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April 11, 1984

To: M. J. Smith
E. A. Ash

From: F. R. Cook FRC

Subject: CONFIRMATION OF CONVERSATIONS ON 4/9 (ASH) AND 4/10 (SMITH) CONCERNING M. J. SMITH'S MINUTES OF DISCUSSIONS WITH DOE, BWIP AND OTHER CONTRACTOR PERSONNEL ON 1/30 AND 1/31/1984

As I noted in our subject conversations, it is not my intent to indentify requirements or any other mandatory provisions not explicitly written in regulations during our discussions. However, the tone of the subject minutes suggests that this is what I did. The "shoulds" and the "musts" create this impression. My intent was to ask questions similar to questions the Staff may have in the future, to communicate their perspective early in the process of procedure preparation.

In addition as I noted in our subject converasations, I am concerned about a conclusion DOE (Olson) voiced to me that the questioning during the subject discussions in January amounted to managing Rockwell. As I noted to him and to you, this is, again, not my intent, although it appears difficult to for me to raise any issue or question which spawns an action without this being preceived as managing. Your recognition of this problem and confirmation that you do not consider my comments during the subject discussions in January as having "managed" Rockwell are appropriately received.

Specific comments which I have made on a copy of Smith's minutes are attached.

ATTACHMENT AS STATED:
cc L. Olson, DOE RO.

MEETING MINUTES

SUBJECT: Meeting with F. R. Cook Regarding Waste Package Data and Procedure Traceability

TO:	BUILDING
Distribution	MO-407/200E; 325/300 Area
FROM:	CHAIRMAN
M. J. Smith	M. J. Smith, Manager, Engineered Barriers

DEPARTMENT-OPERATION-COMPONENT	AREA	SHIFT	DATE OF MEETING	NUMBER ATTENDING
Engineered Barriers/BWIP	2E	day	1/30/84	see attached.

Distribution: see attached list

Meeting minutes attached.

Distribution:
Attendees
P. F. Salter
R. C. Edwards
T. B. McCall
E. L. Moore
G. S. Barney
T. J. Higgins
R. T. Wilde
L. R. Fitch
R. J. Gimera
J. H. LaRue
H. Babad
J. E. Mendel
G. S. Hunt
E. B. Ash

Basalt Waste Isolation Project (BWIP)/Engineered Barriers Department Meeting with F. R. Cook, Nuclear Regulatory Comission (NRC), January 30, 1984-

Attendees:
F. R. Cook
G. J. Bracken
D. H. Dahlem
M. F. Nicol
M. J. Smith
R. C. Edwards
P. E. Lamont
J. Myers

(1) F. R. Cook stated that his objective for the meeting was to determine:

(a) What BWIP documents are pertinent to tracing procedures/tests.

(b) Whether or not the procedure and test traceability documents

needed on a periodic inspection basis and is required to provide an independent check that work was done according to procedure or instruction. A plan for inspection/surveillance should be in place prior to testing. Unannounced QA audits are required in addition to the periodic surveillance performed. Mr. Cook stated that in-house QA systems should be continuously improved and that a QA system that reveals no audit findings for a long period of time will be ~~viewed as suspect when a license is reviewed~~.

(e) Mr. Cook suggested that surveillance by QA should be documented along with data rather than in separate surveillance reports. Key measurements must be observed by QA personnel, and the request for surveillance should be made by the experimenter.

(3) Mr. Cook said he will use information from this visit to help formulate the pending QA workshop in June 1984 and to identify problem areas early.

(4) Mr. Cook suggested that BWIP should categorize all testing into developmental testing vs testing done for initial performance modeling. Any testing done as developmental should be defined by means of test specifications or instructions in order to assure that when a procedure is eventually written, the developmental data can be inspected and determined whether it is admissible for licensing. The test ~~specification~~ procedure should control the critical test parameters that are pertinent to establishing pre- or post-closure performance or the success of the test performed. QA should sign off on the test instructions and all changes to the test instructions. The BWIP ~~should~~ identify which data being collected are critical to establishing the pre- and post-closure safety of the repository.

(5) Work being done by draft procedures should not be allowed, and work should not be started until all signatures are acquired on a procedure.

follow the nine items listed by him (see Attachment 1). Mr. Cook stated that he had given a similar list to the Rock Mechanics Group.

(c) Whether or not the BWIP QA system is adequate to police what is in place?

He added that he was trying to identify problems early so corrections could be made before a large amount of data is collected.

(2) Mr. Cook outlined the list of nine questions he provided to P. E. Lamont (Attachment 1). Further clarifications made by Mr. Cook are written as notes taken by M. J. Smith on the attachment. (Mr. Cook's original list included only the nine major questions given in Attachment 1.)

(a) During the discussion of Item 5, M. F. Nicol stated the BWIP QA plan would be reissued within two months.

(b) G. J. Bracken of DOE-RL QA stated that QA signoff does not mean that they agree that the procedure produces valid techical results. QA cannot possibly determine this.

(c) Mr. Cook stated that no testing or procedures for tests should be approved by QA until test plans, a QA plan and performance requirements are in place. Mr. Nicol stated that QA approval on Basalt Operating Procedures (BOPs) currently does not mean that they have been checked for relevance to the test plan they support. Mr. Cook stated that the BOPs are American Society for Testing Materials (ASTM) type procedures, i.e., they do not instruct the operator as to what needs to be tested, how many tests need to be run, how to treat materials, etc. In Mr. Cook's view, they are generic. Mr. Cook stated that QA should keep records of what they reviewed on each procedure in order to clarify what their approval means.

(d) It was pointed out by Mr. Cook that real-time QA surveillance is

This seems to indicate they was that staff would look at the basic and test procedure was dependent upon a plan content. If this is so I would question as to how they were prepared before plan was completed.

Staff will be interested in what we review and how QA to conclude approval was given

Pacific Northwest Laboratory (PNL)/BWIP Engineered Barriers Department Meeting, January 31, 1984

Attendees:

M. R. Kreiter
G. J. Bracken
F. R. Cook
P. E. Lamont
J. Myers
D. G. Coles
R. E. Westerman
D. E. Ryder
S. Klopfer
B. O. Barnes

(1) M. R. Kreiter presented the basics of how PNL is organized and how BWIP work is handled within the organization.

(2) Mr. Cook stated that NRC has been encouraged to identify potential problem areas that might come up during licensing by NRC-HQ. Most of the prior difficulties NRC has encountered have been related to QA and procedures used to establish operational or long-term safety. Mr. Cook reiterated the items covered in Item 5 in the meeting at Rockwell. Mr. Cook stated that Rockwell should define whether the data being collected are critical to safety (in pre- or post-closure performance) or simply result from method development.

(3) Mr. Cook then covered the nine questions given in Attachment 1 for the PNL staff and management.

(4) Mr. Cook identified that BWIP ~~needs~~ a procedure to identify what to do with data collected by unintentional violations of procedure and how to recover from a problem in this area.

(5) Mr. Cook stated that the QA statement in Statements of Work should require that BWIP QA and the appropriate end function manager agree to

the QA plan prior to the initiation of work, if the work is subcontracted.

(6) Procedures for the preparation and procurement of gases, radionuclides, reagents and waste forms should be in place for all work being conducted by the BWIP. Specifications for all materials should be in place as well as the requirements for vendor certification of materials/equipment supplied. The individual that is authorized to sign the vendor certification and to certify the materials supplied should be identified in the test instructions. All materials used to prepare waste forms need to be certified as meeting requirements. Vendor certification alone is not sufficient. Over-checks need to be completed routinely by the test engineer or his designee. The required over-checks for items critical to safety (i.e., performance) need to be specified in procedures that are written. The justification for the over-check requirements should be documented.

Westinghouse Hanford Company (WHC)/BWIP Engineered Barriers Department Meeting with F. R. Cook, January 31, 1984

Attendees:

A. C. Leaf
J. M. Lutton
J. J. McCown
C. N. Wilson
F. R. Cook
L. D. Blackburn
R. Knecht
W. Clarke
G. J. Bracken
J. Myers.

1. R. Knecht outlined the personnel, procedures and activities associated with BWIP work at WHC. Mr. Cook suggested that it be identified what the signature on each procedure means. A procedure for approval of procedures needs to be put in place.

2. C. N. Wilson stated that a procedure for record keeping exists in HEDL-TC-2405.

3. Mr. Cook discussed the nine items identified in Attachment 1. He reiterated that it is important for each principal investigator to know whether the data being collected is important to establishing pre- or post-closure repository safety and that each investigator be familiar with NQA-1 requirements for record keeping.

I don't think on data point.

4. Design requirements for waste packages, etc. need to specify that the work will be done in accordance with ANSI standards.

5. Mr. Cook questioned HEDL extensively as to what sections of NQA-1 apply to their work. Mr. Cook's approach would be to include the non-mandatory (design control) requirements as well as data control requirements in all work.

That Staff would look at the

6. Mr. Cook stressed that automatic data tapes, computer printouts, and outputs from data loggers need to identify the experiment or test from which they result and that these records become part of that laboratory notebook.

I don't think is recommended between personnel.

7. Mr. Cook added that the training of each principal investigator with respect to QA requirements and procedures is as important as his technical qualifications. This training needs to be documented.

My point was what over the life of the project's the people doing the job would be of interest to the Staff.

QA review 2/84
RHO
etc.

Attachment A

1. Are test plans available and, if so, do they define pertinent test parameters; analyses, etc. or refer to appropriate lower tier planning or procedural documents?

2. Are procedures for selecting sample material identified?

3. Are dates specific on documents, and is it possible to relate data collection sheets with data to specific versions of test procedure specifications, plans, etc. ie with pertinent test documents which data taker needs to run test? Are pertinent documents available to data taker?

4. Are End Function Technical Plans available and are Test Plans consistent with End Function Plans?

5. Are pertinent procedures concurred in by QA organization people?

6. Are procedures for instrument calibration available for instruments specified in test procedure specifications or other pertinent test documents?

7. When authomatic data takers are used are procedures adequate to provide for such data taking and do they require appropriate documentation of such data? Are automatic, data tapes etc, consistent with test procedure data forms. Are provisions provided for QA personnel overchecks?

8. If procedures are violated, is there a procedure for handling data so collected?

9. Do procedures, plans, etc. provide for specific sign offs? Are documents available to people who prepare procedures to tell them pertinent QA requirements including those in NQA-1 and other ANSI documents.

Comment on QA guide

1. All levels of workers from clerks and secretaries to engineers, technicians, QA personnel and managers - at all levels - need qualification courses in QA system implementation. Psychology tests to demonstrate aptitude of work in the QA environs need to be established and implemented and should be considered as important as technical qualification.

   Periodic tests and audits should be performed to ascertain compliance with minimum performance in these areas related to ability and attitude. This is particulary true for managers.

2. QA systems need to establish levels of acceptance, i.e., grades for all personnel in traits and knowledge related to QA.

3. Applicants need to identify themselves now.

4. Management systems of the applicant (also called organization systems) need to have clear responsibilities and commensurate authorities identified. Adherance to management systems must be audited by QA and frequently by NRC QA.

5. I would use terminology (definitions) which are consistent with the laws and rules. Design work R&D, etc.

6. There needs to be a distinction between date collected to verify models and data collected to determine material or barrier characteristics used in the analyses of performance the models.

7. The highest level of QA control should be placed on the data used to validate models.

8. Definitions of accuracy needs to identify that statistical bias are caused by instrument errors and inability to know experimental conditions which affect test parameters being recorded.

9. Precision definitions should include identification of factors which cause it to occur, i.e., instrumentation draft and uncontrolable conditions - also relate to time between measurements if possible.

10. I would use a term for study director which is more in line with the engineering disciplines, i.e., "engineering development director" or R&D director.

11. Quality assurance unit definition should include functional job of shutting down activity by tagging if QA procedures are not being met.

12. Research facility should be more than that to do studies. Products need to be linked back to validation of models and elimination of barrier material characteristics.

13. You should review definitions of 10 CFR 21 and introduce the idea of basic component to cover software analyses.

14. Development of software analyses for determining material properties whereby are "secondary properties," i.e., not measured but deduced by analyses, needs to be addressed. Much of the geophysical data are secondary properties in this regard. (See "raw data" for comparison to this idea.)

15. 60.181-10 should cover consultants. Also refer to 10 CFR 21 for notification of NRC of defects.

16. Use idea of defects in 10 CFR 21. Relate to software and hardware - give examples relative to site characterization activities.

17. 60.181-15. Use words on access which I wrote up for Seth. Idea should be these records subject to discovery. Why the limit in the last sentence of 60.181-15? Inspection needs to be started at any time work begins. Use of funds from waste funds should be main item to distinguish records and work which use/and are not subject to NRC inspection.

18. 60.182-29 should be expanded to be subject to QA overchecking and auditing. See comment above.

19. 60.182-29, item C which relates to scheduling should have QA controls assigned. Schedules must not rush work and must be based on actual experience. They should include some contingency which changes with experience. We should identify an average contingency framework for scheduling repeated activities.

20. 60.182-31. See comment 1 above for training and testing.

21. 60.182-31(b). The idea of records for personnel changes needs to be established for all workers.

*22. Types of documentation should be standardized for the project. Each repository should use the same list of documents. No others should be allowed. Willful use of non-standard documentation whould be subject to civil fines.

23. All provisions should have procedures to assure compliance with the provisions of the rule and QA should have plans to overcheck and audit.

24. Activities which are left to the "judgment" of individuals once development is complete should be identified as such ~~and judging individuals identified as such~~ and judging individuals identified and records maintained current.

25. 60.182-31(e). The idea of schedules as used here should only be introduced when schedules are necessary to assure quality. In general schedules which are not oriented at quality control, but producing results, will result in less quality.

26. Actions which are aimed at reducing costs must be looked at carefully to decide that they don't cause violation of QA procedures, etc. QA takes lots of money becuase of the added control of information. Any action to reduce costs should have QA manager approval, either to go along with QA procedure changes, are to assure QA procedure changes are not necessary.

27. 60.182-35(3) regarding identification of problems should be linked to 10 CFR 21 action concerning defects. Problems should be related to criticality of activity or data taken.

28. The subject rule needs to more comprehensivily address the necessity of classifying activities and measurements, analyses, etc. as critical or etc. Data associated with development of test techniques and analytical procedures, with the exception of analytical model development data, are probably less than the top QA category.

29. 60.182-33. Action of S.D. should include monitoring to assure compliance with procedures required by the protocol.

30. The word protocol needs definition. I would favor a term which more nearly fits the 10 CFR 50, Appendix B, terminology. Test plan is probably better.

31. We need a contractor or in-house talent to work on the changes to your proposal suggested herein.

32. 60.182-35(e). A requirement for keeping validated copies of all records by the applicant needs to be established.

33. See NUREG-0800 for other features for QA systems for incorporation into the document.

34. 60.185-81. Management responsibility for actions controlled by procedure should be identified in the procedure. Appropriate management sign offs should be included along with QA and technical signatures.