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109/CG/85/02/04/0

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MEMORANDUM FOR: L. H. Barrett, WMEG
J. O. Bunting, WMPC
M. R. Knapp, WMGT

FROM: Hubert J. Miller, Chief
Repository Projects Branch, DWM

SUBJECT: GUIDANCE FOR DATA REVIEWS

WMRP has completed a guidance package for data reviews conducted by DWM personnel. The enclosed package is provided for your information. This document will be sent to DOE to inform them of our objectives with respect to data reviews and to describe the ground rules guiding these interactions.

Two earlier drafts of this document were issued to Division staff for review and comment. This revision builds on comments received from PC, EG, GT, and RP.

In preparing this package, questions on external quality assurance (QA) arose, which were beyond the scope of this work. These questions have been brought to my attention with the result that a seminar will be scheduled for WM staff to promote a better understanding of QA and its relationship to data reviews. The seminar will be scheduled after the completion of the EA review. A notice will be issued providing a time and place for the seminar.

If you have any questions concerning this package, please contact me or Chad Glenn of my staff.

ORIGINAL SIGNED BY
Hubert J. Miller

Hubert J. Miller, Chief
Repository Projects Branch
Division of Waste Management

Enclosure:
Data Review Guidance

WM Record File 109
WM Project 1
Docket No.
PDR ✓
LPDR
Distribution:
(Return to WM, 623-SS)

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PDR WASTE
WM-1 PDR

OFC	:WMRP	:WMRP	:WMRP	:WMRP	:WMRP	:WMRP	:
NAME	:CGlenn:lem	:SMCoplan	:JKennedy	:RJWright	:JLinehan	:HMiller	:
DATE	:85/02/04 85/2/15	:85/2/19	:2/12/85	:2/20/85	:2/22/85	:3/27/85	:

DATA REVIEW GUIDANCE

Background and Purpose

An important question in conducting licensing assessments will relate to the quality of data used in support of the license application. In addition to reviewing DOE's overall performance assessment and questioning relevance and completeness of data supplied in the license application, the licensing review process must explicitly address the question of whether or not data are of adequate quality.

Quality of data is largely dependent upon the specific data gathering methods and procedures employed. Therefore, in addition to evaluating the technical adequacy of data, data reviews will include the review of data gathering methods and procedures, so the NRC staff can defend its independent recommendations to the licensing board.

It is essential that the review of data gathering methods and procedures begin now, given: (1) the likelihood that data being generated now will be used by DOE in the license application (and all data will be subject to discovery); (2) key investigators currently involved in site investigations may not be available at the time of licensing; and (3) the need to identify potential licensing problems early, so they can be addressed and resolved during the site characterization process thereby avoiding costly delays in DOE's program.

With the volume of information and time required for DOE to document the results of site investigations in a form that can be widely disseminated, it is necessary that the NRC visit the site or facility where the data resides to review data in a timely manner. Data reviews provide such access in accordance with Section 3.c of the 1984 NRC/DOE Site-Specific Procedural Agreement for geologic repository site investigation and characterization programs. They can be conducted separately or in conjunction with technical meetings.

Objectives

Data review objectives may vary with the type of review, nature of data to be examined and current stage in the pre-licensing process. The following list identifies the key objectives.

- To become familiar with the type, amount, and availability of site data. This will assist the staff's assessment of whether data are suitable and acceptable for intended use.

- To become familiar with methods, procedures, or techniques used to collect and reduce data.

- To evaluate data quality and reliability:

  (1) Are the methods, procedures or techniques for collecting or reducing data technically sound?

  (2) Have documented methods, procedures, or techniques for collecting or reducing data been used?

  (3) Is the documentation of methods, procedures, or techniques used to collect or reduce data adequate to permit an independent evaluation of selected data by technical peers not involved in the collection of data?

Nature of Data Reviews

A data review is an examination (by NRC or NRC Contractor personnel) of selected data gathered and/or generated as part of site screening or characterization and of the procedures used to gather and/or generate that information. The term "data" as used in "data review" includes observations made in the field/laboratory and encompasses raw or processed data. Some specific examples of such data include: rock cores; hydrologic head measurements; well logs; material properties, and computer models. Items that may be examined as part of such reviews include field or laboratory note books, equipment, written procedures, experimental lab facilities, ongoing tests, instrumentation and computer codes that have been used to collect, record, process or analyze data.

A data review, when held independently from a technical meeting, is solely an information gathering activity that focuses on the examination of data by technical specialists. These interactions might include orientations and briefings by DOE investigators, but involves no consultation with DOE or DOE Contractors on interpretations, adequacy, or validity of data nor does it review DOE's site characterization program or plans. The purpose of a data review is to provide the NRC with timely access to selected data and supporting information, so that potential licensing problems can be identified early.

An important objective of a data review is NRC's assessment of the quality of data supporting either site investigations or the resolution of specific issues. Data reviews are conducted to gain a familiarity with information generated from site investigations and to assess the quality of selected data. Where problems or concerns with data quality are identified during a data review, they are highlighted along with any recommendations in a follow up

letter to DOE. Potential licensing issues that cannot be resolved at this level may be taken up through joint consultation (i.e, technical meetings) between DOE and NRC, which might include a data review.

How do data reviews relate to technical meetings? Technical meetings address and work toward the resolution of issues. Such meetings may involve the examination and discussion of data as necessary to resolve issues. Data reviews provide access to information needed to identify issues, and assure that data are adequate to resolve them. Due to the number of issues, volume of data, and time constraints involved, data reviews must limit their focus to information judged critical to the resolution of issues. Therefore, data reviews serve a complementary function to technical meetings, and may be conducted either independently, or as part of a technical meeting.

Quality Assurance (QA) and the review of data to assess quality are inseparable. Overlap exists in such areas as documentation of methods and procedures, and verification of the technical adequacy of procedures. While a data review is principally a technical effort, some QA matters will be addressed. Therefore, the NRC technical staff may be accompanied by NRC staff QA specialists (or technical staff with QA training) in order to evaluate issues concerning implementation of the QA program. QA matters will be evaluated against NRC's Review Plan: Quality Assurance Programs for Site Characterization of High Level Waste Repositories.

Ground Rules for Data Reviews that are Conducted Independent from Technical Meetings

1. No consultation with DOE/DOE contractors. Questions may be asked about what they did or how they accomplished an analysis, measurement or survey, but we should avoid discussion or debate about validity of data, interpretations, methods, procedures or future test plans. This rule is necessary to maintain the distinction between meetings and data examination sessions as provided in the DOE/NRC Site-Specific Procedural Agreement.

2. Since there are no formal discussions or presentations during a data review, a schedule should replace the agenda (see enclosure 1 for an example of a well-developed schedule). A generalized list of data or information to be examined will be prepared with the cooperation of the DOE prior to the data review, as outlined in the attached work plan.

3. A close out session may be held at the conclusion of the data review. Any formal comments concerning the material reviewed made to DOE during a close out session should also be provided in writing, signed by the

designated NRC representative, and placed in the PDR. Two weeks after the data review, NRC will transmit a letter to DOE providing a record of information that will be submitted to the PDR. Normally, a letter report to DOE will follow, consolidating all comments of participating NRC staff and contractors. Trip reports by NRC contractors or NRC staff will be forwarded to DOE along with the letter report within two months of the review.

4. Information gathered by NRC (i.e., apart from personal notes) goes into the PDR.

Follow Up Activities

- NRC staff briefing by the data review team.
- NRC forwards comments to DOE on quality and reliability of data as well as methods, procedures, or techniques used to collect/reduce data.

Work Plan to Prepare for, Conduct, and Follow up Data Reviews

Activities	Lead/Support	Start*
1. Establish need for data review and coordinate with RP; check WM travel budget to ensure that adequate funds for the review exist.	FB/RP	8 wks before
2. Transmit letter to DOE requesting data review	RP	7 wks before
o propose review dates.		
o request data catalog, if applicable.		
NOTE: A data catalog is an index describing the type, amount of, and location of data available for review in a particular technical area. Receipt of catalog expected (3) weeks from date of above transmittal.		
o describe general type(s) of data NRC is interested in reviewing.		
3. Notify on-site licensing representative.	RP	7 wks before
4. Schedule and conduct in-house team meeting to develop inter-branch participation and strategy for data review	RP/FB	4 wks before
o determine NRC data review participants.	FB/RP	
o develop schedule and consider logistics.	FB/RP	
Note: The schedule provides the organizational structure of the data review. It outlines the daily sequence of data review sessions, NRC reviewers, and lead responsibility		

*These times represent ideal lead times, circumstances may dictate that this schedule be compressed.

		Lead/Support	Start
	for each. The schedule should be completed early to clarify responsibilities and logistics before the review.		
	o identify or develop data review checklist.	FB	
	Note: A data review checklist is a list of questions designed to record fundamental information about the data examined during the review process. It also serves to establish the institutional memory for the data review. The particular checklist used may vary from general to detailed according to the specific needs of the review team. (see enclosures 2a and 2b for example checklists).		
5.	Establish with DOE/DOE contractor time and place of data review. Discuss any special requirements of site visit (i.e, test demonstration, etc.); ask for any special materials needed in advance of the data review (maps, etc.).	RP	4 wks before
6.	Identify and transmit to DOE specific data to be reviewed by NRC.	FB	3 wks before
	o data we definitely want to see.		
	o data we may want to see.		
	o data we may wish to bring back in hard copy.		
	Note: The technical team selects the data to be reviewed based on knowledge gained from their ongoing review of site investigations. Data reviews should focus on the most critical data associated with key issues.		

		Lead/Support	Start
	In preparing a list of data for review, the NRC staff and contractors should refer to DOE's data catalog, and consult relevant background information including: technical reports, previous trip reports for data reviews and technical meetings, STP's, etc.		
7.	Send DOE data review schedule, checklist, and list of NRC participants with any necessary security clearance information.	RP	3 wks before
8.	Obtain Division Director's approval for travel		3 wks before
	o prepare meeting notification.	RP	
	o submit request for travel authorization with itinerary and make travel arrangements.	FB,RP	
9.	Place conference call to DOE/DOE contractor	RP/FB	2 wks before
	o confirm availability of data and investigators.		
	o finalize logistics and schedule.		
	o address any questions or concerns.		
10.	Schedule NRC/NRC contractor data review preparation meeting. This meeting is generally held in Silver Spring except where time or budget constraints do not permit. If it is necessary for this meeting to be held on site, prior agreement with RP should be obtained. This meeting is <u>essential</u> to ensure that all team members fully understand and accept their responsibilities in accord with the ground rules and agreements under which the data review is being conducted.	FB/RP	1 wk - 1 day before

		Lead/Support	Start
	This meeting should include a brief review of the following items.		
	o nature and scope of data review.		
	o ground rules.		
	o logistics & schedule.		
	o responsibilities.		
11.	Conduct data review.	RP/FB	
	o DOE/DOE contractor introduction.	DOE	
	o NRC introduction: summarize purpose and objective; describe NRC follow up activities; distribute data review package describing purpose and objective of review, NRC WM Division organizational chart (see enclosure 3), data review checklist, and data request sheet (see enclosure 4); introduce NRC technical team leader; review schedule with DOE/DOE contractor.	RP/FB	
	o review selected data or information.	FB	
	Note: There is little time for detailed analyses of data during the review process. Specific data that warrants in-depth analyses may be listed on the data request sheet. Such analyses may be completed at NRC headquarters or NRC Contractors' offices, where adequate time and resources permit a more detailed review.		
	o caucus each day to exchange information, collect checklists and data requests, report progress, consider priorities, and plan for next day.	RP/FB	

		Lead/Support	Start
o	NRC/DOE/DOE contractor "Close Out" session. Note: This session gives participants an opportunity to briefly summarize their impression of the data review. NRC may offer either preliminary or formal reaction to what was reviewed. Any formal comments concerning the material reviewed made to DOE during a close out session should also be provided in writing, signed by the designated NRC representative, and placed in the PDR. NRC's principal comments are normally transmitted as a follow up activity.	RP/FB	
12.	Follow up activities		
o	brief project team on data review (i.e., open to all NRC staff).	FB/RP	1 wk after
o	NRC transmits a letter to DOE listing information submitted to the PDR. This letter briefly summarizes the purpose of the review and includes: attendees list; data reviewed; copies of all data review checklists; data requested by NRC; and general time frame for any subsequent NRC comments.	FB/RP	2 wks after
o	procure requested data and documents.	RP	1 Mth after
o	prepare any NRC comments on data review and forward to DOE. Note: The NRC normally provides DOE with follow up comments. This package consists of a cover letter with enclosures of detailed comments relating to significant observations concerns or deficiences of data reviewed.	FB/RP	2 Mths after

A suggested outline for follow up comments is presented in enclosure 5.

ENCLOSURE 1

NRC DESIGN/ROCK MECHANICS DATA REVIEW SCHEDULE AT SANDIA NATIONAL LABORATORIES (July 18-20, 1984)

July 18 Wednesday		July 19 Thursday		July 20 Friday		
1:00-3:00	3:00-5:30	8:00-11:30	12:30-5:30	8:30-10:00	10:00-11:30	11:30-12:00
1:00 Introductory Remarks J. Szymanski and K. Stablein 1:30 Synopsis - Data and Records Available T. O. Hunter and J. R. Tillerson Bldg. 822/A All NRC and NWMSI and Participants	Rock Mechanics Testing, Lab tour & data [JT] [RP] [BO] (SB) (LM) (PD)(SB 2) (JC) Bldg. 849 Bldg. 823/1020	Mech. Prop. Data [RP] [BO] (SB) (LM) (TS) (JC) (SB 2) Bldg. 823/1020	Mech. Prop. Data [RP] [BO] (SB) (TS) (PP) (JC) (SB 2) Bldg. 823/1020	Rock Classification Data [BL] [FN] (SB) (MC) (EH) (SB 2) Bldg. 823/1020	NRC Reviewers' Conference Session Bldg. 822/A	Data Review Wrap-up K. Stablein and J. Szymanski Bldg. 822/A All NRC and NWMSI Participants
2:30 Finalize Small Group Scheduling and Badging	Core handling & Storage facility lab tour & thermal prop. data [FN] [BS] (MC) (NT) (PP) (LP) Bldg. 672/2 & 4A Bldg. 892/166MB Bldg. 823/4071A	Bulk Prop. Data Data, Thermal Prop. Data [FN] [BS] (EH) (NT) (PP) (LP) Bldg. 823/4424B	Thermal Prop. Data [FN] [BS] (LM) (EH) (NT) (LP) Bldg. 823/4071A	Seismic Data [HM] [LV] (LM) (TS) (PP) (LP) (JC) Bldg. 823/4071A	NRC Participants Only	
	G-Tunnel Rock Characterization-Data (Insitu Stress Data, Borehole Modulus Data) [RZ] [BL] (JD) (TS) (EH) (JG) (KS) Bldg. 823/4255	Small Diameter Heater Test Data [RZ] [BS 2] (JD) (PD) (MC) (JG) (KS) Bldg. 823/4255	Heated Block Test Data [RZ] [BS 2] (JD) (MC) (PD) (JG) (KS) Bldg. 823/4255	(1) Sealing Test Data (8:30-9:30) (2) Overflow data from any other area (9:30-10:00) [JT] [JF] (JD) (NT) (PD) (JG) (KS) Bldg. 823/4255		

NRC Participants:
Paul Prestholt (PP), Thomas Schmitt (TS), Ed Hollop (EH), Lindsey Mundell (LM), Mark Christianson (MC), Swapan Bhattacharya (SB), Susan Billhorn (SB 2) Jaak Daeman (JD), Naiem Tanious (NT), Piyush Dutta (PD) John Greeves (JG), Larry Pittiglio (LP), King Stablein (KS), John Cutler, (JC).

SNL Participants:
Joe Fernandez [JF], Tom Hunter [TH], Brenda Langkopf [BL], Hugh MacDougall [HM], Fran Nimick [FN], Bill Olsson [BO], Ron Price [RP], Barry Schwartz [BS], Joe Tillerson [JT], Luke Vortman [LV], Roger Zimmerman [RZ], Bill Shepherd [BS 2]

ALL UNCLEARED VISITORS MUST REPORT EACH DAY FOR BADGING AT BUILDING 822

ENCLOSURE 2

Reviewer _____
Date _____

GEOLOGY MAP DATA REVIEW CHECKLIST

1. What area does the map cover?

2. What type of map is it? What is the scale?

3. Who did the field work?

4. What is (are) prominent feature(s) shown to date?

5. Why was this mapping project undertaken and when was the map begun/completed?

6. What methods, procedures, or techniques were used to map this area?

7. When is the map to be published? In what publication series? If already published, when and in what document?

Reviewer _____
Date

GEOLOGY FIELD REVIEW CHECKLIST

1. Outcrop/stop identification.

2. Outcrop/stop description.

Additional: Note if known - Has this outcrop/stop been described in the literature? If so, when and by shown?

ENCLOSURE 2b

Reviewer _____

Date _____

Draft Rock Mechanics Data Review Checklist
(Revision, August 6, 1984)

1. Name/type, identification number, and date of test.

1a. What is the overall objective of the test?

1b. What specific parameters are to be determined by the test?

1c. What criteria were used for test site (or sample) selection?

1d. How is the rock at the test site characterized?

1e. How many of these tests have been performed?

1f. How many tests are planned?

1g. Comments.

Reviewer
Date

2. Is the procedure documented and complete, and is it in written form?

2a. Is it a standard (ASTM) procedure? If yes, provide reference.

2b. If non-"standard", how was the procedure developed, reviewed, documented, and approved? For example, COE, USBM, USBR, USGS, NBS, or other (internal) processes.

2c. Have there been revisions and how and when were the revisions reviewed, documented, approved, and implemented?

2d. How are any deviations from the established procedures that occur during testing documented?

2e. Comments.

Reviewer _____
Date _____

3. What instrumentation is used for the test?

3a. How were the reliabilities* of the instruments specified?

3b. Is there a calibration system and were calibrations systematically carried out according to approved procedure?

3c. Are the calibrations traceable to national or industrial standards?

3d. Comments.

* Reliability is defined as the probability of an instrument to perform a stated function under a stated environment for a stated time.

Reviewer
Date

4. What are the data collection, reduction, and presentation techniques involved in collecting analyzing and interpreting the data? (emperical, analytical, numerical)

4a. How can the raw numerical data be retrieved?

4b. Are the data presented in a complete and clear format? (Comment also on the utility of the presentation.)

4c. Are the data keyed to geological, environmental, and other experimental conditions?

4d. Comments.

Reviewer _____
Date _____

5. What are the acceptance/rejection criteria for the test data?

5a. Were these criteria established prior to test development?

5b. How are the criteria implemented? (Data handling, review procedure, corrective action.)

- Data Handling

- Review Procedure

- Corrective Action

Reviewer _____

Date _____

6. General comments (such as, relationship among different tests, impacts on interpretation, instrument redundancy, factors resulting in test closure, accuracy of measurements, limitations, additional uses of data, computer programs, and other miscellaneous comments).

7. Requested Test Data - (Identify all data and documentation that is needed for further review).

ENCLOSURE 3

DIVISION OF WASTE MANAGEMENT

Director
Robert E. Browning
Deputy Director
Michael J. Bell

On-Site Licensing Representatives
BWIP (Cook)
NTS (Prestholt)
SALT (Verma)

REPOSITORY PROJECTS BRANCH (Hiller)	ENGINEERING BRANCH (Barrett)	GEOTECHNICAL BRANCH (Knapp)	POLICY AND PROGRAM CONTROL BRANCH (Bunting)	LOW-LEVEL & URANIUM PROJECTS BRANCH (Higginbotham)
BWIP Projects Section (Kennedy)	Materials Engineering Section (Johnson)	Hydrology Section (Fliegel)	Policy Section (Surmeier)	Low-Level Projects Section (Jackson Acting)
NTS Project Section (Coplan)	Mining, Geoengineering Facility Design Section (Greeves)	Geology/ Geophysics Section (Justus)	Program Planning Section (Altomare)	Uranium Recovery Projects Section (Martin)
SALT Project Section (Linehan)	Rock Mechanics Section (Nataraja)	Geochemistry Section (Starmer)	Integration Section (Kearney)	
Regulation & Environmental Section (Boyle)			Program Control and Analysis Section (Mattson)	

ENCLOSURE 4

DATA REQUEST SHEETS FOR:

PAGE__OF__

DATE:

ITEM NO.	DATA/ITEM REQUESTED	REQUESTED BY	COMMENT

FOLLOW UP COMMENTS FROM A WORKSHOP OR DATA REVIEW

A. Background

After a workshop or data review, the activities and data reviewed are reevaluated by the NRC staff and contractors. As a rule, new insights are developed that are believed constructive to the DOE program. These are sent to the appropriate DOE location as follow up comments.

B. Form of Follow up Comments

The follow-up comments are in a three part package: transmittal letter, attachment with the comments, and supporting material such as contractors' reports.

Transmittal letter. This is developed by RP and is addressed by the NRC project manager to the DOE project manager. It describes the scope and purpose of the review, and highlights the significant comments that may have programmatic impact.

Attachment. The attachment is a stand-alone document developed by FB. While there is no prescribed form, certain contents should be included, viz:

1. Title.
2. Conclusions, up front, emphasizing the main comments and their importance to site investigations. The comments should present the facts of the matter, along with a brief discussion of their importance, and any recommendation for action by DOE. In presenting the comments, it should be remembered that the purpose is to help DOE improve the program to collect imformation needed for licensing.
3. Signatures, at the end, of the lead NRC author(s).
4. Date of authors(s) signature(s).

Supporting material. This should include all contractors' reports arising from the interaction with DOE. In addition, other supporting materials may be included.

C. Timing

To provide effective guidance on a real time basis, follow-up documents should be delivered to DOE within 2 months after the interaction.