



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

RADIOACTIVE MATERIAL CONTAINER SUPPLIER INSPECTION

ORGANIZATION: Westex Company  
306 Cactus Drive  
Oxnard, California 93030

CONTACT: Mr. Paul Lupo  
Alternate Radiation Safety Officer  
(805) 485-2205

ACTIVITY: Maintenance and use of radioactive material packaging.

QUALITY ASSURANCE PROGRAM APPROVAL NO.: 0765

INSPECTION REPORT NO.: 94203

Inspection Location:  
Oxnard, California

Inspection Date:  
February 9, 1994

Onsite Inspection  
Hours: 8

INSPECTION BASIS AND SCOPE:

- A. BASIS: 10 CFR Part 71, 10 CFR Part 21, and Certificate of Compliance Nos. 9032, and 9033.
- B. SCOPE: To determine whether procedures have been established, documented, and executed which meet the requirements of 10 CFR Part 21 and 10 CFR Part 71. To determine if the procedures fulfill commitments made in the NRC-approved Quality Assurance Program.

## RADIOACTIVE MATERIAL CONTAINER SUPPLIER INSPECTION

INSPECTION REPORT NO.: 94203

## FINDINGS:

Nonconformances with the requirements of 10 CFR Part 71, Sections 111, and 137 were identified.

INSPECTION TEAM LEADER:

Dennis G. Reid  
Dennis G. Reid  
NMSS/IMNS

DATE:

4/11/94

INSPECTOR:

Thomas O. Matula  
Thomas O. Matula  
NMSS/IMNS

DATE:

4/11/94

REPORT APPROVED BY:

Robert L. Baer  
Robert L. Baer, Chief  
Source Containment and  
Devices Branch, NMSS

DATE:

4/14/94

## 1. SUMMARY

A U.S. Nuclear Regulatory Commission inspection team conducted an announced inspection of Westex Company (Westex) in Oxnard, California, on February 9, 1994.

The inspection team reviewed Westex quality assurance (QA) activities to determine whether QA procedures had been established, documented, and executed in fulfillment of commitments made in the NRC-approved QA Program. Inspection findings are based on data collected through review of procedures and controls, inspection of selected documents and records, and interviews with personnel.

The inspection team identified items of nonconformance regarding 10 CFR Part 71, Subpart H. The items of nonconformance are summarized in Table 1.

Table 1  
Items of Nonconformance

10 CFR Part 71, Section	Subject	No. of Findings
111	Instructions, procedures, and drawings	2
137	Audits	2

## 2. DETAILS

NRC conducted an announced inspection at the Westex facility in Oxnard, California, on February 9, 1994. The inspection team reviewed documentation representing implementation of the QA functions. The inspection team focused on maintenance activities and use of transportation packagings with NRC Certificates of Compliance (COCs).

The objectives of the NRC inspection were to verify that the QA functions were accomplished in compliance with regulatory requirements and to determine if Westex's QA program complied with commitments made to NRC.

The inspection team evaluated the performance of QA activities from the perspective of two functional control elements: management and maintenance. The inspection team focused on the QA activities regarding the packaging models listed in Table 2.

Table 2  
Packaging Models

COC No.	Model No.
9032	650
9033	660

### 2.1 Persons Contacted

An entrance meeting was held on February 9, 1994 to present the objectives of the NRC inspection. An exit meeting was held the same day, to present the preliminary findings of the inspection. Paul Lupo, Alternate Radiation Safety Officer, representing Westex, was present at the entrance and exit meetings.

### 2.2 Management Controls

The inspection of management controls focused on the extent to which Westex had implemented the QA Program, and the independence and proficiency of QA personnel responsible for fulfilling QA commitments. The inspection team determined QA program effectiveness by reviewing administrative procedures, inspecting design and fabrication documents, and by interviewing staff members.

Nonconformances were identified regarding 10 CFR § 71.111, "Instructions, procedures, and drawings." This section requires the licensee to prescribe activities affecting quality by documented instructions, procedures, or drawings and requires that these instructions, procedures, and drawings be followed.

Contrary to the above, the inspection team identified instances where procedures were not followed:

1. Paragraph 7.1.1 of the Westex QA Program states that each completed Radioactive Material Transfer Log will be reviewed by the Radiation Safety Officer (RSO), or his designee, when it is received. The Radioactive Material Transfer Logs, inspected by the inspection team, showed no evidence of being reviewed by the RSO. The Radioactive Material Transfer Log form, had no provisions for documenting who performed the radioactive material transfer nor did it provide for the RSO's review or signature.
2. Paragraph 5.2 of the Westex QA Program states that radiography personnel shall perform required inspections and tests in accordance with written procedures and that the RSO shall assure that these functions are performed. Source Serial No. 7311 was transferred from packaging Model No. 660, Serial No. 2853, to storage container Serial No. 1110 on May 13, 1993. The same source was then transferred from storage container Serial No. 1110 to packaging Model No. 660, Serial No. 2852 on

May 14, 1994. Evidence that the required leak tests were performed in both radioactive material transfers was not available to the inspection team.

Nonconformances were identified regarding 10 CFR § 71.137, "Audits." This section requires the licensee to carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.

Contrary to the above, the inspection team identified instances where Westex's internal audits were not performed in accordance with its QA Program. Specifically, Section 7.0, "Audits," requires the following:

1. Paragraph 7.1.3 states that management will perform periodic audits of the RSO for compliance with the program's procedures. No evidence was found to show that management performed the required periodic audits of the RSO during 1993.
2. Paragraph 7.2 states that audits of the entire QA program shall be performed at an interval not to exceed a one-year period. There was no evidence of an internal audit for the year 1993.

### 3.0 DOCUMENTS REVIEWED

#### 3.1 Procedures, Drawings and Specifications

Quality Assurance Program for Use, Maintenance and Repair of Shipping Containers for Radioactive Material, dated 04/28/93. Operating and Emergency Procedures, Revision 1, dated 01/2/90.

#### 3.2 Logs, Training and Inspection Records, and, Inventories.

1993 Sealed Sources Quarterly Inventory.  
1993 Exposure Device Quarterly Inspections for Radiation Safety for:  
Century 100, Model S, Serial Nos. 1738 and 1829.  
Tech. Ops., Model 660, Serial Nos. 2852 and 2854.  
Radiation Survey Report, Utilization and Dosimeter Logs, for Two Radiographers.  
Radioactive Material Transfer Logs for Source Serial Nos. 1738 and 7311.  
Survey Meter Calibration Certificates for:  
Model ND-2000-C, Serial No. 3044, dated 02/02/94.  
Model ND-2000-C, Serial No. 3063, dated 02/03/94 and 11/01/94.  
Training Records for D.C., M.L., R.M., J.J., R.C., and C.B.  
Examination for Radiographer S.S. dated 6/7/93.  
Training Log Sheet for R.Y. for RT, PT, MT, and UT.  
Refresher/Safety Meeting Reports dated 01/11/94, 01/8/94, 12/18/93, 12/16/93, 12/14/93, 12/30/92.