

JUL 05 1988

MEMORANDUM FOR: John Greeves, Deputy Director, NMSS
 Michael J. Bell, Chief
 Regulatory Branch, NMSS
 Tim Johnson, Section Leader
 Regulatory Branch, NMSS

FROM: Larry Pittiglio, QA Project Manager
 Regulatory Branch, NMSS

SUBJECT: REVIEW OF QUALITY ASSURANCE (QA) MANUEL FOR THE DIVISION

I have attached a draft of the QA Manuel for the Division of Low-Level Waste Management and Decommissioning for your review and comments. The document was developed by Dale Hedges, CER Corporation, and myself. The attached document is an early draft which has not been sent to the editorial staff for review.

It is essential, at this stage, that you review the document and provide comments on both the approach and the QA criteria. I have not developed the implementing procedures because they are dependent on both the current approach and application of the criteria. Once your comments are incorporated, it is my intention to schedule a two hour meeting with the Branch Chiefs and Section Leaders, in order to discuss and formalize existing procedures as well as establish additional implementing procedures.

I would appreciate your comments by August 12, 1988.

(Original Signed by _____)

Larry Pittiglio, QA Project Manager
 Regulatory Branch, NMSS

Enclosure:
 As stated

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DRAFT QUALITY ASSURANCE MANUEL FOR THE DIVISION OF LOW-LEVEL WASTE MANAGEMENT AND DECOMMISSIONING

C. L. Pittiglio, Jr.

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



Policy

It is the policy of the Division of Low-Level Waste Management and Decommissioning to perform licensing, inspection, and regulation activities under a formal quality assurance program. The quality assurance program, as described in this document, provides for planning of work activities to meet agency goals, conduct activities to approved procedures, and retain documentation to provide objective evidence of licensing, inspection, and regulation activities performed. The program applies management controls consistent with the importance of licensing, inspection, and regulation activities being performed.

Each individual in the Division performing licensing, inspection, and regulation activities is responsible for ensuring that his or her work is accomplished with the highest degree of quality. Each individual is expected to comply with the policies and procedures of the Divisions quality assurance program described in this manual.

Malcom R Knapp
DIRECTOR-DIVISION OF LOW-LEVEL
Waste Management and Decommissioning

Date

UNITED STATES NUCLEAR REGULATORY COMMISSION
DIVISION OF LOW-LEVEL WASTE MANAGEMENT
AND DECOMMISSIONING
QUALITY ASSURANCE MANUAL

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Introduction

The Division's Quality Assurance Program is based upon the program defined in NUREG-1293 "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility" and in Appendix B of 10CFR50. The criteria ~~NUREG-1293~~ addressed in this document are determined to cover the work activities performed by Division personnel in the conduct of licensing, inspection, and regulation associated with the management, treatment and commercial disposal of low-level nuclear waste (LLW), uranium recovery activities including mill tailings management, and related decommissioning.

This document provides for formal planning of work to be performed to meet the agency's philosophy on regulations and strategic goals outlined in the current issue of the Commission Policy Planning Guidance document, NUREG-0885, Issue 6, and in the Agency's Five Year Plan. All preplanned work will be conducted to approved procedures, and retention of documentation to provide objective evidence of ~~work~~ completion. *the work will be out*

Consistent and high quality licensing and decommissioning decisions will result from the disciplined use of the Quality Assurance policy and requirements described in this manual and the implementing procedures found in the divisions quality assurance procedure manual.

1.0 ORGANIZATION

1.1 OBJECTIVE

The division has structured its organization to provide for optimum achievement and assurance of quality of its products and services which consist of licensing, inspections, and regulation, *development and enforcement*, associated with the management, treatment, and commercial disposal of LLW, uranium recovery activities including mill tailing management, and related decommissioning. Management systems have been designed to result in projects and tasks being staffed with highly qualified team members under the direction of an assigned project leader. Where the size of the project requires a project team, the team functions as an integrated unit to review the task and project requirements, plan activities, provide for needed procedures, implement plans and procedures and assure that products and services meet the divisions goals and policies.

This section describes the division organizational units and their responsibilities and authority to ensure the achievement and assurance of quality consistent with that expected by the Division Director

1.2 DIVISION ORGANIZATION

The division is organized into three branches which provide the necessary support for the division to achieve its designated agency goals. The divisions organization and responsibilities are depicted on page 2.

The Deputy Director, the head of Internal Quality Assurance has delegated to the QA Project Manager the responsibility for conducting periodic, scheduled verification activities such as audits to measure the effectiveness of the implementation of the Quality Assurance Plan. The purpose of the verification activities is to provide Division Director timely status information, to permit the identification and correction of potential problem areas and to ensure the quality of end products and/or services.

Managers of tasks and projects are assigned by the Division Director or appropriate level of management (Branch Chief or Section Leader). The designated individual is delegated the authority and responsibility to carry out their assignment and resource are established and assigned to support this effort.

ORGANIZATIONAL CHART

U.S. NUCLEAR REGULATORY COMMISSION

DIVISION OF LOW-LEVEL MANAGEMENT AND DECOMMISSIONING

Directs the NRC's program for the licensing, inspection, and regulation to assure safety and quality associated with the management, treatment, and commercial disposal of low-level nuclear waste (LLW), uranium recovery (UR) activities including mill tailings management, and related decommissioning. Develops, implements, and evaluates safety and environmental policies and long-range goals for low-level waste, uranium recovery activities, and related decommissioning activities. Identifies and takes action to control safety issues under its responsibility. Interacts with other NRC Offices and international, federal and state organizations and jurisdictions on matters under its cognizance. Coordinates within NRC so that consistent criteria are developed for acceptable LLW disposal, UR activities, and decommissioning practices. Coordinates on research to insure regulatory program commitments are achieved. Represents the agency in international LLW and UR activities; provides guidance for Regional activities relating to LLW disposal, UR activities, and decommissioning; serves as Agency lead for DOE's Remedial Action Plans. Authorities include the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974; the National Environmental Policy Act of 1969; the Uranium Mill Tailings Radiation Control Act of 1978; the Low Level Radioactive Waste Policy Act of 1980; and the Low Level Radioactive Waste Policy Amendments Act of 1985.

Director
Deputy Director

Malcom R. Knapp
John T. Greeves

Operations Branch

Serves as NRC focal point for licensing and operational safety activities associated with the management and disposal of LLW and UR activities including mill tailings management and related decommissioning. Plans and directs the program for 1) safety and environmental evaluation of applications for licenses for low level radioactive waste disposal; 2) inspection and quality assurance of existing facilities 3) maintenance of information on the status of LLW operation, management, and disposal for all NRC licensees and agreement state licensees; 4) NRC's evaluation of and concurrence in the Department of Energy's Remedial Action Plans for cleanup of inactive uranium mill tailings sites and contaminated vicinity properties; and 5) oversight and review of Regional Offices' performance for matters under the Division's cognizance. Identifies and takes action to control safety issues under the Division's responsibility.

Chief John J. Surmeier

Technical Branch

Directs and manages the program necessary for technical review and evaluation of the acceptability of proposed and operational low level waste disposal uranium recovery activities, and decommissioning activities with respect to geology, hydrogeology, geochemistry, facility design, engineered barriers, waste form, and packaging. Identifies specific information needs, data-gathering strategies, and methods needed to obtain acceptable licensing, inspections, and enforcement data in these areas. Develops technical evaluation and assessment codes for these areas. Identifies further research and development needs in these areas and serves a Division liaison with the Office of Research in developing and executing programs to fill these needs. Directs technical assistance contracts and consultants in support of the above functions. Prepares technical positions and other guidance documents in these areas. Responsible for the Division's internal quality assurance program

Chief Michael Bell

Regulatory Branch

Serves as NRC focal point for all NRC regulatory activities under the Uranium Mill Tailings Radiation Control Act of 1978 and the Low Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA). Responsible for interagency and international coordination, development of policy and practices and long-range goals, and initiating the development of standards and guides for matters under the Division's cognizance. Plans and directs the program for financial assurance of licensees (other than Price-Anderson) and decommissioning of non-reactor materials licensees.

Chief Michael Bell

2.0 QUALITY ASSURANCE PROGRAM

2.1 Objective

The division has established a quality assurance program to provide the necessary management controls to ensure careful planning to meet agency goals, effective and efficient implementation of plans, and retention of records to provide objective evidence of performance. The program provides for accomplishing planned activities in accordance with written procedures or instructions. The division's quality assurance program requires that individuals performing licensing, inspection and regulations activities will be indoctrinated, trained and qualified to perform designated assignments.

2.2 Division Quality Assurance Program

The Division Director recognizes the need to develop, implement and maintain a comprehensive and effective Quality Assurance Program. The Division Director is responsible for the overall quality of products and services provided by the Division. The Division Director delegated the responsibility for development, maintenance, control and verification of the Quality Assurance Program and its effectiveness to the Deputy Director. The policies established by this Quality Assurance Manual are

mandatory and shall be addressed in plans and procedures and implemented by all personnel.

The Quality Assurance Program is described in this Quality Assurance Manual, and the implementing procedures.

Division Implementing Procedures are consistent with the Quality Assurance Manual and delineate the measures, systems or methods necessary to address and/or implement specific activities. These procedures are contained in a procedures manual and are issued and controlled by the Deputy Director.

Preparation of procedures is assigned to the Branch with lead responsibility for the activity or area. Review and concurrence includes each affected Branch to assure appropriate requirements and interfaces are defined. Procedures are reviewed and concurred in by the Project QA Manager. Procedures are approved by the Deputy Director for release and use.

3.0 PROCUREMENT DOCUMENT CONTROL

3.1 OBJECTIVE

The Division provides for establishment of controls to assure that agency procurement procedures are properly implemented. Procurement documents include quality requirement as well as technical requirements. Requirements such as appropriate codes, supplier quality assurance programs, purchaser access authority and necessary documentation are included. The technical and quality specifications included in the procurement documents are reviewed by quality assurance organization to assure quality provisions are included. Changes or revisions to quality related procurement documents are reviewed and approved by same group that reviewed the original document.

3.2 Division Procurement Document Control

The individual responsible for a particular division procurement takes appropriate measures to ensure that documents and changes thereto, for the procurement of services, whether purchased by the division or the contractors, include or reference the following as necessary to achieve the required quality:

1. Quality Assurance Program Requirements.
2. Requirements for the documents such as instructions, procedures, drawing, specifications and records be prepared submitted or made available for division review or approval.
3. Requirements for retention, control and maintenance of supplier QA records.
4. Provisions for purchaser's right of access (division) to contractor facility and work documents for inspection and audits.
5. Provision for contractor to report items that do not meet procurement requirements.

4.0 INSTRUCTIONS PROCEDURES

4.1 OBJECTIVE

Quality-related activities are prescribed by documented instructions and procedures and are accomplished in accordance with these documents. These documents are developed as appropriate for quality-related activities included in the scope of work of projects or tasks performed by division. These documents require approval of appropriate personnel prior to initiating work on quality-related activities.

4.2 DIVISION INSTRUCTIONS AND PROCEDURES

The QA Project Manager is responsible for ensuring that quality-related activities are prescribed in appropriate documents and the work is accomplished in accordance with these documents and procedures. Project-level implementing procedures delineate the project-specific documents to be used, the responsibility for preparation, review, approval and control of these quality activity plans.

5.0 DOCUMENT CONTROL

5.1 OBJECTIVE

The Chief of the Operations Branch is responsible for establishing and maintaining a document control system. The Division provides for control of documents which specify quality requirements or prescribes quality-related activities to assure that correct documents are being utilized. These controls include identification of persons who review for adequacy and approve documents for release, provisions for distribution and control and provisions for change control.

5.2 DIVISION DOCUMENT CONTROL

The QA Project Manager ensures that documents are controlled in accordance with this manual. The Branch Chief ensures that needed documents are available and in use at the location where prescribed activities are performed and that work is accomplished in accordance with the latest revision of issue.

Documents developed by the division or its contractors must be controlled in their approval, issuance, and distribution. The division identifies the types of document to be

controlled and the group responsible for the review.

All documents must be:

1. Reviewed for adequacy (i.e., information is clearly and accurately stated) and signed off by appropriate technical and managerial level.
2. Means such as master list or table of contents showing revision number and the date of revisions must be included to ensure that obsolete or superseded sections are replaced in a timely manner.
3. Document changes are reviewed and approved by the Section/Branch that was responsible for the original review and approval, unless responsibility is delegated in writing.
4. Quality requirements for the document are appropriately stated.

6.0 CONTROL OF PURCHASED SERVICES

6.1 OBJECTIVE

The Division provides for control of purchased services. control methods established include procurement planning, source evaluation and selection, monitoring the activities of contractor and confirmation that deliverables conform to procurement documents. When necessary, documentary evidence of conformance of items will be made available at the designated location prior to use. Control and monitoring of contractor activities is accomplished through one or more of the following: review and/or approval of suppliers' Quality Assurance plans and procedures; source inspection; audit; and examination of deliverables upon completion.

6.2 DIVISION SERVICES

The Quality Assurance Project Manager ensures that purchased services are controlled. The control of purchased services is commensurate with the scope of work assigned and the relative importance of the work to be performed. The Quality Assurance Project Manager participates directly or is involved in each activity associated with control of purchased services. The Quality Assurance Project Manager is responsible for monitoring the activities of suppliers,

including review and/or approval of supplier Quality Assurance programs and procedures, source inspection, audit and/or surveillance.

7.0 CORRECTIVE ACTION

7.1 OBJECTIVE

The division provides for the identification and timely correction of conditions adverse to quality. Quality deficiencies are identified on nonconformance reports, audit reports and surveillance reports. Additionally, identified deficiencies are evaluated to determine if a significant condition adverse to quality exists. Significant conditions adverse to quality are documented and reported to the division director. Deficiencies designated as being significant require that the responsible section leader or branch chief determine the underlying (root) cause of the deficiency so that appropriate actions can be taken to preclude recurrence of the deficiency. Follow-up actions are taken to verify that the action taken to preclude recurrence of the deficiency is effective.

7.2 DIVISION CORRECTIVE ACTION

The designated section leader or branch chief responsible for the task ensures that reported deficiencies are corrected in a timely manner and that all deficiency reports are evaluated to determine if a significant condition adverse to quality has been identified. For significant

conditions adverse to quality, the section leader or branch chief ensures that:

- a. Significant conditions are documented and distributed to division management, responsible project management and the contractor.
- b. The identified deficiency is corrected in a timely manner.
- c. The root cause of the deficiency is determined.
- d. Actions are taken to preclude recurrence of the deficiency.
- e. A follow-up is taken to verify that the actions taken to preclude recurrence of the deficiency are effective.

The Quality Assurance Project Manager verifies the determination of a plausible root cause and an effective action to preclude recurrence through the review and concurrence of the completed corrective action.

8.0 QUALITY ASSURANCE RECORDS

8.1 OBJECTIVE

The division as a matter of good business practice will retain records. The division also provides for the identification, protection and storage of records. The division provides for safe retention, indexing, retrieval and storage using procedures established by agency for identification, storage, etc.

8.2 DIVISION QUALITY ASSURANCE RECORDS

The Director of IQA has delegated to the Quality Assurance Project Manager the responsibility for determining what quality assurance records are to be retained. A review is made of the task or contract work activities prior to start of work, and a listing is made of all quality assurance records to be identified, protected and retained. Identified quality assurance records are protected and stored upon their completion in accordance with stated task or contract requirements

9.0 AUDITS, SURVEILLANCES

9.1 OBJECTIVE

The division plans and conducts audits to verify the adequacy of the implementation of the Internal Quality Assurance program. A key objective of the audits and surveillances is to identify potential problem areas such that corrective measures can be taken prior to a problem occurring. The division uses these in-depth reviews to ensure effective and efficient implementation of planned management controls. The Division Director apprised of the status of the implementation of the IQA program through audit and surveillance reports which afford them the opportunity to make timely changes in the management controls.

9.2 AUDITS, SURVEILLANCES

The Deputy Director delegates the responsibility for the planning and execution of quality assurance audits and surveillances to the Quality Assurance Project Manager.

Division Director, Branch Chiefs, Section Leaders and Project Managers support the audit/surveillance program by recommending areas to be audited as well as assigning

technical personnel as needed to be team members of audits and surveillances.

The Deputy Director is responsible for ensuring that those conducting audits and surveillances are qualified and trained.

The results of audits and surveillances are formally reported to the responsible Project Manager and Division Director.

The audits will be:

1. Conducted on regular basis.
2. Results of audits well documented.
3. Where necessary follow-up audits will be scheduled.