



Department of Energy

Washington, DC 20585

JAN 07 1997

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Characterization Project
TRW Environmental Safety Systems, Inc.
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Las Vegas, NV 89109

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-96-D-044 RESULTING FROM OFFICE OF QUALITY ASSURANCE
(OQA) AUDIT YM-ARP-96-07 OF SANDIA NATIONAL LABORATORIES

The OQA staff has verified the corrective action to DR YM-96-D-044 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Stephen D. Harris at (702) 794-5522.

James Blyford Jr

Donald G. Horton, Director
Office of Quality Assurance

OQA:MRD-0571

Enclosure:
DR YM-96-D-044

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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 Performance Report
 Deficiency Report
 DS 71745-D-04
 YMOAB-96-0044
 NO. _____
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: Quality Assurance Requirements and Description, revision 4
 2 Related Report No. YM-ARP-96-07

3 Responsible Organization: Sandia National Laboratory
 4 Discussed With: Michaelc Brady

5 Requirement/Measurement Criteria:
 QARD section 5.2.2D. states in part, "Implementing documents shall include the following information as appropriate to the work to be performed: Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished." QARD section III.2.6A. and III.2.6B. are the specific requirements to be implemented for Model Validation.

6 Description of Condition:
 The Sandia National Laboratory procedure QAIP 2-4, revision 2, references QAIP 1-5, which is in revision 9, for development of a Work Agreement. The Work Agreement, however, does not contain quantitative or qualitative acceptance criteria for implementation of the above QARD requirements. The principal investigator described a process during the audit that appeared to be satisfactory for meeting the needs of model validation for the Geologic Framework Model. The appropriate implementing document needs to reflect the process intended to be used as well as meet the QARD requirements.

7 Initiator *Stephen D. Harris*
 Stephen D. Harris Date 03/01/96
 9 QA Review
 OAR *Stephen D. Harris* Date 3/5/96

10 Response Due Date
 20 working days from issuance
 11 QA Issuance Approval
 OAR (PRI)/AOQAM *[Signature]* Date 3.12.96

12 Remedial Actions:
see page 3

13 Remedial Action Response By:
See pg 3 Date
 14 Remedial Action Due Date
See pg 3 Date

15 Remedial Action Response Acceptance
 OAR *N/A* Date
 16 PR Verification/Closure
 OAR *N/A* Date

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DEFICIENCY REPORT

17 Recommended Actions:

Add quantitative or qualitative acceptance criteria to the Work Agreement to reflect the QARD requirements and the process for Model Validation.

18 Investigative Actions:

See page 3

19 Root Cause Determination:

See page 3

20 Action to Preclude Recurrence:

See page 3

<p>21 Response by: <i>Richard</i> Date <i>4/4/96</i></p>	<p>22 Corrective Action Completion Due Date: <i>May 15, 1996</i></p>
<p>23 Response Accepted QAR <i>Stephen D. Harris</i> Date <i>4/29/96</i></p>	<p>24 Response Accepted AOQAM <i>AC [Signature]</i> Date <i>5/15/96</i></p>
<p>25 Amended Response Accepted QAR <i>N/A</i> Date</p>	<p>26 Amended Response Accepted AOQAM <i>N/A</i> Date</p>
<p>27 Corrective Actions Verified QAR <i>[Signature]</i> Date <i>12/10/96</i></p>	<p>28 Closure Approved by: AOQAM <i>[Signature]</i> Date <i>12/24/96</i></p>

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PR/DR CONTINUATION PAGE

Response to Deficiency Report YMQAD-96-D044

12. *Remedial Actions Work Agreement (WA) 300*, which is the lower-tier WA that directs the performance of the subject model development work, will be revised to address the approach used for model validation and to add qualitative or quantitative criteria (as appropriate) to be used in determining whether the model(s) developed are valid, i.e., model validation activities are successful. For this activity, the model validation approach will consist of verifying that the output is consistent with site data. (Resp. Individ. - L. S. Costin)

18. *Investigative Actions* All other Work Agreements that deal with model development will be reviewed to determine the extent that they meet the requirements for specifying the approach and criteria for the model validation portion of the activity. (Resp. Individ. - R. R. Richards)

19. *Root Cause Determination* In this case, the subject Work Agreement addressed acceptance criteria for the overall activity. However, the criteria for the embedded activity of model validation, as well as the desired approach to be used, were not specified. This indicates that the implementing procedure that guides the process of WA preparation, QAIP 1-5, is understood and was used in this case, but the implementing procedure applicable specifically to model development, QAIP 2-4, was not referred to as the WA was prepared or reviewed. Review of QAIP 2-4 also indicates that the need to specify acceptance criteria in the case of model validation analyses (a specific application of this QAIP) is not addressed.

20. *Action to Preclude Recurrence*

- QAIP 2-4, "Analysis Control and Verification", will be revised to specifically call out the need to establish acceptance criteria for the validation phase of model development in the Work Agreement for the model development activity. (Resp. Individ. - R. R. Richards)
- A QA Advisory will be issued to SNL staff and contractor personnel involved in model development activities in order to highlight the need to specify the approach to be utilized in model validation, as well as the criteria to be applied in determining "validity" of the model, in the governing Work Agreement. (Resp. Individ. - R. R. Richards)
- The checklist used in QA review of Work Agreements will be revised to include a check, for WAs for model development, that the approach to validation and the criteria for validation are included. (Resp. Individ. - R. R. Richards)

22. *(Proposed) Corrective Action Completion Due Date: May 15, 1996*

Remedial Actions: 12.1, Work Agreement 300.

SANDIA NATIONAL LABORATORIES Error! Reference source not found.

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT

WORK AGREEMENT (WA)

WA-0300

Revision 01

Three-Dimensional Rock Characteristics Models

Customer: Laura S. Costin
(L. S. Costin, 6852)

Date: 6/4/96

Supplier: C. A. Rautman
(C. A. Rautman, 6115)

Date: 6/4/96

Supplier: William Zelinski
(W. Zelinski, 6115)

Date: 6/4/96

Supplier: S. McKenna
(S. McKenna, 6115)

Date: 6/4/96

Technical Review: Dill W. Ould

Date: 6/4/96

QA Review: [Signature]

Date: June 4, 1996

(Reviewer signatures above serve to document the review and resolution of comments; Customer and Supplier signatures include comment resolution and approval of the Work Agreement.)

Effective Date: 6/14/96

9666250065

14/11/96

Scope: This Work Agreement establishes responsibilities and interfaces between L. S. Costin (Customer), C. A. Rautman (Supplier and Principal Investigator) and support staff (S. McKenna and W. Zelinski) for activities conducted in support of the three-dimensional rock characteristics models study.

Specifically, the scope of this Work Agreement includes oversight, management of stated resources, and conduct of activities in the following summary accounts for FY96:

WBS #	Upper-Tier WA #	PACS Account #	PACS Account Title	Case #
1.2.3.2.2.2.2	WA-0340	TR3222EB1	Model 2-D and 3-D Thermal and Mechanical Rock Properties	0139.373
1.2.3.2.2.2.2	WA-0340	TR3222EB2	Model 2-D and 3-D Hydrologic Rock Properties	0139.372

Objective: The objective of the work prescribed by this Work Agreement is to conduct geostatistical and geometric modeling of thermal and mechanical properties, and hydrologic properties for a variety of purposes. Work will include:

- compilation and evaluation of available rock-property measurements and similar data;
- compilation and evaluation of available geologic and geometric information;
- integrate rock properties data with geologic/geometric information into an integrated site model;
- statistical and spatial continuity analyses of data;
- generation of appropriate geometrical and geostatistical models;
- validation of the geometrical and geostatistical models by verifying that the output is consistent with site data; and
- support writing of data synthesis reports.

The following models will be developed. Models will be validated by verifying that the output is consistent with site data.

1. Porosity and bulk density model(s) of the Topopah Spring Tuff for the extended site area, or as much of that region as the data allow. The "extended site area" is defined roughly as extending from the vicinity of Yucca Wash south to the latitude of drill holes WT-11 and WT-12, and from Windy Wash east to Fortymile Canyon.
2. Porosity and bulk density model(s) of the Calico Hills Formation and Prow Pass Tuff for the extended site area, or as much of that region as the data allow.
3. Thermal conductivity model(s) of Topopah Spring Tuff for the central repository block area.
4. Matrix saturated hydraulic conductivity model(s) of the Topopah Spring Tuff for the extended site area, to the extent that the data allow modeling of this region.
5. Geostatistical modeling of rock properties to support LBL site-scale unsaturated zone hydrologic model and SNL performance assessment activities.

Tasks: Tasks and responsibilities included in this Work Agreement are described in the matrix below.

Responsibility Matrix

RESPONSIBLE PERSON	SUPPORT	TASK DESCRIPTION
C. A. Rautman	W. Zelinski S. McKenna	Task 1: Develop computer-based 3-D models that <ul style="list-style-type: none"> • integrate site geologic information • integrate quantitative data on rock characteristics • include compilation/evaluation of rock properties data • include borehole geophysics data • validation of models using site data
C. A. Rautman	W. Zelinski S. McKenna	Task 2: Support writing of rock properties, geotechnical and geophysical data synthesis and other reports.
C. A. Rautman		Task 3: Provide technical oversight, management of resources, and interface/information exchange with M&O management and other organizations as needed.

Interfaces: As part of Task 3, technical interfaces will be maintained with USGS and SNL PIs responsible for thermal, mechanical, and hydrological properties testing. The supplier will also maintain an interface relationship with the M&O Office Manager for these activities. Internal management issues (personnel assignments, subcontracts, etc.) will be jointly addressed with the customer as part of the responsibilities delegated under upper-tier WA-0340.

Quality Assurance Controls: The work defined in this Work Agreement is related to Site Characterization/Performance Assessment. The following matrix lists the QA procedures that are determined to be applicable to the work defined within this Work Agreement, and identifies the parties in this Work Agreement responsible for complying with the controls. (Note that this table does not replace QAIP 2-5 training assignments).

QA Procedure Matrix

PROCEDURE #	DESCRIPTION	CUSTOMER	SUPPLIER
QAIP 1-5	Establishing Work Agreements	X	All*
QAIP 2-5	Training	X	
QAIP 2-6	Qualification and Certification of Personnel	X	
QAIP 4-1	Procurement		Rautman
QAIP 6-2	Reviewing, Approving, and Issuing Technical Documents	X	All
QAIP 6-3	Conducting Document Reviews	X	All
QAIP 17-1	Protecting, Preparing, and Submitting YMP QA Records		All
QAIP 19-1**	Software Quality Assurance		All
QAIP 20-2	Scientific Notebooks		All
APQ-16.1Q	Performance/Deficiency Reporting	X	All
APQ-16.2Q	Corrective Action and Stop Work	X	All

* "All" indicates that procedure applies to all suppliers named in this WA.

** Procedure may apply after QARD Rev. 5 is implemented. Under QARD Rev.4 Procedure is not required.

No hold points or quality verification points are defined for this work. QA surveillances and process checks included in procedural controls are used to verify quality

Readiness Review Prerequisite: Not Applicable.

Records: The QA records generated by activities described in this Work Agreement result from implementing the QA procedures in the preceding matrix. Completed records will be reviewed, authenticated, and submitted to the SNL YMP Records Center by the Supplier. The file code(s) to be used for records packages resulting from work in this WA is YMP:1.2.3.2.2.2:WA-0300:XX:YY, where XX is either QA or NQ and YY is a descriptor for the record (see NWMC File Code, 4/7/95). Records related to the production, review, and approval of a formal report (SAND or SLTR) will be filed under code YMP:1.2.3.2.2.2:PUB:XX:(SAND# or SLTR#).

Deliverables: Report input and records shall be completed and transmitted in accordance with the deliverable dates in the Project Baseline as modified by the SNL Basis of Estimate and identified on the following matrix.

Deliverables Matrix

<u>RESPONSIBILITY</u>	<u>DESCRIPTION</u>	<u>MILESTONE LEVEL</u>	<u>DUE DATE</u>
C. A. Rautman	Submit letter with attachments to M&O Office Manager containing input on 2-D and 3-D hydrologic rock properties modeling for inclusion into site geotechnical report, and use in other performance assessment models.	4	5/15/96
C. A. Rautman	Submit letter with attachments to M&O Office Manager containing input on 2-D and 3-D thermal and mechanical rock properties for inclusion into site geotechnical report, 3D geologic framework model, and use in other performance assessment models.	4	3/15/96
C. A. Rautman	Submit letter with attachments containing integrated site model to M&O Office Manager in support of M&O Level 3 milestone.	Supports Level 3 Milestone	6/3/96

Other Customer Requirements: The Supplier will provide weekly technical status updates to the Customer, as well as input to monthly cost and schedule updates. The Supplier is responsible for identifying, developing, and issuing all lower-tier Work Agreements necessary to support the conduct of the work and deliverables described.

All personnel participating in the work described in this Work Agreement are responsible for complying with all safety, ES&H, and other requirements.

Schedule: The schedule and due dates for the activities described in this Work Agreement are identified in the Deliverables matrix. Additional information may be obtained from the Project and Control System.

Budget: The estimated budget for this effort is \$239,139.

Training: Personnel assigned to this Work Agreement shall be qualified to QAIP 2-6 and trained to the appropriate procedures as identified in the QA Procedure Matrix and in accordance with QAIP 2-5 as assigned by the Task Manager (see WA-0340).

Acceptance Criteria: The work shall be accepted as complete when the three deliverables defined in the matrix above are delivered to the M&O Office Manager and associated records packages have been submitted to the SNL local records center. The submittals must meet the criteria established for the deliverables in the Participant Planning Sheets (kept on file in the SNL project control office.)

YUCCA MOUNTAIN SITE
CHARACTERIZATION
PROJECT

Sandia
National
Laboratories

Rationale for Revision

Document No.: WAD 300 Rev. No.: 1 Effective Date: 6/14/96

Document Title: Three-Dimensional Rock Characteristics Models

ICN Nos. That Are Incorporated: N/A

Change No. 1 pg(s) 2/6 Sect/Subset Step No.(s) objective/workscope

Description (Briefly describe the change):
add statement to address approach for model validation.

Rationale (Provide justification including the source causing the change, e.g., QAPD change, SDR, etc):

Response to Efficiency Report YMCAD-96-0044

Change No. _____ pg(s) _____ Sect/Subset Step No.(s) _____

Description:

Rationale:

Change No. _____ pg(s) _____ Sect/Subset Step No.(s) _____

Description:

Rationale:

(Locate this page on the reverse side of the document cover page.)

**Investigative Actions: 18.1, Memo from R. Richards to
M. Brady, dated 5/30/96.**

date: May 30, 1996

to: Michael C. Brady, 6850, M/S 1399

QA:



from: R. R. Richards, 6812, M/S 1333

subject: Investigative Action for Deficiency Report (DR) YMQAD-96-D044 Concerning Model Validation

The subject DR included an investigative action as follows, "All other Work Agreements (other than WA-300) that deal with model development will be reviewed to determine the extent that they meet the requirements for specifying the approach and criteria for the model validation portion of the activity." I have completed that evaluation; the results are presented in the attachment to this memo.

This evaluation, together with reviews of reports concerning model application and validation done for the Burn-up Credit effort, made clear to me that there is a wide conceptual difference between how our investigators think about validation and the concept behind the cited DR. The concept (and requirements) embodied in the DR is that to determine that a mathematical model is "valid" (i.e., an adequate representation of actual physical phenomena), some specific criteria must be applied in the comparison of the model output to real-world data. That, in turn, implies that those criteria be established before the comparison is made. This approach to model validation seems rigorous and reasonable, being a specific application of the concept of determining if something is "good enough" or "meets specifications" by comparing to a standard.

However, the idea of using criteria in determining whether a model is valid for a given purpose is not a concept that is readily and inherently applied by our investigators, if the text of the evaluated Work Agreements is any indication. As the attached results show, the existing approach to validating models is uniformly different in practice than the concept embodied in the DR (which arises from QARD requirements). That suggests either that the concept embodied in the DR is not appropriate for validation (although we ought to establish why the existing practice can be considered rigorous enough), or that we should take some action to cause our investigators to be more structured and demanding in their validation efforts.

copy to:

M/S 1326	H. A. Dockery	6851
M/S 1325	L. S. Costin	6852
M/S 1333	C. P. Jaramillo	6812

Model Validation Approach and Criteria

An evaluation was made of existing Sandia National Laboratories Work Agreements for activities supporting the Civilian Radioactive Waste Management Program. This evaluation was performed as investigative action arising from Deficiency Report YMQAD-96-D034. Specifically, the investigative action portion of that Deficiency Report states that , "All other Work Agreements (other than WA-300) that deal with model development will be reviewed to determine the extent that they meet the requirements for specifying the approach and criteria for the model validation portion of the activity."

The results of the evaluation are shown below. The Work Agreements (WAs) listed are those currently active* WAs that involve model development in some way, except for WA-300.

WA Number	WA Title	Comments
040, rev. 2	Development and Validation of Flow and Transport Models	Activity includes 3 main activities that are said to involve model devel. and validation. The work description covers data generation in detail, is sketchy on model development efforts, and silent on validation approach. No validation criteria are provided.
106, rev. 4	Numerical Climate Model Validation	Approach to validation well described. No specific criteria stated (or intended); desired result was to simply state the qualitative comparison between model results and data.
119, rev. 2	Empirical Model of Ground Motions from Underground Nuclear Explosions	Activity is wholly devoted to development of a model for ground motion prediction. Validation not addressed (may have been intended to be covered in another WA that was never developed).
132, rev. 0	Conduct Studies to Support Calculations of Ground Water Travel Time	Activity involves model development. Approach to validation is either absent or unclearly stated (step 7 of sec. 9?). No criteria specified for validation.
165, rev. 0	Analysis Code Validation	Validation approach not clearly described; no criteria for successful validation are specified.
166, rev. 0	Numerical Validation of Rock-mass Thermal Expansion, Stiffness, and Strength	Approach to validation specified for all 3 parameter models. However, no criteria for determining that the models are 'valid' are specified.

* "Active" in this sense means that the WA remains open as a controlled document. In several cases, the work is complete, or otherwise ended.

181, rev. 0 Enhance Groundwater Travel Time (GWTT) Modeling Capabilities

Activity calls for enhancing existing models, then using the models for analysis of GWTT. No validation actions are included.

192, rev. 0 Develop Bounding Representations of Unsaturated Fracture Flow

Activity includes modifying or enhancing existing models. 'Validation' not addressed, per se. However, 'evaluation' of models, via benchmark analysis comparisons required; no criteria for these comparisons is specified.

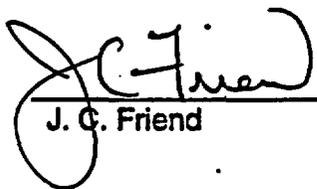
**Action to Preclude Recurrence:
20.-1, Copy of QAIP 2-4.**

**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 2-4**

CONDUCTING AND DOCUMENTING ANALYSES/CALCULATIONS

Revision 03

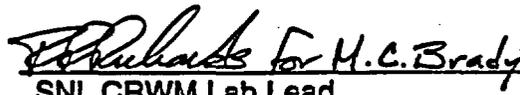
Effective Date: June 30, 1996

Author: 
J. C. Friend

Date: 5/2/96

Concurrence: 
QA Reviewer

Date: 4/22/96

Approval:  for M.C. Brady
SNL CRWM Lab Lead

Date: 5/30/96

M.C. Brady approval signature on faxed copy of this page in Document Control Records

~~9606250070~~

7 pp.

REVISION HISTORY

REVISION

REVISION HISTORY

- 00 Total revision to shorten the analysis process. Revised to address new QARD requirements and to simplify the procedure.
- 01 Add a requirement to document the use of models, clarify wording, and revise references. Revised to address QARD requirements not totally covered and update references.
- 02 Combine the requirements of QAIP 3-10 with this procedure to clarify performing and documenting calculations. Revised as a response to SNL CAR 94-38.
- 03 Total Revision. Revised to incorporate the requirements of QARD Rev. 5 with regard to model development and use. Added clarification of documentation requirements. Per resolution of Deficiency Report YMQAD-96-DO44, clarified that qualitative or quantitative acceptance criteria must be specified for model validation. Revised the QA records section to change the name of the records organization and to add scientific notebooks and DRCs as records. Revised the references.

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1.0 PURPOSE

The purpose of this procedure is to identify actions needed for conducting and documenting analyses and calculations, including the development and use of models.

2.0 SCOPE

This procedure applies to scientific and engineering analyses and mathematical calculations performed by or for Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) activities.

3.0 DEFINITIONS

Model: A system of postulates, data, and inferences presented in a mathematical description of a physical phenomena.

Model Validation: The process that demonstrates that the model is an acceptable representation of the process or system for which it is intended.

4.0 PROCEDURE

4.1 Model Selection, Development, and Use

Responsible Individual(s)	Step	Procedure
Principal Investigator (PI)	1	Shall identify model to be used and justify its selection in the WA or require in the WA that the Analyst shall document model to be used and justify its selection in the analysis documentation.

4.0 PROCEDURE

4.1 Model Selection, Development, and Use (continued)

Responsible Individual(s)	Step	Procedure
Analyst	2	Reviews WA controlling model development or analysis. If WA does not exist, requests PI to initiate WA according to QAIP 1-5.
	3	Shall document the selection and determination of suitability of any input data and model(s) to be used in the analysis. Ensure that these data are adequately identified to provide traceability, indicate usability, and indicate document data validation status for model development.
	4	Shall identify the principal lines of investigation considered.
	5	Validates the model by comparing the results against the following sources: a. data acquired from laboratories b. data acquired from field experiments c. natural analogue studies d. observations that were not used in the original development of the model. To ensure that model validation has been satisfactorily accomplished, appropriate qualitative or quantitative acceptance criteria must be applied in comparing analysis results with sources listed above. If such criteria were not provided in the WA, document the criteria used in the analysis documentation.
	6	Documents validation results and justification to ensure that the model represents actual physical phenomena to a degree of detail commensurate with the intended use.
	7	When data are not available from the above sources, alternate approaches used for validation shall be documented. If a Peer Review is selected as an alternate approach, it shall be conducted in accordance with QAIP 3-12.

Continued on next page

4.0 PROCEDURE

4.1 Model Selection, Development, and Use (continued)

Responsible Individual(s)	Step	Procedure
Analyst	7 cont.	<p>Note: For calculations that the analyst considered routine (e.g., hand calculations or those readily performed on a non-programmable hand calculator), consider the appropriateness of assumptions, input data, and the calculation method used. Check the results through:</p> <ul style="list-style-type: none"> (a) Separate independent calculations using the same or different analytical methods as the original calculations, or (b) A check of the calculational steps in the original calculations, or (c) A spot or random check of the original calculations.

4.2 Performance, Documentation, and Review of Analysis

Responsible Individual(s)	Step	Procedure
Analyst	1	Conducts analyses to requirements specified in a Work Agreement (WA).
	2	Documents the conduct and results of the analysis/calculation. Should use a scientific notebook (prepared in accordance with QAIP 20-2) to document the conduct and results of analysis, or ensure that the records meet documentation and review criteria of QAIP 20-2.
	3	Analysis documentation shall provide sufficient detail to allow verification of the analysis and confirmation of results by an independent, qualified reviewer.
	4	Submits analysis documentation for technical review and documents the results in accordance with QAIP 20-2.
	5	Submits analysis and review documentation to the SNL CRWM Local Records Receiving Organization in accordance with QAIP 17-1.

5.0 RECORDS

QA records, including corrections and changes thereto, generated as a result of implementing this QAIP shall be prepared and submitted to the SNL CRWM Local Records Receiving Organization in accordance with Procedure 17-1, "Protecting, Processing, and Submitting CRWM QA Records," and the "SNL NWM File Code."

The QA records, record package segments, and record packages include:

- a. Analysis and review documentation, i.e., the scientific notebook(s) for the analysis.
-

6.0 REFERENCES

QAIP 1-5 Establishing Work Agreements
QAIP 3-12 Peer Reviews
QAIP 17-1 Protecting, Preparing, and Submitting CRWM QA
Records
QAIP 20-2 Scientific Notebooks

20.-2, Copy of QA Advisory.

Ym-96-D-044

SNL Civilian Radioactive Waste Management

Quality Assurance Advisory

May 3, 1996
WBS: 9.1.3.2
QA:

Model Development, Validation, and Use in Analysis

The processes of model development and validation and the use of those models for analysis are extremely central to Site Characterization and Performance Assessment activities. As you would expect, these topics are addressed in the Office of Civilian Radioactive Waste Management "QA Requirements and Description;" those requirements are stated toward the end of this advisory, for your information. You will note that it is a fairly short set of requirements. Nevertheless, some of those requirements deserve emphasis. Some key points are:

- The preferred approach for validation is to compare analysis results using the model with data gathered in the lab, field, or in natural analogue studies.
- If that is not feasible, the investigator performing model validation can devise an alternative approach (such as benchmarking against another model of the same or similar phenomena, peer review, etc.). Whatever approach is used must be documented, however (adequately enough to permit reproduction of the results by others). The approach to be used should either be specified in the Work Agreement (QAIP 1-5) which governs the work, or, if left to the discretion of the investigator, be described in the Scientific Notebook (QAIP 20-2) in which the validation process and results are documented.
- Note paragraph D in the requirements, below. In addition to requiring the use of models to be documented, it also calls for the selection of the specific model used to be justified. That would best be done in the Scientific Notebook in which the analysis is documented; it may additionally be included in any report which provides the results of the analysis.
- In model validation, in order for a mathematical model to be determined to be "valid" it must meet some quantitative or qualitative criterion (or criteria) established by the investigator prior to the conduct of the validation activity. These criteria must be specified in the Work Agreement that governs the validation activity, or, as a minimum, in the Scientific Notebook that documents the activity. Such criteria might be that "the model validation analysis results agree with field data within (some percent or absolute value) over the range of the model application," or that "all members of the peer review panel can reach consensus that the model appropriately depicts the natural phenomenon in question." Mention of the criteria in any technical report that results from the activity would also be appropriate.

I hope that these explanations concerning model development, validation, and use are helpful to the practitioners of that magical art. I also encourage you to refer directly to the QAIPs most closely associated with such work, QAIP 2-4 for conduct of analyses and QAIP 20-2 for

documentation of scientific investigation activities (including model development, validation and use in analysis).

The Office of Civilian Radioactive Waste Management "QA Requirements and Description," which provides our customer's requirements and expectations concerning quality assurance in Yucca Mountain Project and Waste Acceptance, Storage, and Transportation activities, states the following with respect to development and validation of models:

A. The development of models of natural phenomena shall be documented. Documentation shall identify the principal lines of investigation considered.

B. Models of natural phenomena shall be validated to confirm that the mathematical representation appropriately depicts the natural phenomena.

C. Model validation shall be accomplished by comparing analysis results against data acquired from the laboratory, field experiments, natural analogue studies or observations that were not used in the original development of the model.

1. When data are not available from these sources, alternative approaches shall be documented and used for model validation.

2. The need to perform a peer review as an alternative approach shall be consistent with consideration criteria specified for peer review in section 2.0 (of the QARD).

D. The selection and use of models of natural phenomena shall be documented and justified."

Finally, if you have questions about the application of the QA program in model development, validation, or use, please contact me at 848 0786.



Robert R. Richards
Manager, Nuclear Waste Mgmt. QA Dept.

Distribution:

(Please distribute to the appropriate persons within your department)

- MS-1399 M.C. Brady, 6850
- MS-1399 F. J. Schelling, 6853
- MS-1325 L. S. Costin, 6852
- MS-1324 P. B. Davies, 6115
- MS-1326 H. A. Dockery, 6851
- MS-1330 S. Sharpton, 6752
- MS-1333, R. R. Richards, 6812
- YMP:9.1.3.2:QAP:QA:QA Advisory
- YMP RPC

20.-3, QA Checklist for reviewing WAs.

YM-97-D-44
94

From: Robert R. (Bob) Richards
To: tfhrho, cpjaram, jcfrien
Subject: QA Checklist for WA Reviews.

I believe I have given the attached checklist to you before and orally asked you to use it during reviews of Work Agreements, but let me make it official.

When performing reviews of Work Agreements, use this checklist to supplement the criteria provided in QAIP 6-3, to enhance the thoroughness and value of your review.

Thank you.

Bob

YM-96-D-044

Mail Envelope Info: (317526B9.5FA : 15 : 24487)

Subject: QA Checklist for WA Reviews
Creation Date: 4/17/96 11:13am
From: Robert R. (Bob) Richards

Created By: NWER.NWMC:rrricha

Recipients	Action	Date & Time
Post Office NWER.NWMC	Delivered	04/17/96 11:14am
cpjaram (Claudette P. Jaramillo)		
jcfrien (John C. Friend)		
tfehrho (Thomas F. Ehrhorn)		

Domain.Post Office	Delivered	Route
NWER.NWMC	04/17/96 11:14am	NWER.NWMC

Files	Size	Date & Time
CKLST_WA.DOC	12800	03/25/96 09:27am
MESSAGE	340	04/17/96 11:13am

Options

Auto Delete:	No
Expiration Date:	None
Notify Recipients:	Yes
Priority:	Normal
Reply Requested:	No
Return Notification:	None

Concealed Subject:	No
Security:	Normal

To Be Delivered:	Immediate
Status Tracking:	Delivered & Opened

Checklist for QA Review of Work Agreements

First, review to ensure that WAs adhere to the content requirements of QAIP 1-5.

Second, apply the criteria for QA review, to the extent that they apply, from the back of the DRC form.

Beyond that, check:

- That the front sheet title heading refers to "Civilian Radioactive Waste Management," rather than to "Yucca Mountain Project."
- That the text at the bottom of the cover page reads, "Reviewer signatures...Customer and Supplier signatures *indicate* comment resolution and *commitment to the content* of the Work Agreement." (Italics added to emphasize text that may be different than what you get to review.)
- That, generally CRWM (or nothing) is used in the text instead of YMP. (Although certain topics are indeed YMP-specific, like Site Performance Assessment, and certain others are WAST-specific, like burn-up credit, so those acronyms may be appropriate in such cases.)
- For upper-tier WAs, that the Acceptance Criteria section include mention of timely response to and corrective actions for QA deficiency documents as a performance-measurement criterion.
- For lower-tier WAs, that the Training Assignment section not include a requirement for training on the WA itself (unless the customer has a strong, overriding need for such training to be done and an effective way to do it).
- For certain lower-tier WAs, that the Acceptance Criteria section covers all that is necessary. ~~Most of them will mention acceptance criteria for any technical-report-type products/deliverables, which is fine.~~ However, some work requires more in the way of acceptance criteria; for example, model validation requires qualitative or quantitative criteria to be used in determining if the model is, in fact, valid. Similarly, data collection efforts deserve to have criteria established to determine when or whether the objectives of the work have been met.
- For lower-tier WAs in particular, that the Records section clearly require that the records generated by the work be submitted to the Local Records Receiving Org., including records associated with closing out the work. The frequency of records submittal should also be specified (e.g., as soon as

authenticated, quarterly, upon completion of each Sci. Notebook binder, upon task completion, etc.) The frequency should be such that records are captured into the RMS in a timely manner and that a large quantity of records is not left to be submitted during close-out of the work.

- For lower-tier WAs for scientific investigation work, which includes analysis, that the frequency of technical review of the Scientific Notebook(s) is specified (daily, monthly, quarterly, or whatever based on the pace of the work).

Amended Response to Deficiency Report YMQAD-96-D044

12. Remedial Actions Work Agreement (WA) 300, which is the lower-tier WA that directed the performance of the subject model development work, was revised to address the approach used for model validation and to add qualitative or quantitative criteria (as appropriate) to be used in determining whether the model(s) developed are valid, i.e., model validation activities are successful. For this activity, the model validation approach consists of verifying that the output is consistent with site data. (Resp. Individ. - L. S. Costin) **Completed.**

18. Investigative Actions All other Work Agreements that deal with model development were reviewed to determine the extent that they meet the requirements for specifying the approach and criteria for the model validation portion of the activity. (Resp. Individ. - R. R. Richards) **Completed.**

19. Root Cause Determination In this case, the subject Work Agreement addressed acceptance criteria for the overall activity, but the criteria for the embedded activity of model validation, as well as the desired approach to be used, were not specified. This indicates that the implementing procedure that guides the process of WA preparation, QAIP 1-5, is understood and was used in this case. However, review of QAIP 1-5 shows that it is not specific about inclusion of adequate process detail in WAs. Review of QAIP 2-4 also indicates that, in the case of model validation analyses (a specific application of this QAIP), the need to describe or specify the approach to be used and to specify acceptance criteria for successful validation is not addressed.

20. Action to Preclude Recurrence

- QAIP 2-4, "Analysis Control and Verification", has been revised to specifically call out the need to establish acceptance criteria for the validation phase of model development in the Work Agreement for the model development activity. **Completed.**
- QAIP 1-5, "Work Agreements," will be revised to call either for the inclusion of process detail in individual lower-tier Work agreements, or for a specification in lower-tier WAs that the process detail must be addressed (specified or described) in the documentation resulting from the work (e.g., in Scientific Notebooks). Additionally, it will be further revised to require that technical reviewers check that apparently adequate process detail is either included in the WA or required in the documentation which will result from the work. (Resp. Individ. - R. R. Richards)
- A QA Advisory was issued to SNL staff and contractor personnel involved in model development activities in order to highlight the need to specify the approach to be utilized in model validation, as well as the criteria to be applied in determining "validity" of the model, in the governing Work Agreement. **Completed.**
- An additional QA Advisory will be issued pointing out the need and rationale for process detail in technical implementing documents. (Resp. Individ. - R. R. Richards)
- The checklist used in QA review of Work Agreements has been revised to include a check, for WAs for model development, that the approach to validation and the criteria for validation are included. **Completed**

22. (Proposed) Corrective Action Completion Due Date: November 15, 1996

9/24/96 Brady & Spence

Attachment to SNL letter, Brady to Spence, subject: Submittal of Amended Response for Deficiency Report YMQAD-96-D044

YMQAD letter # YMQAD:RBC-2000 offered a number of items, identified by bullets, as being appropriate in order to resolve the situation stated in the letter. The SNL amended response to the subject DR addresses some of those items; others are not addressed, for appropriate reasons, as described below:

1. First bullet - The concept behind this item is included in the amended response in that we have committed to revising QAIP 1-5, rather than QAIP 2-4. The effect will be that process detail in technical implementing documents will be addressed for all SNL technical work that is subject to the QA Program, not just work in the specific area of model validation.
2. Second and third bullets - No actions which call for revision of WA-300 are included in the amended response because the work governed by that WA is complete. Since there will be no further work implemented in accordance with WA-300, there is no value in revising that WA.
3. Fourth bullet - This issue is not addressed in the amended response. At the mutual agreement of SNL and the QAR, this issue is being addressed via a separate SNL deficiency document (SNL-96-D009), in order to not encumber resolution of DR YMQAD-96-D044 with the moderately complex situation identified by the cited investigation.
4. Fifth bullet - The amended response commits to issuing a QA Advisory addressing the topic of process detail in technical implementing documents.
5. Sixth bullet - The amended response commits to further revising QAIP 1-5 to require that technical reviewers of WAs verify that adequate process detail is included.

YM-96-D-044



**Sandia National Laboratories
YMP Quality Assurance**

**To: Steve Harris
Company: YMQAD
Phone: 702.794.5522
Fax: 702.794.1328
Date: 11/27/96**

**From: Joe Schelling
Company: SNL 6850
Phone: 505.848.0643
Fax: 505.848.0739
Pages: 9**

1-19196 e9<

Comments:

Steve

Here are copies of objective evidence you asked for to close YMQAD-96-D044, including:

- 3/3/96 QA Advisory re Model Development, Validation, and Use In Analysis
- 3/25/96 Checklist for QA Review of Work Agreements
- 11/15/96 QA Advisory Process Detail
- Pages 1, 3, 7, and 9 of QAIP 1-5, Rev. 11 highlighting changes made per the DR (A full copy of the procedure was mailed 12/4 to Don Horton, attn:D. J. Harris, entitled "Completion of Corrective Actions for Deviation Report YM-96-D080."

Let me know if there is any other information you need. Thanks. Joe

Ym-96-D-044

SNL Civilian Radioactive Waste Management

Quality Assurance Advisory

May 3, 1996
WBS: 9.1.3.2
QA:

Model Development, Validation, and Use in Analysis

The processes of model development and validation and the use of those models for analysis are extremely central to Site Characterization and Performance Assessment activities. As you would expect, these topics are addressed in the Office of Civilian Radioactive Waste Management "QA Requirements and Description;" those requirements are stated toward the end of this advisory, for you information. You will note that it is a fairly short set of requirements. Nevertheless, some of those requirements deserve emphasis. Some key points are:

- The preferred approach for validation is to compare analysis results using the model with data gathered in the lab, field, or in natural analogue studies.
- If that is not feasible, the investigator performing model validation can devise an alternative approach (such as benchmarking against another model of the same or similar phenomena, peer review, etc.). Whichever approach is used must be documented, however (adequately enough to permit reproduction of the results by others). The approach to be used should either be specified in the Work Agreement (QAIP 1-5) which governs the work, or, if left to the discretion of the Investigator, be described in the Scientific Notebook (QAIP 20-2) in which the validation process and results are documented.
- Note paragraph D in the requirements, below. In addition to requiring the use of models to be documented, it also calls for the selection of the specific model used to be justified. That would best be done in the Scientific Notebook in which the analysis is documented; it may additionally be included in any report which provides the results of the analysis.
- In model validation, in order for a mathematical model to be determined to be "valid" it must meet some quantitative or qualitative criterion (or criteria) established by the investigator prior to the conduct of the validation activity. These criteria must be specified in the Work Agreement that governs the validation activity, or, as a minimum, in the Scientific Notebook that documents the activity. Such criteria might be that "the model validation analysis results agree with field data within (some percent or absolute value) over the range of the model application," or that "all members of the peer review panel can reach consensus that the model appropriately depicts the natural phenomenon in question." Mention of the criteria in any technical report that results from the activity would also be appropriate.

I hope that these explanations concerning model development, validation, and use are helpful to the practitioners of that magical art. I also encourage you to refer directly to the QAIPs most closely associated with such work, QAIP 2-4 for conduct of analyses and QAIP 20-2 for

documentation of scientific investigation activities (including model development, validation and use in analysis).

The Office of Civilian Radioactive Waste Management "QA Requirements and Description," which provides our customer's requirements and expectations concerning quality assurance in Yucca Mountain Project and Waste Acceptance, Storage, and Transportation activities, states the following with respect to development and validation of models:

A. The development of models of natural phenomena shall be documented. Documentation shall identify the principal lines of investigation considered.

B. Models of natural phenomena shall be validated to confirm that the mathematical representation appropriately depicts the natural phenomena.

C. Model validation shall be accomplished by comparing analysis results against data acquired from the laboratory, field experiments, natural analogue studies or observations that were not used in the original development of the model.

1. When data are not available from these sources, alternative approaches shall be documented and used for model validation.

2. The need to perform a peer review as an alternative approach shall be consistent with consideration criteria specified for peer review in section 2.0 (of the QARD).

D The selection and use of models of natural phenomena shall be documented and justified."

Finally, if you have questions about the application of the QA program in model development, validation, or use, please contact me at 848 0786.

Robert R. Richards
Manager, Nuclear Waste Mgmt. QA Dept.

Distribution:

(Please distribute to the appropriate persons within your department)

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- MS-1330 S. Sharpton, 6752
- MS-1333, R. R. Richards, 6812
- YMP:9.1.3.2:QAP:QA:QA Advisory
- YMP RPC

Ym-96-D-14

Checklist for QA Review of Work Agreements

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- That, generally CRWM (or nothing) is used in the text instead of YMP. (Although certain topics are indeed YMP-specific, like Site Performance Assessment, and certain others are WAST-specific, like burn-up credit, so those acronyms may be appropriate in such cases.)
- For upper-tier WAs, that the Acceptance Criteria section include mention of timely response to and corrective actions for QA deficiency documents as a performance-measurement criterion.
- For lower-tier WAs, that the Training Assignment section not include a requirement for training on the WA itself (unless the customer has a strong, overriding need for such training to be done and an effective way to do it).
- For certain lower-tier WAs, that the Acceptance Criteria section covers all that is necessary. ~~Most of them will mention acceptance criteria for any technical-report-type products/deliverables, which is fine. However, some work requires more in the way of acceptance criteria; for example, model validation requires qualitative or quantitative criteria to be used in determining if the model is, in fact, valid. Similarly, data collection efforts deserve to have criteria established to determine when or whether the objectives of the work have been met.~~
- For lower-tier WAs in particular, that the Records section clearly require that the records generated by the work be submitted to the Local Records Receiving Org., including records associated with closing out the work. The frequency of records submittal should also be specified (e.g., as soon as

7m-96-D-044

authenticated, quarterly, upon completion of each Sci. Notebook binder, upon task completion, etc.) The frequency should be such that records are captured into the RMS in a timely manner and that a large quantity of records is not left to be submitted during close-out of the work.

- For lower-tier WAs for scientific investigation work, which includes analysis, that the frequency of technical review of the Scientific Notebook(s) is specified (daily, monthly, quarterly, or whatever based on the pace of the work).

4m-96-D-04

SNL Civilian Radioactive Waste Management

Quality Assurance Advisory

November 15, 1996

WBS: 9.1.3.2

Including "Process Detail" in Implementation Documents

QA:

The objective of this QA Advisory is to point out the need and rationale for including sufficient "process detail" in implementation documents used on Civilian Radioactive Waste Management Program work.

Definitions:

Implementing documents: documents used to plan, direct, and guide work, and which implement the QA Program. At SNL, these include Work Agreements, Technical Procedures, QA Implementing Procedures, and that part of Scientific Notebooks that specifies how an investigation is to be carried out.

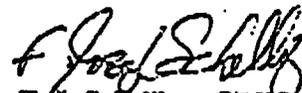
Process detail: the inclusion of enough detail concerning the actions to be performed that the individuals who will use an implementation document can carry out those actions without the author of the document being present to explain or elaborate on what is to be done.

At SNL, process detail has been purposely minimized in most procedural implementation documents. The philosophy is that this provides the user more flexibility in performing the work and minimizes revisions, while ensuring that the underlying requirements being implemented by the document are satisfied. However, it is important that these documents include an appropriate degree of process detail.

After all, their purpose is to direct or guide the work in a manner that ensures satisfactory compliance with requirements. Sufficient information must be included, considering the knowledge level of those who will use the instructions, to ensure that the activity will be performed as intended, all necessary data will be recorded, and actions will occur in a particular sequence, if required. In the interest of completing activities within imposed time constraints, it is always better to have enough information in implementation documents to perform the task correctly the first time. The alternative case, in which the author of a Work Agreement, for example, assumes that he or she will be present to guide the work, or assumes that the users of the document will know or remember to perform some action not specified in the WA, often produces results wherein the work is performed incompletely, critical data is not collected, or the work has to be redone, which can obviously impact the work schedule or result in quality deficiencies.

Implementation documents become, after the fact, the record of how we performed the associated activities. For that reason alone, they should include enough information to unambiguously portray how the work was conducted.

When preparing any of the above-mentioned implementation documents, particularly those used directly in technical work (Work Agreements, Technical Procedures, and Scientific Notebooks), ensure that you consider the reasons cited above for including an appropriate degree of process detail, as a balance to any motivation you may have to minimize the details in the document.


F. J. Schelling, CRWM QA Lead

Ym 96-D-044

QAIP 1-5
Revision 11
Page 1 of 15

SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 1-5

ESTABLISHING WORK AGREEMENTS

Revision 11

Effective Date: _____

Author: G. F. Ell 12/4/96
Date

Concurrence: F. Joseph Schell 12/4/96
QA Reviewer O Date

Approval: Michael C. Brady 12/4/96
Michael C. Brady, SNL CRWM Lab Lead Date

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REVISION HISTORY
(Continued)

Revision	Summary
09	This revision include sections 4.1 and 6.0. The following changes were made, deleted the reference to QAIP 1-3 and 16-1, added the reference to OCRWM procedures AP16.1Q and AP-16.2Q after 07/02/95.
10	This revision was a total rewrite to incorporate new QARD requirements and to reformat according to QAIP 5-1, Rev.5. It also incorporated provisions for mandatory and non-mandatory review comments according to QAIP 6-3, per resolution of Deficiency Report YMQAD-98-D34.
11	Changes made to section 4.1 in response to Deficiency Report YM-95-D044. Added text requiring process detail to be included either in the content of lower-tier WAs or in the documentation (TPs, Scientific Notebooks, analysis documentation, etc.) resulting from the work. Added text requiring technical reviewers to verify same. Added reference to QAIP 2-6 in section 4.2. Changes made to sections 4.3 and 5.0 in response to Deficiency Report YM-95-D080. Clarified that the customer is the management level who authorizes expedited changes to WAs, provided a methodology for evaluating the effect of differences between temporary revisions and subsequent formal revisions and specified that memos or e-mail is to be used to notify affected parties of temporary revisions. Added record retention designations to section 6.0.

4.0 PROCEDURE

4.1 Preparing, Reviewing, and Approving a Work Agreement

Responsible Individual(s)	Step	Procedure
Customer	1	Obtains the document identifier from the Document Control staff.
	2	<p>Prepares a draft WA that includes or references by number the following elements. Enters "NA" for any element that is not applicable</p> <p>WA ELEMENTS:</p> <ol style="list-style-type: none"> 1) Agreement title, revision number, and WA identifier. 2) Customer name and organization. 3) Supplier(s) name and organization(s). 4) Dated technical and QA reviewer signature lines. 5) Dated Customer and Supplier approval signature lines. 6) Upper-tier WA number. 7) WBS 8) Charging case number(s). 9) Scope of work, objectives, and primary tasks. Shall describe or specify the work to be done, including the objectives to be achieved. Specify, as a minimum, the primary tasks to be accomplished. Specify roles and responsibilities of individuals, teams, or organizations. Shall specify any needed planning or coordination activities with organizations that will use the results of the work or that will provide input to the activities. Lower-tier WAs governing work subject to the QA Program must either, themselves, include the necessary process detail (e.g. sequential actions) required to perform the specified activities, or require that such process detail be specified or described in the documentation resulting from the work (e.g. TPs, Scientific Notebooks, analysis documentation, etc.).

Continued on next page

4.0 PROCEDURE, Continued**4.1 Preparing, Reviewing, and Approving a Work Agreement (continued)**

Responsible Individual(s)	Step	Procedure
Customer (continued)	2 cont.	<p>16) Training Requirements (Identify what training is required for personnel doing work under the WA, for example, training to Technical Procedures and/or Administrative Procedures).</p> <p>17) Any Customer additional requirements.</p> <p>Example: In cases where the WA governs analysis activities in which a model is used, the Customer may specify the model to be used and justify its selection. If the Supplier is selecting the model, the Customer will require that the supplier identify the model and justify its selection in the documentation provided as a result of the analysis.</p> <p>18) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished.</p> <p>Example: Models need to be validated. The WA will specify the appropriate qualitative acceptance criteria that indicate that the model accurately represents the actual physical phenomena.</p> <p>19) History of WA revisions, e.g. previous WA number if this current WA replaces another WA with a different number.</p>
QA/Technical Reviewer(s)	3 4 5	<p>Identifies each technical organization affected by this WA and assures that all technical organizations are represented by the technical reviewer(s) in the review process.</p> <p>Submits draft WAs for technical review and QA review. Attaches any pertinent background information or data necessary for the reviewers.</p> <p>Note: When practical, the supplier's immediate manager conducts the technical review.</p> <p>Reviews the draft WA according to QAIP 6-3. Technical reviewers shall additionally verify that apparently adequate process detail is either included in the lower-tier WA itself, or that the WA requires such process detail in resulting documentation (see step 2, WA element 9 above).</p>

Continued on next page

SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 2-4

CONDUCTING AND DOCUMENTING ANALYSES/CALCULATIONS

Revision 03

Effective Date: June 30, 1996

Author: J. C. Friend
J. C. Friend

Date: 5/2/96

Concurrence: [Signature]
QA Reviewer

Date: 4/22/96

Approval: [Signature] for H.C. Brady
SNL CRWM Lab Lead

Date: 5/30/96

H.C. Brady approval signature on faxed copy of this page in Document Control Records

CONTROLLED DOCUMENT
(If Numbered in Red Ink)

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Copy Number: 000007

REVISION HISTORY

REVISION

REVISION HISTORY

- 00 Total revision to shorten the analysis process. Revised to address new QARD requirements and to simplify the procedure.
- 01 Add a requirement to document the use of models, clarify wording, and revise references. Revised to address QARD requirements not totally covered and update references.
- 02 Combine the requirements of QAIP 3-10 with this procedure to clarify performing and documenting calculations. Revised as a response to SNL CAR 94-38.
- 03 Total Revision. Revised to incorporate the requirements of QARD Rev. 5 with regard to model development and use. Added clarification of documentation requirements. Per resolution of Deficiency Report YMQAD-96-DO44, clarified that qualitative or quantitative acceptance criteria must be specified for model validation. Revised the QA records section to change the name of the records organization and to add scientific notebooks and DRCs as records. Revised the references.

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4.2 Performance, Documentation, and Review of Analysis.....	6
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6.0 REFERENCES	7

1.0 PURPOSE

The purpose of this procedure is to identify actions needed for conducting and documenting analyses and calculations, including the development and use of models.

2.0 SCOPE

This procedure applies to scientific and engineering analyses and mathematical calculations performed by or for Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) activities.

3.0 DEFINITIONS

Model: A system of postulates, data, and inferences presented in a mathematical description of a physical phenomena.

Model Validation: The process that demonstrates that the model is an acceptable representation of the process or system for which it is intended.

4.0 PROCEDURE

4.1 Model Selection, Development, and Use

Responsible Individual(s)	Step	Procedure
Principal Investigator (PI)	1	Shall identify model to be used and justify its selection in the WA or require in the WA that the Analyst shall document model to be used and justify its selection in the analysis documentation.

4.0 PROCEDURE

4.1 Model Selection, Development, and Use (continued)

Responsible Individual(s)	Step	Procedure
Analyst	2	Reviews WA controlling model development or analysis. If WA does not exist, requests PI to initiate WA according to QAIP 1-5.
	3	Shall document the selection and determination of suitability of any input data and model(s) to be used in the analysis. Ensure that these data are adequately identified to provide traceability, indicate usability, and indicate document data validation status for model development.
	4	Shall identify the principal lines of investigation considered.
	5	Validates the model by comparing the results against the following sources: a. data acquired from laboratories b. data acquired from field experiments c. natural analogue studies d. observations that were not used in the original development of the model. To ensure that model validation has been satisfactorily accomplished, appropriate qualitative or quantitative acceptance criteria must be applied in comparing analysis results with sources listed above. If such criteria were not provided in the WA, document the criteria used in the analysis documentation.
	6	Documents validation results and justification to ensure that the model represents actual physical phenomena to a degree of detail commensurate with the intended use.
	7	When data are not available from the above sources, alternate approaches used for validation shall be documented. If a Peer Review is selected as an alternate approach, it shall be conducted in accordance with QAIP 3-12.

Continued on next page

4.0 PROCEDURE

4.1 Model Selection, Development, and Use (continued)

Responsible Individual(s)	Step	Procedure
Analyst	7 cont.	<p>Note: For calculations that the analyst considered routine (e.g., hand calculations or those readily performed on a non-programmable hand calculator), consider the appropriateness of assumptions, input data, and the calculation method used. Check the results through:</p> <ul style="list-style-type: none"> (a) Separate independent calculations using the same or different analytical methods as the original calculations, or (b) A check of the calculational steps in the original calculations, or (c) A spot or random check of the original calculations.

4.2 Performance, Documentation, and Review of Analysis

Responsible Individual(s)	Step	Procedure
Analyst	1	Conducts analyses to requirements specified in a Work Agreement (WA).
	2	Documents the conduct and results of the analysis/calculation. Should use a scientific notebook (prepared in accordance with QAIP 20-2) to document the conduct and results of analysis, or ensure that the records meet documentation and review criteria of QAIP 20-2.
	3	Analysis documentation shall provide sufficient detail to allow verification of the analysis and confirmation of results by an independent, qualified reviewer.
	4	Submits analysis documentation for technical review and documents the results in accordance with QAIP 20-2.
	5	Submits analysis and review documentation to the SNL CRWM Local Records Receiving Organization in accordance with QAIP 17-1.

5.0 RECORDS

QA records, including corrections and changes thereto, generated as a result of implementing this QAIP shall be prepared and submitted to the SNL CRWM Local Records Receiving Organization in accordance with Procedure 17-1, "Protecting, Processing, and Submitting CRWM QA Records," and the "SNL NWM File Code."

The QA records, record package segments, and record packages include:

- a. Analysis and review documentation, i.e., the scientific notebook(s) for the analysis.
-

6.0 REFERENCES

QAIP 1-5 Establishing Work Agreements
QAIP 3-12 Peer Reviews
QAIP 17-1 Protecting, Preparing, and Submitting CRWM QA
Records
QAIP 20-2 Scientific Notebooks

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 Performance Report
 Deficiency Report

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PR/DR CONTINUATION PAGE

Verification of Corrective action:

Quality Assurance Advisory, dtd. May 3, 1996, was issued highlighting the need to specify the approach to be used in model validation and the criteria to be applied.

Another Quality Assurance Advisory, dtd. November 15, 1996, was issued to describe "process detail" in implementation documents.

The checklist used for QA Review of Work Agreements was modified to include a check for approach to validation and the criteria for validation.

QAIP 1-5, rev. 11, "Work Agreements," was modified to include process detail either in the content of lower-tier WAs or in the documentation resulting from the work (TPs, Scientific Notebooks, analysis documentation ,etc.). Also, technical reviewers are to verify this.

QAIP 2-4, rev. 3, "Conducting and Documenting Analyses/Calculations," was modified to include qualitative or quantitative acceptance criteria for comparing analysis results with sources of validation.

Stephen D. Harris 12/10/96
Stephen D. Harris Date