Clarence Williams, Jr. Chairman, ASME Subcommittee on Nuclear Waste Management Battelle Project Management Division 505 King Avenue Columbus, Ohio 43204

MAY 1 6 1988

Dear Mr. Williams:

At the April 28, 1988 ASME Subcommittee meeting in Orlando, Florida on Nuclear Waste Management, Bill Belke, representing Mike Bell, was assigned an action item. The action item was for the NRC to identify the differences between the NRC's Generic Technical Positions on "Qualification of Existing Data for High-Level Nuclear Waste Repositoires," (NUREG-1298) and "Peer Review for High-Level Nuclear Waste Repositories," (NUREG-1297) and the proposed requirements in ANSI/ASME NQA-3, Draft 3, Revision 1, dated February 1988. This was subsequently discussed with you, Jim Donnelly, Bill Belke and Mike Bell in a conference call on May 2, 1988. The results of our action item are listed in the attached enclosures.

Should you have any questions on our review, please feel free to contact me on FTS 492-3402 or Jim Donnelly of my staff on FTS 492-0453.

Sincerely,

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James E. Kennedy, Section Leader QA Section Operations Branch Division of High-Level Waste Management Office of Nuclear Material Safety and Safeguards

Enclosure: As stated

cc: W. Morris, RES A. Gormley, RES

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Dear Mr. Williams:

At the April 28, 1988 ASME Subcommittee meeting in Orlando, Florida on Nuclear Waste Management, Bill Belke, representing me, was assigned an action item. The action item was for the NRC to identify the differences between the NRC's Generic Technical Positions on "Qualification of Existing Data for High-Level Nuclear Waste Repositoires," (NUREG-1298) and "Peer Review for High-Level Nuclear Waste Repositories," (NUREG-1297) and the proposed requirements in ANSI/ASME NQA-3, Draft 3, Revision 1, dated February 1988. This was subsequently discussed with you, myself, Jim Donnelly and Bill Belke of my staff in a conference call on May 2, 1988. The results of our action item are listed in the attached enclosures.

Should you have any questions on our review, please feel free to contact me on FTS 492-3406 or Jim Donnelly of my staff on FTS 492-0453.

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Enclosure 1

COMPARISON OF NUREG-1298 AGAINST ANSI/ASME NQA-3 (DRAFT 3, REV. 1, FEBRUARY 1988)

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After comparing the subject documents, the following differences between the documents have been identified.

- 1. ANSI/ASME NQA-3 does not contain the definitions of "Qualification", "Qualified Data", "Corroborating Data", "Confirmatory Testing", or "Equivalent QA Program." These definitions could not be found in either Supplement SW-1, "Terms and Definitions" or Supplement 3SW-1, "Supplementary Requirements for Design Data Requiring Control." The staff considers these definitions essential to a clear, unified understanding of the data qualification process. The definition of "Existing Data" is not uniquely identified; however, it is implied in the text of NQA-3 and is adequate to the staff. Likewise, the definition of "Peer Review" has been commented on in the comparison of NQA-3 against NUREG-1297.
- 2. Section IV., 3., of the NUREG is not addressed in Supplement 3SW-1.
- 3. Where other omissions exist with respect to the Staff Positions found in NUREG-1298, these have been identified in the attached mark-up of the appropriate section in ANSI/ASME NQA-3.

ANSI/ASME NOA-3 Laft 3. Rev 1

8 EVALUATING AND REPORTING RESULTS

Data collection and analysis shall be critically reviewed and questions resolved before the results are either used or reported. Uncertainty limits shall be assigned to the data prior to its use.

9 QUALIFICATION OF DATA WITH INDETERMINATE QUALITY

Data to be used which was not collected under the control of a quality assurance program in accordance with this standard shall be qualified for its intended use. This includes data collected from such sources as professional journals. technical reports and symposia proceedings. The organization using the data shall establish procedures for the data qualification process considering both technical and quality assurance programmatic criteria. Factors to be considered when available and measurable include:

- (a) Qualifications of personnel or organizations generating the data
- (b) Technical adequacy of the equipment and procedures used to collect and analyze the data
- (c) Environmental conditions, (if Sunder which the data were obtained 22 dermane)

- (d) Quality and reliability of the measurement control program under which the data were generated
- Extent to which data demonstrate (e) properties of interest (e.g. physical chemical, geologic, mechanical)
- (f) Extent to which conditions generating the data may partially meet requirements of this standard
- · (g) Prior uses of the data and associated verification processes
 - (h) Prior peer or other professional reviews of data and their results
 - (i)Extent and reliability of the documentation associated with the data
 - **(j)** Extent and quality of corroborating data or confirmatory testing results
 - (k) Degree to which data generating processes were independently audited.

The data qualification process shall describe how data will be assessed for their quality characteristics such as accuracy, precision completeness. representativeness and comparability. Acceptable qualification methods include, but are not limited to, any one or a combination of the following: peer reviews, corroborating data, confirmatory testing (either by alternate methods or

(1) The importance of the data to showing that the repository design meets the performance object ives.

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replication), or demonstration that the data were collected under a quality assurance program equivalent to this standard. If confirmatory testing, corroborating data, or the equivalent QA program is used, these methods shall 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.

Enclosure 2

COMPARISON OF NUREG-1297 AGAINST ANSI/ASME NQA-3 (DRAFT 3, REV. 1, FEBRUARY 1988)

After comparing the subject documents, the following differences have been identified.

- ANSI/ASME NQA-3 does not contain the definitions of "Peer", "Peer Review Group", and "Peer Review Report." These definitions, could not be found in either Supplement SW-1, "Terms and Definitions" or Basic Requirement 3, "Design Control."
- 2. The definition of "Peer Review," as found in SW-1, is not consistent with the definition found in the GTP. One example, the SW-1 definition of Peer Review states: "A documented critical review of work that goes beyond...or where <u>potential</u> uncertainty exists." Uncertainty exists in all measurements, assumptions, designs, etc. Consequently, this definition would make a peer review appropriate for basic and well understood operations, tests, etc. - this is not the intent of the NUREG.
- 3. Section IV., 2., of the NUREG on the Structure of Peer Review Group is not discussed in Basic Requirement III of ANSI/ASME NQA-3. Concepts such as the number of peer reviewers, a greater proportion of reviewers with technical expertise central to the work being reviewed, and limiting technical and organizational partiality are not addressed.
- 4. Section IV., 3., of the NUREG on the Acceptability of Peers is only partially addressed. The concepts of technical qualifications and independence have been discussed in Basic Requirement III; however, the guidance that technical qualifications should be the primary consideration when selecting peer reviewers and that these qualifications should be verifiable are not emphasized.
- 5. Section IV., 4., of the NUREG on the Peer Review Process is not addressed in Basic Requirement III. The guidance on what should be reported on and the need for procedures is not discussed in ANSI/ASME NQA-3.
- 6. Section IV., 5., of the NUREG on Peer Review Report is only partially addressed in Basic Requirement III. The omitted concepts, from the NUREG are the signature of each reviewer and a clear statement as to what was reviewed.
- 7. The staff suggests that a separate section on the peer report requirements be created. As presently written, the reporting requirements are not clearly organized. Basically, the report should contain documented results and conclusions, the signatures of each reviewer, a clear statement of what was reviewed, differing minority positions, and the acceptability information (i.e., technical qualifications and independence) of each reviewer.

- Page 6, the right column, the middle paragraph of ANSI/ASME NQA-3 states that peer reviewers shall document their results and shall address whether the work conforms to specified requirements. If the work can clearly be designated as meeting specified requirements, then it probably should not undergo the peer review process. For example, one of the criteria in Basic Requirement III for identifying situations where a peer review is appropriate states, "Detailed technical criteria or standard industry procedures do not exist or are being developed." Although a small portion of a complex test or investigation can clearly be identified as conforming or not conforming to specified requirements (and this could be examined by the peer review group as a small part of their review), the overriding, large scale question is whether or not the overall investigation is adequate for the desired information. This overriding question usually is not a clear conformance or non-conformance to specified requirements. Peer review is a mechanism by which these questions can be answered. Consequently, the staff believes this paragraph in NQA-3 should be clarified.
- NOTE: Those sections of the NUREGs which are not addressed in NQA-3 have been identified. However, it should be pointed out that the NUREGs contain some detailed examples and explanations which may not be appropriate in a national standard. Likewise, in the omitted NUREG sections identified, selected examples of specific omissions have been provided. It would be prudent to take a detailed look at each omitted section and determine whether all or portions should be considered for inclusion into this Standard.