

MINUTES DOC

- 1 -

FEB 14 1989

Mr. Ralph Stein, Associate Director  
 Office of Systems Integration and Regulations  
 Office of Civilian Radioactive Waste Management  
 U. S. Department of Energy RW-24  
 Washington, D. C. 20545

Dear Mr. Stein:

SUBJECT: MINUTES OF JANUARY 25, 1989 QUALITY ASSURANCE MEETING

The purpose of this letter is to transmit to you the minutes from the January 25, 1989 meeting on quality assurance (QA). The minutes were prepared by members of the U. S. Nuclear Regulatory Commission (NRC) staff and representatives from the U. S. Department of Energy (DOE), and include a written statement from the State of Nevada.

The major area of discussion at the meeting was DOE's revised schedule for qualifying the DOE and DOE contractor QA programs. As discussed in the enclosed minutes, the DOE presentation did not cover the QA programs for the West Valley Demonstration Project or the Savannah River Facility. Although the staff agreed to the proposed schedule for the repository programs, it is concerned that DOE is proceeding with a riskier approach to qualifying the QA programs than the approach originally developed by DOE. This is based on the fact that DOE will be qualifying the contractors QA programs before it qualifies the Yucca Mountain Project Office's (the Project) QA program. Because the Project is the organization responsible for integrating the activities of the contractors, the staff believes that it would be best for DOE to qualify the Project's QA program as one of the first to be done. However, as stated earlier, the staff agrees to the DOE schedule, but emphasizes that this is a riskier approach that could cause work to be repeated at a later time.

In addition to the above concern, the staff also expressed some reservations about the fact that DOE would begin Title II, exploratory shaft facility (ESF) design work prior to having the QA programs qualified. Without having qualified programs, the staff is concerned that all of the QA plans and procedures necessary to cover the design activities would not be in place. Based on its experience from the ESF, Title I design work, it is essential that DOE have the necessary controlling documents in place. Although DOE will be conducting a readiness review for the start of ESF, Title II design, the staff plans to expand the scope of its on-site visit covering the ESF, Title I design acceptability analysis to include DOE's readiness to begin ESF, Title II design.

Besides the major points discussed here, there are several other issues of significance in the enclosed minutes. Also, the State of Nevada has provided a written statement that has been incorporated into the minutes. No statement was provided by Nye County, Nevada, which was the only affected unit of local government to attend.

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If you have any questions, please feel free to contact the project manager for this area, Joe Holonich, who can be reached on (301) 492-3403 or FTS 492-3403.

Sincerely,

**ORIGINAL SIGNED BY**

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

Enclosure: As stated

cc: C. Gertz, DOE/NV  
R. Loux, State of Nevada  
S. Bradhurst, Nye County, NV  
D. Bechtel, Clark County, NV  
D. Baughman, Lincoln County, NV  
K. Turner, GAO

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ENCLOSURE

On January 25, 1989, members of the U. S. Nuclear Regulatory Commission (NRC) staff met with representatives from the U. S. Department of Energy (DOE), the State of Nevada, and Nye County, Nevada. The meeting was the first monthly meeting that will be held to discuss issues in the quality assurance (QA) area on an ongoing basis. Attachment 1 is a list of attendees at the meeting. The topics that were discussed included: (1) a revised schedule for qualifying the DOE and DOE contractor QA programs pertaining to new site characterization activities; (2) protocol for observers who participate in DOE verification activities; (3) a summary of the NRC staff observations of the DOE audits the NRC staff has observed during 1988; and (4) items of interest to the State of Nevada and Nye County, Nevada.

The major area of discussion was the revised schedule presented by DOE for conducting the qualification of the DOE and DOE contractor QA programs. A copy of the DOE presentation is given in Attachment 2. Although the DOE presentation covered the QA programs for the repository, it did not include the schedules for the West Valley Demonstration Project or the Savannah River Facility. In its presentation, DOE stated that the schedule was based on supporting the start of exploratory shaft facility (ESF) construction in November 1989. To support this, DOE will provide all of the QA program plans (QAPPs) for the DOE contractors and the Yucca Mountain Project Office (the Project Office) by the end of February 1989. DOE has also scheduled one qualification audit approximately every two weeks from April through August. In addition, DOE stated that the DOE Office of Civilian Radioactive Waste Management (OCRWM), the Project Office, and program participants will conduct a total of approximately 100 surveillances that will be completed prior to starting the qualification audits. By doing these surveillances, DOE will have assurance that the QA programs are in place, and this will allow DOE to begin work on the ESF, Title II design prior to completing the qualification of the QA programs.

Besides discussing the qualification effort for the QA programs, DOE presented its schedule for starting Title II, ESF design work. In summary, DOE would conduct a surveillance of the readiness to start new design work. This surveillance is scheduled for the week of January 29, 1989, and start of Title II, ESF design work was scheduled for early February 1989. The readiness surveillance would check those items that need to be complete in order for Title II, ESF design work to start.

Based on the information presented, the NRC staff raised several points. First, the staff was concerned that the original approach for qualifying the programs was to start with the Yucca Mountain Project's QA program, and then proceed with the prime contractors. Now, DOE had proposed that the qualifications begin with the contractors who are involved in the ESF design, then proceed to those involved with data collection activities, and finally be completed with the Project's and the OCRWM QA program. Because the Project is the organization responsible for integrating all of the activities being performed by the contractors, the staff felt that DOE should qualify the Project's QA program as one of the first to be done. DOE responded that the Project and OCRWM QA programs were being qualified last because it was focusing its efforts on those organizations involved in the ESF, Title II design work. Basically, DOE wanted

to have the QA programs in place for those organizations before new design work began and is currently focusing its efforts to complete the development of procedures necessary to implement all of the Project's or OCRWM's QA program. Because of this, neither of these organizations would be ready to be audited until the procedures were in place.

The staff believed that not qualifying the Project's program before that of the contractors could result in problems with the ESF, Title II design. This concern was based on the staff's experience with the ESF, Title I design and the results of surveillances conducted on the ESF, Title I design acceptability analysis. DOE noted that there would be surveillances and qualifying audits of the contractors' programs that would allow it to identify any problems with ESF, Title II design that may have resulted from a problem with QA at the Project level. Although the staff felt that the Project's QA program should be qualified earlier, it agreed to the schedule noting that DOE was proceeding with a riskier approach that could cause work to be repeated at a later time.

Another area where the staff raised a concern with the proposed schedule was the lack of time for the NRC to review the DOE contractor's QAPPs before the performance of the qualification audits. DOE noted that in preparing the schedule, it had taken into account that the NRC had copies of all of the contractors programs prepared to Revision 1 of the "Nevada Nuclear Waste Storage Investigation Quality Assurance Plan," (NNWSI/88-9). Although the QAPPs that would be submitted in February 1989 were prepared to NNWSI/88-9, Revision 2, DOE stated that the NRC had accepted NNWSI/88-9, Revision 2, and the changes to update the QAPPs were not major. Therefore, DOE hoped that this would allow the staff to expedite its review of the QAPPs. The staff did not agree to the DOE assumption. However, it did state that it would start its review of the individual QAPPs, and if no major deficiencies were identified in the review, the qualification audit for that particular contractor could be performed even though there were some minor open items with the QAPP.

A third schedule issue that was discussed was when the staff would issue its acceptance of the individual QA programs. During the meeting, it was agreed that once the qualification audits were complete DOE would issue a letter to the NRC staff stating that it had accepted the program. Coincidentally, the staff would issue its observation audit report evaluating the acceptability of the DOE audit. Both of these would be issued within thirty days of completion of the audit. Following the DOE letter, the staff would determine if it had accepted the program and inform DOE seven days after receipt of the DOE letter. Both DOE and the staff agreed that final NRC acceptance was contingent upon receipt of the DOE letter; therefore, any delay in the letter would result in the delay of staff acceptance.

Finally, the staff expressed its concern that the start of ESF, Title II design work would begin prior to qualification of the QA programs. Without having qualified programs, the staff was concerned that all of the QA plans and procedures necessary to cover the design activities would not be in place. Based on its experience from the ESF, Title I design work, the staff concluded that it was essential for DOE to have the necessary controlling documents in place. However, prior to the start of ESF, Title II design, the staff will be

conducting an on-site review of the ESF, Title I design acceptability analysis. As part of this review, the staff would expand its effort to cover the readiness of DOE to begin ESF, Title II design. However, the early February scheduled initiation of ESF, Title II design will not await the NRC on-site review. The inclusion of readiness of DOE to begin ESF, Title II design would result in a substantial increase in the staff's evaluation effort during the on-site review. In addition, DOE agreed that the staff could participate in any of the approximately 100 surveillances, and this would give the staff a number of opportunities to see how the Project is proceeding with design activities prior to qualification.

During the presentation, the State of Nevada participated in the discussion, and based on the information presented, was concerned that DOE had developed an optimistic schedule. The State also noted that it wanted to echo Chairman Zech who at a recent Commission briefing on the high-level waste repository stated that the staff should take the time necessary to do the job right. During the meeting, Mr. Hugh Thompson, Director, Office of Nuclear Material Safety and Safeguards, NRC, and Mr. Franklin Peters, Deputy Director, OCRWM were briefed on the results of the schedule discussions.

After the discussion of the revised schedule had been completed, the meeting covered the protocol of observers on DOE verification activities. In particular, DOE stated that the observers on the recent surveillances did not result in a problem. The State of Nevada asked if it could include a second observer on the larger surveillance teams, and DOE felt that two observers from the State would not be a problem.

Besides discussing the observation activities for surveillances, the staff also raised two points concerning its participation as observers in audits. The two points dealt with when it would be appropriate for observers to ask questions, and the timeliness of the audit team responses. In response to the first point, it was generally agreed that the observers need to raise problems as early as possible consistent with the staff's need to independently evaluate the effectiveness of the DOE audit. For example, observers should review the checklists prior to the audit and identify any questions it may have during the initial team meeting. Questions could also be asked at the end of the day when the audit team holds its daily caucus. The staff, DOE, and the State of Nevada agreed that although questions can be asked at any time, the questioner would use the observer inquiry form to document the question.

With respect to the second issue, DOE stated that if questions were asked pertaining directly to the activities that were being conducted, the DOE auditor should respond to the question within a reasonable time frame, most likely immediately but not longer than a day. If, however, the question asked did not deal directly with the area being audited it may take more time to obtain a response. The staff noted that its concern deals with the latter type of question and the fact that the auditor or audited organization sometimes do not respond until the entire audit is complete. DOE said that the audit teams will try to be more responsive to observer questions as long as the questions dealt with the area being audited.

In the next agenda item the staff presented a summary of its observations from the DOE QA audits conducted during 1988. A copy of the presentation is contained in Attachment 3. In its presentation, the staff: (1) provided guidance to DOE on what it expected DOE to do and accomplish on its audits; (2) discussed its observations from audits, and their significance to the DOE qualification audits; and (3) discussed those recurring problems that DOE has identified for all or a majority of the contractor programs. For the first two items, DOE stated that the feedback was helpful and that it would help future audit teams be better prepared. With respect to the third, the staff noted that it had identified seven areas where DOE audit teams had issued standard deficiency reports to more than one contractor. The staff noted that this could indicate that there may be an implementation problem resulting from the Project level or higher, and asked DOE to review these areas to determine if this were the case. Finally, the staff identified the future actions that should be taken to prepare for the qualification audits.

The final area covered during the meeting was a discussion of any issues that the State of Nevada or affected units of local governments wanted to raise. The only issue discussed was the schedule for submission of the State of Nevada responses to the staff questions on the Nevada QA program plan. Responses to the questions would be submitted by the State on February 6, 1989, and a meeting to discuss the responses would be held on February 22, 1989. Because it wanted to send an observer to the February 22, 1989 meeting, DOE requested that the staff provide it with a copy of the questions. A similar request was made by the Edison Electric Institute (EEI). The staff provided copies to DOE and EEI.

Based on the information presented, several items were identified for the next meeting scheduled for February 23, 1989. The proposed agenda items include:

- (1) a schedule from DOE on the surveillances planned before the qualification audits;
- (2) a discussion of what the staff meant in its January 10, 1989 letter on the potential that DOE was applying QA too strictly;
- (3) a presentation by the staff on its revised observation audit procedure;
- (4) a determination of the timing for and how the staff will provide feedback on the scope of future DOE audits; and
- (5) items of interest to the State of Nevada or affected units of local governments.

Statement by the State of Nevada

Following the meeting, the State of Nevada provided the following written statement for incorporation into the minutes.

"The State encourages the NRC staff to perform fully adequate reviews of the DOE contractor QA programs regardless of the pressure from DOE to fit the reviews into an overly optimistic DOE schedule. Given the results of last year's audits, DOE's schedule for the qualification audits is not a realistic one. NRC should do its best to ensure that each DOE contractor

is indeed ready to begin site characterization activities that are covered by a qualified QA program. Anything less would be unacceptable to the State and the public at large. The State also urges the NRC to be fully aware of what DOE activities will entail site preparation and the drilling of the multi-purpose borehole; which of these activities are quality-affecting; and the status of the QA programs that will cover these activities. Some of these activities could easily affect the safety and waste isolation of the site; therefore, quality assurance should be rigorously applied."

*Linda Desell 2/9/85*

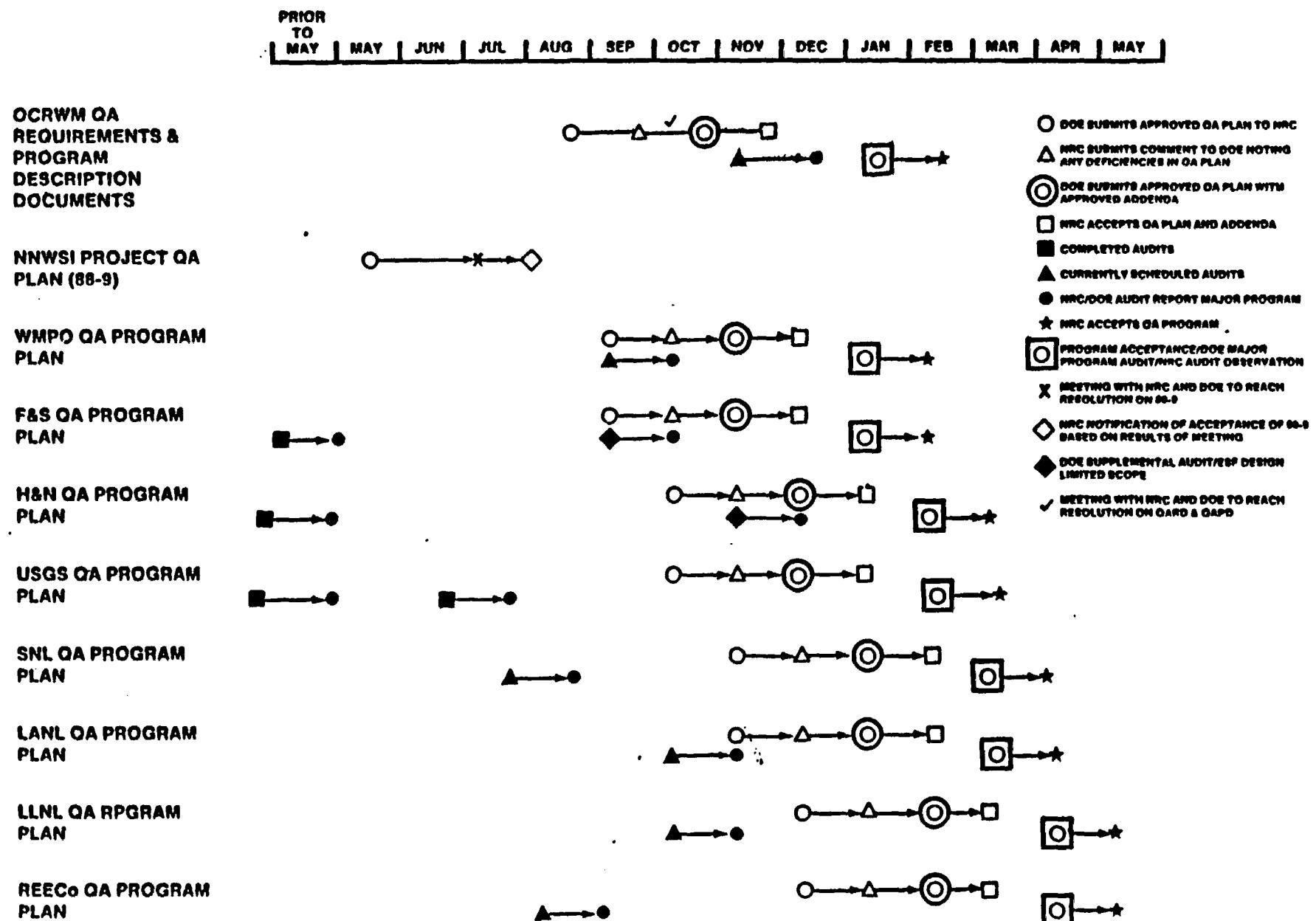
Linda Desell  
Office of Civilian Radioactive  
Waste Management  
U. S. Department of Energy

*Joseph J. Holonich*

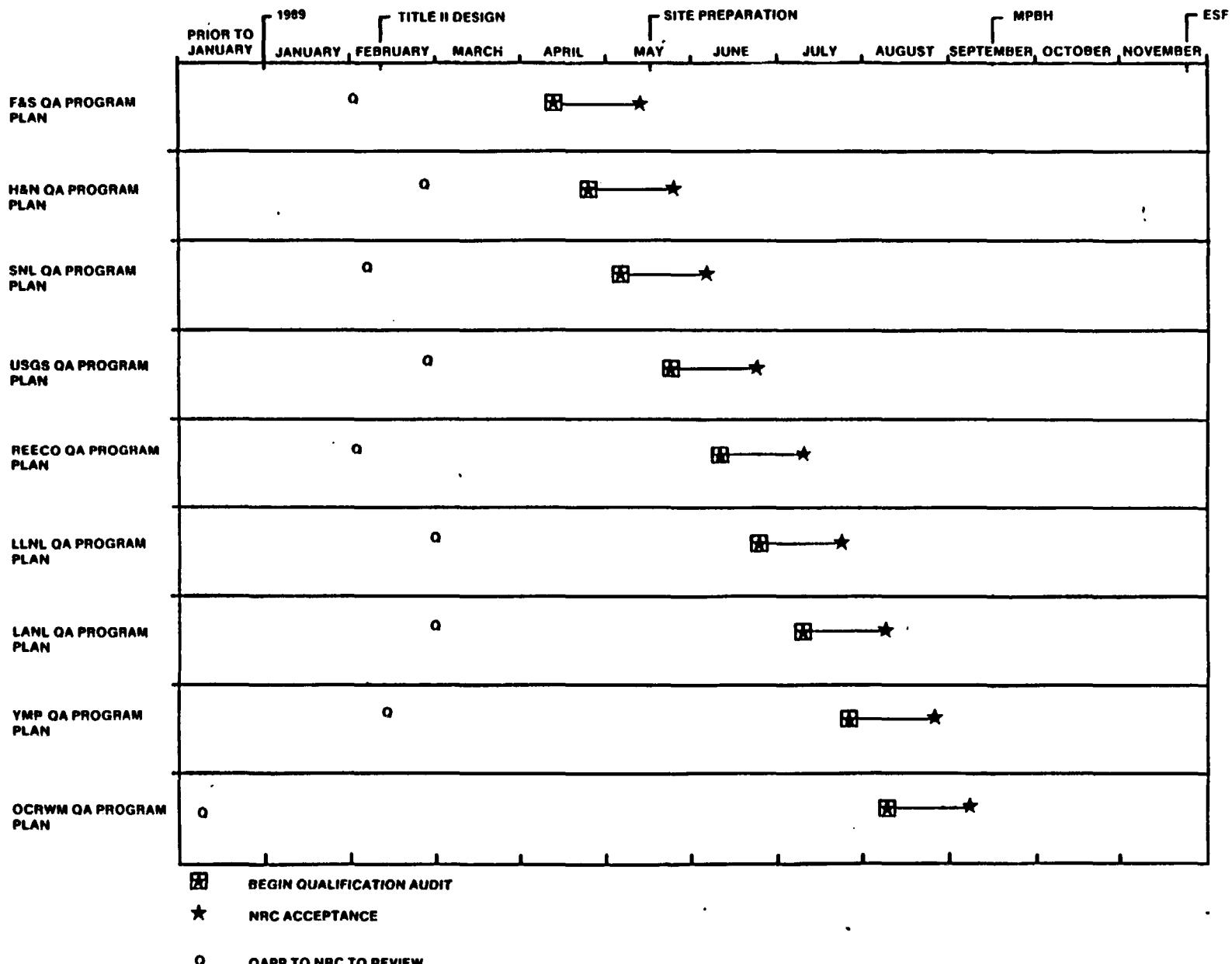
Joseph J. Holonich, Sr. PM  
Office of Nuclear Material  
Safety and Safeguards  
U. S. Nuclear Regulatory  
Commission

**ATTACHMENT 2**  
**DOE Presentation on the**  
**Revised Schedule for Qualifying QA Programs**

## SCHEDULE FOR NRC ACCEPTANCE OF DOE QA PROGRAM



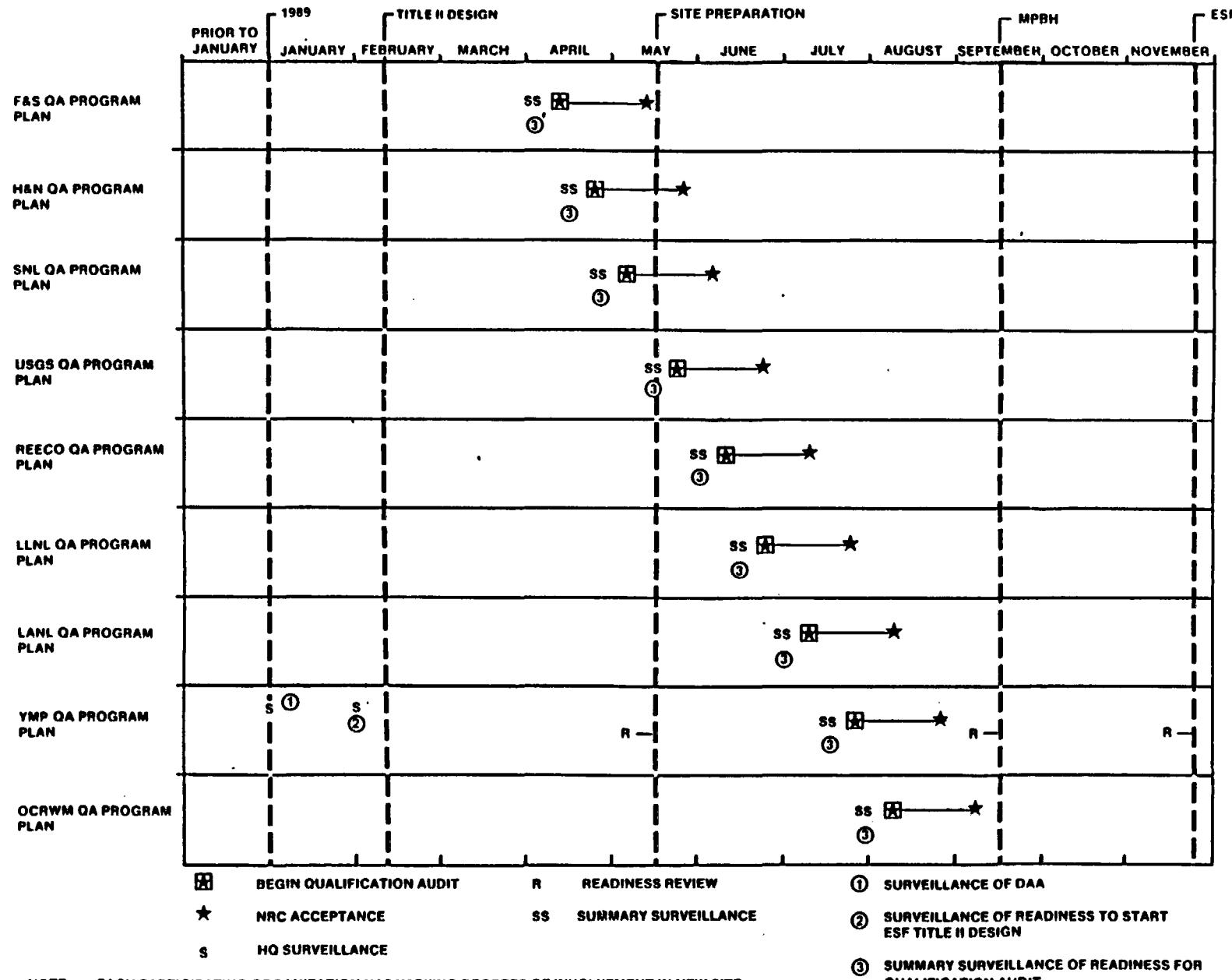
# REVISED DOE QA PROGRAM QUALIFICATION AUDIT SCHEDULE FOR NEW SITE CHARACTERIZATION ACTIVITIES



NOTE: EACH PARTICIPATING ORGANIZATION HAS VARYING DEGREES OF INVOLVEMENT IN NEW SITE CHARACTERIZATION ACTIVITIES. THE DEGREE OF QA IMPLEMENTATION, AND HENCE THE QUALIFICATION AUDIT WILL BE COMMENSURATE WITH THEIR DEGREE OF INVOLVEMENT IN NEW SITE CHARACTERIZATION ACTIVITIES.

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# DRAFT PRELIMINARY DOE QA PROGRAM VERIFICATION SCHEDULE FOR NEW SITE CHARACTERIZATION ACTIVITIES



NOTE: EACH PARTICIPATING ORGANIZATION HAS VARYING DEGREES OF INVOLVEMENT IN NEW SITE CHARACTERIZATION ACTIVITIES. THE DEGREE OF QA IMPLEMENTATION, AND HENCE THE QUALIFICATION AUDIT WILL BE COMMENSURATE WITH THEIR DEGREE OF INVOLVEMENT IN NEW SITE CHARACTERIZATION ACTIVITIES.

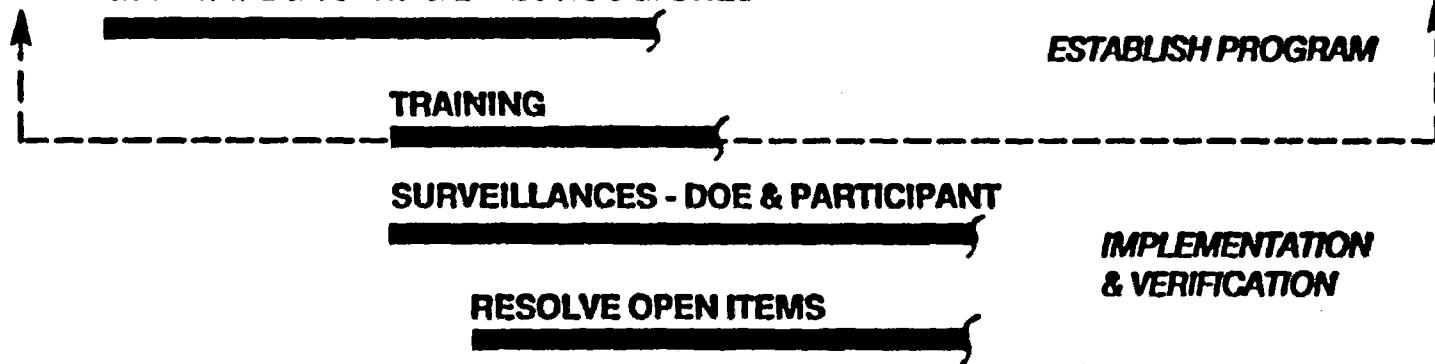
# GENERIC CRITICAL PATH

QAPP - QUALITY ASSURANCE PROGRAM PLANS  
[REDACTED]

APQ - QUALITY AFFECTING ADMINISTRATIVE PROCEDURES  
[REDACTED]

QAAP - QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES  
[REDACTED]

IMP - IMPLEMENTING LINE PROCEDURES  
[REDACTED]



MANAGEMENT REVIEW - PARTICIPANT  
[REDACTED]

DOE MANAGEMENT REVIEW  
[REDACTED]

YMPO/NRC AUDIT  
[REDACTED]



# **QA PROGRAM QUALIFICATION DOE MANAGEMENT REVIEW**

## **DEFINITION**

- A REVIEW OF THE RESULTS OF THE PARTICIPANT  
MANAGEMENT REVIEWS AND THE DOE SURVEILLANCES**

## **PURPOSE**

- TO ENSURE THAT THE PARTICIPANTS ARE READY FOR THE  
YMP/NRC AUDIT**

**ATTACHMENT 3**

**NRC Presentation on Summary of Observation**

**Audit Results**

**SUMMARY OF NRC STAFF OBSERVATIONS OF DOE AUDITS**

J. KENNEDY  
JANUARY 25, 1989

**PURPOSE**

- o **DEFINE OUR EXPECTATIONS**
- o **GIVE FEEDBACK ON PAST AUDITS FOR UPCOMING GOLD STAR AUDITS**
- o **GIVE FEEDBACK ON CONTRACTOR QA PROGRAMS**

#### **STAFF EXPECTATIONS**

- **QUALITY LEVEL CLASSIFICATIONS FOR SPECIFIC CONTRACTOR ACTIVITIES**
- **SUFFICIENT SCOPE TO MAKE FINDING ON OVERALL PROGRAM--VIZ. 18 CRITERIA PLUS SELECTED TECHNICAL PRODUCTS**
- **COMPLETENESS AND ADEQUACY OF PROCEDURES FOR ITS AND ITWI WORK**
- **COMPLIANCE WITH PROCEDURES**
- **EFFECTIVENESS OF PROGRAM IN PRODUCING ACCEPTABLE END PRODUCTS SUCH AS DESIGNS, DATA, TECHNICAL REPORTS, BY INCLUDING TECHNICAL SPECIALISTS ON TEAM**

AUDITS OBSERVED IN 1988

PACIFIC NORTHWEST LABS--FEBRUARY 22-26

FENIX AND SCISSION--FEBRUARY 22-MARCH 2

HOLMES AND NARVER--MARCH 28-APRIL 1

USGS/MENLO PARK--APRIL 27-29

USGS/DENVER--JUNE 8-24

SANDIA LABS--JULY 25-29

REECO--AUGUST 23-29

LOS ALAMOS--OCTOBER 3-7

LIVERMORE--OCTOBER 24-26

HOLMES AND NARVER--NOVEMBER 1-4

FENIX AND SCISSION--NOVEMBER 7-14

#### **SUMMARY OF STAFF OBSERVATIONS**

- AUDITS HAVE OFTEN FOCUSED ON PROCEDURAL COMPLIANCE
- TECHNICAL PORTIONS OF AUDITS HAVE VARIED IN EFFECTIVENESS
  - QA LEVEL ASSIGNMENTS
  - AUDITOR QUALIFICATIONS
- STATEMENT ON OVERALL EFFECTIVENESS LACKING IN SOME AUDITS
- AUDITS HAVE BEEN IMPROVING, HOWEVER.

## **CONTRACTOR PROBLEMS IDENTIFIED BY DOE IN ITS SDRS**

- QA TRAINING AND INDOCTRINATION**
- PROJECT WIDE INTERFACE CONTROLS**
- QA LEVEL ASSIGNMENTS AND VERIFICATION**
- CORRECTIVE ACTIONS**
- SOFTWARE QA CONTROLS**
- DATA CONTROLS**
- INSUFFICIENT IMPLEMENTING PROCEDURES**

#### **FUTURE ACTIONS RELATED TO GOLD STAR AUDITS**

- o REVISED PROCEDURE FOR STAFF OBSERVATIONS OF AUDITS DUE TO BE COMPLETED MARCH 1, 1989
- o QMP 18-01 AND 18-03 REVISIONS
- o CONSULTATION WITH STAFF ON SCOPE BEFORE GOLD STAR AUDITS
- o DOE RESPONSES TO AUDIT OBSERVATION REPORTS
- o INCREASED USE OF SURVEILLANCES BEFORE GOLD STAR AUDITS