6, 16, 17.	6AUG90	10AUG90
➪	REYNOLDS ELECTRICAL AND ENGINEERING		
	CALIBRATION	26JUN90	25JUN90
➪	SAIC		
	CRITERIA 1, 2, 5, 6	16JUL90	20JUL90
	CRITERIA 4, 7, 15, 17	27AUG90	31AUG90
➪	SANDIA NATIONAL LABORATORIES		
90-030	CRITERIA 4, 7, 15, 17, 2.	29MAY90A	1JUN90A
	CRITERIA 1, 5, 16, 18	24SEP90	28SEP90
➪	PROJECT OFFICE/T&MSS		
90-031	STUDY PLANS	4JUN90A	21JUN90A
	EPA (RADIOLOGICAL MONITORING)	26JUN90	25JUN90
	CRITERIA 1, 2, 5, 6.	20AUG90	24AUG90
➪	U.S. GEOLOGICAL SURVEY		
	CRITERIA 4, 12, 15, 16.	10SEP90	14SEP90



NOTES:

1-POSTPONED ON REV 5.

2-FOLLOW UP TO AUDIT 90-1.

3-POSTPONED UNTIL FURTHER NOTICE.

4-CRIT 1 AND 5 COVERED DURING US16.

5-RESCHEDULED DUE TO AUDIT.

Activity Bar/Early Dates
Critical Activity
Progress Bar

Primavera Systems, Inc. 1984-1990

DEPARTMENT OF ENERGY
YUCCA MOUNTAIN PROJECT OFFICE
FY-90 STATUS, REV 8, SURV SCH W/ORG

Project Start : 10CT89
Project Finish: 15EP90M

Sheet 1 of 1

Data Date: 26JUN90
Plot Date: 29JUN90

APPROVED BY 7/2/90 DATE:

ENCLOSURE

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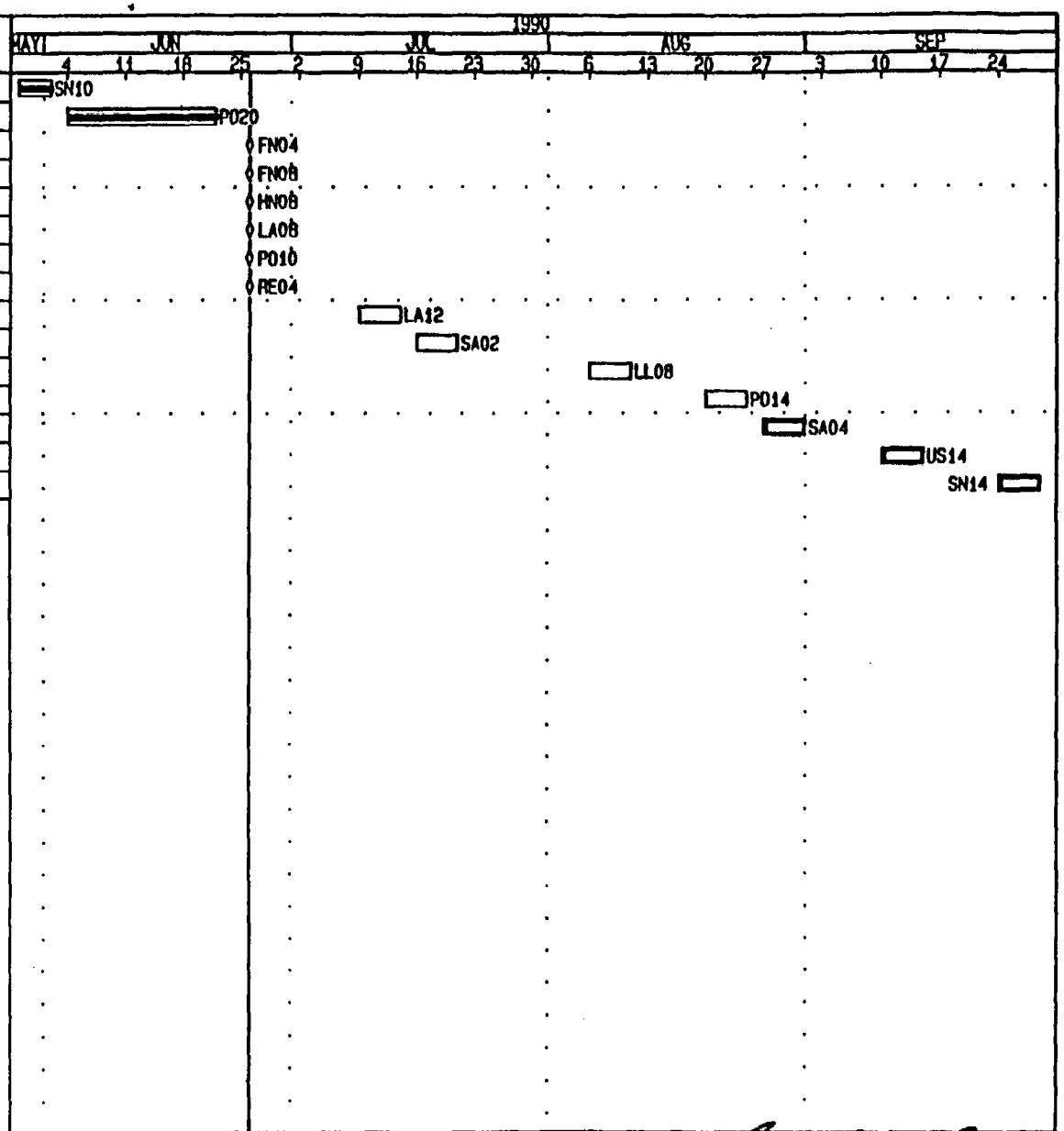
ATTACHMENT 4

REPT	ACTIVITY DESCRIPTION	EARLY START	EARLY FINISH
90-030	CRITERIA 4, 7, 15, 17, 2.	29MAY90A	1JUN90A
90-031	STUDY PLANS	4JUN90A	21JUN90A
	SOFTWARE CONTROL	26JUN90	25JUN90
	TITLE I & II DOCUMENTATION	26JUN90	25JUN90
	SOFTWARE CONTROL	26JUN90	25JUN90
	SOFTWARE/CRITERIA 16, 17, 18.	26JUN90	25JUN90
	EPA (RADIOLOGICAL MONITORING)	26JUN90	25JUN90
	CALIBRATION	26JUN90	25JUN90
	CRITERIA 2, 5, 6, 16, 17, 18	9JUL90	13JUL90
	CRITERIA 1, 2, 5, 6	16JUL90	20JUL90
	CRITERIA 2, 5, 6, 16, 17.	6AUG90	10AUG90
	CRITERIA 1, 2, 5, 6.	20AUG90	24AUG90
	CRITERIA 4, 7, 15, 17	27AUG90	31AUG90
	CRITERIA 4, 12, 15, 16.	10SEP90	14SEP90
	CRITERIA 1, 5, 16, 18	24SEP90	28SEP90



Activity Bar/Early Dates
Critical Activity
Progress Bar

Primavera Systems, Inc. 1984-1990

DEPARTMENT OF ENERGY
YUCCA MOUNTAIN PROJECT OFFICE
FY-90 STATUS, REV 8, SURV SCH W/ORG

Project Start : 10CT89
Project Finish: 1SEP90A

Sheet 1 of 1

Data Date: 26JUN90
Plot Date: 26JUN90

7/2/90

APPROVED BY DATE

ENCLOSURE

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5.10 Summary of NRC Staff Findings

(a) Observations

- The NRC staff did not identify any observations relating to deficiencies in either the DOE/YMPO audit process or the LLNL QA program.

(b) Weaknesses

- The overall audit was marginal in achieving its purpose of determining the effectiveness of the LLNL QA program due to limited implementation of the QA program. Few programmatic records and technical products were available upon which audit conclusions could be based.

- A large number of audit questions could only be resolved by the LLNL QA Manager, which may suggest a lack of delegation of activities by the QA Manager to his staff, or a lack of depth and experience in the LLNL QA organization.

- LLNL administrative procedures do not address the resolution of comments for all reviewers of technical documents. The internal review procedures for this process appear to be questionable.

- Although DOE has verbally agreed to evaluate earlier observations, the DOE audit procedure(s) does not explicitly require that previous NRC and State of Nevada findings be reviewed to determine the scope of the audit.

- LLNL completed a Peer Review Report on "Selection Criteria for the Yucca Mountain Project Waste Package Container Material" in December 1988. To date, neither the report nor information on the peer review process has been made available to the NRC staff.

- The YMP Leader noted that LLNL does not receive copies of the DOE/YMPO Audit Reports for other participant programs. Receipt of these reports would enable LLNL to be aware of and look for deficiencies common to other participant programs.

(c) Good Practices

- Improved performance in coordinating the QA programmatic and technical evaluations simultaneously to allow the integration of these two aspects of the audit.

- The audit team was well prepared and conducted a thorough audit in a professional manner.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 17 1990

Mr. Ralph Stein, Associate Director
for Systems Integration and Regulations
Office of Civilian Radioactive Waste Management
U. S. Department of Energy, RW 30
Washington, D.C. 20585

Dear Mr. Stein:

SUBJECT: UNITED STATES NUCLEAR REGULATORY COMMISSION (NRC) ACCEPTANCE OF LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) QUALITY ASSURANCE (QA) PROGRAM

Your letter of April 13, 1990, to Mr. Robert Browning, Director of the NRC Division of High-Level Waste Management, requested acceptance by the NRC staff of the QA program at LLNL "... to initiate activities supporting new site characterization". As indicated in my letter to you dated August 1, 1989, which transmitted the NRC staff's Observation Audit Report of DOE's Audit No. 89-06 of LLNL, the NRC found that LLNL had an adequate QA program for the areas which were audited, and qualified QA and technical personnel. The NRC staff continues to believe that the LLNL QA program has adequate controls in place to continue Yucca Mountain Project work, such as the development of study plans and technical procedures (i.e., activities which support new site characterization). Such activities will allow LLNL to demonstrate its ability to implement its QA program prior to the start of any new site characterization activities.

Our evaluation of the acceptability of the QA program for new site characterization work (i.e., data collection, testing, etc), thus resolving the NRC QA objection in the Site Characterization Analysis for LLNL, will occur after DOE has determined that LLNL has demonstrated the ability to effectively implement an adequate QA program. As discussed in the February 15, March 21, and April 27, 1990 NRC/DOE QA meetings, the NRC staff requires the following information to complete our evaluation of each DOE program participant QA program: a statement regarding resolution of program deficiencies identified by the participant, DOE or the NRC (all significant deficiencies resolved); identification of the extent of program implementation since the last NRC-observed DOE audit (including work products produced and audits/surveillances conducted); a statement as to whether DOE can now determine the effectiveness of the participant QA program (and if so, what determination has been made); a statement of what areas of the QA program are still on hold (and the steps being taken to resolve the problems in these areas); and a statement of DOE's current position on the acceptability of the participant QA program to initiate new site characterization activities.

In documenting your evaluation of the adequacy and effectiveness of implementation of the LLNL QA program, the NRC staff believes that you should specifically address unresolved items from your audits and surveillances of the LLNL QA program. As an example, the DOE Report for Audit No. 89-06 from June 5-9, 1989 (ref. Wilmot/Jardine letter dated July 2, 1989) stated:

It should be noted that the LLNL QA Program does not fully meet the

ATTACHMENT 6

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provisions of the Yucca Mountain Project Quality Assurance Plan NWWSI/88-9, Revision 2. Neither the LLNL Software QA Plan nor QA Level Assignment and grading efforts have been approved by the Project Office. The effectiveness of the LLNL QA Program cannot be determined at this time because the implementing plans and technical procedures have not been completed and the limited quantity of technical products issued to date is insufficient to allow an effectiveness conclusion.

As agreed at the April 27, 1990, NRC/DOE QA meeting, DOE will write a letter to the NRC requesting NRC acceptance of the LLNL QA program for new site characterization activities after DOE determines that program implementation is effective. The NRC staff would expect this letter documenting your evaluation of the LLNL QA program to include a statement as to whether DOE can now determine the effectiveness of the QA program (and if so, what determination has been made) and a statement of what areas of the QA program are still on hold (and the steps being taken to resolve the problems in these areas).

The NRC wishes to note that your letter of April 13, 1990, which specifically requests NRC acceptance of the LLNL QA program "...to initiate activities supporting new site characterization" appears unnecessary, since subsequent discussion between the NRC and DOE established that this phrase meant development of study plans, technical procedures and other documents to control work rather than generation of data to be used in licensing. The NRC staff presented a summary of the status of NRC reviews of DOE QA programs at the February 15, 1990 NRC/DOE QA meeting (enclosed), which indicated that LLNL was "acceptable for continued implementation." The NRC believes that all the QA programs identified in the enclosed list as "acceptable for continued implementation" are adequate "...to initiate activities supporting new site characterization," as defined above.

If you have any questions concerning our position, please contact Mark Delligatti of my staff on 301/FTS 492-0430.

Sincerely,

John J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

cc: C. Gertz, DOE/NV
S. Bradhurst, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO

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STATUS OF NRC REVIEWS OF QA PROGRAMS

ORGANIZATION	EFFECTIVENESS OF DOE AUDIT	ADEQUACY OF AUDITED PROGRAM	ACCEPTABILITY FOR STARTING SITE CHARACTERIZATION
FSN	OK	ACCEPTABLE FOR CONTINUED IMPLEMENTATION	?
H&N	OK	" "	?
LLNL	OK	" "	?
SANDIA	OK	" "	? AUDIT OR SURVEILLANCE REQ'D
USGS	MARGINAL	" "	? AUDIT OR SURVEILLANCE, INDEPENDENT NRC AUDIT REQ'D
LANL	OK	CORRECTIVE ACTIONS REQUIRED	? AUDIT REQUIRED
REECO	NO TECHNICAL TEAM	ACCEPTABLE FOR CONTINUED IMPLEMENTATION	? AUDIT OR SURVEILLANCE REQ'D
YMPO	N/A	N/A	?
OCRWM	N/A	N/A	?

ENCLOSURE

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OVERVIEW OF OCRWM HQ

AND

YMP INTERNAL REVIEWS

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ATTACHMENT 7

HQ PROGRAM REVIEW
FEBRUARY 5-16, 1990

STATUS OF REVIEW

CRITERION 2 & 17	INDETERMINATE
CRITERION 3, 4, 7	SIGNIFICANT DEFICIENCIES AND PROGRAM EFFECTIVENESS
CRITERION 1, 5, 6, 16, 18	SOME DEFICIENCIES
CRITERION 8 THRU 15	DELEGATED TO PROJECT OFFICES ANDOTHER PROGRAM PARTICIPANTS

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SUMMARY CONCLUSION

SIGNIFICANT IMPROVEMENTS IN COMPLIANCE AND IMPLEMENTATION ARE NECESSARY BEFORE THE QA PROGRAM CAN BE PRESENTED TO THE NRC AS A QUALIFIED AND ACCEPTABLE FOR THE OCRWM/HQ SUPPORT OF THE START OF NEW SITE CHARACTERIZATION ACTIVITIES.

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HQ ACTIONS

A HQ TASK FORCE WAS FORMED TO IDENTIFY AND CATEGORIZE ACTIONS NEEDED TO BRING THE HQ PROGRAM REVIEW DR'S AND CAR'S TO CLOSURE. THIS IS AN ONGOING ACTIVITY AND THE DR'S AND CAR'S WILL BE PROCESSED IN ACCORDANCE WITH THE ESTABLISHED PROCEDURES. EXPECTED COMPLETION DATES AS THEY CURRENTLY APPEAR ON THE DR'S AND CAR'S THAT REMAIN OPEN ARE SUBJECT TO CHANGE AS A RESULT OF THE HQ QUALIFICATION AUDIT POSTPONEMENT AND THE REORGANIZATION OF OCRWM.

FULL TEXT ASCII SCAN

YMP PROGRAM REVIEW
APRIL 16-20, 1990

STATUS OF REVIEW

CRITERION 1, 5, 15, 18	ACCEPTABLE
CRITERION 2, 6, 16, 17	INDETERMINATE
CRITERIA 3	INDETERMINATE (SEE HANDOUT)
CRITERION 4, 7, 8, 12, 13	TO BE INCLUDED IN THE SECOND PART OF REVIEW
CRITERION 9, 10, 11, 14	CONSIDERED NOT APPLICABLE TO SCOPE OF WORK AT THIS TIME

FULL TEXT ASCII SCAN

SUMMARY CONCLUSION

ADDITIONAL ACTIONS ARE REQUIRED BY THE PROJECT OFFICE TO ENSURE THAT SUFFICIENT CONTROLS ARE IN-PLACE FOR THE OVERALL CONTROL OF ITS QUALITY RELATED ACTIVITIES.

FULL TEXT ASCII SCAN

YMP PROGRAM REVIEW
JUNE 11-15, 1990

STATUS OF REVIEW

CRITERION 4, 7, 12	INDETERMINATE
CRITERION 8, 13	ACCEPTABLE

FULL TEXT ASCII SCAN

Criterion III - Scientific Investigation and Design Control

a. The aspects of Criterion III discussed below were reviewed and found to be acceptable.

The study plan reviews appeared to be in compliance with procedural requirements. However, there was one SDR written on the prequalification of reviewers that did not impact on the quality of the review.

The acceptance of design control documents by the Project Office appears to be in compliance with the procedural requirements. However, based upon the recommendations provided, the procedures governing the activities appear to need review for adequacy/consistency with recent changes that have occurred on the Project.

The implementation of the Change Control Process was found to be in compliance with procedural requirements.

The technical assessment review for the Waste Package Design Requirements Document (in progress) was reviewed and found to be in compliance with procedural requirements.

Work performed on Quality Assurance Level Assignments by Technical and Management Support Services (T&MSS) was in compliance with procedures and had been reviewed and approved by the Project Office.

b. The aspects of Criterion III discussed below were reviewed and found to be unacceptable.

The Air Quality Monitoring Program is operating under six open SDRs. The quality of the data being obtained is indeterminate because the weight standards being used for calibrating the one available balance are not traceable to the National Institute of Standards and Technology. This area must be considered unacceptable.

The Meteorological Monitoring Program is operating. The data being acquired has indeterminate quality since it has been processed with unqualified software at Science Applications International Corporation in San Diego. There are at least three open SDRs in the field at this time. The quality of this program is judged to be ineffective.

The Radiological Monitoring Program by T&MSS has been stopped by internal directive. Until new quality procedures are approved and implemented, this area must be considered unacceptable.

Software development and application by T&MSS has been stopped by internal directive. Until an approved Software Quality Assurance Program becomes effective, this area must be considered unacceptable.

FULL TEXT ASCII SCAN

RESOLUTION OF QARD/QAPD COMMENTS

ON JUNE 6, 1990 NINE COMMENTS WERE RECEIVED FROM THE USNRC.

DRAFT RESPONSES TO ALL NINE COMMENTS ARE CONTAINED IN THE MEETING HAND-OUT.

BASED ON OCRWM'S EVALUATION OF USNRC COMMENTS, 3 CHANGES TO THE QARD AND QAPD ARE REQUIRED.

ATTACHMENT 8
FULL TEXT ASCII SCAN

RESOLUTION OF QARD/QAPD COMMENTS

PROPOSED CHANGES BASED ON USNRC COMMENTS

1. THE RESPONSIBILITIES OF PRIME CONTRACTORS, DELETED FROM REVISION 1 OF THE QAPD, ARE INCLUDED IN REVISION 2

2. THE TERM ADVANCE CONCEPTUAL DESIGN, ADOPTED IN REVISION 3 OF THE QARD AND REVISION 2 QAPD, IS REVISED TO CONCEPTUAL DESIGN

3. SECTION 16 OF THE QARD AND QAPD ARE REVISED TO STATE THAT A PERIODIC ANALYSIS OF NONCONFORMANCES IS PERFORMED BY THE QUALITY ASSURANCE ORGANIZATION TO HELP IDENTIFY ROOT CAUSES

FULL TEXT ASCII SCAN

RESOLUTION OF QARD/QAPD COMMENTS

OTHER PRINCIPAL CHANGES

1. THE TERM AFFECTED ORGANIZATION IS USED AND REPLACES PROGRAM PARTICIPANT

2. REFERENCE TO THE RMPR IS DELETED

3. REFERENCE TO THE QCMS IS DELETED

4. THE REQUIREMENT FOR ANNUAL PROFICIENCY EVALUATIONS IS APPLIED TO INSPECTION AND TEST PERSONNEL ONLY

FULL TEXT ASCII SCAN

RESOLUTION OF QARD/QAPD COMMENTS

5. NQA-1-1989, APPENDIX 2A-3 "NONMANDATORY GUIDANCE ON THE EDUCATION AND EXPERIENCE OF LEAD AUDITORS" IS ADOPTED

6. STATEMENTS THAT THE QARD AND QAPD SUPERSEDED NNWSI/88-9 AND YMPO/88-1 ARE INCLUDED

7. SECTION 1 OF THE QAPD, AND THE APPENDICES, ARE REVISED TO ADDRESS THE PROPOSED OCRWM ORGANIZATION

FULL TEXT ASCII SCAN

RESOLUTION OF QARD/QAPD COMMENTS

SCHEDULE FOR SUBMITTAL

- INCORPORATE CHANGES
- COMPLETE INTERNAL REVIEW
- SUBMIT TO NRC - AUGUST 1990

THE IMPACT OF THESE CHANGES ON THE AFFECTED ORGANIZATIONS IS EXPECTED TO BE MINIMAL

FULL TEXT ASCII SCAN

LOS ALAMOS NATIONAL LABORATORY

90 NOT ALL ELEMENTS AUDITED DURING 1989 - INCLUDES INTERNAL AND EXTERNAL APPLICATION

89 AUDIT PLANS DO NOT IDENTIFY ORGANIZATIONS TO BE NOTIFIED AND APPLICABLE DOCUMENTS TO BE USED DURING THE AUDIT

89 AUDIT REPORT LANL-YMP-89-02 CONTAINS NUMEROUS DEFICIENCIES

88 LOS ALAMOS INTERNAL AUDITS DO NOT INDICATE ELEMENTS OF THE QAPP HAVE BEEN AUDITED

FULL TEXT ASCII SCAN

U.S. GEOLOGICAL SURVEY

90 NCRs NOT PROCESSED IN ACCORDANCE WITH PROCEDURAL REQUIREMENTS

89 NCRs NOT INITIATED IN TIMELY FASHION FOR INSTRUMENT BEYOND CALIBRATION DUE DATE

90 INCONSISTENCIES IN STUDY PLANS, I.E., OUTDATED PROCEDURES, QA LEVEL

89 LACK OF EVIDENCE THAT TECHNICAL REVIEWER COMMENTS ACKNOWLEDGED OR RESOLVED AS RESULT OF TECHNICAL REVIEW

88 COMMENTS GENERATED FOR TECHNICAL REVIEW NOT AVAILABLE IN QA RECORDS FILE

88 TECHNICAL REVIEWERS NOT CERTIFIED

88 SIPs DID NOT INCLUDE TECHNICAL PROCEDURES

90 CRITERIA LETTERS TO HAVE QA REVIEW - NOT PERFORMED

88 NO CRITERIA LETTER FOR CALILBRATION SERVICES BY REECo AT NTS

90 RECORDS PACKAGES DID NOT MEET ALL REQUIREMENTS

90 INTERIM RECORDS PACKAGES TO LRC IN 45 DAY INTERVAL

89 DEFICIENCIES ASSOCIATED WITH CALIBRATION QA RECORD FORMS

89 RECORDS NOT PROCESSED TO PRC AS REQUIRED

90 AUDIT PROGRAM NOT CONSISTENTLY IMPLEMENTED

88 NOT ALL CONTRACTORS AUDITED DURING FY87 AND FY88

FULL TEXT ASCII SCAN

LAWRENCE LIVERMORE NATIONAL LABORATORY

90 PURCHASE ORDERS WERE NOT THE SAME AS PURCHASE REQUISITIONS

88 QA REVIEW OF PURCHASE AWARD DOCUMENTS NOT PERFORMED

88 NO DOCUMENTATION OF BID EVALUATION

90 LLNL PROCEDURES DID NOT REQUIRE FOLLOW-UP OBSERVATIONS

88 CORRECTIVE ACTION SYSTEM INEFFECTIVE

FULL TEXT ASCII SCAN

TREND

(SHORT-TERM)

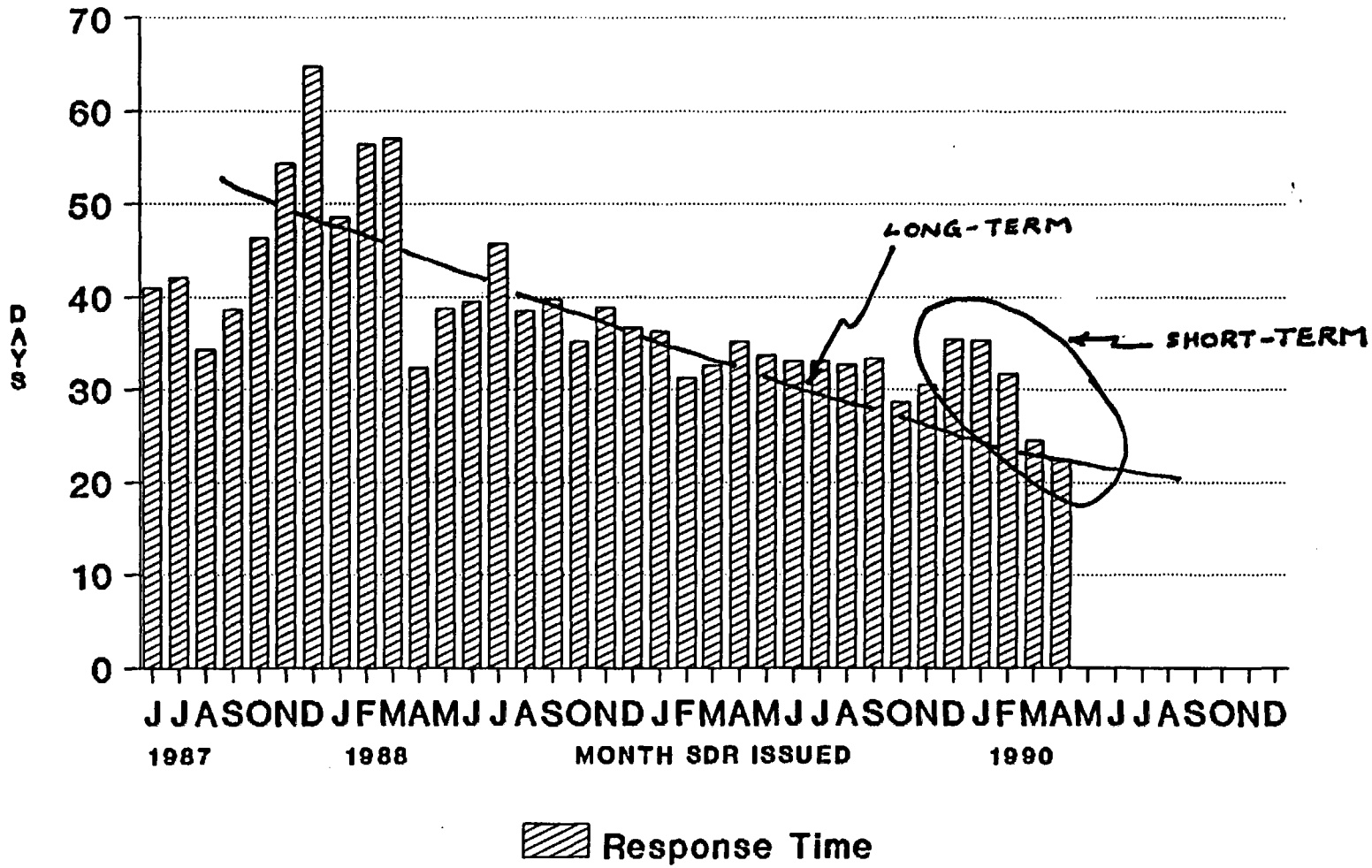
TWO OR MORE CHANGES, IN THE SAME DIRECTION, OF SEQUENTIAL VALUES OF A PARAMETER

(LONG-TERM)

CURRENT NON-ZERO SLOPE OF A CURVE FITTED TO A PLOT OF SEQUENTIAL VALUES OF A PARAMETER

FULL TEXT ASCII SCAN

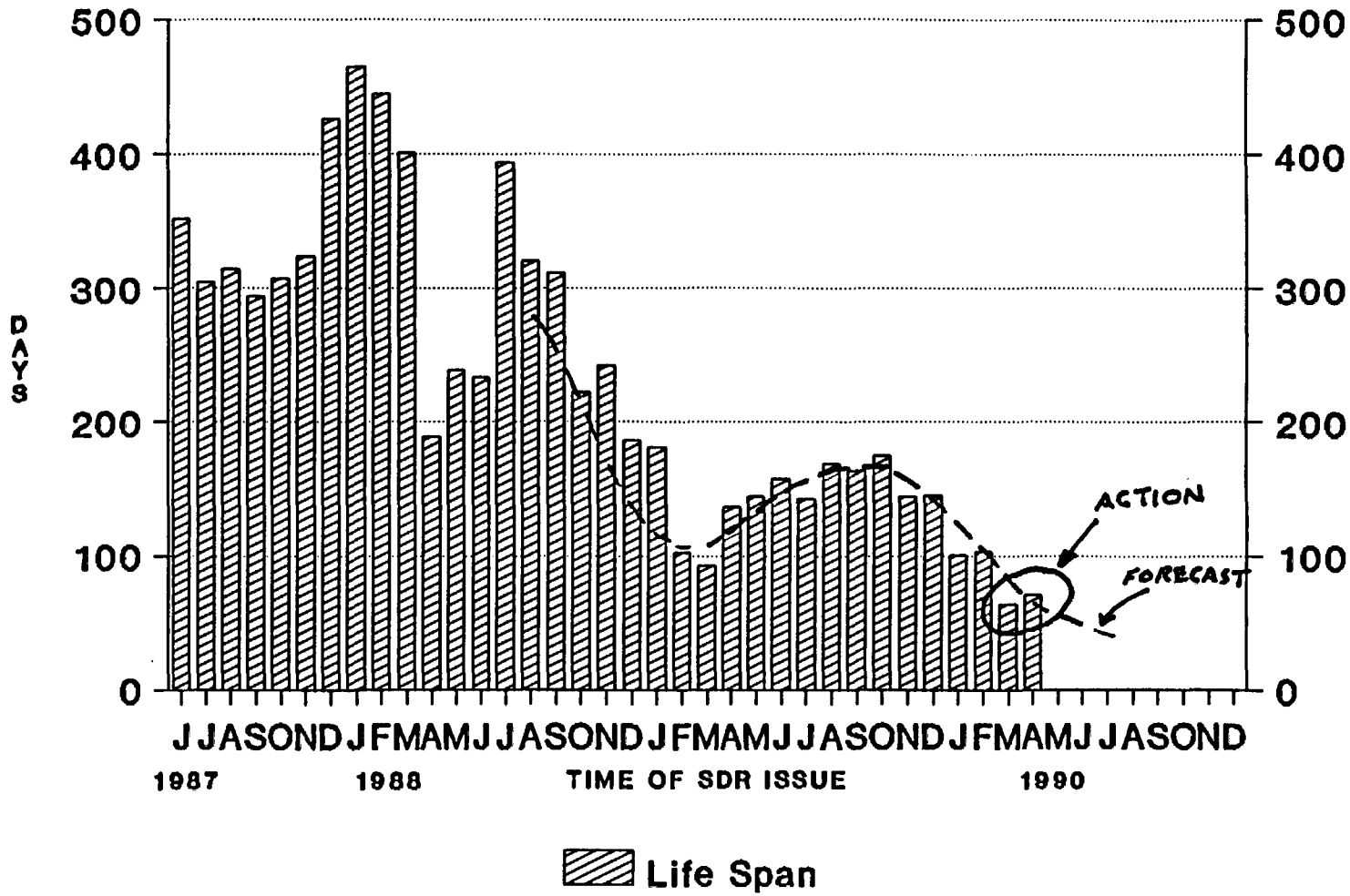
SDR RESPONSE TIME



3-MONTH RUNNING AVERAGE

FULL TEXT ASCII SCAN

AVERAGE LIFE OF CLOSED SDRs



3-MONTH RUNNING AVERAGE

FULL TEXT ASCII SCAN

EVIDENCE BIT

A SINGLE OBJECTIVE INDICATOR OF CONFORMANCE OR NONCONFORMANCE TO A DISCRETE, EXPLICIT REQUIREMENT

FULL TEXT ASCII SCAN

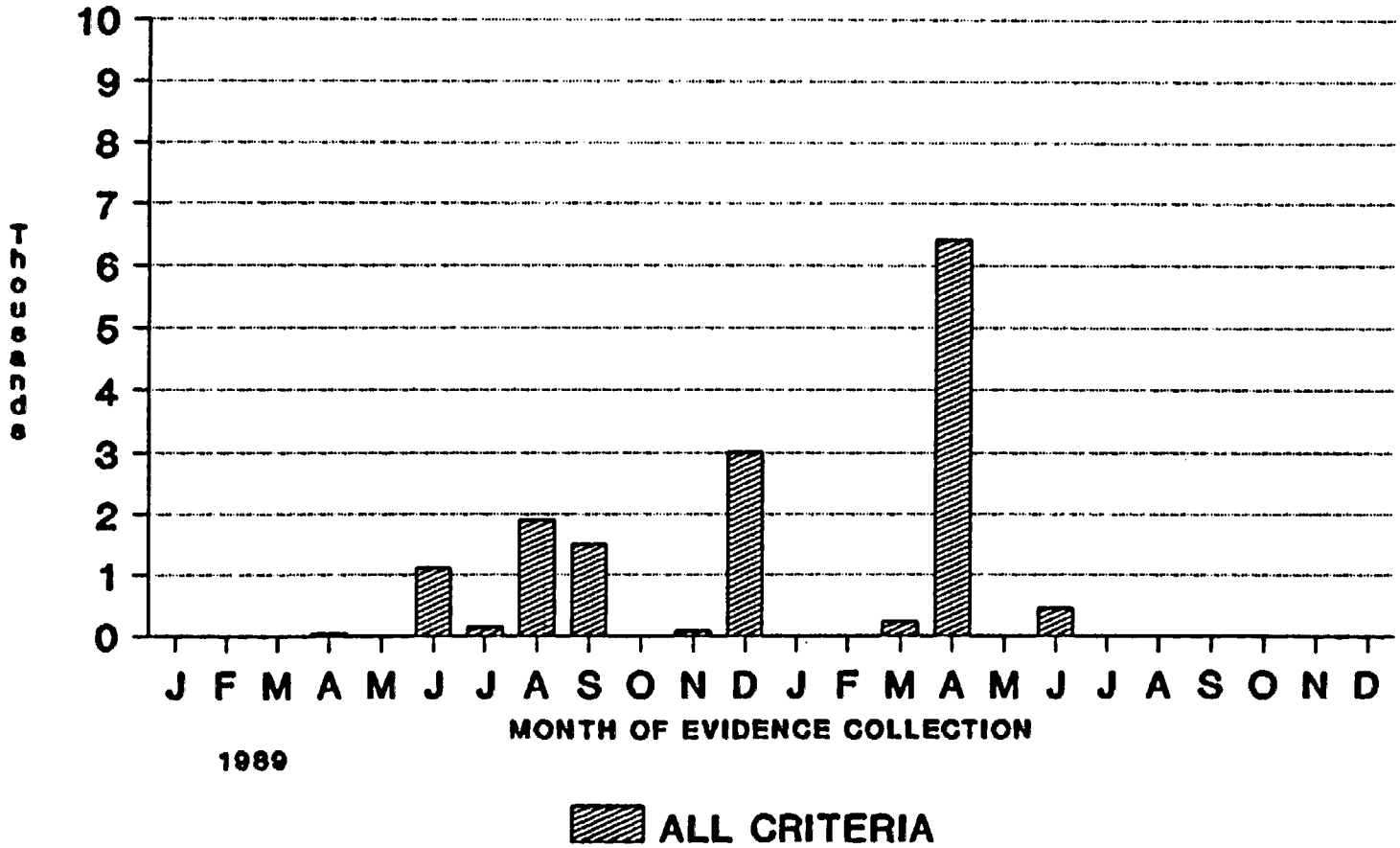
EVIDENCE BASE

THE SET OF EVIDENCE BITS EXAMINED

DURING AN EVALUATION OR VERIFICATION

FULL TEXT ASCII SCAN

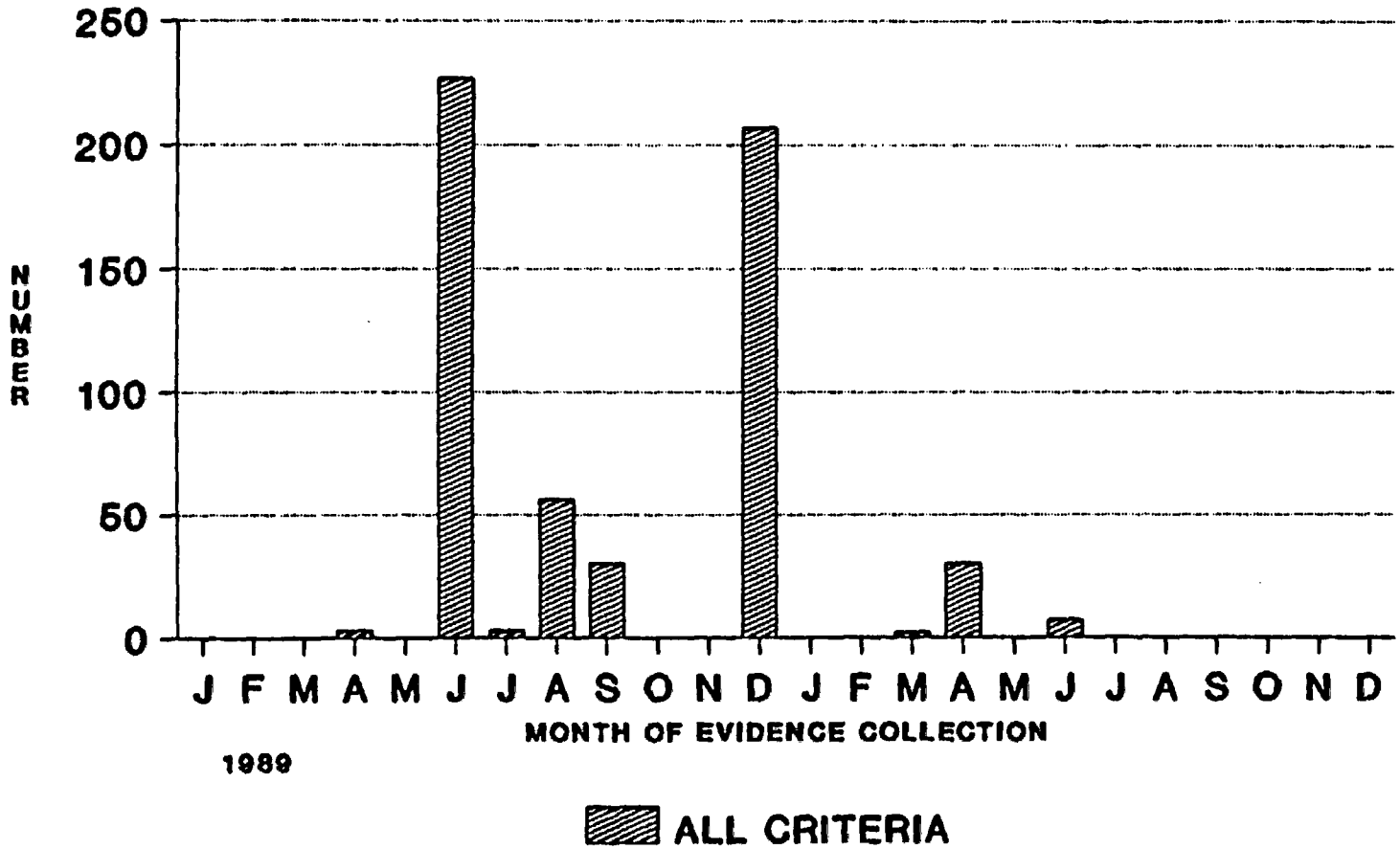
PROJECT OFFICE EVIDENCE BASE



07-17-1990

FULL TEXT ASCII SCAN

PROJECT OFFICE DISCREPANCIES OBSERVED



07-17-1990

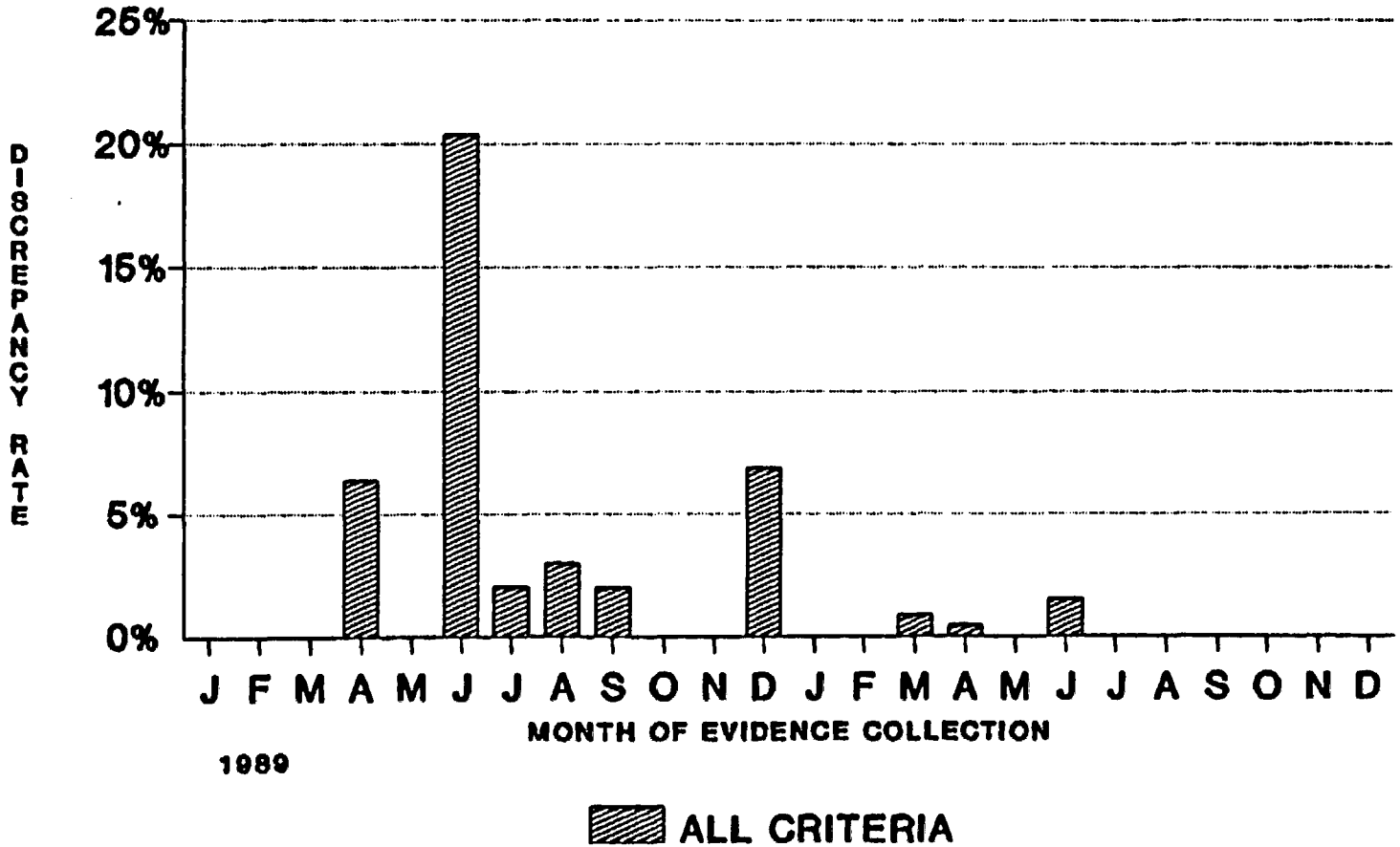
FULL TEXT ASCII SCAN

DISCREPANCY RATE

$$\frac{\text{NUMBER OF DISCREPANCIES}}{\text{NUMBER OF EVIDENCE BITS EXAMINED}}$$

FULL TEXT ASCII SCAN

PROJECT OFFICE DISCREPANCY RATE



07-17-1990

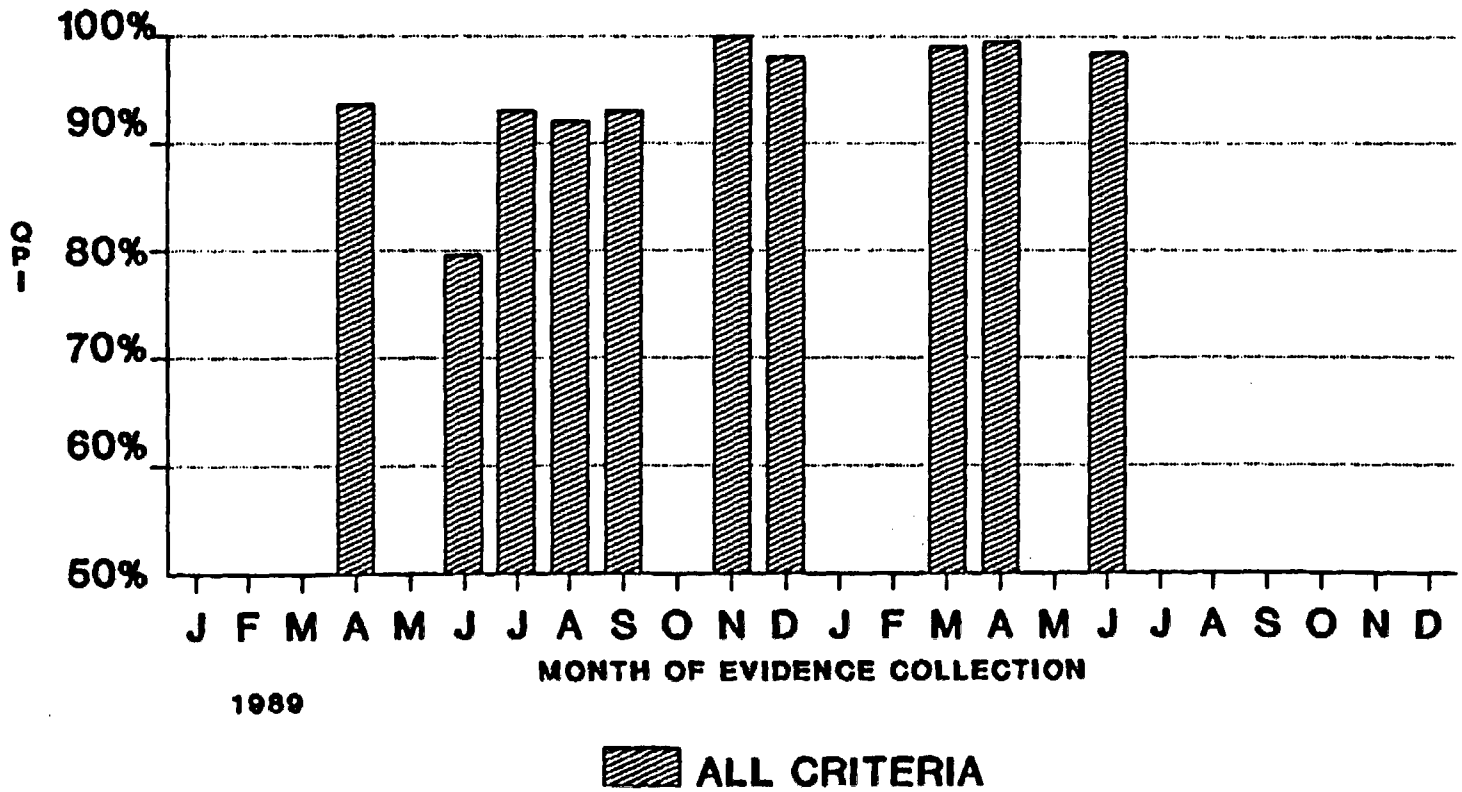
FULL TEXT ASCII SCAN

QUALITY PERFORMANCE INDEX

QPI = 1-(DISCREPANCY RATE)

FULL TEXT ASCII SCAN

PROJECT OFFICE
QUALITY PERFORMANCE INDEX



07-17-1990

FULL TEXT ASCII SCAN

1989 AND 1990 PROJECT OFFICE EVALUATION BASE AND DISCREPANCIES

CRITERIA	1989 VALUES (EB)	1989 VALUES (D)	1990 VALUES (EB)	1990 VALUES (D)
1	80	79	758	0
2	323	9	1392	25
3	845	1	626	0
4	37	1	202	0
5	414	32	54	0
6	2046	40	240	2
7	44	0	47	0
8	281	6	42	0
9	0	0	0	0
10	0	0	0	0
11	0	0	0	0
12	58	0	13	5
13	0	0	10	0
14	0	0	0	0
15	15	0	1686	0
16	2727	112	1262	0
17	336	152	149	4
18	1	0	466	3
19	0	0	0	0
20	24	0	169	0

07-17-1990

FULL TEXT ASCII SCAN

SUBJECT: STATUS OF NRC/DOE OPEN ITEMS-July 19, 1990

ITEM	DESCRIPTION	STATUS	RECOMMENDATION FOR CLOSURE/REMARKS
1-90 (i) QA-F-1 (ii) QA-F-2 (iii) QA-F-3	DOE Waste Glass QA Program	Open	NRC staff has received Rev. 3 of the QARD which addresses the staff's comments on OGR B-14. This is currently being evaluated by the NRC staff. DOE will be developing a draft position on OCRWM/NRC overview/verification activities. Development of a Memorandum of Understanding (MOU) among DOE-RW, NE, and NE is in question as the idea of an MOU has not been settled among the 3 DOE offices. At the 5/23/90 QA meeting, DOE stated that they intended to meet (Duffy/Shelor) to determine if an MOU is required.
2-90 NRC Items 9 & 11	ESF Q-List and QA Measures	Open	DOE should meet with NRC to discuss and resolve concerns related to Q-List for the ESF and ESF conceptual design.
3-90 NRC Item 7	NNWSI Core Handling Procedures	Open	DOE submitted the Core Handling procedures to the NRC staff in a 8/11/89 transmittal (Gertz to Stein). The issues raised in the YMP Surveillance Report (YMP-SR-89-134) will need to be resolved before this item can be closed. NRC will determine acceptability of implementation and adequacy of procedures when they are issued in final form and subsequently implemented.
4-90 QA-A-1 QA-B-1d (1) QA-G-3 QA-G-4 QA-G-5	Qualified QA Program before start of new site characterization activities.	Open	DOE has made a committment to having a qualified QA program before the start of new site characterization activities. However, this item remains open up until the the NRC staff accepts the DOE QA program as qualified for the start of new site characterization activities.

ATTACHMENT 11

FULL TEXT ASCII SCAN

5-90	Definitions for Conceptual, Title I, II, & III Design	Closed	(2/15/90 QA Mtg.)
6-90 NRC Item 13	Access to Project Participant's personnel files.	Open	DOE is working with General Counsel to initiate a mutually acceptable system. At the 5/23/90 QA meeting, DOE indicated the Federal Register Notice was at the DOE Secretary level. This would permit QA directors to maintain separate records on personnel qualifications and allow access to NRC, DOE, NV, and local governments.
7-90 QA-E-1	Qualification of Existing Data	Open	DOE has provided NRC with a procedure for qualifying existing data. This procedure was reviewed by the NRC staff for consistency with NUREG-1298 and comments were given to DOE via a 1/90 telecon. The NRC staff is waiting for a DOE response before formally transmitting comments to DOE.
8-90	SCA comments	Open	DOE should provide a response to the 7/31/89 NRC SCA QA comments on the DOE SCP.
9-90	DOE response (Stein to Youngblood dated 12/28/88) to 7 NRC concerns for DOE Audit 88-01 of PNL	Closed	DOE letter (Appel to Linehan dated 8/10/89) provided responses.
10-90 QA-G-1; a & d	Responses to NRC Observation Audits		DOE should respond within 30 days after NRC Observation Audit Report transmittal. The DOE responses are to be reviewed and considered by NRC staff in accepting DOE QA programs. DOE should respond to the following NRC staff Observation Audit Reports:
10.a	Holmes & Narver S89-1, 11/1-4/89	Closed	DOE letter (Appel to Linehan datec 6/13/89) provided responses.
10.b	Holmes & Narver 89-2, 4/24-28/89	Closed	(2/15/90 QA Mtg.)
10.c	Sandia Ntl. Lab. 89-3, 9/11-15/89	Closed	(2/15/90 QA Mtg.)

FULL TEXT ASCII SCAN