

CHANGE NOTICE

CN No.: 2.5-0-1

Affected Document: 033-YMP-OP 2.5, "Acceptance of Data Not Generated Under the Control of the YMP QAPP", Rev.0

Prepared by: Raymond E. Hamati

Approved by: N/A
(Technical Area Leader) (Date)

Approved by: RK Denny 2-14-91
(YMP QA Manager) (Date)

Training Required:
Yes No

Approved by: Robert J. Foreline 2/20/91
(YMP Project Leader) (Date)

Currently Read as Follows:

1. Section 2.5.2, First paragraph, Second sentence: As published
2. Section 2.5.2, Second paragraph: As published
3. Section 2.5.5, First paragraph, First sentence: As published
4. Section 2.5.5.5, First paragraph, First sentence: As published

CHANGED TO READ:

1. Section 2.5.2, First paragraph, Second sentence: Replace "QA Levels I and II" by "quality affecting"
2. Section 2.5.2, Second paragraph: Delete
3. Section 2.5.5, First paragraph, First sentence: Replace "QA Levels I and II" by "quality affecting"
4. Section 2.5.5.5, First paragraph, First sentence: Replace "QA Levels I and II" by "quality affecting"

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM
CONTROLLED COPY NO. 0100

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Subject: ACCEPTANCE OF DATA NOT GENERATED UNDER THE
CONTROL OF THE YMP QAPP

Approved:

Approved by: *J. S. Sellen* 4/13/89
YMP Project Leader

Approved by: *R. W. E. Schatz* 1/17/87
YMP Quality Assurance
Manager

2.5.1 PURPOSE

This procedure describes the controls necessary for the acceptance into the quality assurance records system of existing data or data interpretations not generated under the controls of the YMP Quality Assurance Program Plan (QAPP).

2.5.2 SCOPE

This procedure applies to existing data and data interpretations not generated under the controls of the YMP QAPP that are intended for support of licensing activities. This acceptance procedure is intended to qualify such existing data and data interpretation for use in QA Levels I and II activities by meeting the requirements of NUREG-1298, "Qualifications of Existing Data for High-Level Nuclear Waste Repositories" (February 1988). Once accepted, the existing data are classified as "primary data" for licensing purposes.

This procedure may not be used to qualify data collected in a QA Level III activity.

2.5.3 RESPONSIBILITIES

The Project Leader is responsible for the overall implementation of this procedure.

The Technical Area Leader is responsible for approval of the reviewers selected to perform the technical review process. The Task Leader is responsible for initiating the controls specified in this procedure. The Task Leader is also responsible for coordinating the acceptance action and for collecting any available supporting documentation that is used during the acceptance process.

The Quality Assurance Manager is responsible for assuring implementation of the requirements of this procedure.

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2.5.4 TERMS AND DEFINITIONS

Existing Data: Data developed prior to the implementation of a 10 CFR Part 60, Subpart G quality assurance program by DOE and its contractors; or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities; or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).

2.5.5 PROCEDURE

There are four methods or combination of methods that are acceptable to qualify existing data or data interpretations for use in QA Levels I and II activities. These methods are:

- [1] The implementation of the peer review process in accordance with provisions of Procedure No. 033-YMP-QP 2.2, "Peer Review."
- [2] The use of corroborating data to support or substantiate other existing data. Inferences drawn to corroborate the existing data must be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed is dealt with on a case-by-case basis in the documented review for qualification.
- [3] The use of a confirmatory testing program conducted in accordance with the provisions of Procedure No. 033-YMP-QP 3.0, "Scientific Investigation Control," which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base. The amount of confirmatory testing required is dealt with on a case-by-case basis in the documented review for qualification.
- [4] The demonstration that a QA program meeting the requirements of the YMP QAPP was utilized for the collection of the data being reviewed.

Methods [2] through [4] require a technical review process conducted in accordance with the provisions of this procedure. Two sets of review forms are utilized, one for acceptance of existing data or data interpretations from a technical journal, and the other set for acceptance of existing data or data interpretations from other sources.

2.5.5.1 Initiating Acceptance Activities

The need for qualification of existing data is identified by the cognizant Task Leader directing the activity for which it is to be used. The Task Leader begins the acceptance process by completing Part I of the Data/Data Interpretation Acceptance Review Form (Exhibit A) and any Continuation Sheets as needed (Exhibit B). If the existing data to be qualified is from a technical journal, the Task Leader follows the procedure sequence of Section 2.5.5.5.

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The Task Leader provides the following information as part of the Review Form:

1. Detailed description of the data and the activity for which its use is being considered.
2. Justification why the data should be used and why the data acquisition process need not be repeated under controlled conditions. Also included is a recommendation of which of the four acceptance methods (or combination of methods) is preferred for accepting this existing data. If confirmatory testing is recommended, then the amount of testing is addressed. Cost and schedule considerations are included in the justification.
3. Description of the procedures and resources used during the data acquisition process.

The Task Leader collects any available supporting documentation for use during the acceptance process. Supporting documentation may include: statements of work, logs or notebooks, technical procedures, documented reviews, and calibration records.

2.5.5.2 Peer Review

If a peer review is the recommended and approved acceptance method, then the review proceeds according to the requirements of Procedure No. 033-YMP-QP 2.2, "Peer Review."

2.5.5.3 Technical Review

If a selection other than a peer review is the recommended and approved acceptance method, the Task Leader selects a review team comprised of three individuals to conduct separate and independent reviews of the data. Two of the reviewers have the appropriate technical background and were not involved in data collection or interpretation. The third reviewer, also not involved in the data collection or interpretation, has expertise in quality assurance. The selections are noted in Part II of the Review Form (Exhibit A), and statements of their qualifications are attached. The Task Leader forwards the package to the Project Leader for concurrence in the selection of the review team. The Project Leader indicates concurrence by initial and date in Part II of the Review Form.

When the Task Leader has received Project Leader concurrence, copies of the Review Form (Exhibit A, and B if required) and the supporting documentation are submitted to each of the reviewers with a Data/Data Interpretation Acceptance Review - Appendix Sheet (Exhibit C). The Task Leader retains the original of the review package. Each reviewer performs his review separately and independently from the other reviewers.

2.5.5.4 Conduct of Technical Review

The reviewer responds to the questions on the Appendix Sheet, documenting these responses on the Appendix or Continuation Sheets. As appropriate to the category of data being reviewed, the reviewer considers the following attributes during the review process:

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1. Qualifications of personnel or organizations generating the data compared to qualification requirements of personnel generating similar data under the YMP QAPP.
2. The technical adequacy of equipment and procedures used to collect and analyze the data.
3. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
4. The environmental conditions under which the data were obtained if germane to the quality of the data.
5. The quality and reliability of the measurement control program under which the data were generated.
6. The extent to which conditions under which the data were generated may partially meet requirements of 10 CFR Part 60, Subpart G, "Quality Assurance."
7. Prior uses of the data and associated verification processes.
8. Prior peer or other professional reviews of the data and their results.
9. Extent and reliability of the documentation associated with the data.
10. Extent and quality of corroborating data or confirmatory test results.
11. The degree to which independent audits of the process that generated the data were conducted.
12. The importance of the data to showing that the proposed repository design meets the performance objectives of the YMP.
13. Replication of test results.

When the review is complete, the reviewer signs and dates the Appendix Sheet (Exhibit C) and returns the package to the Task Leader.

The Task Leader reviews the package and is responsible for resolving any issues raised by the reviewers. All resolutions are made part of the review package. The Task Leader signs and dates Part III of the Review Form and forwards the original package with the reviewers comments to the Project Leader. The acceptance process continues per the requirements of Section 2.5.5.6.

2.5.5.5 Data or Data Interpretation from a Technical Journal

The Task Leader is responsible for initiating acceptance actions for data from a technical journal that will be essential to support the end result of QA Levels I and II activities. The Task Leader begins the review process by completing Part I of the Technical Journal Data/Data Interpretation Acceptance Form (Exhibit D). The Task Leader provides the following information as part of the Review Form:

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1. Complete reference of the technical journal, including other relevant references if the article is part of a series.
2. Description of the data in the journal article and its relationship to the current activity in which the data is to be used.
3. Justification why the data should be used and why the process cannot or need not be repeated under controlled conditions. Cost and schedule considerations are included in the justification. Also included is a recommendation of which of the four acceptance methods (or combination of methods) is preferred for accepting this existing data. If confirmatory testing is recommended, then the amount of testing is addressed.
4. An attached list of published supporting articles and a list of published rebuttal articles, if appropriate.
5. A complete reference of known independent verification of the data, if available, including how the verification was performed.

The Task Leader selects one individual to review the information independently. The reviewer has the appropriate technical background, and was not involved in data collection or interpretation. A statement of the reviewer's qualifications is included with the review package. If the reviewer selected by the Task Leader is acceptable to the Technical Area Leader, he indicates approval by initiating and dating Part II of the Review Form.

After concurrence is received, the Task Leader forwards a copy of the review package to the reviewer along with a Technical Journal Data/Data Interpretation Acceptance Review - Appendix Sheet (Exhibit E). The reviewer responds to the questions on the Appendix Sheet, documenting these responses on the Appendix (and/or Continuation Sheet). As appropriate to the category of data being reviewed, the reviewer considers the attributes of Section 2.5.5.4 in his review. When the review is complete, the reviewer signs and dates the Appendix Sheet and returns the package to the Task Leader."

The Task Leader reviews the package and responds to any issues raised by the reviewer. All resolutions are made part of the review package. If the reviewer and Task Leader have a difference of opinion that cannot be resolved, the Technical Area Leader appoints another individual to review the article independently. The second review is done in accordance with this section (2.5.5.5). Upon resolution of the difference of opinion, the Task Leader signs and dates Part II of the Review Form and forwards both packages to the Project Leader.

2.5.5.6 Review Approvals

The Project Leader reviews the package to assure that the subject information had adequate controls for its intended use in the Project. The Project Leader indicates concurrence by signature and date in Part IV of the Review Form. If the Project Leader does not concur, a meeting is held with the Task Leader to resolve any comments. These resolutions are also made part of the review package. After the Project Leader concurs, the package is reviewed and approved by the QA Manager and submitted to the Yucca Mountain Project Office for approval.

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If the Yucca Mountain Project Office does not concur in the review, a meeting is held with the Task Leader, Project Leader, and the appropriate Yucca Mountain Project Office personnel to resolve any comments and obtain approval.

After Yucca Mountain Project Office approval, the review package is returned to the Project Leader who forwards it to Document Control for distribution and incorporation into the quality assurance records system.

2.5.6 RETAINED DOCUMENTATION

Quality assurance records created by the implementation of this procedure are collected, handled, stored, and maintained in accordance with the requirements of Procedure No. 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records resulting from this procedure includes:

- o Technical Journal Data/Data Interpretation Acceptance Reviews, and
- o Data/Data Interpretation Acceptance Reviews.

2.5.7 EXHIBITS

- Exhibit A Data/Data Interpretation Acceptance Review Form
- Exhibit B Data/Data Interpretation Acceptance Review Continuation Sheet
- Exhibit C Data/Data Interpretation Acceptance Review - Appendix Sheet
- Exhibit D Technical Journal Data/Data Interpretation Acceptance Review Form
- Exhibit E Technical Journal Data/Data Interpretation Acceptance Review - Appendix Sheet

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DATA/DATA INTERPRETATION ACCEPTANCE REVIEW FORM			
Use continuation sheets when necessary.		Activity Number _____	
PART I - BACKGROUND INFORMATION			
Task Leader (TL) _____	Organization _____		
Original Investigator _____	Organization _____		
Subject Data Description _____			
Activity in which data will be used: _____			
Technical Justification (why data should be used and need not be repeated under YMP QAPP Plan controlled requirements)			

Cost and Schedule Justification _____			

Procedure/Resources used during Data Collection _____			

PART II - REVIEW INFORMATION (Comments documented on Appendix Sheets)			
Technical Reviewer 1 _____	Affiliation _____	Date _____	
Technical Reviewer 2 _____	Affiliation _____	Date _____	
QA Reviewer _____	Affiliation _____	Date _____	
Technical Area Leader Concurrence _____ (Initial and Date)			
PART III - TL COMMENTS ON REVIEW			
TL _____	Date _____		
PART IV - MANAGEMENT CONCURRENCE			
Project Leader _____	()	()	Date _____
DOE PO Branch Chief _____	()	()	Date _____
DOE PO POM _____	()	()	Date _____

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EXHIBIT A
DATA/DATA INTERPRETATION
ACCEPTANCE REVIEW FORM

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DATA/DATA INTERPRETATION ACCEPTANCE REVIEW CONTINUATION SHEET

Identify Parts that are continued.

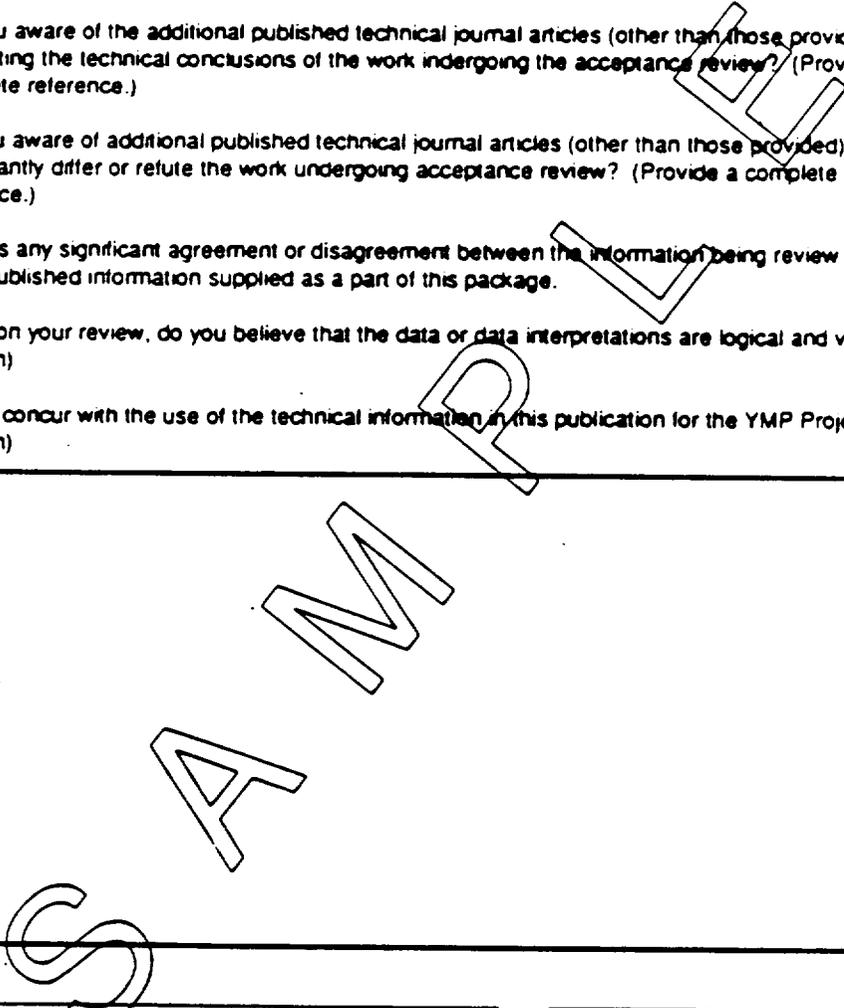
Activity Number _____

Handwritten text: S A M P L E

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TECHNICAL JOURNAL DATA/DATA INTERPRETATION ACCEPTANCE REVIEW FORM	
Use continuation sheets when necessary. Activity Number _____	
PART I - BACKGROUND INFORMATION	
Task Leader (TL) _____	Organization _____
Subject Technical Journal _____	
Date _____ Issue _____	Author(s) _____
Article Title _____	
Relevant Reference _____	
Description of Subject Data/Interpretation _____	
Activity in which data will be used: _____	
Technical Justification (why the data interpretation should be used) _____	
Cost and Schedule Justification _____	
List of Supporting Articles Attached _____	() (Provide a complete reference.)
List of Rebutting Articles Attached _____	() (Provide a complete reference.)
Documentation of Independent Verification Attached _____	() No. of Pages _____
PART II - REVIEW INFORMATION (Comments documented on Appendix Sheets)	
Technical Reviewer _____	Affiliation _____
	(Date) _____
Technical Area Leader Concurrence _____	Date _____
PART III - TL COMMENTS ON REVIEW	
TL _____	DATE _____
PART IV - MANAGEMENT CONCURRENCE	
Approval	Disapproval
Project Leader _____	() () Date _____
DOE PO Branch Chief _____	() () Date _____
DOE PO POM _____	() () Date _____

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EXHIBIT D
TECHNICAL JOURNAL DATA/DATA INTERPRETATION
ACCEPTANCE REVIEW FORM

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TECHNICAL JOURNAL DATA/DATA INTERPRETATION ACCEPTANCE REVIEW - APPENDIX SHEET				
Activity Number _____				
<p>REVIEWER'S COMMENTS. Evaluate the subject information using the following questions as guides; you may use others that you feel are relevant to the review. Use continuation sheets as necessary.</p>				
<ol style="list-style-type: none"> 1. Are you aware of the additional published technical journal articles (other than those provided) supporting the technical conclusions of the work undergoing the acceptance review? (Provide a complete reference.) 2. Are you aware of additional published technical journal articles (other than those provided) that significantly differ or refute the work undergoing acceptance review? (Provide a complete reference.) 3. Address any significant agreement or disagreement between the information being review and other published information supplied as a part of this package. 4. Based on your review, do you believe that the data or data interpretations are logical and valid? (Explain) 5. Do you concur with the use of the technical information in this publication for the YMP Project? (Explain) 				
				
_____ Reviewers signature		_____ Date		
_____ Organization		_____ Phone Number		

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