Department of Energy
Washington, DC 20585

SEP 24 1990,

Mr. John Linehan, Director
Repository Licensing & Quality
Assurance Project Directorate
Division of High-Level
Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Linehan:

On August 7, 1990, the first phase of the DOE QA Workshop was held at the Sheraton Hotel, in Lakewood, Colorado. The purpose of the workshop was to provide an opportunity for personnel from each project participant to discuss their concerns associated with implementation of the OCRWM Quality Assurance (QA) Program. A copy of the minutes is provided in the enclosure.

In summary, there were four main areas of concern that resulted from this workshop:

1. Lack of flexibility in the application of the QA Program during scientific research, required restrictive predictions without consideration for unknowns, and the need for an increased acceptability of peer review, the application of dual research, further definition of requirements, and procedures commensurate with acceptable (good) scientific practices.

2. The computer software QA Program is too complex, does not allow freedom to develop conceptual/prototype design/analysis, is based upon obsolete model concepts, is not updated to the present state-of-the-art, requires excessive documentation during development, lacks flexibility, requires a lengthy process for making changes and, in general, needs an in-depth review.

3. With respect to data requirements, the need for a definition of the term data and an indication of what form the data should take, a determination of when data is considered to be complete, and, most importantly, the difficulty of complying with the requirement to transfer data to the appropriate participant's data archive within 45 days of completion of data acquisition or development.

102.7
WM-11
NH03 1/

4. Inter-participant/project communications need to be improved and expanded.

The above areas of concern will be addressed in individual workshops, comprised of DOE and project participant personnel with expertise in the specific subject areas. They will review, analyze, and provide recommendations for resolutions to the respective concerns. You will be invited to participate in these workshops to provide clarification and offer both recommendations and assistance to DOE on regulatory matters.

Phase Two of the QA Workshop will be held as early as possible after completion of the individual workshops to present proposed resolutions to the concerns noted above.

If you have any questions regarding these meeting minutes, please contact Cori Macaluso on 586-2837.

Sincerely,

Linda J. Desell

Linda J. Desell
Licensing Branch
Office of Civilian Radioactive
Waste Management

Enclosure: Meeting Minutes for DOE QA Workshop, Phase 1, held on August 7, 1990

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

Minutes of the
DOE/NRC Quality Assurance Workshop, First Phase
Lakewood, Colorado
August 7, 1990

The first phase of the U.S. Department of Energy (DOE)/U.S. Nuclear Regulatory Commission (NRC) workshop on quality assurance (QA) was held in Lakewood, Colorado, on August 7, 1990, to provide to participants the opportunity to articulate their perceived concerns about the application of a QA program consistent with the requirements of 10 CFR 50, Appendix B to the program for scientific investigations at Yucca Mountain. The concerns expressed by each participant covered two basic areas: QA requirements for research and Software QA requirements. These concerns are summarized below. A list of attendees is provided as Attachment 1.

Sandia National Laboratory (SNL) observed that the nature of geological science is such that unanticipated results must be expected and that, therefore, the governing QA program must provide the flexibility required to permit the program to proceed. With respect to software quality assurance (SQA), SNL stated that some see the structured QA approach as not allowing for the use of existing software and that SQA requirements have actually impeded work and are inconsistent with requirements for hardware and stand-alone equipment. SNL also felt that SQA requirements complicate the use of proprietary codes because the originators of the codes are not ready to publicize them, but can't use them without entering them into the system. SNL also observed that the relationship between scientists and QA is adversarial and destructive and that this relationship needs to be balanced in order to achieve the goal of a licensed repository.

Lawrence Livermore National Laboratory (LLNL) stated that more flexibility is required in a QA program governing scientific research, that the detail and rigidity of the traceability requirements are excessive, and that SQA requirements focus on tracking, documenting, and filing, and not on the process for developing and improving software and therefore need to be changed. LLNL also noted that QA requirements weren't made for scientific research, that they make difficult changing plans when new findings indicate they should be changed, that they get in the way of procurement, that the requirement for turning in raw data within a certain number of days doesn't provide an opportunity for review, that they detract from quality because of the time that has to be spent on forms, classes and getting approvals, and that there is a need to get back to traditional methods for scientific review.

The U.S. Geologic Survey (USGS) noted that engineered and geologic systems are different and that the scientific approach is absolutely essential to understand the unpredictability of the earth. It referred specifically to the National Research Council's recent report, noting that, as applied now, QA is characteristic of a system that is hostile to surprises, that flexibility is absolutely necessary, and that it is peer review that should be the foundation of QA of the scientific method. USGS characterized administrative and management procedures as open to misinterpretation, as having conflicting requirements, and as preventing the procurement of industry-standard items with a history of quality. It expressed the opinion that the existing sample management procedure emphasizes control and archiving, and barely mentions the use of samples and getting data from them. With respect to quality grading guidelines, it noted that they are much too prescriptive for corroborative use and for middle and lower quality-level activities and that the procedure for exempting elements is burdensome. It observed that the process for the evaluation and approval of technical plans and procedures is burdensome, too high up in the management structure, and that the change process discourages the improvement of approaches and methods and prevents necessary modifications. (At this point, NRC stated that it has effectively operated under an NRC QA program for many years and that a key to making the QA program work for DOE is to give the control back to the people who actually know the project and to allow them to make functional decisions.) The USGS also noted that the requirement to submit all raw and technical data within a specified number of days should be a flexible requirement dependent on the type of data in question. (LANL, during the discussion, stated that this requirement is based on a wrong idea of how data is obtained and that it is not a QA requirement. SNL noted that the requirement was designed to protect records from loss, to respond to agreements with NRC about providing access to data, and to stimulate timely release. SNL also noted that part of the problem has to do with the fact that we haven't defined what data is.) The USGS noted that it has an SQA system in place that has passed surveillance, that it allows for prototyping and the use of supplemental software, and that its biggest problem is that of communicating with PIs about the system. Finally, the USGS noted the need for better communication between scientists and QA.

Los Alamos National Laboratory (LANL) stated that its current QA programs prohibit it from doing its best, that its difficulty is in making implicit quality explicit, and that it hasn't been successful in adapting Appendix B requirements to the repository program, i.e., to scientific investigations and research, particularly with respect to Criterion 3, Design Control. It suggested that the application of this criterion to the program be revisited and that, in the process, all the concerns expressed about rigidity, flexibility, data management, and SQA would be addressed. With respect to SQA, however, LANL noted that it has

a system based on ANSI standards and derived from a system in place at a research institution for five years and that the LANL system promotes control and traceability and still permits a spiral lifecycle and easy prototyping.

Fenix & Scisson noted that the QA program has many features, but the procedures aren't difficult to follow. With respect to SQA, however, it stated that it eventually developed a program at a great cost of time and money.

NRC stated that it is confident that the participants can make the QA program work. It observed that there is some degree of trying not to make it work and of carrying literal interpretations too far, that scientists need to tell QA what controls they need and not vice versa. NRC noted that its role is not to tell participants what they should do, but rather to help resolve problems when advised that specific NRC requirements prevent them from doing their job. It pointed out, consistent with the views of other participants noted above, that the requirement for submitting data within 45 days is not a QA requirement and that the problem should be reviewed and resolved.

In conclusion, DOE stated that, after issuance of the minutes, participants would proceed to resolve the issues identified in group and one-on-one meetings and that, later this year if appropriate, they would meet again to discuss the proposed resolutions.

Attachment 1

Attendance List
DOE/NRC Quality Assurance Workshop, First Phase
Lakewood, Colorado
August 7, 1990

NAME	ORGANIZATION	TELEPHONE
Tom Hunter	SNL	505-844-9160
Robert Richards	SNL	505-844-1280
Joe Schelling	SNL	505-844-3138
David Harris	USBR	303-236-5992
Jim Kinney	USBR	303-236-0827
David Appel	USGS	303-236-1418
Tom Chaney	USGS	303-236-1483
Dwight Hoxie	USGS	303-236-5119
William Dudley	USGS	303-236-4920
Ardell Whitesing	USGS	303-279-7242
Eugene Rosebaum	USGS	703-648-4922
Larry Hayes	USGS	303-236-0516
Bill Steinkampf	USGS	303-236-4939
Brian Marshall	USGS	303-236-7886
Mark Delligatti	NRC	202-492-0430
Mona Fox	REECo	702-794-7562
Richard DeKlever	H&N	702-794-7592
Ralph Musick	H&N	702-794-7086
Kenneth Hooks	NRC	301-492-0447
B.J. Youngblood	NRC	301-492-3410
Nancy Voltura	DOE	702-794-7972
J.R. Caldwell	MACTEC	702-794-7559
A.W. Spooner	WESTON	202-646-6668
J.H. Rusk	MACTEC	702-794-7247
J.P. Jackson	MACTEC	619-259-5003
Leslie Jardine	LLNL	415-423-5032
David Short	LLNL	415-422-1287
Roxanne Edwards	DOE/YMP	702-794-7999
E.V. Tiesenhausen	CCCP	702-455-4181
Richard Van Konynenburg	LLNL	415-422-0456
Richard Bullock	FSN	702-794-7014
Richard Herbst	LANL	FTS 843-9256
David Brocton	LANL	FTS 843-2492
Henry Paul Nunes	LANL	FTS 843-8039
Gary Cort	LANL	FTS 855-1427
Larry Vaughan	DOE	301-353-3137
Edward Patera	LANL	FTS 855-3465
Gary Prott	Raytheon Service Number (? Unreadable, see attached)	
M.J. Regenda	FSN	702-794-7226
John Trapp	NRC	301-492-0509
James Conway	NRC	301-492-0453
Susan Zimmerman	NWPO	702-687-3744
Chris Henkel	EEI/WASTE	202-508-5510
R.S. Saunders	T&MSS	303-236-7349

Carl Wright	H&N	702-295-7719
James Harper	T&MSS	702-799-7745
Cecil Hughey	CER Corp	703-276-9300
Jon Woolverton	USGS	FTS 776-4184
Virginia Glanzman	USGS	FTS 776-1247
R.B. Raup	USGS	FTS 776-1272
D.D. Porter	SAIC/Golden	303-279-7242
Corinne Macaluso	DOE/HQ	202-586-2837
Bob Clark	DOE/HQ	202-586-1236
Donald Horton	DOE/HQ	FTS 544-7504

Meeting: DEPARTMENT OF ENERGY QA WORKSHOP

Location: LAKEWOOD, CO

Rm. SHERATON HOTEL DENVER-WEST

Date: TUESDAY, AUGUST 7, 1990

Time: 9:00 - 2:00

Attendee	Company	Phone	Attendee	Company	Phone
1. Tom Hunter	SNL	505-844-9166	26.		
2. Robert R. Richards		505 844 1280	27.		
3. Joe Schelling		(505) 844-3138	28.		
4. David Harris	USBR	303 236 5492	29.		
5. Jim Kinney	USBR	(303) 236-6527	30.		
6. David H. Appel	USGS	(303) 236-1418	31.		
7. Tom Chaney	USGS	FTS 776-[illegible]	32.		
8. Dwight T. Hoxie	USGS	FTS 776-5119	33.		
9. William W. Dudley, Jr.	USGS	776-4930	34.		
10. Ardell Whitesing	SAIC-Golden w/ USGS	(303) 279-7242	35.		
11. Eugene H. Roseboom	USGS Dir. Office	(703) 648-4422	36.		
12. Larry Hayes	USGS	776-0516	37.		
13. Bill Steinkampf	USGS	FTS 856-4939	38.		
14. Brian Marshall	USGS	FTS 776-7886	39.		
15. Mark J. Delligatti	NRC	FTS 492-0430	40.		
16. Mona A. Fox	REECo	(702) 794-7562	41.		
17. Richard DeKlever	H&N	(702) 794-7592	42.		
18. Ralph Musick	H&N	702-794-7086	43.		
19. Kenneth R. Hooks	USNRC	(301) 492-0447	44.		
20. B. J. Youngblood	USNRC	(301) 492-3415	45.		
21. Nancy Voltura	DOE	702 794-7972	46.		
22.			47.		
23.			48.		
24.			49.		
25.			50.		

Meeting: DEPARTMENT OF ENERGY QA WORKSHOP

Location: LAKEWOOD, CO Rm. SHERATON DENVER-WEST

Date: TUESDAY, AUGUST 7, 1990 Time: 9:00 - 2.00

Attendee	Company	Phone	Attendee	Comp.	P
1. T.R. CALDWELL	MACTEC	(702) 794-7555	26. BECKY HUSHEY	CER CORP	(7
2. AW SPOONER	WESTON	202 646 [illegible]	27. JON B. WOOLVERTON	USGS	FTS
3. J.H. RUSK	MACTEC	(702) 794-7247	28. VIRGINIA M. GLANZMAN	USGS	FT
4. J P JACKSON	MACTEC	(FTS [illegible]	29. R.B. RAUP	USGS	FTS
5. Leslie Jardine	LLNL	4154235032	30. D.D. PORTER	SAIC/Golden	CO
6. DAVID W. SHORT	LLNL	4154221287	31. Corinne MacLaus	DOE/HQ	FTS-
7. Roxanne Edwards	DOE/NV	FTS 544-7499 702	32. Bob Clark	DOE/HQ	FTS 9
8. E.V. TIESENHAUSEN	CCCP	453-4181	33. Donald Horton	DOE/HQ	FTS 54
9. Richard A. Van Konynenburg	LLNL	(415) 422-0451	34.		
10. Richard L Bullock	FSN	FTS 574-7911-2014	35.		
11. Richard J. Herbst	LANL	FTS 843-7256	36.		
12. DAVID BROXTON	LANL	FTS 843-2492	37.		
13. HENRY PAUL NUNES,	LANL,	FTS 843-8039	38.		
14. Gary Cort,	LANL,	FTS 855-1427	39.		
15. LARRY VAUGHAN,	DOE/EM-30		40.		
16. Edward Patera	LANL	FTS 855-7465	41.		
17. Gary Pratt	Raytheon Service Nevada		42.		
18. M.J. REGENDA	FSN	702-794-7224	43.		
19. John S. TRAPP		301-492-[illegible]	44.		
20. JAMES T. CONWAY		301-492-8453	45.		
21. Susan Zimmerman,	NWPO	702-687-3244	46.		
22. Chris Henkel	EEI/UMTRA	(202) 508-5504	47.		
23. R.S. SAUNDERS	W TOTUS	303 236 7249	48.		
24. CARL O. WRIGHT	HYN	202 295-7219	49.		
25. James R. Harper	TRAS	702-794-7745	50.		

ENGINEERED SYSTEM	vs.	EARTH SYSTEM
	SYSTEM OR STRUCTURE	
• CONSTRUCTED UNDER STRICT CONTROLS		• EXISTS
	DESIGN	
• ACCEPTED PRACTICES • REVIEWED IN DETAIL		• UNKNOWN • MUST BE DEFINED
	COMPONENTS	
• DISCRETE AND STANDARDIZED • MOST ARE DIRECTLY TESTABLE • SAMPLING ALMOST UNLIMITED		• COMPLEXLY VARIABLE • GENERALLY NOT TESTABLE FOR DESIRED FUNCTION • SAMPLING VERY LIMITED
	INHERENT CHANGES	
• AGING, CLOGGING, FATIGUE, CORROSION, ETC. • CONTROL IMPACT BY DESIGN		• LARGE-SCALE, COMPLEX AND SIGNIFICANT -- E.G., FAULTING, CLIMATE
	MITIGATION	
• MOST COMPONENTS CAN BE REPLACED OR REPAIRED		• MODIFICATION OF CHARACTERISTICS VERY LIMITED
	FUNCTIONAL PERFORMANCE	
• HIGH CERTAINTY WITH FACTOR OF SAFETY		• HIGH RESIDUAL UNCERTAINTY

Attachment 2

APPLICATION OF QA REQUIREMENTS

FOR

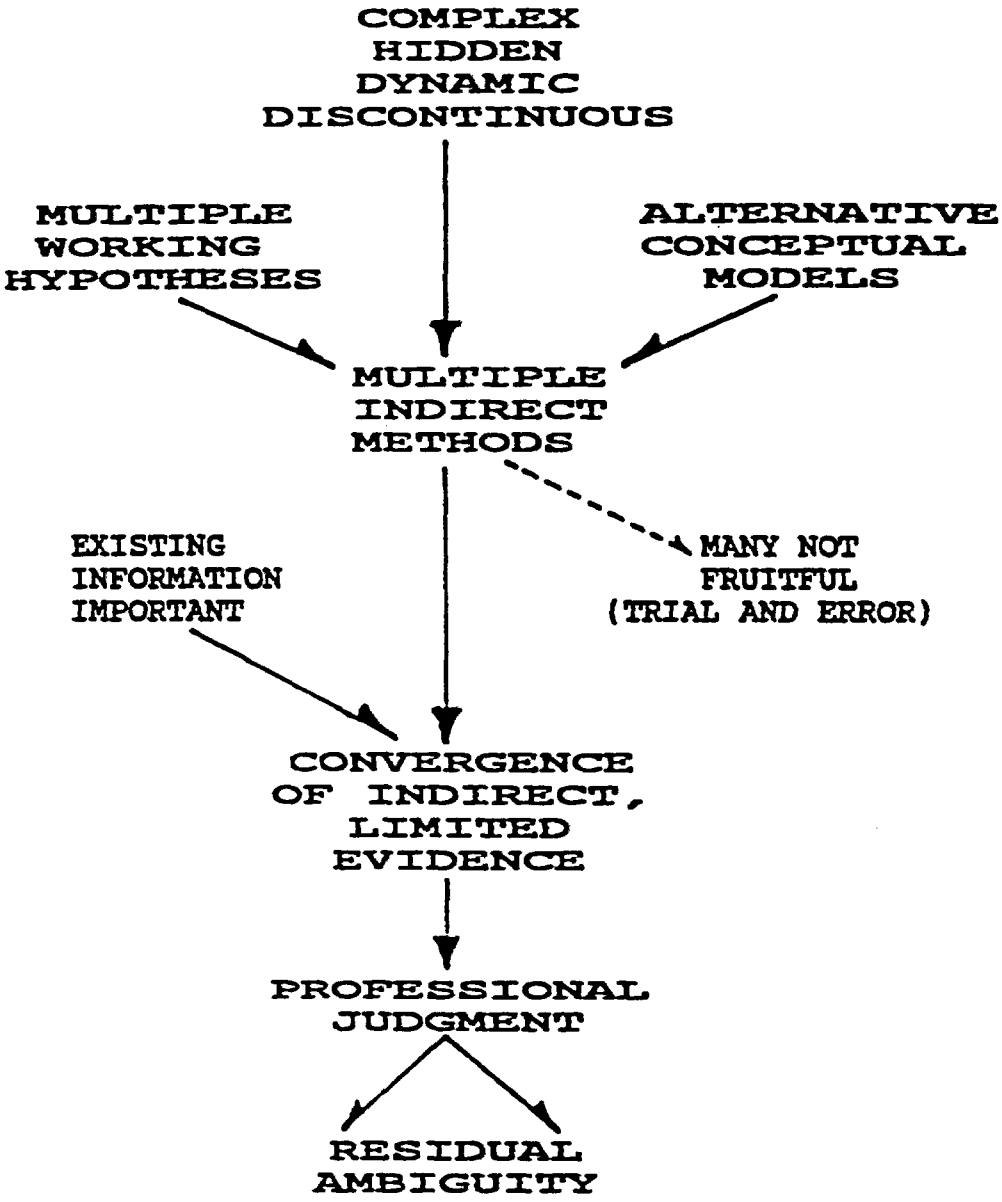
EARTH-SCIENCE INVESTIGATIONS

William W. Dudley, Jr.

U. S. Geological Survey

August 7, 1990

EARTH CHARACTERISTICS AND PROCESSES



NATIONAL RESEARCH COUNCIL

Commission on Geosciences, Environment, and Resources

"RETHINKING HIGH-LEVEL RADIOACTIVE WASTE DISPOSAL"
"A Position Statement
of the Board on Radioactive Waste Management"

U. S. Waste Disposal Program

- Inflexible, prescriptive, based on high degree of certainty
- If successful, is robust in face of administrative/legal challenge
- Unrealistic because of inherent uncertainties
  - Geological medium cannot be specified in advance.
  - Vulnerable to being derailed by small surprises.
- Will result in unforeseen delays, rising costs, frustration among field personnel, and loss of public confidence.

NATIONAL RESEARCH COUNCIL
HLW Position Statement
(Continued)

ALTERNATIVES -- A MORE FLEXIBLE APPROACH

- Iterative performance assessment
  - Start with simple concepts
  - Test concepts as knowledge is gained
  - Give priority to major uncertainties and risks
  - [Not explicit enough in SCP]
- Meet problems as they emerge
  - "Design (and improve design) as you go"
  - Expect surprises
  - [Flexible approaches to site characterization]
- Define the goal broadly
  - " ... in ultimate performance terms ..."
  - [study objectives]

CHARACTERISTICS

- Uses a scientific approach
  - Accommodates, not replaces, scientific method
- Importance of peer review

NATIONAL RESEARCH COUNCIL
HLW Position Statement
(Continued)

"Quality Assurance"

- "... bête noire of frustrated field personnel ..."

- "... A system that is hostile to surprises in a world that is full of them"

- "Because almost any geologic phenomenon has more than one possible cause, flexibility (including the recognition that uncertainty is inevitable and must be accommodated) is more likely to lead to the design and construction of a safe repository system than are rigid, predetermined protocols."

- [Site characterization is implicitly part of "design".]

ADMINISTRATIVE/MANAGEMENT PROCEDURES AND PLANS

- Upper-tier and subsidiary
- Mixing of management and QA requirements
- Wordy and unclear
  - "redundant", "inconsistent", "incomprehensible", "unrealistic", "illiterate", "written for QA staff"
  - Open to interpretation -- and misinterpretation
  - Common cause of audit findings
- Redundant or conflicting requirements
  - Within procedures
  - Between procedures
- Frequently changed
  - Lack of careful, competent preparation
  - Lack of sufficient review
  - Failure to consider reviews thoughtfully
- Leads to confusion as to applicability
- Incorporation, by required reference, into technical plans causes changes in latter

SELECTED EXAMPLES

PROCUREMENT

- Procedures, as implemented, do not distinguish between IITS/IITWI and items/materials not closely related to safety or waste-isolation items or analyses
- Proliferation of forms, signature requirements, and time/effort
- "Off-the-shelf", "history-of-quality" items not exempted
- Reputable vendors decline business

SAMPLE MANAGEMENT

- Rigid, though ambiguous requirements
- Emphasize control/archiving rather than use/data
- Some aspects guarantee unsuitable samples
- PI's responsible can and should refuse samples

OUTSIDE DATA

- Existing guidelines appropriate for direct use in highest quality-graded activities
- Too prescriptive for middle and lower grades
- PI judgment/good scientific practice adequate for required uses in regional studies, scoping evaluations, and as corroborative information

GRADED QA

- GRADING CONSIDERATIONS
  - + Importance to safety and waste isolation
    - Design/construction of critical systems and operations
    - Assessment of safety/isolation performance
    - Information critical to design/assessment
  - + Potential for damage to site
    - Focused controls
  - + Inherent limitations
    - Realistic expectations, not false promises

- AP 5.28Q & AP 6.17Q
  - Subterfuge of USNRC intent (NUREG-1318) to grade according to importance
  - Lumps "site characterization" as important to safety

- TAILORED APPLICATION OF QA CRITERIA
  - + Currently -- Detailed, burdensome, prescriptive approach to exemption discourages focusing QA effort on important elements
  - + Proposed -- Investigators define controls
    - -- Technical reviewers recommend
    - -- Contiguous management approves
    - -- QA monitors process & advises

SCIENTIFIC PLANS AND PROCEDURES

CURRENT REQUIREMENTS

- Excessive detail, beyond realistic ability to plan
- Inflexible format, often inappropriate or irrelevant to topic
- Burdensome and time-consuming process for approval and reapproval

IMPACTS

- Waste of scientific resources
  - Nonproductive effort consumes time and money
- Discourages improvement of methods, approaches
  - Prescribed mediocrity
- Prevents (or places scientist at risk for) necessary field modifications
  - Lost information

PLAN OF INVESTIGATION

- Incorporate Guidance
  - + Objectives within framework of subsequent project goals
  - + Graded quality level of final product
  - + Constraints -- budget, schedule, etc.
- Define
  - + Scope of Investigation
  - + Alternative conceptual models, if applicable
  - + General approach, protecting flexibility
  - + Major decision/hold points, if predictable
    - - Affect attainment of objectives
    - - Affect constraints
  - + Expected products, within framework of subsequent use
  - + Graded quality level of principal elements
  - + Special considerations
    - - Interfaces
    - - Sample control
    - - Site integrity
- Processing - Initial
  - + Review and comment by technical review panel
  - + Recommendation by contiguous management
  - + Approval by lowest knowledgeable management
  - + Monitored by QA unit

PLAN OF INVESTIGATION
(Continued)

- Implementation
  - + Detailed approach/technical procedures
    - Defined by Principal Investigator
    - Reviewed/recommended by technical review panel
    - Approved by contiguous management
  - + Documentation by memorandum, review panel minutes/reports, or in interim/final study reports
  - + Monitored by QA unit
- Changes
  - + Guidance elements -- Repeat initial processing steps, but approval by guidance originator
  - + Elements defined in plan -- Repeat initial processing steps
  - + Detailed approach/procedures -- Review panel
    -- Approved by contiguous management
  - + Necessary field changes -- By PI or on-site CI
    -- Impact evaluated and documented

INTERNATIONAL WASTE MANAGEMENT CONFERENCE
Las Vegas, Nevada
April 2-5, 1989

SESSION F

QUALITY GRADING AND FLEXIBILITY IN EARTH SCIENCE INVESTIGATIONS

William W. Dudley, Jr.
US Geological Survey

Earth-science investigations related to waste management require an approach which contrasts markedly with that for design and fabrication of state-of-the-art engineered systems. The properties and behavior of the earth's crust exist prior to the investigation. They are the complex, hidden subjects of inquiry, rather than the controlled products of design, component testing, and careful assembly or construction. Whereas defects in the components of an engineered system can usually be identified and repaired or replaced, the inhomogeneities and imperfections of the crust can be neither completely characterized nor mitigated. The characteristics of the earth, including the movement of water, generally cannot be measured directly. Instead, current conditions are usually inferred from corroborative sets of observations and measurements, and future conditions are extrapolated spatially and temporally, based on theories of rock behavior, crustal processes and hydrology. Sampling density is typically limited; individually, most methods of study do not yield conclusive results, particularly with respect to prediction of changes caused, for example, by tectonism and climate change.

Effective management of earth-science investigations should emphasize removing unnecessary controls by grading the assignment of quality levels and by assuring the flexible tailoring of control methods to individual investigations. For high-level nuclear-waste disposal, the grading criteria include: (1) the degree to which the results will influence major objectives such as facility design and performance assessment; (2) the potential of the study methods for damaging natural barriers that are depended on for waste isolation; and (3) the inherent limitations of the methods of investigation to characterize the complexities of the crust accurately. The desired level of confidence associated with a high quality grade can rarely be achieved by the rigorous control of a single or primary approach; rather, confidence more often results from the weight of convergent, corroborative evidence from several approaches that, individually, could not support a high quality grade for the overall investigation. Flexibility considerations include the grading criteria themselves and, in addition, such factors as the complexity and interrelationships of the geologic properties and processes, the

importance of observational skill and professional judgment to the results, the feasibility of thorough scientific review, the corroborative information that can be used, and the existence of accepted geotechnical practices.

Planning to resolve complex problems necessarily evolves as the results unfold because, in many cases, the best approaches and necessary measurements cannot be identified until a preliminary set of data has been obtained. A pre-investigative plan should concentrate on an accurate understanding of the objectives within the framework of subsequent or higher level project goals; on the selection of the overall, graded quality level, on credible alternative conceptual models; and on general approaches that are consistent with the goals and importance of the study. For complex investigations, detailed advanced planning and rigorous procedural controls are usually less effective in achieving quality than are highly skilled, unburdened investigators and thorough scientific review throughout the investigation. If detailed planning and procedural controls are absolutely necessary, then the selection and modification of approaches and procedures should, to the extent possible, be functions of the investigators and scientific reviewers.

Attachment 3

Comments on the Yucca Mountain Project Quality Assurance Program

by

Richard A. Van Konynenburg

Lawrence Livermore National Laboratory

August 4, 1990

Comments on the Yucca Mountain Project
Quality Assurance Program

The following comments represent the personal opinions of the author and do not constitute an official position of any of the organizations of which he is a member. These comments are intended to be constructive in nature. The last section recommends what the author believes is a better approach to performing quality assurance.

Requirement for Detailed Planning

The planning process required in the YMP QA system appears to be based on an inaccurate view of scientific research. Its premise seems to be that the conduct of scientific research is similar to the process of baking a cake. One just write down a cookbook recipe to which few changes will be necessary, and then follow the recipe.

The true nature of scientific research, on the other hand, is better described as probing in uncharted territory, while remaining alert to make significant observations, and staying flexible enough to follow promising paths that appear only after the search has already begun.

Scientific research is a creative activity, requiring the researcher to come up with ideas and to try them. Many of them lead up blind alleys, but this can only be discovered by trying them. A scientist therefore needs an environment of freedom to carry out his work. To determine the future course of his work, he must be able to respond to what he finds at each step of the way. He cannot know in detail what he is going to do very far in the future.

In such a situation, detailed planning in advance is a pointless activity. It is akin to writing a detailed plan for fighting one side of an entire war before the war is fought, with no regard for what the enemy might do.

Faced with a requirement to write a detailed plan in advance, a scientist either attempts to get approval for a vague plan that will be broad enough to accommodate the inevitable changes, or attempts to "live within the system," subjecting himself to costly delays waiting for approvals of changes, and risking criticism from auditors later, wondering why he did not stick to the plan."

It would be much more efficient if we would simply agree on goals and leave the changing details of the scientific work to the scientists themselves and their immediate supervisors. Science functions best in an

environment of decentralized control.

The Importance of Time

The YMP QA system seems to ignore the importance of time in the conduct of research. A scientist must respond to deadlines established by the budget cycle, by project milestones, and by conference dates. It is very difficult for a scientist in the YMP to meet his commitments to these deadlines, because of the interminable delays resulting from the QA bureaucracy and the multiple levels of micromanagement that have been spawned by QA. Scientists feel powerless to deliver on their promises while waiting for signature after signature on plans that will very likely be made obsolete as soon as the work begins and something new is learned, or while waiting for a stop-work order to be lifted, or for a readiness review to be held, or for a QA-approved way to calibrate instruments to be worked out. Scientists are embarrassed to go to conferences and admit to their peers how little progress they have been able to make, not because they are incompetent or lazy, but because their hands have been tied by QA delays. This lack of progress is also noted by their employers when salary reviews come around. All of this leads to a great deal of frustration.

NQA Means Non-Quality Assurance

Although the program goes by the name "quality assurance", it is actually counterproductive, and probably constitutes the dominant factor working against the true quality of the work. This happens in many ways. Here are some that come to mind:

1. QA is particularly demoralizing to the most creative scientists. This tends to drive these scientists away from the project to others in which there is more freedom. This is a grave error. The project is not well served by the loss of their contributions.

2. Scientists who elect to remain on the project find that they have less time to think about the scientific substance of their work than they normally would have, since a significant amount of time is taken up by filling out forms, going to classes, carrying documents around to get signatures, calling to "encourage" someone to sign something that was not carried around personally, etc. This prevents them from giving the

scientific issues the depth of consideration they should have.

3. When all the approvals are finally received on his plans, a scientist may find that he can now no longer carry out the work because budgetary decisions in the meantime have removed support for it, or laboratory facilities or technicians have been assigned to other projects, since no work was being carried out. There seems to be no coordination between QA, milestone planning, and budget decisions.

4. Because of delays resulting from the QA planning and approval process, the research that is intended to support the making of a decision may not be carried out at the time the decision must be made . It will therefore be made on the basis of work already published in the literature, which is not specific to Yucca Mountain conditions and has had no QA applied to it, or it will be made simply by "the seat of the pants" (such undocumented command decisions are difficult to explain to auditors after the fact and frequently are later reversed). As a result, decisions will not be as well-informed as they might have been, had the research been allowed to proceed.

5. Once a scientist gets a plan approved, he has a strong incentive not to ask for any changes in it, because of the delays involved. Therefore, he is less inclined to incorporate improvements or new techniques, even though he might believe them to be superior. The result is that the most advanced methods are not always used, and the scientist loses self-respect for not following his own desire to use the most up-to-date approaches in his work.

6. Stop-work orders have been used to enforce new QA requirements put in place after experiments were begun. This has caused a considerable loss of invested work, demoralizes the scientists involved, and precludes the gathering of just the kind of long-term data that are necessary to begin to make predictions.

7. There are frequent changes in the QA rules. This fact has a number of consequences:

a. It makes it difficult for scientists to stay up-to-date on QA requirements.

b. It engenders an expectation among scientists that the current set of rules will not survive very long; i.e., the rules are not dependable. There have been four QA plans at LLNL since the project began, and each has undergone many changes. It is difficult to take them seriously. Scientists are reluctant to start new work because they suspect, based on past experience, that the rules will change again, and they will be caught in the middle.

c. New rules have been applied in reviewing reports of old work in an "ex post facto" manner, after it is too late to make the changes demanded, because the reported experiments have already been completed.

d. These constant changes lead to a considerable waste of time and resources.

It appears that QA has become a research project on its own, and the scientists feel as though they are its guinea pigs. It is difficult to do experiments while someone else is doing experiments on you.

Reduced Communication

When a scientist has managed to accomplish some work and wants to report his results at a conference or in a journal, he finds that the YMP QA system, rather than encouraging him to do so, has erected hurdles in front of him in the form of a lengthy review and approval process. Long lead times are mandated for project review of research reports. The result is that scientists cannot report their latest results in written conference papers. Even when scientists submit their drafts in time to conform to the long lead times, approvals are often slow in coming, so that they still have no assurance that they can meet conference deadlines.

Reviewers seem to take the position that a research paper represents a "position" taken by the project, whereas scientists regard these documents as interim reports of work in progress, subject to change as more is learned. As a result, comments made by reviewers often appear to be trivial or legalistic in nature, and irrelevant to the work itself. Nevertheless, it has taken months or years in some cases to resolve these comments and get reports through the QA approval process.

The result of all this is that scientists become reluctant to report their work. This decreases communication of research results to true peers (as opposed to designated reviewers), which is counterproductive to

obtaining the scientific consensus that will be necessary to obtain approval of a repository license.

Misperception of the Project's "Clout"

The YMP QA system lays down edicts without regard to the project's actual power position in the real world. Although the project is of significant overall size and is of undoubted importance to the country, it does not contribute a very large part of the overall research budgets of the laboratories who do research for it, nor does it constitute a significant customer for most of the commercial firms which supply materials and equipment for its research. This being the case, it is unrealistic to expect commercial suppliers or the support departments (such as purchasing) in the laboratories to be anxious to conform to stringent YMP procurement requirements, audits, calibration standards, etc., when their other clients do not require these things, and there is no significant incentive for them to do it. The scientists are the ones who find themselves at the cutting edge of this problem. They don't make the rules, but they must try to enforce them. The result of this unrealistic perception is that scientists are not always free to obtain materials and equipment from suppliers they believe to be best, or to get their instruments calibrated in a timely manner.

Exaggerated Emphasis on Calibration

A great deal of scientific research does not require that apparatus have absolute calibration to national standards. Decisions about the need for and timing of calibration should be left to the scientists involved, rather than being prescribed in an arbitrary manner. It is wasteful to require periodic calibration to NIST standards of equipment that is not currently in use, simply because it has been included on a list. Scientists should be free to calibrate when it is actually necessary in the conduct of research, not according to an arbitrary schedule. The criterion should be whether it actually affects the conclusions to be drawn from the research, and the scientists are in the best position to determine this.

Format of Records

Scientists have developed methods of keeping records that they find to be most useful in their work. These include laboratory notebooks or log

books, strip charts, computer output, etc. Some scientists prefer to use large notebooks so that 8 1/2" x 11" pages can be pasted directly into them. Some records are automatically generated by machines using ink of several colors. Different styles of record-keeping have been found to be most effective for different scientific disciplines.

The QA record system has attempted to dictate the format of records in order to make it more convenient for QA personnel to reproduce them, without regard to their usefulness to scientists. It would be better for the QA record system to adapt its copying process to this variety of record styles rather than attempting to dictate the color of ink or the size of pages to be used by all scientists. The QA record system should endeavor to be as unobtrusive and nondisruptive as possible, so that the scientific work can go forward unhindered, and maximum progress can be made.

Submittal of Raw Data

Scientists should not be required to submit raw data to the YMP project office before they have had a chance to analyze them. There are several reasons for this:

1. There is a longstanding ethical principle in scientific research that a scientist who gathers data has the first right to interpret and to publish them. Without this foundational principle, a scientist feels that he is not treated fairly, and he is not motivated to gather data.

2. If data are turned in prematurely, there is a very real possibility that they could be misinterpreted by others who are not aware of the conditions under which they were gathered. This would lead to misunderstandings and loss of credibility.

3. There is always the possibility that the data will be found to be irrelevant, useless, or inaccurate, because of an error not detected initially. Scientists should be given an opportunity to analyze their data carefully before releasing them. Not doing so could undermine their professional credibility and reputations.

The Human Factor

In general, scientists are dedicated people. Their work requires

courage and perseverence. They spend many years earning degrees, learning to do research, and building stature in their careers. Progress in science depends on one scientist being able to trust that another has honestly reported his results. Therefore, scientists hold each other responsible for what each reports in the scientific literature. A scientist's reputation among his peers depends on his regard for truth. In general, then, scientists see themselves as honest and competent, and they look forward to continuing to carry out research in their respective fields.

The best motivation to use on people of this type is positive motivation--the carrot rather than the stick. Unfortunately, the QA system operates with negative motivation. Imagine the feelings of a scientist who views himself as honest and competent, and is looking forward to some longevity, when he encounters the QA system. He quickly discerns that this system is based on the premise that he may very well be dishonest, incompetent, and/or likely to lose his memory or to die at any moment. He can think of no other explanation for all the detailed planning, documenting, approving, and auditing that is stipulated. These are not encouraging or positively motivating thoughts. It is not surprising that scientists lack enthusiasm for QA, since it deals such a brutal blow to their image of themselves.

The audit itself is symbolic of this negative management approach. In banking, audits are necessary because there is no other independent way of verifying that the accounts are accurate. In science, on the other hand, there is a built-in way to verify the validity of the work. (See next section). Using this way, we could return to a positive management approach.

A Better Approach

A better approach to real quality assurance for the scientific research to be done in the YMP would be a return to the traditional, time-proven scientific method. This involves the constant comparison of ideas and theories with observations and experiments. This is best done by funding more than one researcher or group of researchers to work in the same field. In this way, progress is more rapid, because of several factors:

1. "Two heads are better than one."

2. One group can check the other's work. This is genuine quality

assurance.

3. There is a built-in audience of truly qualified peers for each researcher. A scientist is much more motivated when there is someone to talk to who genuinely understands and appreciates his results.

4. Competition is one of the most powerful motivators in any field of human endeavor.

It may be argued that this would constitute wasteful duplication. I would only submit that the present QA system is very expensive, and that many of its costs are intangible and not easily identified.

Agreement should be reached between the project management and the scientists on the goals for the research, and progress toward the goals should be reviewed at intervals spaced far enough apart that there is time to make some progress. The details of the work should be left to the scientists themselves and their immediate supervisors.

Rapid and free communication of results to truly qualified peers should be fostered. Scientists should be free to present their results at conferences where their particular discipline is well-represented, so that they can get feedback from others most familiar with the field. Publication in refereed journals should be encouraged and expedited.

The scientific method should be allowed to operate in an atmosphere of trust, respect, and freedom. A positive working environment is easily damaged, but is all-important for scientific progress.

Satisfaction of the legal needs of the repository licensing process should take place after the scientific work has established something to provide a basis for a licensing approach. Application of a strict QA system at this early stage will strangle the scientific work, and "kill the goose that lays the golden eggs."

Attachment 4

USGS

"THERE IS MUCH WORLD-CLASS SCIENCE THAT [MUST] BE DONE AT AND AROUND YUCCA MOUNTAIN. THERE IS MUCH WORK THAT COULD BE DONE AT RELATIVELY MODEST COST (AND NO-TO-MINIMAL SURFACE DISTURBANCE) TO FURTHER DOCUMENT AND CHARACTERIZE [THE SITE]. . . . POTENTIALLY CRITICAL SCIENTIFIC PROBLEMS THAT NEED TO BE ATTACKED TO DETERMINE THE SUITABILITY (OR OTHERWISE) OF YUCCA MOUNTAIN AS A HIGH-LEVEL WASTE REPOSITORY. . .

USGS

[WE] . . . HAVE A LONG HISTORY OF PRODUCTIVE SCIENTIFIC WORK AT THE NEVADA TEST SITE . . . HAVE ALWAYS MADE A GOOD-FAITH EFFORT TO DO GOOD WORK WITHIN WHATEVER CONSTRAINTS WERE IMPOSED ON US, AND WE SHALL CONTINUE TO DO SO AS LONG AS WE HAVE SUPPORT FROM YMP. TO THE EXTENT THAT THE QA SYSTEM CAN BE STREAMLINED, SIMPLIFIED AND HUMANIZED, . . . OUR SCIENTIFIC PRODUCTIVITY AND THAT OF OTHERS, AS WELL AS THE SCIENTIFIC CREDIBILITY OF THE USGS, SHOULD BE ENHANCED CORRESPONDINGLY."