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Quality Assurance Guidance for a Low-Level Radioactive Waste Disposal Facility

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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ABSTRACT

This document provides guidance to an applicant on meeting the quality control (QC) requirements of 10 CFR 61.12(j) for a low-level radioactive waste (LLRW) disposal facility. The QC requirements, plus audits and managerial controls requirements, establish the need for developing a quality assurance (QA) program and the guidance provided herein. The criteria developed for this document are similar to the criteria developed for Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50. Although Appendix B is not a regulatory requirement for an LLRW disposal facility, the criteria that were developed for 10 CFR Part 50 are basic to any QA program. This document establishes QA guidance for the design, construction, and operation of those structures, engineered or natural systems, and components whose function is required to meet the performance objectives of Subpart C of 10 CFR Part 61 and to limit exposure to or release of radioactivity.

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1 INTRODUCTION

The United States Congress passed laws in 1980 and 1985 that require States to take specific actions to deal with the low-level radioactive waste (LLRW) generated by facilities operating within their boundaries. The 1980 law (Public Law 96-573, The Low-Level Radioactive Waste Policy Act) specifies that each State will be responsible for disposing its own radioactive waste after January 1, 1986; authorizes States to join together to form regional compacts; and authorizes those compacts to prohibit disposal of LLRW generated outside the regional compact. The 1985 amendment (Public Law 99-240, The Low-Level Radioactive Waste Policy Amendments Act) extended the effective date to January 1993. This amendment imposes intermediate milestones that the States are required to meet to demonstrate progress and authorizes the States accepting this waste for disposal to impose a surcharge on the existing waste disposal costs.

In an attempt to assist the States in meeting these milestones, the Nuclear Regulatory Commission (NRC) has developed and issued several documents providing guidance on the development of an LLRW disposal facility. This document provides guidance to an applicant on establishing a quality assurance program to meet the quality control requirements of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 61, Section 61.12(j). Although the NRC is in the process of revising the requirements of 10 CFR 61.12(j), the rule change will not affect use of the guidance provided herein. The staff intends to change the current QC requirements, including managerial controls and audits, to require a QA program, which, in fact, will further support this guidance.

Revision 1 of this document incorporates comments provided by participants during workshops conducted on the application of the document. Appendix A to this document summarizes the essential elements of a quality assurance (QA) program. Appendix B summarizes the public comments received on the draft version and the NRC's responses to those comments and where the necessary changes were incorporated in the final report.

The guidance offered herein is not a regulatory requirement. In addition, the NRC is in the process of developing QA guidance in several other related areas and is continuing to conduct workshops on the QA principles to be used by an applicant for license of an LLRW disposal facility, including workshops for site characterization activities.

2 REGULATORY BASIS FOR QUALITY ASSURANCE PROGRAM

The NRC staff prepared this QA guidance document for application in the development of LLRW disposal facilities to provide guidance to an applicant on meeting the quality control (QC) requirements of 10 CFR 61.12(j). The regulation requires that a license application for an LLRW facility include a description of the QC program to be applied for determining the characteristics of a natural disposal site. The regulation also requires a QC program during design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included. The purpose of the managerial controls, audits, and QC program required by 10 CFR 61.12(j) is to ensure a planned, organized, and documented approach to meeting the performance objectives and the technical requirements of 10 CFR Part 61. The requirements stated in 10 CFR 61.12(j) establish the need for developing a QA program and the guidance provided herein.

A QA program includes a multidisciplinary system of management controls supported by quality verification and overview activities that demonstrate completeness and appropriateness of achieved quality. A QA program serves as a means to meet the requirements for audits and managerial controls along with demonstrating that the QC requirements are met. A QA program includes QC.

This document provides guidance to an applicant for developing an acceptable quality assurance program, using 18 criteria that are similar to the criteria developed for Appendix B to 10 CFR Part 50. Although Appendix B is not a regulatory requirement for an LLRW disposal facility, the criteria that were developed for 10 CFR Part 50 are basic to any QA program. Some of the criteria addressed here are identical to criteria addressed in 10 CFR Part 50, and some criteria have been modified to address an LLRW disposal facility.

This document specifically establishes QA guidance for the design, construction, operation, and closure of structures, engineered or natural systems, and components whose function is required to meet the requirements of 10 CFR Part 61. These include designing, purchasing, fabricating, erecting, installing, and cleaning activities; inspecting, testing, operating, receiving, handling, and emplacing waste; and closure and active maintenance. In addition, at the time of licensing, the applicant will have to demonstrate that the facility will meet the performance objectives and technical requirements of 10 CFR

Part 61. A properly designed and implemented QA program will provide the required audits, managerial controls, and QC program necessary for demonstrating that the requirements will be met.

QA is defined in regulations, codes, and standards as comprising all those planned and systematic actions necessary to prove that a structure, system, or component will perform satisfactorily in service, and includes QC. When the product is a report of a significant study or investigation, QA also comprises those planned and systematic actions necessary to provide adequate confidence in the validity and integrity of the reported data, methods, and procedures and in the protection, retrievability, and replicability of the data.

Chapter 9 of NUREG-1199, "Standard Format and Content of a License Application for Low-Level Radioactive Waste Disposal Facility," and Chapter 9 of NUREG-1200, "Standard Review Plans for Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," provide the applicant additional QA guidance. NUREG-1383, "Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site" provides guidance on the application of QA for site characterization.

3 QUALITY ASSURANCE CRITERIA

The following 18 criteria are identified to provide guidance on the development of a QA program for an LLRW disposal facility.

1. *Organization*

The applicant is responsible for establishing and executing the QA program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the QA program or any part thereof, but the applicant retains ultimate responsibility for that program. The authority and duties of persons and organizations performing functions affecting the performance of those activities, structures, systems, or components to be covered by the QA program should be clearly established and delineated in writing. These functions include both the performing functions of attaining the required quality of work (quality achieving) and the assurance functions that verify the attainment of quality (quality assuring).

The applicant should clearly describe the organizational structure, including authority, responsibility, and interface of organizations performing quality-achieving and quality-assuring functions. Quality achievement is defined as satisfactory performance of a work activity such as drilling, designing, constructing, or testing in accordance with technical criteria, requirements, and procedures. The quality-assuring functions are verifying that an appropriate QA program has been established and effectively executed and verifying, by surveillance, audit, or inspection, that activities meet the performance objectives and technical requirements for 10 CFR Part 61.

The persons and organizations performing quality-assuring functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. This is not to suggest that identifying quality problems and finding solutions is limited to those performing quality-assuring functions. Such persons and organizations performing quality-assuring functions should report to management at such a level that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

Because of the many variables involved (such as the number of personnel, the type of activity being performed, and the location or locations at which activities are performed), the organizational structure for executing the QA program may take various forms, provided the persons and organizations assigned the quality-assuring functions have the required authority and organizational freedom to perform their assuring and verifying assignments. Irrespective of the organizational structure, the individual(s) assigned the responsibility for ensuring effective execution of any portion of the QA program at any location at which activities subject to this guidance document are being performed should have direct access to whatever levels of management may be necessary to perform this function.

2. *Quality Assurance Program*

The applicant should establish, at the earliest practicable time and consistent with the schedule for accomplishing the activities, a QA

program that complies with the recommendations of this document. The QA program should be documented by written policies, procedures, or instructions and should be carried out in accordance with those policies, procedures, and instructions throughout the life of the facility, from characterization through license transfer or termination. The applicant should identify for the life of the facility the activities, structures, systems, and components to be covered by the QA program and the major organizations participating in the program, together with the functions of the organizations.

The QA program should provide control over all activities affecting the quality of the identified activities, structures, systems, and components to an extent consistent with their required performance. Activities affecting quality should be performed under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for performing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.

The program should take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality of the designated activities, structures, systems, or components, and the need for verification of quality by inspection and testing. The program should provide for indoctrinating and training personnel performing activities affecting quality to ensure understanding of the technical procedures and QA requirements. The applicant should regularly review the status and adequacy of the QA program.

One of the principal managerial controls is a self-assessment program. Personnel and organizations responsible for carrying out the self-assessment function, including safety committee activities, audits, and independent assessments, are to be cognizant of day-to-day activities so that they can act in an advisory capacity. Personnel performing self-assessment activities are to be technically and performance oriented, primarily focusing on the quality of the end product and then focusing on procedures and processes; they are not to have direct responsibilities in the area they are assessing. Self-assessments are to be accomplished using procedures, or appropriate means that are of a detail commensurate with the complexity and importance to safety of the activity. Management personnel from other organizations participating in the QA program should regularly review the status and adequacy of their particular QA program. Appendix A of this document provides a summary of the essential elements of a QA program.

3. *Design Control*

The following definition of design is consistent with the definition as defined in the Atomic Energy Act of 1954. The term "design," as defined for an LLRW facility, refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the LLRW facility. It includes design at each stage of development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analysis that are used in supporting design development and verification. The design includes general plans and detailed procedures for data collection and analysis that are used to support design development. Data analysis includes the initial step of data reduction, as well as the performance assessments that integrate many other data and analyses of individual parameters.

The design of an LLRW facility includes (1) characterizing the geologic setting, (2) predicting the long-term stability of the site, (3) predicting the environmental interactions between the site and its surroundings, (4) planning and specifying processes for handling LLRW, and (5) specifying requirements for constructing facilities for handling LLRW. The design process includes developing computer codes used in modeling the characteristics of the geologic setting or in predicting environmental impacts, such as groundwater travel and seismic activity. The degree of design control that management must exercise over a given element of the design depends to a great degree on how important that element is for meeting the performance objectives or the technical requirements for the LLRW facility, or both. The ability to demonstrate the soundness of the design is a key consideration in establishing managerial controls.

Scientific investigations carried out to characterize the site should be defined, controlled, and verified. The intended use of data should be documented as part of the planning. Any alternative use of the data should be evaluated for its appropriateness and the justification

documented. Planning should ensure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning should establish provisions for the evaluation of data quality to ensure that data generated is valid, comparable, complete, representative, precise, and accurate.

The range, accuracy, and precision of equipment used for scientific investigations should be specified in order to be commensurate with requirements. Scientific investigations should be performed in accordance with nationally recognized standards where available. Standards used without modification require documentation by reference only. If deviation from standards or establishment of specifically prepared procedures is deemed appropriate, the modifications or new methods should be documented in sufficient detail to be repeatable and should be evaluated, justified, and approved.

Data not collected under the control of a quality assurance program meeting the guidance of this document should be qualified before its use for characterizing the site. The guidance, provided in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," should be used to determine acceptable qualification methods.

Peer reviews may be used to provide adequate confidence in the work under review; this work may be a design, a plan, a test procedure, a research report, a materials choice, or a site exploration. Because of the potential uncertainty in most geotechnical data and their analyses, the need to make projections over several hundred years, and the lack of unanimity among experts, expert judgment will need to be used in assessing the adequacy of some work. Peer reviews are a mechanism by which these judgments may be made. The guidance of NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," should be used for determining the applicability and conducting a peer review.

A design control program should be documented and implemented before design work starts. Measures should be established to ensure that applicable regulatory requirements, as defined in 10 CFR Part 61, are correctly translated into specifications, plans, drawings, procedures, and instructions. These measures should include provisions to ensure that appropriate quality standards are specified and included in the design documents and that deviations from such standards are controlled. Measures also should be established for selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components. The program should (a) describe the measures that ensure verification or checking of design adequacy, such as design review, use of alternative calculational methods, or performance of a qualification testing program under the most adverse design conditions; (b) identify the positions or organizations responsible for design verification or checking; and (c) describe the measures taken to ensure that the verification or checking process is performed by individuals or groups other than those responsible for the original design, but who may be from the same organization.

The applicant should describe the measures of identifying and controlling design interrelationships, both internal and external, and for providing coordination between participating design organizations.

Neither the original designer nor normally his immediate supervisor should be responsible for design verification. Design verification consists of confirming that the design of the structure, system, or component is suitable for its intended purpose. Design checking, which also should be performed, includes such things as confirming the numerical accuracy of computations and the accuracy of data input to computer codes. Confirming that the correct computer code has been used is part of design verification. Design verification requires that the responsible individual or group possesses a level of skill at least equal to that of the original designer; design checking, however, can be performed by less skilled persons. Design should not be verified by persons who checked the design.

Design changes, including field changes, should be subject to design control measures commensurate with those applied to the original design and should be approved by the organization that performed the original design, unless the applicant designates another responsible organization.

Errors and deficiencies in the design, including the design process, that could adversely affect the performance of any structures, systems, components, or activities covered by the QA program are documented, and corrective action, including root-cause evaluation of

significant errors and deficiencies, is taken to prevent repetition.

Computer software used to calculate or develop data to support a license application should be verified, validated, and documented. NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," provides guidance on documentation. Guidance for preparation of software quality assurance plans is found in the Institute of Electrical and Electronics Engineers (IEEE) Standard 730-1984, "IEEE Standard for Software Quality Assurance Plans." Computer software verification is defined as the process that demonstrates that the computer software performs its stated capabilities and functions. Computer software validation is defined as the process that demonstrates that the mathematical model embodied in the computer software is a correct representation of the process or system for which it is intended.

Computer software should be placed under configuration control as each baseline element is approved. Changes to computer software should be systematically evaluated, coordinated, and approved to ensure that the effect of a change is carefully assessed before updating the baseline.

4. *Procurement Document Control*

Measures should be established to ensure that applicable regulatory requirements, design bases, and other requirements needed to ensure adequate quality are suitably included or referenced in the document for procurement of material, equipment, and services whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents should require contractors or subcontractors to provide a QA program consistent with this guidance.

Procedures should be established that clearly describe the sequence of actions to be performed in the preparation, review, approval, and control of procurement documents. Procurement documents are the medium of exchange of information between the applicant and its contractors or between the prime contractors and subcontractors. It is paramount to the success of the design, construction, and operation of an LLRW facility that these documents be planned, released, and distributed with utmost care. For the more important instructions conveyed by procurement documents, it is prudent to also conduct meetings to review the contents and ensure that the resulting actions will take place as planned.

Particular care should be exercised in communicating the required management controls to contractors and subcontractors supplying services related to site characterization to ensure that results can be reliably demonstrated. Procedures that are to be followed and records that are to be generated and retained must be clearly identified in the procurement documents. It is the responsibility of the applicant to ensure that contractors and subcontractors have the needed information and that they fully comprehend the information and the significance of its use.

Qualified personnel should review and concur in the adequacy of quality requirements stated in procurement documents. This review should determine that quality requirements are correctly stated, inspectable, and controllable and contain adequate acceptance and rejection criteria and that the procurement document has been prepared, reviewed, and approved in accordance with QA program requirements. The review and approval of procurement documents should be documented before such documents are released, and the documentation should be available for verification. Changes and revisions to procurement documents should receive the same or equivalent review and approval as the original documents.

Procurement documents should identify (a) the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval and (b) those records needed to be retained, controlled, and maintained by the supplier and those to be delivered to the purchaser before the hardware is used or installed.

Procurement documents should contain a statement specifying the procuring agency's right of access to the supplier's facilities and records for the purpose of source inspection and audit.

5. *Instructions, Procedures, and Drawings*

The applicant is responsible for ensuring that activities affecting quality are prescribed and performed in accordance with documented instructions, procedures, or drawings. Procedures should be established that clearly delineate the sequence of actions to be performed in the preparation, review, approval, and control of instructions, procedures, and drawings. Instructions, procedures, or drawings should include appropriate quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Two primary reasons exist for maintaining planned and approved instructions, procedures, and drawings for the performance of the designated activities, structures, systems, and components. The first occurs when there is a need to perform an activity in a specific way and sequence. The formal instruction, procedure, or drawing provides not only the specific way and sequence but provides criteria to permit an independent verification that the activity was performed correctly. The second occurs when there is a need to document the tools, methods, and in-process results for the benefit of others who will later review the decision process and evaluate the conclusions reached. The conduct of field and laboratory geotechnical tests requires preplanned procedures to be followed by a scientist, but as the testing progresses, the procedures will be changed to reflect new and different practices dictated by in-process information. At the conclusion, the procedure followed by the scientist and the information gathered will be fully documented.

A key question for the applicant to consider when determining whether instructions, procedures, and drawings are needed is: "What information will be needed to demonstrate that the LLRW facility was designed, constructed, and operated in a way that ensures the performance objectives and technical requirements of 10 CFR Part 61 are met?" It is the applicant's responsibility to ensure that the needed records are identified, collected, and stored regardless of whether the records are generated by the applicant or by a contractor.

6. *Document Control*

Documents that contain design, construction, operation, closure, and active maintenance requirements should be procedurally controlled in their approval, issuance, and distribution. Before such documents and changes thereto are released, they should be procedurally controlled to ensure the contents of the documents are adequate, the quality requirements are appropriately stated, and the appropriate distribution is established. Approved changes should be included in instructions, procedures, drawings, and other documents before the change is implemented.

Procedures should be established for identifying those individuals or groups responsible for reviewing, approving, and issuing documents and revisions to those documents. Changes to documents should be reviewed and approved by the same organization that reviewed and approved the documents originally, or by other qualified responsible organizations delegated by the applicant.

Obsolete or superseded documents should be controlled to prevent inadvertent use. A master list or its equivalent should be established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents. The list should be revised and distributed to predetermined, responsible personnel to prevent use of superseded (outdated) documents.

Documents related to an activity, such as maintenance or modification, should be available at the work site at which the activity will be performed before the work commences.

7. *Control of Purchased Material, Equipment, and Services*

Measures should be established to ensure that material, equipment, and services purchased directly or through contractors and subcontractors conform to the procurement documents. As appropriate, for source evaluation and selection, these measures should provide objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and

examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements should be available at the LLRW disposal facility before such material and equipment are installed or used. This documentary evidence should be retained by the applicant and should be detailed enough to identify the specific requirements imposed on the purchased material and equipment. At intervals consistent with the importance, complexity, and quantity of the product or services, the applicant or its designee should assess how effectively contractors and subcontractors control quality.

This criterion can be difficult to implement if a component or service is contracted and subcontracted through a series of subcontractors or if it is broken down into elements and subcontracted. Because the applicant retains the responsibility for the end results, it should review the contracting and subcontracting to ensure that the controls exercised guarantee that the planned products and services are acceptable.

8. *Identification and Control of Material, Parts, and Components*

Measures are needed to provide formal control over and identification of items such as core, laboratory test samples, raw materials to be used in construction, fabricated parts and assemblies, and material or components found to be defective. All material collected for observation or tests that contribute to the design bases, all material that contributes to the constructed LLRW facility, and all material related to the operation of the LLRW facility should be identified and controlled for a period of time specified by the technical organizations.

Procedures should be established for identifying and controlling materials, parts, components, geologic cores, and field and laboratory samples. These procedures should ensure that, where appropriate, identification of the item, core, or sample is maintained by appropriate identification either on the item, core, or sample, or on records traceable to the original item, core, or sample. These identification and control measures should be designed and maintained to ensure that geologic and environmental data are correctly identified to the time and exact location of origin and that identification is maintained from collection through shipment, sample split (subsample), and subsequent analysis.

Procedures established for identifying and controlling materials, parts, and components should ensure that, where appropriate, the item is identified by heat number, part number, serial number, or other suitable means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures should be designed to prevent the use of incorrect or defective material, parts, and components.

9. *Control of Processes*

Processes affecting the quality of items or services should be controlled by instructions, procedures, drawings, checklists, or other appropriate means. Processes that control or verify quality should be performed by qualified personnel using documented procedures.

Qualification records of procedures, equipment, and personnel associated with special processes should be established, filed, and kept current.

10. *Inspection*

Inspection should be performed as a verification activity to ensure that work, including prior inspections, has been properly performed.

A program for inspecting the results of the activities affecting quality should be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for conducting the activity. Such inspection should be performed by individuals other than those who executed the activity being inspected. Examinations, measurements, and tests of material or products processed should be performed for each work operation as appropriate.

If inspection of processed material or products is impossible or provides a hindrance, processing methods, equipment, and personnel should be monitored, and thus controlled indirectly. Both inspection and process monitoring should

be provided when control is inadequate without both. If mandatory inspection hold points (which require witnessing or inspecting by the applicant's designated representative and beyond which work should not proceed without the consent of its designated representative) are required, the specific hold points should be indicated in appropriate documents.

11. *Test Control*

A test may be conducted to determine if an item or service is acceptable or to acquire additional information. Test is defined as an operation employed to resolve an uncertainty; a process to ascertain effectiveness, value, proper function, quality, or other characteristics; or a process to understand a system, subsystem, component, or structure. The results of a test should be documented to indicate an item's acceptance or rejection.

A test program should be established to ensure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements and acceptable limits contained in applicable design documents. The description of the test should indicate the purpose of the test. The test program should include tests conducted before installation, preoperational tests, and tests performed during operations.

Tests should be planned and conducted according to documented procedures, and results should be documented and retained as QA records. Test procedures should include provisions for ensuring that all prerequisites have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results should be evaluated to ensure that test requirements have been satisfied.

12. *Control of Measuring and Test Equipment*

All measurements that affect site characterization, the quality of the design, construction, or operation of an LLRW facility should be taken only with instruments, tools, gauges, or other measuring devices that are accurate, controlled, calibrated, and adjusted at predetermined intervals to maintain accuracy within necessary limits.

Provisions contained in procedures should describe the calibration technique and frequency, maintenance, and control of the measuring and test equipment that is used in the measurements, as well as inspection and monitoring of any activities, structures, systems, and components important to meeting the applicable requirements.

Measuring and test equipment should be labeled, tagged, or otherwise documented to indicate when the next calibration is due and to provide traceability to calibration test data. It should be calibrated at specific intervals based on required accuracy and equipment history of drifting, precision, purpose, and other characteristics that could affect accuracy. When a piece of measuring and test equipment is found to be out of calibration, evaluations should be made to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests should be repeated on suspect items.

Reference and transfer standards should be traceable to nationally recognized standards or, should national standards not exist, provisions should be established to document the basis for calibration.

13. *Handling, Storage, and Shipping*

Measures should be established to control handling, storage, cleaning, packaging, preservation, and shipping of items affecting the quality of the design, construction, operation, closure, and active maintenance of an LLRW facility. It is of particular importance that attention be given to application of this criterion to the control of samples to prevent damage, loss, deterioration, and misidentification. When necessary for particular products, a special protective environment (such as an inert gas atmosphere), moisture content levels, and temperature levels should be specified and provided.

Procedures should be prepared that provide for the cleaning, handling, packaging, preservation, storage, and shipping of samples, materials, components, and assemblies, in accordance with design and specification requirements to

prevent damage, loss, or deterioration by environmental conditions. Qualified individuals should perform these activities in accordance with preplanned work instructions.

Samples should be controlled during handling, storage, and shipment to preclude damage or loss and to minimize deterioration. Controls should be established for appropriate packaging, handling, and modes of transportation, with consideration being given to types of containers, time constraints on perishable materials (that is, shelf life), and other environmental or safety considerations applicable to the samples. Measures should be taken to avoid sample contamination during handling and shipment. Where multiple organizations are involved, appropriate procedures should describe interface and custody responsibilities. Sample identification should be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another.

Provisions should be made to maintain sample characteristics, integrity, and identification while in storage. These provisions should be consistent with the planned duration and conditions of storage and should describe actions to be taken where samples have a maximum life expectancy while in storage. Storage methodology should be developed and implemented to ensure that samples are maintained in predetermined environmental conditions commensurate with the samples' intended purposes. Samples should be controlled to preclude mixing of like samples or contamination. Provisions should be made for identification and storage of tested samples in areas physically separated from untested sample materials.

14. *Inspection, Test, and Operating Status*

The inspection and test status of samples, structures, systems, and components should be identified. Such identification will prevent inadvertent use of a sample, structure, system, or component yet to be inspected or tested or that has been found unacceptable for use.

Measures should be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed on individual items of the LLRW disposal facility. These measures should provide for identifying items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests.

Measures also should be established for indicating the operating status of structures, systems, and components of the LLRW disposal facility to prevent inadvertent operation. Such measures should be subject to the same controls as the original review and approval.

15. *Nonconforming Materials, Parts, or Components*

Measures should be established to control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use or installation. These measures should include, as appropriate, procedures for identification and documentation, including followup verification for the proper implementation of corrective actions by the QA organization in a timely manner, as well as segregation, disposition, and notification to affected organizations. Nonconforming items should be reviewed and either accepted, rejected, repaired, or reworked in accordance with documented procedures.

16. *Corrective Actions*

Corrective measures should be established to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected by those individuals or groups that have been authorized to perform this function. The measures should ensure that the cause of the condition is determined and that corrective action is taken to prevent the condition from occurring again. Actions taken should be documented and reported to appropriate levels of management in a timely manner.

17. *Quality Assurance Records*

QA records furnish evidence that activities affecting quality have been properly performed. The records should include the following: operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. The records also should include closely related data such as qualifications of personnel, procedures, and equipment and the evaluations of the various radiation exposure pathways and the analyzed doses from the pathways included in the license application. Inspection and test records should, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records should be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant should establish requirements concerning record retention, such as duration, location, and assigned responsibility.

18. *Audits, Surveillance, and Managerial Controls*

A comprehensive system of planned periodic surveillance and audits should be carried out to verify effective implementation of the QA program. The audits should be performed in accordance with the written procedures or checklists by appropriately trained personnel who do not have direct responsibilities in the area audited. Audit results should be documented and reviewed by management personnel who have responsibility in the area audited. Controls should include documentation, review, and record maintenance of the audit program; frequency of audits; and followup action of deficient areas, including correction, surveillance, or examination.

Well-planned verification techniques provide the means to measure and control the status of the design, construction, and operation activities as they relate to meeting 10 CFR Part 61 requirements. Real-time awareness of anomalies permits immediate analysis and correction of identified problems and of the cause of the problems.

Audit and surveillance planning should be determined by the work schedule and the significance of the work that is to be observed. Audit and surveillance planning should not be based on conducting such reviews every so many months because such routine can only cause the verification process to lose credibility to the auditee and the auditors as well.

4 APPLICATION OF THE REGULATORY REQUIREMENTS FOR MANAGERIAL CONTROLS, AUDITS, AND QUALITY CONTROL

4.1 Timeframe for Applying Managerial Controls

The regulatory requirements for managerial controls, audits, and quality control apply to the preoperational phase, the operational phase, the site closure phase, and the post-closure institutional control phase, and covers any structure, engineered or natural system, or component whose performance is required to meet the performance objectives of 10 CFR Part 61 and limit the exposure to or release of radioactivity.

The applicant should develop and implement an effective quality assurance program before start of site characterization activities and, as the licensee, should continue the implementation of an effective quality assurance program through license transfer or termination.

An applicant is obligated to have management controls in place during the investigation of the disposal site's characteristics and the analyses to establish a base for its suitability. The applicant must be prepared to demonstrate in the license application that the proposed disposal site, disposal site design, land disposal facility operations (including equipment, facilities, and procedures), disposal site closure, and post-closure institutional control are adequate to demonstrate that the performance objectives and technical requirements of 10 CFR Part 61 will be met. The applicant should expect that the validity of information contained in the license application will be challenged during licensing review and hearing, and the applicant must be prepared to defend the validity of the data, the analyses, or the conclusions reached. A well-designed and effectively implemented QA program provides the disciplined approach, verification of results, and records to support the positions taken in the license application.

4.2 Graded Approach for the Application of Managerial Controls

The QA program provides the necessary controls over activities to ensure the performance objective and the technical requirements are met and that the results can be demonstrated. The management controls applied to an item or activity to ensure the integrity of the results will vary as a function of the degree of confidence needed regarding the quality of the item or activity. Critical items or activities may require extensive controls throughout all stages of development, whereas less critical items or activities may require only limited controls. The application and degree of management controls applied to an item or activity is a process to be exercised by the responsible technical staff during the planning stages. The criteria and method used for grading the application of managerial controls should be described in a procedure.

A graded approach in the application of managerial controls provides confidence in the quality of a product commensurate with the product's importance to meeting predetermined objectives. However, the quality of a product or data is not necessarily improved by increasing the managerial controls. Appropriately applied controls will provide confidence in the end product quality and provide objective evidence to demonstrate that requisite quality was attained.

The graded approach permits the scientists or engineers to predetermine, during the work planning phase, the managerial controls needed to provide confidence in end products and to provide objective evidence of end product quality. As an example, if a field test could be conducted only once and the resulting data from the test was key to a decision as to the stability of a potential disposal site, carefully planned managerial controls should be applied. On the other hand, if the same test were being conducted to check equipment or establish a process, very few managerial controls would be applied and perhaps there would be no documentation other than the scientist's personal log.

Effective use of the graded approach dictates that a decision process be established and used during work planning. The decision process can be conveniently tied to the breakdown structure of the work elements.

Attempts to characterize large blocks of items or activities in one category and apply the same controls to all items and activities under the category umbrella is discouraged. An example of this approach is to characterize all items and activities that support a licensing process as being category "A" and conclude that all of the QA program applies. If the decision process stops at this point, the important decisions have not been made and confusion will reign when the work process starts. Still needed is a decision as to what are the end products, what is the importance of predetermined objectives, and what documentation is needed.

The use of a graded approach is recommended, but it must be carefully planned and executed to be effective.

4.3 Identification of Structures, Systems, and Components Requiring Managerial Controls

The applicant is responsible for listing all structures, systems, and components whose function is required to meet the performance objectives of 10 CFR Part 61 or to limit the exposure to or release of radioactivity. In addition, the applicant should identify activities that, if not performed or if performed incorrectly, could result in structures, systems, or components not meeting the performance objectives. The list should be distributed by the applicant to all participating organizations so that they clearly understand the effect of applying managerial controls on the design and on other quality-related activities. All these activities, structures, systems, and components will be reviewed by NRC for their completeness, accuracy, and basis for the degree of managerial controls to be applied.

5 REFERENCES

American National Standards Institute/The Institute of Electrical and Electronics Engineers, Inc., ANSI/IEEE Std. 370-1984, "Standard for Software Quality Assurance," December 17, 1984.

U.S. Government Printing Office, *Code of Federal Regulations*, Title 10, "Energy," Chapter I, U.S. Nuclear Regulatory Commission, Parts 50 and 61, Washington, DC, revised annually.

U.S. Nuclear Regulatory Commission, NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," June 1983.

——, NUREG-1199, "Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility," January 1988.

——, NUREG-1200, "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," January 1988.

——, NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories," February 1988.

——, NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," February 1988.

——, NUREG-1383, "Guidance on the Application of Quality Assurance for Characterizing a Low-Level Waste Disposal Site," October 1990.

Appendix A

Summary of the Essential Elements of a QA Program

The applicant should provide a description of its quality assurance program as a part of the license application. The description should include the following as a minimum:

- a brief description of the work covered by the QA program
- a chart of the applicant's organization
- a descriptive breakdown of responsibilities and authorities of the organizational entities, including the administrative, technical, and quality responsibilities of each entity
- a descriptive breakdown of delegations of work to major contractors by name
- a description of what is to be done to address each of the applicable 18 criteria
- a listing of procedures to be used to implement the QA program and a schedule for their issue

The applicant also should provide the major contractors' descriptions of their respective quality assurance programs. The descriptions should include the above information and should be approved by the applicant before submittal with the license application.

If any of the descriptions defer to the implementing procedures for identification of "who is to do what," the procedures should accompany the application for staff review.

Appendix B

Summary of Public Comments on Draft Technical Position Statement (*Federal Register*, Vol. 51, No. 44, December 14, 1987, 52 FR 44398)

Commenter	General/Comment	Major Comments	NRC's Response
1. Tennessee Valley Authority (Nuclear Licensing & Reg. Affairs)	Supports/Agrees	Recommended deemphasizing the importance of Quality Levels A & B and necessary management	The discussion on quality levels has been revised since several readers believed that NRC was recommending a two-level approach. The revision clearly states that the applicant may have a single or multi-level approach, and that it is the applicant's responsibility to select a single or multi-level approach. The emphasis of the guidance provided in this document is to develop and implement effective managment controls to ensure that the requirements are met.
2. State of Indiana (Hazardous Waste Facility)	------	Several comments were made, related to differences between the QA and QC.	Each of the comments was evaluated and, where necessary, changes were incorporated in the guidance. The difference between QA and QC was addressed.
3. State of Texas (Low-level Radioactive Waste Disposal Authority)	Strongly Supports	Guidance on quality levels very helpful.	No response required.
4. Battelle (Project Management Division)	Supports/Agrees	Requested additional information be provided in design area.	Each of the comments was evaluated and additional information was included to address the areas of concern.
5. University of Illinois (Dept. of Nuclear Engineering)	Supports/Agrees	Recommended modifying the document to include additional guidance on performance monitoring.	The suggestions were evaluated and NRC concluded that this may be the type of additional guidance to be developed. However, it will not be addressed in this revision.

Commenter	General/Comment	Major Comments	NRC's Response
6. Paine College	———	Recommended changing guidance to regulatory requirement.	The NRC staff concluded that a rule change was not warranted at this time. However, at a later date, if a rule change is warranted, this recommendation will be reevaluated.
7. Envirosphere Co.	Supports/Agrees	Recommended include additional guidance on quality level and on site characterization.	See first response to TVA response, related to quality levels. Also additional guidance was included on site characterization.
8. Bechtel National	Supports/Agrees	Recommended deemphasizing Quality Levels A and B and emphasizing required management controls.	The document was revised to reflect that a one, two, or multi-level classification system was acceptable. Also emphasis in this revision was placed on importance of necessary management controls to meet the requirements. See response to TVA comment.
9. United States Environmental Protection Agency (QA & Methods Development Division)	Agrees	———	———
10. Golder Associates	Agrees	Recommend deemphasizing Quality Levels A and B and emphasizing required management controls.	See response to TVA and to Bechtel National.
11. Mactec	Guidance too detailed	Recommending deemphasizing Quality Levels A and B. Also several editorial type changes were recommended to clarify certain areas.	In response to the comment related to Quality Levels A and B, see the first response and B, see the first response to TVA and to Bechtel National. Remaining comments were evaluated and incorporated as appropriate.
12. U.S. Ecology	Agrees	Recommend clarifying quality levels.	See first response to TVA.

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11. ABSTRACT (200 words or less)

This document provides guidance to an applicant on meeting the quality control (QC) requirements of 10 CFR 61.12(j) for a low-level radioactive waste (LLRW) disposal facility. The QC requirements, plus audits and managerial controls requirements, establish the need for developing a quality assurance (QA) program and the guidance provided herein. The criteria developed for this document are similar to the criteria developed for Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50. Although Appendix B is not a regulatory requirement for an LLRW disposal facility, the criteria that were developed for 10 CFR Part 50 are basic to any QA program. This document establishes QA guidance for the design, construction, and operation of those structures, engineered or natural systems, and components whose function is required to meet the performance objectives of Subpart C of 10 CFR Part 61 and to limit exposure to or release of radioactivity.

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