This document is a Change Notice. Original document was signed by L. B. Ballou as Yucca Mountain Project Leader, 12/22/88, and Ronald E. Schwartz, QA Manager, 12/22/88.

Approved by: N/A
Yucca Mountain Project Leader — Date

Approved by: N/A
YMP Quality Assurance Manager — Date

1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The Quality Assurance (QA) Program for the LLNL-YMP consists of the LLNL-YMP Quality Assurance Program Plan (QAPP), quality procedures, and technical implementing procedures, and its subcontractors' QA Program Plans, quality procedures, and technical procedures. The LLNL-YMP submits this QAPP to the DOE Project Office for approval. **If a change to this QAPP is not a reduction in committed QA requirements, it may be issued prior to DOE approval.** Approval of QA Plans by the DOE Project Office is documented.

The Quality Assurance Program Plan (QAPP) includes consideration of the technical aspects of the activities affecting quality and is generated by the LLNL-YMP QA organization with assistance from the LLNL-YMP technical staff. The QAPP provides instructions to implement and apply the QA requirements to the technical activities of the LLNL-YMP. The QAPP is planned, implemented, and maintained in accordance with the DOE Project Office QAPP and is consistent with and addresses all of the applicable requirements of the DOE Project Office QA Plans. Management above or outside of the QA organization regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA Program.

Management performs readiness reviews, as deemed appropriate. Readiness reviews apply to major scheduled/planned activities which affect quality. Readiness reviews are used to verify that specified prerequisites and programmatic requirements are identified prior to starting a major activity.

The hierarchy of criteria applicable to the Yucca Mountain Project are shown in Figure 1. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in the Figure and this QAPP exist, the requirements of this document prevail.

1.1 QA CRITERIA

The QA Criteria and specific requirements associated with those criteria are adapted to the LLNL-YMP activities through this QA plan. When a specific criteria is not applicable to LLNL-YMP activities, it is noted in the QAPP and recorded on the DOE Project Office's checklist with justification of its exception as required in Paragraph 1.2.

1.2 CONTENTS OF THE QAPP

The Quality Assurance Program of the LLNL-YMP includes the QAPP plus the implementing procedures required to provide and implement control over activities affecting quality. The control is consistent with the importance of the activity. Implementing procedures are developed by qualified personnel and are reviewed and approved by the LLNL-YMP QA organization prior to implementation to assure that the implementing procedures meet all the requirements of the LLNL-YMP QAPP.

The LLNL-YMP QAPP is submitted to the DOE Project Office for review and approval prior to implementation and includes a checklist based on the DOE Project Office QAPP which identifies how and where each requirement of the DOE Project Office QAPP is addressed.

1.3 QAPP VERIFICATION

Assurance that the QA requirements are adequately addressed and effectively implemented is provided by the DOE Project Office during the review and approval of the LLNL-YMP QAPP, monitoring and surveillance operations, and audits of activities. The LLNL-YMP also monitors the LLNL-YMP QAPP through internal audits, audits of subcontractors, and surveillance of operations to assess the adequacy of LLNL-YMP program and assure its effective implementation.

1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The QA program for the LLNL-YMP provides for the acceptance of data or data interpretations for use in licensing activities that were not generated under the controls of a QA program which meets the requirements of 10 CFR 60, Subpart G. These requirements are contained in Appendix G of this document. Once accepted, this data is classified as "primary data" for licensing purposes.

1.5 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST

Items and activities to be placed on the Project Q-List are determined by the DOE Project Office. Requirements for the identification of items and activities to be included on the Q-list are contained in Appendix I to the LLNL-YMP QAPP.

1.6 APPROACH TO QA

The LLNL-YMP uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. The approach is designed to assure that each item or activity is assigned a QA control level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The LLNL-YMP or DOE Project Office identifies the appropriate quality assurance control levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Once assigned, the QA control level for a particular item or activity is applied by all LLNL-YMP personnel involved in the activity. CN R2-0-3

1.7 APPLICATION OF QA

A QAPP that complies with the requirements of the DOE Project Office QAP is established by the LLNL-YMP at the earliest practicable time consistent with the schedule for accomplishing the activities. The LLNL-YMP QAPP specifies that procedures required to implement the requirements are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. The QAPP is applied throughout the life of the LLNL-YMP in accordance with the established policies, procedures, and instructions. The QAPP applies to all items and activities affecting quality. It also identifies other organizational entities participating in the LLNL-YMP and the designated functions of these organizations. The QAPP provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity are satisfied. The program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program provides for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The DOE Project Office and the LLNL-YMP regularly assess the status and adequacy of the QA Programs of the LLNL-YMP by means of overview, surveillance, and audit activities.

2.0 APPLICATION OF GRADED QUALITY ASSURANCE

2.1 SCOPE

2.1.1 EXTENT OF APPLICATION

The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents do not require QA ~~level~~ controls, ~~assignments~~, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA ~~level assignments~~ controls. The LLNL-YMP is charged with developing an implementing procedure for the application of graded QA. The procedure is in consonance with the QA requirements specified herein. It may be necessary to exempt certain LLNL-YMP items and activities from QA ~~level~~ controls. ~~assignment~~. Requests for exemptions are documented and contain sufficient justification to support the exemption request. Such exemptions are approved by the DOE Project Office Quality Assurance Manager. CN R 2-0-3

2.1.2 PURPOSE OF A GRADED QA PROGRAM

The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Yucca Mountain Project consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This is accomplished by deliberate quality planning and selective application of QA requirements on the item or activity performed, with varying degrees of QA applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) assuring that these items and activities are covered by a commensurate QA program. Alternatively, an item whose failure or malfunction would result only in operational inconvenience or negligible economic loss deserves only a quality inspection by the LLNL-YMP upon the delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.

2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

The graded approach set forth provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

2.2 REQUIREMENTS

The requirements specified in this section are used to apply the graded quality philosophy to all YMP items and activities.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate Quality Assurance Level for any item or activity is determined by the application of decision criteria as provided by the DOE Project Office. The basis for the selection of the Quality Assurance Level and assigned QA requirements are documented. The assigned Quality Assurance Levels and QA requirements are submitted to the DOE Project Office for review, resolution of comments, and approval prior to implementation or use. This review and approval is performed by the DOE Project Office Quality Assurance Manager and appropriate DOE Project Office Branch Chiefs.

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2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three quality assurance levels (QA level) of which one is assigned to each technical task that affects the quality of the LLNL-YMP. The definition, application, and assignment to each of the three QA levels are described in the following discussion.

2.2.2.1 QA Level I - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

2.2.2.2 QA Level II - are those activities and items related to the systems, structures, and components requiring a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE Project Office concerns and the environment.

2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I or II.

2.2.3 APPLICATION OF LEVELS

2.2.3.1 QA LEVEL I

QA Level I is the most stringent level of quality assurance. It is applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. QA Level I activities on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. QA Level I control and documentation are applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard. To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and assure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:

- Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.

- Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.

- Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.

- Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.

- Where items and activities that, having failed, could cause a failure of a QA level I item, or irretrievable loss of QA level I data.

- The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) is assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationalships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities are governed by the QA level assigned to the item.

2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation are applied to the LLNL-YMP activities and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will utilize engineered systems, structures, and components which are designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones are appropriately controlled. Therefore, Quality Assurance Level II is applied to activities and items as follows:

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- Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.

- Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.

- Where items and activities could affect the retrievability of waste up to the time of repository closure.

- Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.

- The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, is assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment is made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities are governed by the QA Level assigned to the item.

- o Where items and activities that, having failed, could result in a major cost overrun.

- o Where items and activities that, if failed, could result in a major schedule slippage.

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with the DOE Project Office Administrative Procedures.

2.2.3.3 QA LEVEL III

QA Level III is the least stringent level of Quality Assurance. Level III Quality Assurance items and activities are such that they have no major function in the characterization of the site and design of the repository, but they require good practices for the intended use. Design phases which are purely preliminary and are conducted to define the range of alternatives/methods/equipment which are felt to be worthy of more detailed study are assigned a QA level of III prior to execution. Those activities controlled in accordance with a Quality Assurance Level III program cannot subsequently be used to directly support Quality Assurance Level I activities.

In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the LLNL-YMP QAPP may be used in the licensing process as background or corroborative information.

2.2.4 GENERAL

The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by the LLNL-YMP.

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3.0 QA ACTIVITIES

3.1 OVERVIEW

The LLNL-YMP performs an overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. Overview includes the following as appropriate:

- The review and approval of subcontractor QAPPs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA programs.

3.2 REVIEW AND APPROVAL OF THE LLNL-YMP QA PROGRAM

The LLNL-YMP establishes procedures for the review of its subcontractor QA program documentation for adequacy, completeness and relevance. The procedures identify the types of documents to be submitted by the subcontractor for review and approval, assign project responsibility for review, and identify the methods for documenting review and approval action. Reviews of the subcontractor's QA program documentation may be recorded on checklists or other forms designated by the LLNL-YMP that specify the criteria for acceptability and indicate conformance or nonconformance.

4.0 MANAGEMENT ASSESSMENT

4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS

Management assessments are conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) the adequacy of resources and personnel provided to the QA program. Management verifies that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.

4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS

Management assessments are performed by the DOE Project Office and the LLNL-YMP. Procedures are developed for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are provided to the DOE Project Office and the DOE Project Office Quality Assurance Manager. The DOE Project Office makes appropriate submittals of management assessment reports to OCRWM. Management above or outside the QA organization is responsible for the management assessment activity.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 ESTABLISHMENT OF REQUIREMENTS

Requirements are established for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) are certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.

5.1.1 POSITION DESCRIPTION

Minimum education and experience requirements are established and documented in position descriptions for each position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience are verified. This verification is documented. The initial capabilities of an individual are based upon an evaluation of their education, experience, and training and are compared to those established for the position. Evaluations are documented by managers or supervisors responsible for the activities to be performed.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, the personnel are indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination is accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- o QAPPs
- o Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).
- o Regulations
- o Project level Documents

5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities, training is conducted, if needed, to gain the required proficiency. The training (in-depth instruction) includes the principles, techniques, and requirements of the activity. In-depth instruction is achieved through internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality is evaluated and documented at least annually. Proficiency evaluations are performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations are performed by managers or supervisors who have responsibility for the activities being performed or verified.

5.1.6 RECORDS

Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations are retained as lifetime QA records. These records include, as a minimum, the items listed below.

.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.

5.1.6.3 Training Records

Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

5.1.6.4 Proficiency Evaluation Records

Records of proficiency evaluation include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

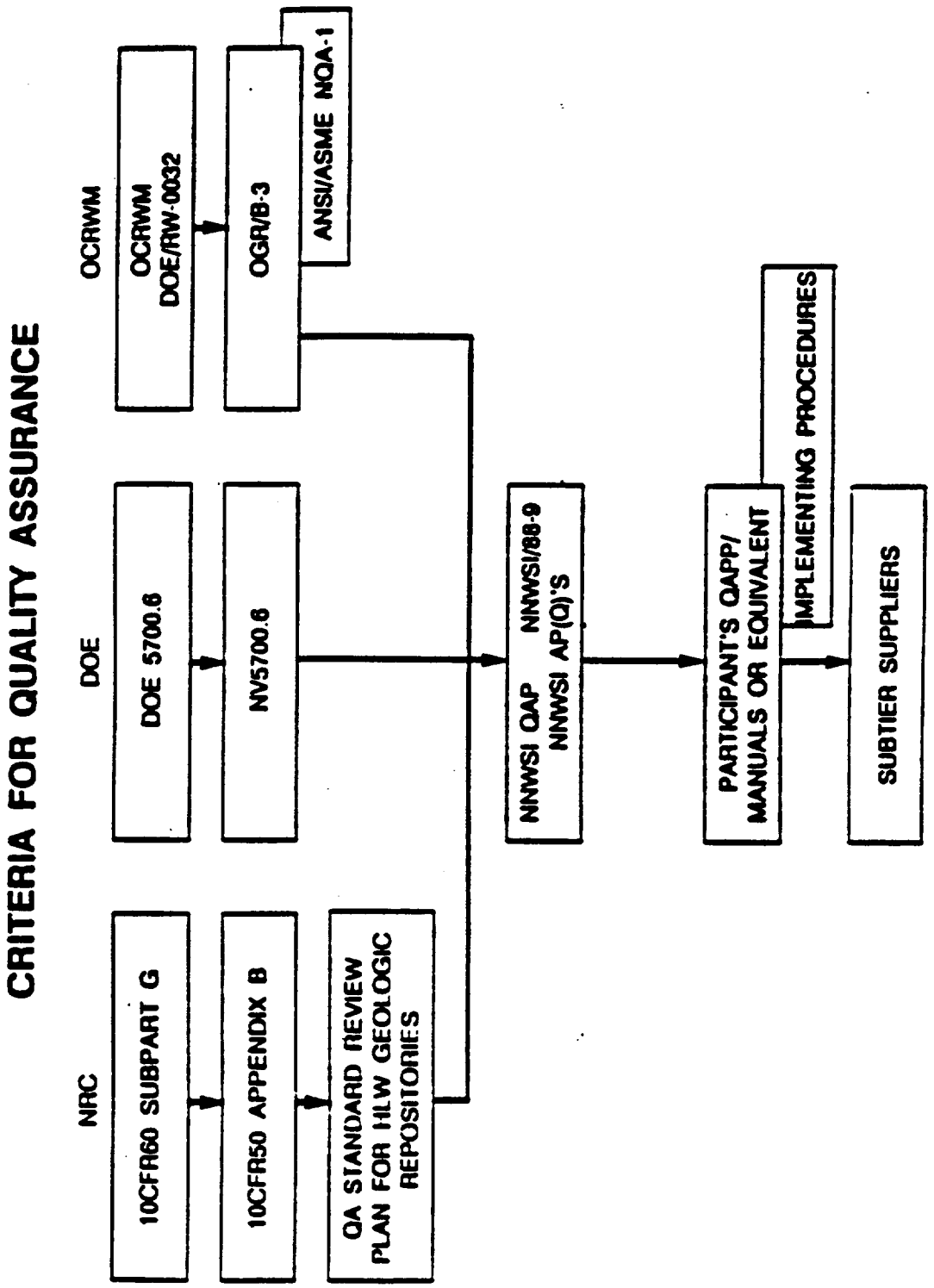
CRITERIA FOR QUALITY ASSURANCE
OCRWM
OCRWM DOE/RW-0032
OGR/B-3
ANSI/ASME NQA-1
DOE
DOE 5700.6
NV5700.6
NRC
10CFR60 SUBPART G
10CFR50 APPENDIX B
QA STANDARD REVIEW PLAN FOR HLW GEOLOGIC REPOSITORIES
NNWSI QAP NNWSI AP(Q)'S
PARTICIPANT'S QAPP/ MANUALS OR EQUIVALENT
IMPLEMENTING PROCEDURES
SUBTIER SUPPLIERS

FIGURE 1