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# Qualification of Existing Data for High-Level Nuclear Waste Repositories

Generic Technical Position

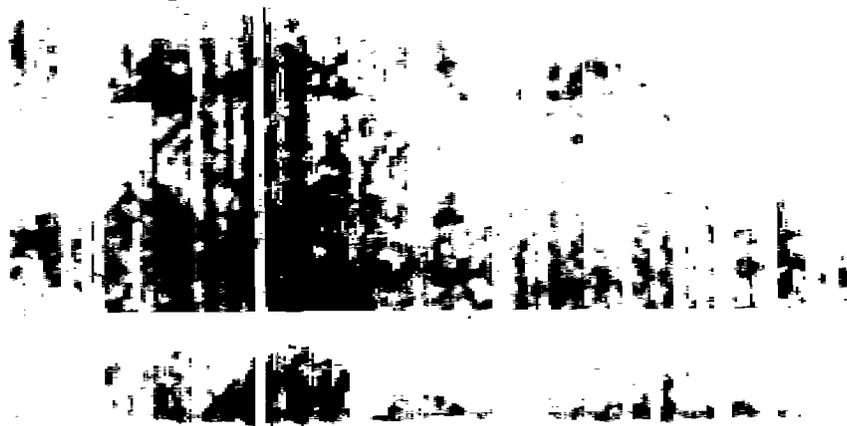
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**U.S. Nuclear Regulatory  
Commission**

Office of Nuclear Material Safety and Safeguards

W. D. Altman, J. P. Donnelly, J. E. Kennedy



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Generic Technical Position

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**Division of High-Level Nuclear Waste Management  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555**





## ABSTRACT

This document provides guidance on methods of qualifying data not initially collected under a 10 CFR Part 60, Subpart G quality assurance (QA) program. The license applicant for a geologic repository must demonstrate that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a QA program.

Some data which have not been initially generated under a 10 CFR Part 60, Subpart G QA program may be needed to support a license application to construct and operate a geologic repository. This document provides guidance on the use and qualification of data not initially collected under a Subpart G, QA program.

This document is identical to that which was noticed in the Federal Register, Vol 52, No. 131, July 9, 1987, 25932-25933. The NUREG format is being used to facilitate referencing and use of the document.

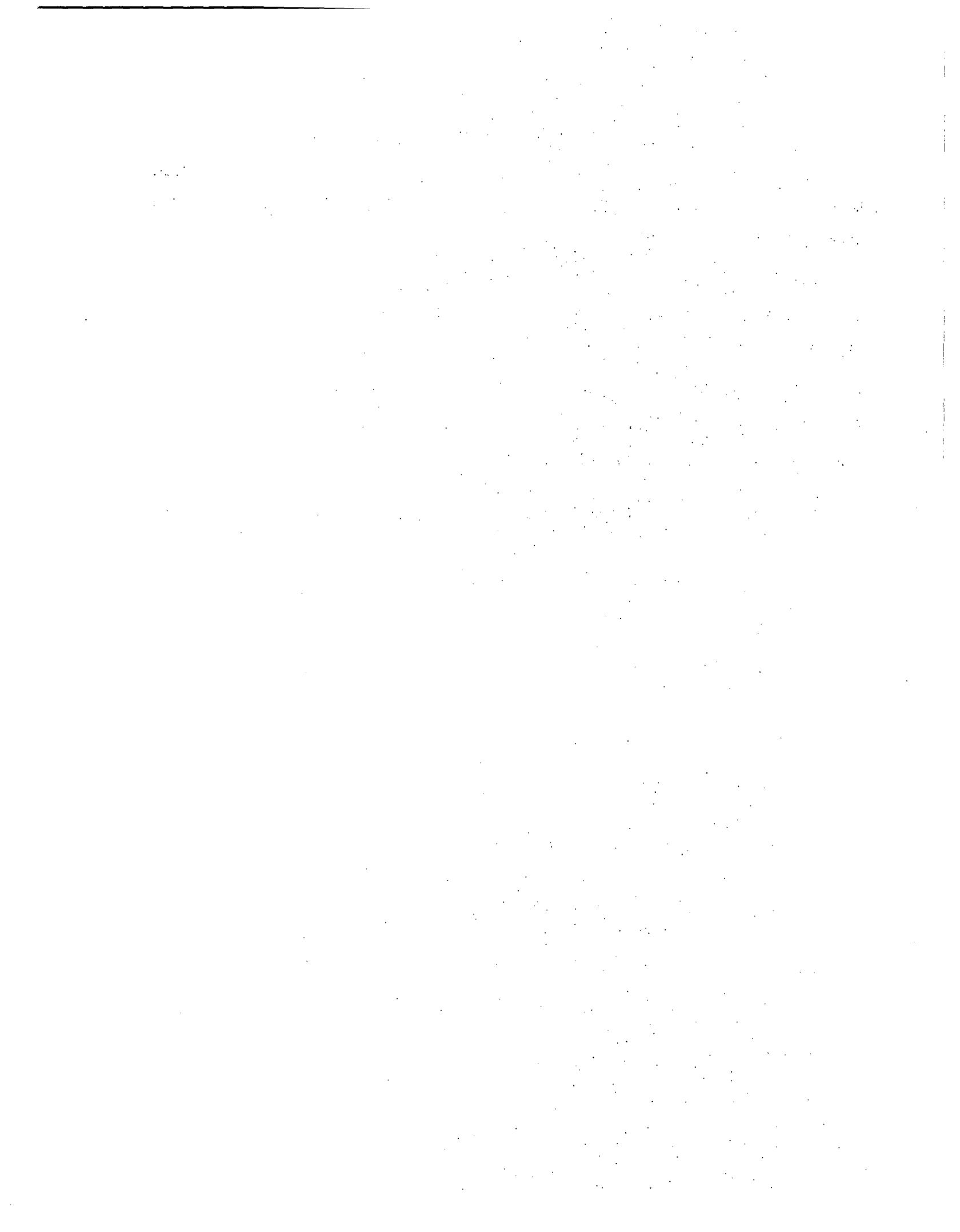
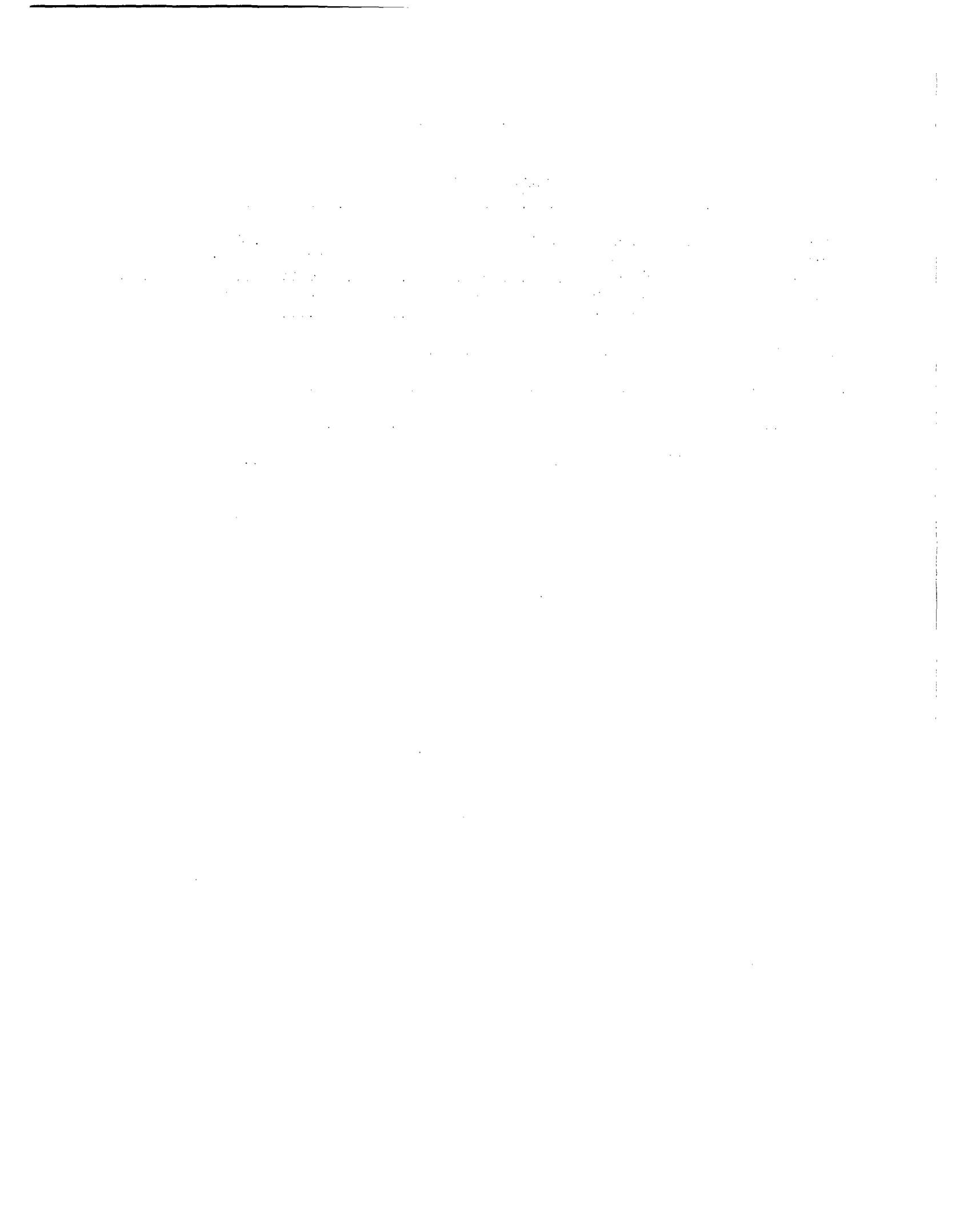


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## ACKNOWLEDGEMENTS

A number of Nuclear Regulatory Commission staff members contributed to the development of this Generic Technical Position. The primary authors were Willard Altman, James Donnelly, and James Kennedy. Linda Riddle, Fred Forscher, Francis Cameron, Tom Jungling, John Trapp, and Dinesh Gupta also made significant contributions to the position.



GENERIC TECHNICAL POSITION ON  
QUALIFICATION OF EXISTING DATA  
FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

I. INTRODUCTION

To obtain a license to operate a high-level nuclear waste repository, the Department of Energy (DOE) must be able to demonstrate in a license application that the applicable health, safety, and environmental regulations in 10 CFR 60 have been fulfilled. Confidence in the adequacy of data, data analyses, construction activities, and other items and activities associated with the license application is obtained through a quality assurance (QA) program. Subpart G of 10 CFR 60 specifies a QA program for items and activities important to safety and waste isolation. DOE should have a QA program in place, consistent with 10 CFR 60, Subpart G and any applicable regulatory guidance, prior to the start of site characterization activities.

The staff expects that some data which have not been initially generated under a QA program meeting the requirements of 10 CFR 60, Subpart G will be needed to support DOE's license application to construct and operate a geologic repository for high-level nuclear waste. The purpose of this Generic Technical Position (GTP) is to provide guidance to DOE on the use and qualification of data that have not been initially collected under a 10 CFR 60, Subpart G QA program.

II. REGULATORY FRAMEWORK

NRC regulations (10 CFR 60, Subpart G) require that DOE implement a QA program that applies to all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. These activities will include the development of site characterization data which will be used in support of the DOE license application. All data used in support of the license application that is important to safety or waste isolation must ultimately be qualified to meet the QA requirements of 10 CFR 60, Subpart G. Data may meet these requirements by being initially developed under a Subpart G QA program or by satisfying alternative conditions. This GTP provides guidance on a set of alternative conditions which may be used to qualify data not initially collected under a 10 CFR 60, Subpart G QA program. Other methods may be proposed or used and will be reviewed for acceptability by the NRC on a case-by-case basis.

III. DEFINITIONS

Qualification (of data):

A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

### Qualified Data:

Data initially collected under a 10 CFR 60, Subpart G quality assurance (QA) program, or existing data qualified in accordance with this GTP.

### Existing Data:

Data developed prior to the implementation of a 10 CFR 60, Subpart G QA 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.)

### Peer Review:

A peer review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer, a) was not involved as a participant, supervisor, technical reviewer or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review," as used in this GTP, refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

### Corroborating Data:

Existing data used to support or substantiate other existing data.

### Confirmatory Testing:

Testing conducted under a 10 CFR 60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base.

### Equivalent QA Program:

A QA program which is similar in scope and implementation to a 10 CFR 60, Subpart G QA program.

## IV. STAFF POSITIONS

1. Data related to systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto which are used in support of a license application should be qualified to meet the quality assurance requirements of 10 CFR 60, Subpart G.

2. Four alternative methods or combinations of methods are acceptable for the process of qualifying existing data: (a) peer review in accordance with the NRC's Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories; (b) use of corroborating data; (c) use of confirmatory testing; and (d) demonstrating that a quality assurance (QA) program equivalent to Subpart G had been utilized. Methods b, c, and d should be accompanied by a documented technical review to determine the quality of the data. Additional confidence/credibility could be achieved when a combination of methods is used. These methods are briefly described in Section V, Discussion.
3. Existing data should be qualified in accordance with approved and controlled procedures. These procedures should provide for the documentation of the decision process, and provide an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the data (item). The procedures may provide for a graded approach to qualification depending on the importance of the data to assuring safety or waste isolation.

## V. DISCUSSION

The process of qualification of existing data may consist of any of the four methods or combination of methods stated in Section IV. 2., above. The level of confidence in the data should be commensurate with their intended use. Attributes which may need to be considered in the qualification process are:

Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G program.

The technical adequacy of equipment and procedures used to collect and analyze the data.

The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

The environmental conditions under which the data were obtained if germane to the quality of data.

The quality and reliability of the measurement control program under which the data were generated.

The extent to which conditions under which the data were generated may partially meet Subpart G.

Prior uses of the data and associated verification processes.

Prior peer or other professional reviews of the data and their results.

Extent and reliability of the documentation associated with the data.

Extent and quality of corroborating data or confirmatory testing results.

The degree to which independent audits of the process that generated the data were conducted.

The importance of the data to showing that the proposed DOE repository design meets the performance objectives of 10 CFR 60, Subpart E.

It is not expected that all of these attributes will need to be examined for each data set under review. In certain cases, replication of test results, for example, could provide confidence in data in lieu of specific QA measures such as independent audits. The four qualification methods and a brief description are as follows:

A. Peer Review

Existing data may be qualified through the use of a peer review process in accordance with the staff's Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories.

B. Corroborating Data

Existing data may be qualified through the use of corroborating data. Inferences drawn to corroborate the existing data should 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 should be dealt with on a case-by-case basis in the documented reviews for qualification.

C. Confirmatory Testing

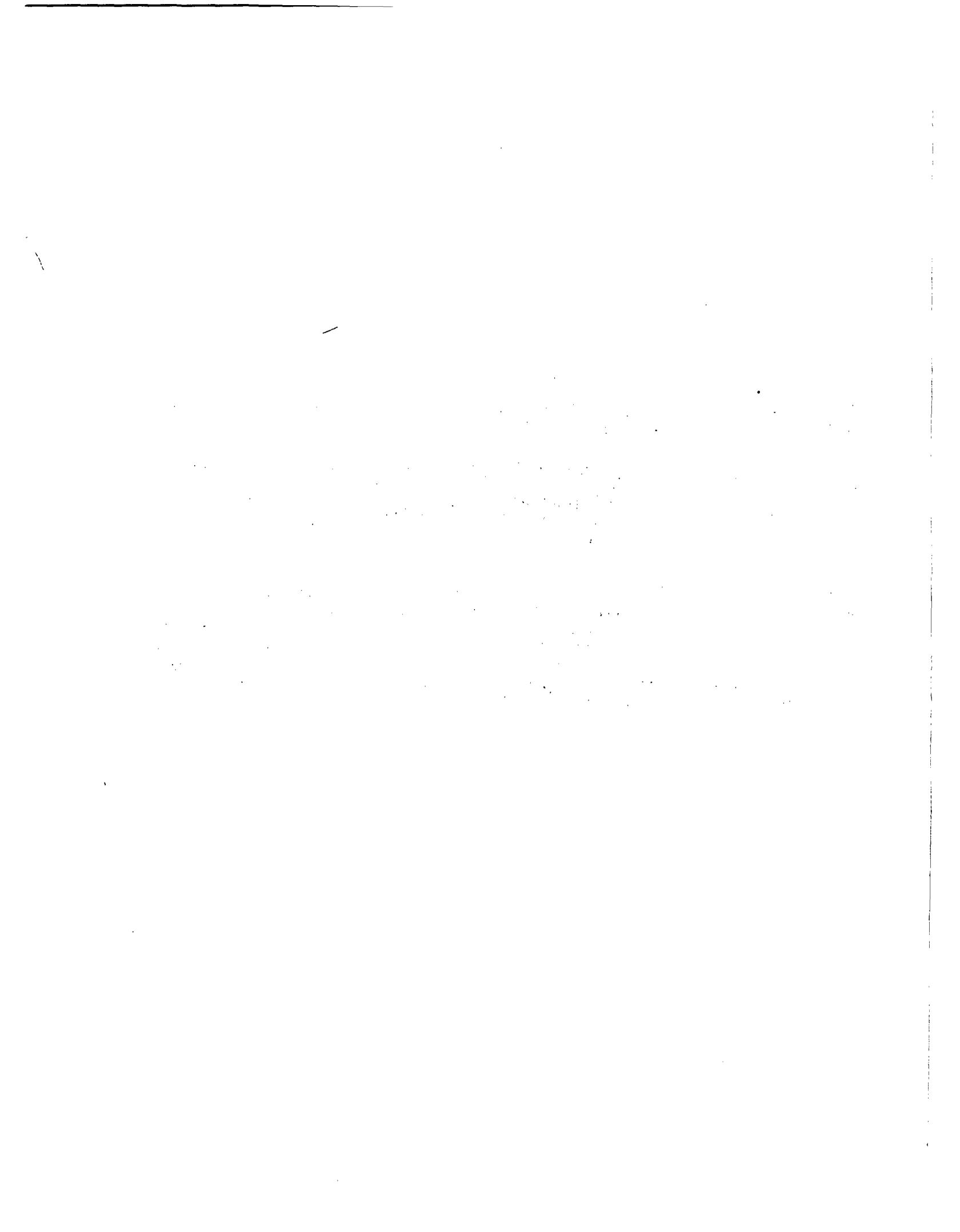
Existing data may be qualified through confirmatory testing. Such confirmatory testing should be conducted in accordance with a 10 CFR 60, Subpart G quality assurance (QA) program. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required should be dealt with on a case-by-case basis in the documented reviews for qualification.

D. Equivalent QA Program

Existing data may be qualified by showing that it was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

**APPENDIX**

**RESOLUTION OF COMMENTS FOR  
THE GENERIC TECHNICAL POSITION  
ON QUALIFICATION OF EXISTING DATA  
FOR  
HIGH-LEVEL NUCLEAR WASTE REPOSITORIES**

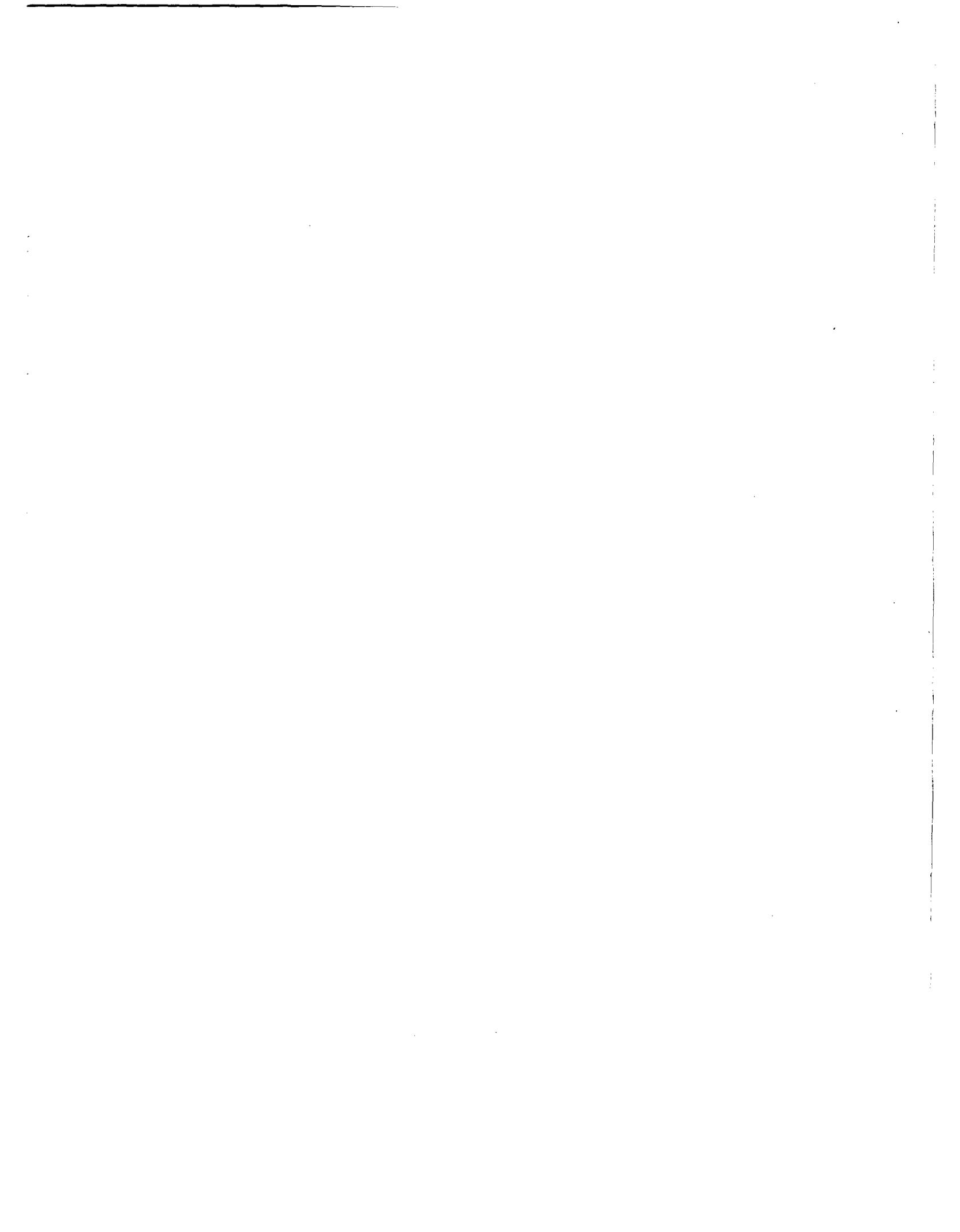


## INSTRUCTIONS

The following instructions are being provided so that the comment resolution package is easy to reference and follow.

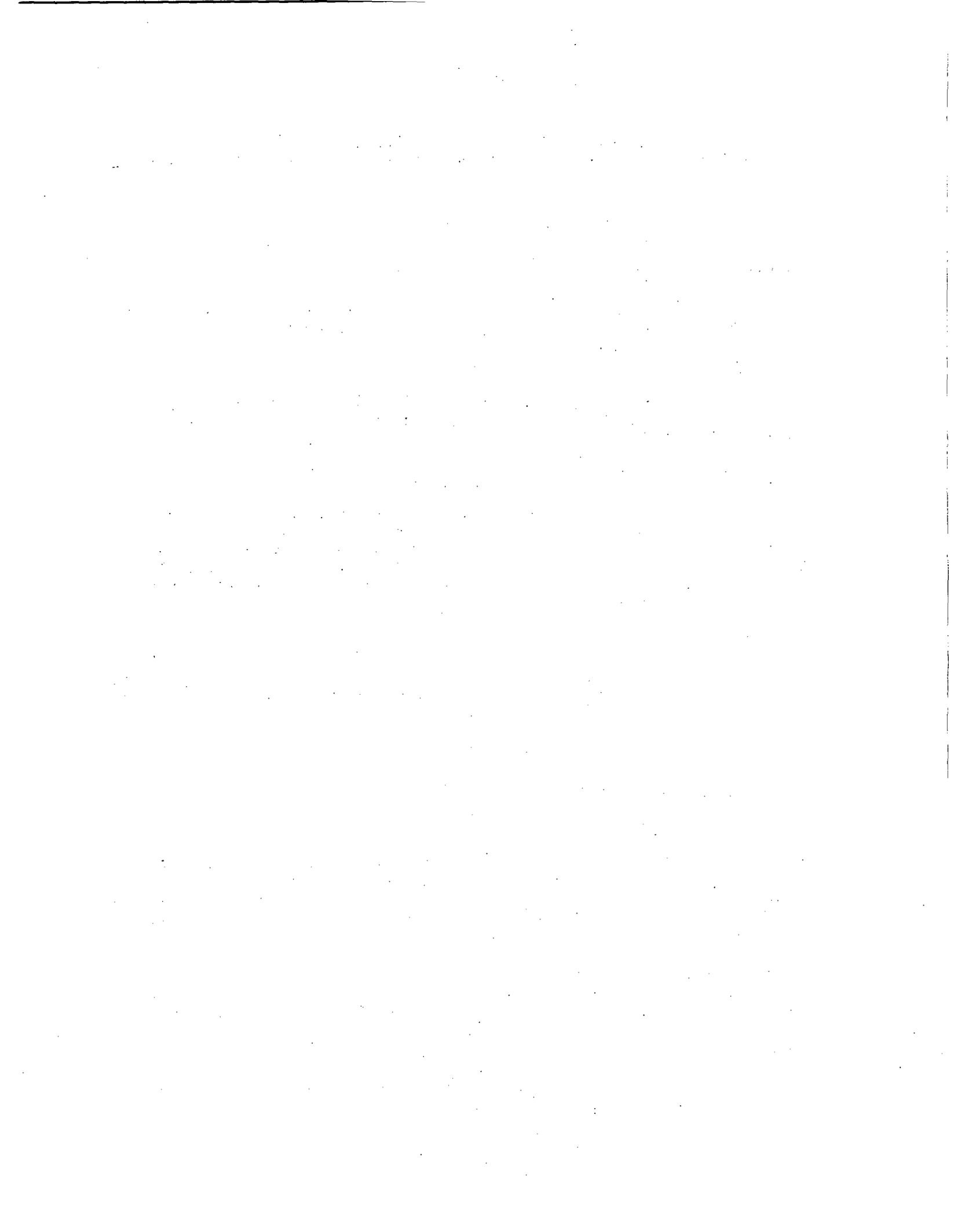
First, all the comments have been grouped under the section of the Generic Technical Position (GTP) which they address. For example, "Section III Definitions" would be a heading and all comments corresponding to that section would follow. If a comment did not address a specific section of the GTP, it was grouped under "General" or another appropriate heading and placed in the beginning of the comment response package.

Second, the individual comments have been identified. An example is "9. Comment #4-2 (DOE)." The numeral "9" is merely the chronological numbering system. The numeral "4" corresponds to numeral "4" of the "Reference Key of Commentors" (see the next page). The numeral "2" simply indicates it was the second comment made by the commentor. If the commentors did not number their respective comments, the NRC assigned numbers to each. Lastly, "(DOE)" is merely an abbreviated reference to an individual commentor.



REFERENCE KEY ON COMMENTS  
 RECEIVED FOR GENERIC TECHNICAL POSITIONS (GTPs)  
 ON " PEER REVIEW " AND " QUALIFICATION OF EXISTING DATA. "

<u>Commentor</u>	<u>Affiliation</u>	<u>Date of Comment</u>
1. Norman C. Frank	Private Citizen	8-1-86
2. Robert R. Loux	State of Nevada Nuclear Waste Project Office	10-3-86
3. John J. Kearney	Edison Electric Institute	10-29-86
4. James P. Knight	Department of Energy	11-7-86
5. David G. Scott	State of New Hampshire Office of State Planning	11-7-86
6. Richard A. Strait	Department of the Interior National Park Service	11-12-86
7. Patrick D. Spurgin	State of Utah High Level Nuclear Waste Office	11-13-86
8. John W. Green	State of Mississippi Department of Energy and Transportation	11-14-86
9. Max Eisenberg	State of Maryland Department of Health and Mental Hygiene	11-17-86
10. Steve Frishman	State of Texas Nuclear Waste Programs Office	11-21-86
11. Robert M. Hallisey	State of Massachusetts Department of Public Health	12-12-86



RESOLUTION OF COMMENTS FOR THE GTP ON  
QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

General

1. Comment # 1-8 (Norman Frank):

For ease of reference, each paragraph should have a number. I will assume that the format will be corrected as needed before issue.

Response:

The staff believes the present format for this GTP is clear and easy to reference. Major sections of the GTP and individual positions are identified by numbers. Thus, the format will not change.

2. Comment # 8-1 (Mississippi):

It is noted in the past that Battelle's Pacific Northwest Laboratory, while under contract to DOE, has had problems with its quality assurance program. The State realizes that existing data must be qualified, but there is some concern over the function of and deficiencies related to existing information which have not been evaluated and documented so that it can be considered in future work.

Response:

The staff agrees with your concerns. Data of indeterminate quality is not acceptable to the NRC. The guidance set forth in this GTP should be used to qualify existing data in order that it can be considered in future work.

Section II: Regulatory Framework

3. Comment # 3-2 (EEI):

Second, EEI/UNMG believes that it is desirable for the GTP to make it clear that data qualified by NRC-approved alternative means is in no way inferior to that initially collected or developed under a program based on 10 CFR Part 60, Subpart G. Accordingly, the following sentence should be added to the end of Part II of the draft GTP:

Non-qualified data qualified by any method approved by the NRC shall not be considered in any way inferior to that initially collected or developed under a quality assurance program based on 10 CFR Part 60, Subpart G.

Response:

As stated throughout the GTP, all data used in the license application for items and activities important to safety or waste isolation, must be

qualified to meet the QA requirements of 10 CFR 60, Subpart G or qualified in accordance with this GTP. By meeting the qualification criteria of this GTP, the minimum qualification level has been achieved and that data is acceptable to the NRC staff. Therefore, the staff feels the present language is adequate and no additions are necessary.

4. Comment # 4-1 (DOE):

Page 1, Section II, second from last sentence: "...currently..." implies that these methods may be unacceptable at some future time. This is an unacceptable concept and should be revised.

Delete "currently."

Response:

Agreed. This comment has been incorporated. The quoted sentence has been removed because it is a repeat of the previous sentence.

Section III: Definitions

5. Comment # 1-1 (Norman Frank):

Definition of "Qualified Data" - change to read. "Data collected under a quality assurance program that met the requirements of 10 CFR 60, Subpart G or acceptable alternative requirements of IV below."

Response:

Agreed. This comment has been incorporated. The new definition, slightly reworded, reflects this thought.

6. Comment # 1-2 (Norman Frank):

Definition of "Existing Data" - (1) where is this term used in this document; (2) add "(may be qualified or non-qualified)."

Response:

This comment has been incorporated. The term "non-qualified data" has been replaced by "existing data" throughout the GTP.

7. Comment: # 1-3 (Norman Frank):

Definition of "Confirmatory Testing" - using the word "verification" will force contractors to qualify their people to three levels as interpreted by NQA-1, Appendix 2A-1, through 10 CFR 50, Appendix B. This is a gross overkill in application.

Response:

At this time, the NRC has not endorsed NQA-1 for the repository program. Thus, the definition of "Confirmatory Testing" has been revised to avoid confusion. The new definition should read, "Testing conducted under a 10 CFR 60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base."

In addition, Appendix A of the NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories is being revised and the qualifications of inspection and test personnel will be evaluated and appropriate guidance provided.

8. Comment # 1-4 (Norman Frank):

Add definition of "Non-qualified Data." Is this the same as "existing data?" The use of these two terms is confusing to me in this document.

Response:

See the response to comment # 6.

9. Comment # 4-2 (DOE):

Page, 2, Sect. III, Qualified Data: The definition of Qualified Data is not compatible with the intent of this GTP. This would not permit existing data to be "qualified" without meeting 10 CFR 60, Subpart G requirements.

Add the following after "program": "or existing data that is qualified in accordance with this GTP."

Response:

Agreed. This change has been incorporated. However, it should be pointed out that this GTP is an interpretation of 10 CFR 60, Subpart G. This interpretation is based on the language in 10 CFR 60.152 which states that the QA program requirements are to be used "... as applicable, and appropriately supplemented by additional criteria as required by 60.151." Thus, by meeting the guidance found in this GTP, 10 CFR 60, Subpart G requirements are satisfied.

10. Comment # 4-3 (DOE):

Page 2, Sect. III, Existing Data: Data presented in technical and scientific articles should be included in this definition.

Add the following after "universities": "or in technical or scientific publications."

Response:

Agreed. This comment has been incorporated.

Section IV: Staff Positions

11. Comment # 1-5 (Norman Frank):

Under IV, Paragraph 2 - add "alternative" after "Four" in the first line.

Response:

Agreed. Paragraph 2 should start: "Four alternative methods or combination of methods are acceptable...."

12. Comment # 1-6 (Norman Frank):

The "graded approach to qualification" allowed in IV, Paragraph 3 will require extensive amplification in order to prevent confusion and inconsistent implementation by all the different contractors involved. I have found that "graded approach" means different things to different people.

Response:

Paragraph 3 requires that existing data be "qualified in accordance with approved and controlled procedures." It is expected that such procedures would help "prevent confusion and inconsistent implementation."

Additional clarification on graded QA is found in the NRC's draft GTP entitled Items and Activities in the High-Level Geologic Repository Program Subject to 10 CFR 60 Quality Assurance Requirements. This draft GTP was noticed in the Federal Register in July 1986. Thus, the staff believes this GTP provides the needed amplification on graded QA.

13. Comment 2-1 (Nevada):

Section IV. 2., outlines four methods acceptable for qualifying non-qualified data. While these methods seem pretty airtight, we are concerned that they are not used as a method to justify use by DOE of data collected under less than ideal conditions. Example: drill data that was not developed under proper QA program and later resulted in "stop work" orders at Yucca Mountain. Nevada believes that all Level I data critical to health and safety must be developed and collected under an approved QA program. All Level I data developed and collected prior to having an approved QA program in place can only be qualified through corroborating data or complete reconstruction. Therefore, the existing core data, previously referred to, can only be qualified through corroboration.

Response:

The Introduction states, "The purpose of this Generic Technical Position (GTP) is to provide guidance to DOE on the use and qualification of data that have not been initially collected under a 10 CFR 60, Subpart G QA program." The NRC staff believes your concern for collection of data "under less than ideal conditions" has been addressed. At the same time, we disagree with your last sentence that "existing core data can only be qualified through corroboration." This GTP allows "four alternative methods or combination of methods" for qualification, of which corroboration is only one of the four methods.

With respect to drill data collected at Yucca Mountain, a decision on its acceptability or qualification has not been made at this time.

14. Comment # 4-4 (DOE):

Pages 2 and 3, Sect. IV and V: The term "non-qualified data" is used throughout these sections. The defined term is "existing data."

Change "non-qualified data" to "existing data." (9 places)

Response:

Agreed. This comment has been incorporated. Also, see the response to comment # 6.

15. Comment # 4-5 (DOE):

Page 2, Section IV.1: This paragraph could be deleted as it was already stated in Section II, Regulatory Framework.

Delete Section IV.1.

Response:

The staff believes this paragraph is the most important QA condition for licensing and deserves to be repeated as a staff position.

16. Comment 9-1 (Maryland):

Section IV.3: NRC is to be congratulated for putting the meat of the document in this paragraph. However, there seems to be a need to distinguish between the "qualification process" and "qualification" (of data) itself. A more complete statement in the second sentence would be: "...trail of all factors used in arriving at the choice of the qualification process, and the decision as to the qualification of the data (item).

Response:

Agreed. The second sentence of Section IV.3., should read: "These procedures should provide for the documentation of the decision process, and provide an auditable trail of all factors used in arriving at the

choice of the qualification method(s), and the decision as to the qualification of the data (item)."

17. Comment # 10-1(Texas):

Section IV.1: "Data related to systems... should be qualified..." should be changed to read "Data related to systems... shall be qualified..."

Response:

GTPs (like Regulatory Guides) are always written in terms of the permissive "should", rather than the mandatory "shall". The former is used for staff guidance, the latter for NRC regulations.

18. Comment # 10-2 (Texas):

Section IV.3: The approved and controlled procedures for qualifying existing data should be developed by DOE and then reviewed by the NRC for adequacy. The NRC should also elaborate in this section on the graded approach to qualification of data especially on data that should have been collected under Quality Level 1.

Response:

The staff agrees with your first sentence. Since DOE will be the license applicant, it will be up to DOE to provide quality data. Such data should be qualified in conformance with approved and controlled procedures which meet the guidance of this GTP. The NRC staff will review these procedures.

Second sentence. Please see the response to comment # 12 regarding the "graded approach."

Section V: Discussion

19. Comment #1-7 (Norman Frank):

For clarity, please delete the reference to procedure in V.B. The statements of IV, Paragraph 3 should be sufficient for this level of document.

Response:

Agreed. The reference to procedures has been reworded for clarity.

20. Comment # 2-2 (Nevada):

Section V. A., Peer Review. The composition of the peer review committee should be stated more precisely. It should be emphasized if the affected state should be part of the peer review, and if so, in what capacity. Usually, the DOE will perform internal peer reviews only. The

independence of the subject peer review from DOE should be discussed and emphasized.

Response:

Independence of the peers and the composition of the peer review group is discussed in greater detail in the staff's GTP on Peer Review for High-Level Nuclear Waste Repositories. In addition, the staff has provided detailed responses to public comments on peer independence in the peer review response package. Refer to these documents for the necessary clarification.

In accordance with staff position IV.2., the GTP on peer review is the appropriate guidance that should be applied whenever peer reviews are employed by DOE.

21. Comment # 2-3 & 2-4 (Nevada):

Section V, B. and C., Corroborating Data and Confirmatory Testing. The composition of the groups that are responsible for approving the type and amount of data collected and the nature of tests run should be more fully described. The need and participation of technically independent personnel should be discussed.

Response:

The composition of the groups approving the type, amount, and nature of data and tests should be a DOE management prerogative. However, the NRC will review the rationale for the selection of the qualification method(s) and the decision as to the qualification of the data.

Also, an approved and controlled procedure should be required (as per staff position IV.3.) that describes the qualifications and independence of the involved personnel. With respect to peer review members, the independence issue is discussed in NRC's GTP on peer review. Therefore, this issue will not be elaborated upon here.

22. Comment # 2-5 and 2-6 (Nevada):

Two additional points are made relative to use of corroborating information to qualify existing data. As part of NRC's responsibility to provide clear guidance to DOE, the GTP must define what is the minimum level of corroborating information NRC will accept to qualify existing data. The GTP is absent on this subject. The GTP should also state that corroborating data not collected under an approved QA program is not acceptable.

Response:

Because of the diverse types, amounts, and importance of existing data to be qualified (e.g., design data, material properties data, geological field data, etc.) it is not possible to "define a minimum level of corroborating information". Thus, Sections V.B. and V.C. state that the

amount of corroborating data or confirmatory testing should be dealt with on a case-by-case basis.

With regard to your last sentence, the level of confidence associated with corroborating data is related to the QA program under which it was developed and the number of independent data sets. Thus, some corroborating data could be acceptable even though it was not initially collected under a 10 CFR 60, Subpart G QA program.

23. Comments # 3-1 (EEI):

With regard to the "Draft Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," the stated purpose of this GTP is to provide guidance on a set of conditions that may be used to qualify data not initially collected under a quality assurance program based on 10 CFR Part 60, Subpart G. The draft GTP indicates, in Part II, that in addition to the four methods acceptable to the Staff for qualification on non-qualified data, "Other methods may be proposed or used and will be reviewed for acceptability by the NRC on a case-by-case basis." The first sentence of Part V of the draft GTP, however, states that "The process of qualification of non-qualified data should consist of any of the four methods or combination of methods described below." (Emphasis added.) To make it completely clear that other methods may be equally acceptable for the qualification of non-qualified data, in addition to the four methods described in the draft GTP, the first sentence in Part V should be reworded to state that:

The process of qualification of non-qualified data may consist of any of the four methods or combination of methods described below, or other methods proposed or used and reviewed and found acceptable by the NRC.

Response:

The staff agrees that "should" should be changed to "may." However, the staff believes the GTP is very clear on other proposed qualification methods and that no additional rewording is necessary.

24. Comment # 4-6 (DOE):

Page 2, Sect. V. A: In the first sentence "the use of a peer reviews" should be clarified to read "the use of a peer review process." This is a broader term to include the decision process to use a peer review, procedures to be used and the results of the peer reviews.

Change end of sentence to read: "...the use of a peer review process."

Response:

Agreed. This comment has been incorporated.

25. Comment # 4-7 (DOE):

Pages 2 and 3, Sect. V. A., 2nd paragraph: This sentence concerning attributes to be considered for qualification applies not only to peer review but also the other methods of qualifying existing data.

Move this sentence to Sect. V under Discussion.

Response:

Agreed. Section V., has been revised and reorganized to reflect this comment.

26. Comment # 9-2 (Maryland)

Section V.B: The inference (not stated) in this paragraph seems to be that a larger quantity of low-quality data will lead to a higher-quality product. This is not true. One of the first concerns is to look for any bias in each data item, which has to be treated before the data is used. If this can be corrected, then a large quantity of inaccurate data will demonstrate the size of the inaccuracy through the standard deviation, and the variances will provide additional information. In any event, the paragraph needs to be expanded to include some sort of statistical approach to clarify the meaning of the paragraph.

Response:

The paragraph states: "Inferences drawn to corroborate the existing data should be clearly identified, justified, and documented." The possible use of statistical methods depends on the type of data, and need not be discussed in this GTP.

27. Comment # 9-3 (Maryland)

Section V.C: The meaning of confirmatory testing could be greatly improved with at least two examples, indicating the process in detail.

Response

Since this guidance is intended for a wide range of data sets and technical disciplines, the staff believes specific examples are inappropriate. However, in generic terms, additional guidance has been provided under Section V.C.

28. Comment 10-3 (Texas):

Section V, A: This section on peer review should state that the peer review process used in the qualification of existing data shall be in accordance with the NRC GTP on Peer Review.

Response:

Agreed. This comment has been incorporated.

29. Comment # 10-4 (Texas):

Section V, B: The discussion on corroborating data should state that the corroborating data used to qualify existing data must be or have been collected under a 10 CFR 60, Subpart G quality assurance program or its equivalent. The discussion should also state that corroborating data not collected under a 10 CFR 60, Subpart G program or its equivalent will not be acceptable. Guidance should also be given on the minimum level of corroborating data that NRC will accept.

Response

With regard to the first two sentences the staff disagrees. The level of confidence associated with corroborating data is related to the QA program under which it was developed and the number of independent, existing, data sets. Thus, some corroborating data could be acceptable even though it was not collected under a "10 CFR 60, Subpart G quality assurance program or its equivalent." As for specifying a "minimum level of corroborating data" please see the response to comment # 22.

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<p>This document provides guidance on methods of qualifying data not initially collected under a 10 CFR Part 60, Subpart G quality assurance (QA) program. The license applicant for a geologic repository must demonstrate that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a QA program.</p> <p>Some data which have not been initially generated under a 10 CFR Part 60, Subpart G QA program may be needed to support a license application to construct and operate a geologic repository. This document provides guidance on the use and qualification of data not initially collected under a Subpart G QA program.</p>		11a. TYPE OF REPORT
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