

OVERVIEW OF NRC'S GUIDANCE ON QUALITY ASSURANCE FOR A LOW-LEVEL RADIOACTIVE WASTE DISPOSAL FACILITY

Clayton L. Pittiglio, Jr. P.E.
United States Nuclear Regulatory Commission

ABSTRACT

The Nuclear Regulatory Commission (NRC) developed guidance to assist an applicant in complying with the quality control (QC) requirements of 10 CFR 61.12. This quality assurance (QA) guidance has been developed for the design, construction and operations of those systems, structures, components, as well as for site characterization activities necessary to meet the regulatory requirements. This paper briefly discusses and summarizes existing guidance including recently published guidance on site characterization and discusses future guidance NRC plans to develop if resources permit. Future guidance will also include a discussion on NRC's participation in QA workshops as a mechanism to provide guidance for the States.

This paper summarizes the information related to quality assurance presented in NRC's principal guidance documents:

- NUREG-1293, "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility";
- NUREG-1199, Rev. 2, "Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility";
- NUREG-1200, Rev. 1, "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility";
- NUREG-1383, Draft, "Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site."

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 of 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 low-level radioactive waste generated outside of the regional compact. The 1985 amendment (Public Law 99-240, The Low-Level Radioactive Waste Policy Amendments Act) extended the 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 with meeting this date, the Nuclear Regulatory Commission (NRC) has developed and issued several reports providing guidance on the development of a low-level radioactive waste disposal (LLRW) facility.

REGULATORY BASIS FOR QUALITY ASSURANCE PROGRAM

Title 10 of the Code of Federal Regulations, Part 61, Section 61.12(j)(10 CFR 61.12(j)), requires that a license application for a LLRW disposal facility include a description of the quality control (QC) program to be used in to determining the natural characteristics of a disposal site.

The regulation also requires that a QC program be used during design, construction, operation, and closure of the LLRW disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included. These requirements provide the bases for the need to develop a quality assurance (QA) program.

The regulatory requirements for managerial controls, audits, and QC apply to the preoperational phase, the operational phase, the site closure phase, and the post-closure institutional control phase. These requirements cover all activities, structures, systems, or components whose failure could result in not meeting the performance objectives of 10 CFR Part 61 or not limiting the exposure to or release of radioactivity. The applicant should develop and implement an effective QA program before starting site characterization activities and, as the licensee, should continue an effective QA program until the license has been transferred or terminated. Site characterization is one of the initial and most significant activities used to determine the suitability of a site and to demonstrate adequate performance of an LLRW disposal site; therefore, it is important that proper QA procedures are developed and applied to all site characterization activities. The applicant should expect that the validity of information contained in the license application will be challenged during the licensing review and the hearing, and the applicant must be prepared to defend the validity of the data, the analyses, and 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.

GUIDANCE

The principal QA guidance documents developed by NRC staff and discussed in this document are listed below:

1. NUREG-1293, "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility";
2. NUREG-1199, Rev. 2, "Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility";
3. NUREG-1200, Rev. 1, "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility";
4. NUREG-1383, Draft, "Guidance on the Application of Quality Assurance for Characterizing a Low-Level Radioactive Waste Disposal Site."

NUREG-1293

NUREG-1293 establishes QA guidance for any activity, structure, system or component that is required to meet the performance objectives of 10 CFR Part 61 and to limit exposure to or releases of radioactivity. This report specifically establishes QA guidance for the design, construction, and operation of those structures, systems, and components and the site characterization activities that affect the implementation of the 10 CFR Part 61 requirements.

The criteria developed for this guidance report are similar to the criteria developed for Appendix B to 10 CFR Part 50. Although Appendix B to 10 CFR Part 50 does not apply to a LLW disposal facility, the criteria that were developed for 10 CFR Part 50 are basic to any QA program. Some of the criteria in this report are identical to criteria addressed in 10 CFR Part 50 and some of the criteria addressed have been modified to address an LLW disposal facility.

This report also provides guidance on developing a system for categorizing work activities. Some work activities require more rigid management controls, while other activities need more flexible or limited controls. Within the industry, applicants and licensees use several categorization systems. The categorization system described in this guidance report provides for a two-level categorization system, although the applicant may propose a single or multi-level system. Important factors to be included in the system are the identification and control of any activities that are required to meet the performance objec

tives of 10 CFR Part 61 or required to limit exposure to or releases of radioactivity.

NUREG-1199, Rev. 1

Chapter 9 of NUREG-1199, Rev. 1, the Standard Format and Content Guide (SF&CG) provides guidance on the type of QA information to be included in a license to ensure that the performance objectives of 10 CFR Part 61 will be accomplished and can be demonstrated. This report provides guidance to help ensure that the QA program provides a multi-disciplinary system of management controls, backed by quality verification and overview activities that demonstrate completeness and appropriateness of achieved quality. An effectively planned and executed QA program includes the participation of all organizations associated with an LLW disposal facility. The policies and procedures for implementing the program are described in this section and require integrated technical and administrative activities to ensure successful accomplishment of the performance objectives of 10 CFR Part 61 and the design bases stated in the application. Chapter 9 requests that the applicant describe the QA program that will be established and executed in determining the characteristics of natural disposal during design, construction, and operation of the facility. The QA program will include a description of controls and verifications to be exercised during the development and use of computer codes. Chapter 9 of the SF&CG requires that the applicant describe how the QA program will be established at the earliest practical time consistent with the schedule for performing the activity to which it applies.

NUREG-1200, Rev. 1

Chapter 9 of NUREG-1200, Rev. 1, the Standard Review Plan (SRP) describes how the staff will review each element of the QA program description against the acceptance criteria established in Section 4.3 of Chapter 9. The staff's judgment during the review will be based on an assessment of the material presented. The staff review will also determine if the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions will be completed and ready to use before work starts. The review should determine whether "quality achieving" and "quality assuring" responsibilities are clearly assigned and whether the activities associated with these responsibilities are sufficiently integrated that the QA program is an integral part of the everyday work activities. Chapter 9 also points out that the staff review will determine whether the applicant will be able to monitor the effectiveness of the QA program implementation and to make needed adjustments on a timely basis. The staff will

look for and measure the effectiveness of the QA program design, not just look for the existence of its elements.

NUREG-1383, Draft

As part of defining the QA procedures for a license application, the draft report NUREG-1383 identifies the most significant parameters for characterizing a site. This report provides insight into the magnitude of work required for site characterization. It lists tests and procedures that can be used to evaluate or document approximately 70 important site parameters for licensing a LLRW disposal site.

The most common and most costly error applicants make is to not carefully plan the investigations needed to characterize the site with a goal of ensuring that the license application will be technically complete, procedurally defensible, and fully supported by traceable documentation of the quality of the technical work. A well-planned and implemented QA program will ensure that organizational responsibilities are assigned, personnel are adequately trained, and plans and procedures are written before site characterization activities begin.

This report also provides guidance on documentation of laboratory or field test procedures; qualifications and training for personnel conducting site characterization activities; storage of site characterization data, and records required for site characterization activities.

Workshops

Over the past two years, NRC has participated in several QA workshops for State LLW authorities sponsored by the U.S. Department of Energy and EG&G Idaho. Listed below are the QA workshops that have been conducted:

- QA workshop for the State of Texas
- QA workshop for the State of Illinois
- QA workshop for the State of Pennsylvania
- QA workshop for the State of Colorado
- QA workshop for the State of New York
- QA workshop for the State of North Carolina

The workshops address the QA requirements for a license application for a low-level radioactive waste disposal facility, specifically addressing the 18 criterion devel-

oped in NUREG-1293, as well as discussing the QA requirements for site characterization activities. Several similar workshops are currently being scheduled.

FUTURE

In the future, NRC intends to develop additional QA guidance and to participate in future state QA workshops. Specifically, in near term, NRC will be evaluating public comments on NUREG-1383 and finalizing that guidance and developing guidance on QA program plans. It has become clear, based on participation in workshops and QA program reviews, that guidance on QA program plan development is needed. NRC staff has been requested by the State of Pennsylvania to consult with them in the development of their QA program plan.

SUMMARY

NRC will continue to provide QA guidance to the states as resources permit. The key focus of NRC's staff effort for the next year will be to: participate in QA workshops; finalize guidance on site characterization; initiate guidance on QA program plans; and initiate QA guidance for computer codes.

BIBLIOGRAPHY

U.S. Government Printing Office, Code of Federal Regulations, Title 10, "Energy," Chapter 1, U.S. Nuclear Regulatory Commission, Parts 0 to 199, Washington, DC, revised annually.

U.S. Nuclear Regulatory Commission, NUREG-1199, Revision 1, Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility, Washington, DC, January 1988.

---, NUREG-1200, Revision 1, Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility, January 1988.

---, NUREG-1293, Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility, January 1989.

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