



April 29, 2005

U.S. Nuclear Regulatory Commission  
Mary Jane Ross-Lee, Chief  
Transportation and Storage Safety and Inspection Section  
Spent Fuel Project Office/NMSS  
Washington, DC 20555-001

Sub: Application for approval of a previously approved Quality Assurance Program.

Dear Ms Ross-Lee:

CIS-US, Inc. has reacquired the necessity, pursuant to clarifications, definitions and interpretations of NRC Information Notice 2004-13, to be the shipper of licensed material pursuant to general license under 10 CFR 71 Subpart C. The enclosed Quality Assurance Program had retained USNRC Approval No. 0642 through expiration of Rev. 7 (11/30/02), and would be applicable for our infrequent shipments of medical irradiators in NRC-approved and DOT-revalidated, foreign-approved packages.

We respectfully request your expedited action at this time, as we have contractual issues related to a shipment that had been long-term-planned for 16-MAY-05. A category 10.B application fee in the amount of \$2100.00 is remitted herewith.

Thank you for your consideration and timely review of our application. Please contact me immediately if there are questions or issues in this matter.

Sincerely,

Paul M. Tyree  
Radiation Safety Officer  
Ph: 781.687.1258  
[ptyree@cisusinc.com](mailto:ptyree@cisusinc.com)

Enclosure(s): Described above (2 copies); remittance cheque

FedEx:  
M/S 013D13  
11555 Rockville Pike  
Rockville, MD 20852

NMSS01



**Quality Assurance  
Procedures Manual  
for Transportation of Radioactive Material**

**Copy 2**

Assigned to: Paul Tyree



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 14, 2002

Mr. Paul Tyree  
Corporate Radiation Safety Officer  
CIS-US, Inc.  
10 De Angelo Drive  
Bedford MA 01730

**SUBJECT: TERMINATION OF QUALITY ASSURANCE PROGRAM APPROVAL FOR  
RADIOACTIVE MATERIAL PACKAGES NO. 0642, REVISION 7**

Dear Mr. Tyree:

As requested in your letter dated October 22, 2002, Quality Assurance Program Approval No. 0642, Revision 7, is hereby terminated. Your general license under 10 CFR Part 71, Subpart C, to transport licensed material and your registration as a user of NRC-approved packagings under 10 CFR 71.12(c)(3) are also terminated. Therefore, you are no longer authorized to procure, maintain, repair, or use radioactive material packagings under 10 CFR Part 71.

If you wish to have your QA program approved in the future, please submit a request in writing, along with a description of your QA program, in accordance with the requirements of Subpart H of 10 CFR Part 71.

Please note that records required by 10 CFR 71.91 and 71.135 are to be retained for a period of three years.

If you have any questions, please contact me at 301-415-3567 or Jim Pearson at 301-415-1985.

Sincerely,

A handwritten signature in cursive script that reads "Michael Tokar".

Michael Tokar, Chief  
Transportation and Storage Safety  
and Inspection Section  
Spent Fuel Project Office  
Office of Nuclear Material Safety  
and Safeguards

Docket No.: 71-0642



October 22, 2002

U. S. Nuclear Regulatory Commission  
Spent Fuel Project Office, NMSS  
Michael Tokar, Chief  
Transportation and Storage Safety and Inspection Section  
Washington, D.C. 20555-0001

Sub: QA Program Approval No. 0642, Docket No. 71-0642

Dear Mr. Tokar:

Thank you for your letter of August 1, 2002 regarding a timely filed application for renewal of the subject RM package QA program approval.

Whereas CIS-US, Inc. has sold its radiography source business assets to Industrial Nuclear Co., Inc., effective 02-JUL-02, and INC holds a comprehensive RM package QA program approval [#0062], CIS-US will not file to renew the subject user-level approval. Prior CIS-US registrations as user of various NRC-approved packages were essentially superseded by INC registration dated 26-JUL-02. Also, records of such use, and others retained pursuant to the subject approval have been transferred to the successor INC program.

Thank you for your prompt disposition in this matter. Please contact me regarding any remaining issues or actions.

Sincerely,

Paul M. Tyree  
Corporate Radiation Safety Officer

Cc: Jerry A. Tucker, QA Manager, Industrial Nuclear Company, Inc.  
Alfonso DeSimone, Operations Manager, INC, North Andover, MA 01845



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

August 1, 2002

Mr. Paul M. Tyree  
CIS-US, Inc.  
10 Deangelo Drive  
Bedford, MA 01730

SUBJECT: 10 CFR PART 71 QUALITY ASSURANCE APPROVAL EXPIRATION NOTICE

Dear Mr. Tyree:

Your Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0642 expires on November 30, 2002.

Please note that if you are a Nuclear Regulatory Commission (NRC) licensee and conduct activities under the General Licenses of Subpart C of 10 CFR Part 71, or if you are an Agreement State Licensee subject to 10 CFR 150.20, you must have an NRC-approved QA Program that satisfies the provisions of Subpart H of 10 CFR Part 71. You should request renewal of your QA Program at least 30 days before the expiration date. This will provide for continuation of your QA Program to satisfy certain provisions of Subpart C of 10 CFR Part 71 until a final determination has been made on your application.

Please note that there is no fee required for renewal. If you do not desire to renew your QA Program, please let me know.

Sincerely,

A handwritten signature in cursive script that reads "Michael Tokar".

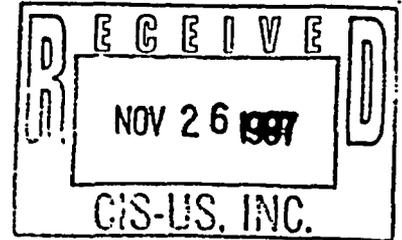
Michael Tokar, Chief  
Transportation and Storage Safety  
and Inspection Section  
Spent Fuel Project Office  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 71-0642



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

November 13, 1997



Mr. David B. Reader  
Executive Vice President  
CIS-US, Inc.  
10 DeAngelo Drive  
Bedford, MA 01730

Dear Mr. Reader:

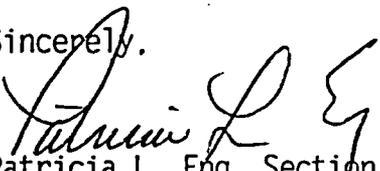
Enclosed is Quality Assurance Program Approval for Radioactive Material Packages No. 0642, Revision No. 7. This Approval satisfies the requirements of 10 CFR § 71.12(b) for a Quality Assurance Program approved by the Commission.

Please note the conditions in the Approval.

This Approval will remain in effect until the expiration date, indicated in Block No. 3. Termination of your materials license does not cause this Approval to be automatically terminated. If you wish to renew, amend, or terminate this Approval, please request it in writing.

This letter also serves as a reminder that if you are using or planning to use an NRC-approved packaging, you must be registered for use of that packaging with NRC. Registration for use of NRC-approved packagings should be made pursuant to 10 CFR § 71.12(c)(3).

Sincerely,

  
Patricia L. Eng, Section Chief  
Transportation and Storage Inspection Section  
Spent Fuel Project Office, NMSS

Docket No: 71-0642

Enclosure: As stated

**QUALITY ASSURANCE PROGRAM APPROVAL  
FOR RADIOACTIVE MATERIAL PACKAGES**

0642

REVISION NUMBER

7

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the person named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

2. NAME

3. EXPIRATION DATE

CIS-US, Inc.  
STREET ADDRESS

November 30, 2002

10 DeAngelo Drive

4. DOCKET NUMBER

CITY

STATE

ZIP CODE

Bedford

MA

01730

71-0642

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)

May 23, 1996 and October 27, 1997

6. CONDITIONS

Activities authorized by this approval: procurement, maintenance, repair, and use to be executed with regard to transportation packagings. All other activities (i.e., design, fabrication, assembly, testing, and modification) shall be satisfied by obtaining certifications from packaging suppliers that these activities were conducted in accordance with an NRC-approved Quality Assurance Program. It shall remain the responsibility of the Quality Assurance Program holder that all transportation activities meet the requirements of 10 CFR § 71.101.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

*Patricia L. Eng*  
PATRICIA L. ENG, SECTION CHIEF  
TRANSPORTATION AND STORAGE INSPECTION SECTION  
SPENT FUEL PROJECT OFFICE, NMSS

11/13/97  
DATE

# CIS-US, Inc.

Subsidiary of CIS bio international  
35 Flagship Drive, North Andover, MA, 01845, USA  
Tel: 508-683-5211; Fax: 508-683-9469



## Memorandum

To: File  
From: John J. Munro III  
Date: 28 March 1997  
Subject: Quality Assurance Procedure Distribution

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On 28 March 1997, Revision 6 to the CIS-US Quality Assurance Procedures for Transportation of Radioactive Material was distributed. The following individuals indicate by signature their acknowledgment of receipt.

Copy No. 1 Alfonso DeSimone

Copy No. 2 Paul Tyree

Copy No. 3 John J. Munro III

Copy No. 4

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 01.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: Organization

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**1.0 Purpose**

This procedure describes and implements the organization of CIS-US, Inc. as it relates to quality assurance for procurement, use, maintenance and repair of transport packaging for radioactive materials. Design, assembly, testing and modification of such packaging shall not be conducted under this quality assurance program.

**2.0 Procedure**

2.1 The CIS-US, Inc. Quality Assurance Program is implemented using the organization described in Figure 1 of this procedure. Quality assurance and quality control functions are established and executed by CIS-US, Inc. CIS-US may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program. However, the final responsibility for the quality assurance program is retained with CIS-US, Inc.

2.2 The Executive Vice President is responsible for corporate management and regulatory compliance of the program. The Director of Source Operations, Safety and Transportation (DSO), who reports to the Executive Vice President, is responsible for overall administration of the program, and for regularly assessing its scope, status, implementation and effectiveness. Responsibilities for specific portions of this program are delineated in the applicable Quality Assurance Procedure.

2.3 The quality assurance personnel functions may be performed by employees of CIS-US, Inc. or contractors or consultants to CIS-US, Inc. In cases where these functions are performed by individuals who are not direct employees of CIS-US, Inc., these individuals will, in all cases, organizationally report to an individual who is a direct employee of CIS-US, Inc. and who is responsible for assuring that the activities are performed in accordance with the Quality Assurance Program. In all cases, inspections shall be performed by individuals other than those performing the activities being inspected.

2.4 Inspection personnel have the responsibility and authority to stop unsatisfactory work and control further processing, delivery or installation of nonconforming items.

2.5 All employees of CIS-US, Inc. have the responsibility to report immediately to their supervisor any knowledge of any nonconformance, or a condition which could create a nonconformance.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 02.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Quality Assurance Program

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**1.0 Purpose**

This procedure describes the general aspects of the CIS-US, Inc. Quality Assurance Program.

**2.0 Application**

The CIS-US, Inc. Quality Assurance Program applies to the purchase, maintenance, inspection and testing of all materials, parts, components, subassemblies and assemblies of Type B packaging for the transportation of radioactive material. Design, assembly, testing and modification of such packaging shall not be conducted under this quality assurance program.

**3.0 Procedure**

3.1 The management of CIS-US establishes and implements this Quality Assurance Program. All activities to which this procedure applies shall be conducted in accordance with the Quality Assurance Program, Quality Assurance Procedures and all applicable regulatory requirements. The Quality Assurance Program and its associated written procedures and instructions remain in effect throughout the period during which packaging is used.

3.2 The purchase, manufacture, inspection, and testing of components of packages used for the shipment of radioactive material that are classified as important to safety are governed by the quality assurance program. Items important to safety are determined and categorized in accordance with established definitions, based upon the complexity and proposed use of the package and its components, including the impact of malfunction or failure of the item to safety; the degree to which functional compliance can be demonstrated by inspection or test; and the quality history and degree of standardization of the item. The rationale for these determinations is documented. A listing of classifications is maintained and updated as necessary.

3.3 Quality related activities shall be performed under suitable controlled conditions, including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, such as adequate cleanliness, and assurance that all prerequisites for the given activity have been satisfied. The need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test shall be incorporated.



## 4.0 Training

4.1 Personnel performing quality activities shall be instructed in the purpose, scope and implementation of the Quality Assurance Procedures. This instruction shall include initial training in the contents of the Quality Assurance Manual and on-the-job training in its implementation. This training shall include notification that quality policies, Quality Assurance Procedures and Operating & Emergency Procedures are mandatory requirements which must be implemented and enforced. In addition, instruction shall be provided each time a Quality Assurance Procedure or an Operating & Emergency Procedure is revised. A record of the implementation of this training shall be maintained.

4.2 Inspection personnel shall also be instructed in the requirements of each Operating & Emergency Procedure each time such a procedure is issued or revised.

4.3 Personnel performing activities important to safety shall be trained in the principles and techniques of the activity being performed. The proficiency of personnel performing activities important to safety shall be assessed and evaluated at least annually by the Director of Source Operations, Safety and Transportation (DSO) or his designee.

## 5.0 Management

5.1 The company management shall assess on an annual basis, the scope, status, implementation and effectiveness of the quality assurance program to assure that the program is adequate and complies with all applicable regulatory criteria. This shall be accomplished through the use of audit reports, field equipment problem reports, customer and field service reports and internal reports.

5.2 Any disputes involving quality, arising from a difference of opinion between quality personnel and other personnel shall be resolved by the Executive Vice President.



**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 03.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: Design Control

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1.0 Design, assembly, testing and modification of Type B packaging for the transportation of radioactive material shall not be conducted under this quality assurance program.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 04.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Procurement Document Control

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**1.0 Purpose**

The purpose of this procedure is to set forth the method for assuring that all contractual and internal quality requirements have been properly and completely specified in procurement documents. This procedure applies to the procurement of all packaging for the transportation of radioactive material, including spare and replacement components.

**2.0 Procedure**

2.1 Procurement of all items to which this procedure applies shall be made using the standard CIS-US Purchase Order. The Purchase Order shall require that the supplier of packages to supply appropriate certifications verifying that the designated package was manufactured under the control of a US Nuclear Regulatory Commission approved quality assurance program. Procurement documents shall require the supplier of packages to supply the certificate of compliance for the package, the drawings and other documents referenced in the certificate relating to the use and maintenance of the package and the identification of the types of tests and inspections required during use and maintenance.

2.2 All procurement documents for packages and for spare and replacement parts for packages shall be reviewed by the Director of Source Operations, Safety and Transportation (DSO) or his designee to assure that the appropriate technical and quality assurance requirements are included in the documents and that orders are to be placed with suppliers previously qualified. If replacement parts are to be purchased from suppliers not previously identified as qualified sources, the DSO must assure that the replacement parts meet requirements at least as stringent as the original criteria. This is generally accomplished by requiring items to be manufactured in accordance with the applicable revision of the appropriate engineering drawing. For those items where an engineering drawing does not exist, the Purchase Order shall reference the appropriate engineering specification. The Purchase Order shall also require compliance with 10 CFR 71 and 10 CFR 21.

2.3 All Purchase Orders covered by this procedure require the approval of the DSO prior to issuance. Any changes or revisions to Purchase Orders shall also require the approval of the DSO prior to issuance.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 05.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Instructions, Procedures and Drawings

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**1.0 Purpose**

The purpose of this procedure is to specify the requirements for the documentation relating to the loading, unloading, handling, storage and inspection of packaging for the transportation of radioactive material.

**2.0 Procedure**

2.1 Instructions for the loading of radioactive material into a package, and the unloading of radioactive material from a package are incorporated into the appropriate sections of the CIS-US, Inc. Operating & Emergency Procedures Manual.

2.2 Instructions for the receipt, handling, and storage of a radioactive material package are incorporated into Section 3 of the CIS-US, Inc. Operating and Emergency Procedures Manual.

2.3 Instructions for the inspection, maintenance and shipping of packages are incorporated into Section 4 of the CIS-US, Inc. Operating and Emergency Procedures Manual. The Director of Source Operations, Safety and Transportation (DSO) or his designee shall assure that Section 4 properly incorporates the acceptance test, maintenance and preparation for shipment requirements referenced in the Certificate of Compliance for the appropriate packages to be used prior to his approval of this section of the Operating and Emergency Procedure. These procedures shall include appropriate qualitative and/or quantitative acceptance criteria for determining the acceptability of the package prior to authorization for shipment. These procedures shall specify the requirements for the documentation relating to packaging for the transportation of radioactive material.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 06.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: Document Control

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**1.0 Purpose**

This procedure establishes the method for the control of all documents relating to radioactive materials packages, including engineering drawings, procedures and instructions.

**2.0 Procedure**

All documents, including Drawings and Instructions, Quality Assurance Procedures, Operating & Emergency Procedures, and documents relating to a specific shipping package will be controlled through this procedure.

**2.1 Quality Assurance Procedures**

Copies of the Quality Assurance Procedures shall be distributed to all individuals with responsibilities in the quality assurance program. Copies shall be numbered and records of distribution shall be maintained. Revisions to Quality Assurance Procedures will be made only in writing, and shall be approved by the Executive Vice President. The Director of Source Operations, Safety and Transportation (DSO) is responsible for assuring that revisions to the manual are distributed to manual holders. The DSO or his designee shall also maintain a listing of latest revisions to Quality Assurance Procedures, and this listing shall be distributed to all individuals with responsibilities in the quality assurance program.

**2.2 Operating & Emergency Procedures**

Copies of the Operating & Emergency Procedures shall be distributed to all individuals with responsibilities in the quality assurance program. Copies shall be numbered and records of distribution shall be maintained. Revisions to Operating and Emergency Procedures will be made only in writing, and shall be approved by the DSO. The DSO is responsible for assuring that revisions to the manual are distributed to manual holders. The DSO or his designee shall also maintain a listing of latest revisions to Operating & Emergency Procedures, and this listing shall be distributed to all individuals with responsibilities in the quality assurance program.

**2.3 Use of Documents**

Users of these documents shall assure that all quality assurance functions are conducted in accordance with the latest applicable revisions to these documents. This shall be accomplished by referring to the list of latest applicable revisions. The DSO or his designee shall verify that all quality assurance functions are conducted in accordance with the latest applicable changes to these documents through the audit process delineated in Quality Assurance Procedure 18.01.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 07.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Control of Purchased Material, Equipment and Services

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**1.0 Purpose**

This procedure establishes requirements to assure that purchased items conform to the requirements of the procurement and engineering documents. These measures include vendor evaluation, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

**2.0 Procedure****2.1 Receipt of Type B Packages**

Type B Packages received from a supplier shall be accompanied by appropriate certifications verifying that the designated package was manufactured under the control of a US Nuclear Regulatory Commission approved quality assurance program. The supplier of packages shall furnish the Certificate of Compliance for the package, the drawings and other documents referenced in the certificate relating to the use and maintenance of the package and the identification of the types of tests and inspections required during use and maintenance.

**2.2 Receipt of Parts, Components and Materials**

2.2.1 Parts received from a supplier shall be accompanied by documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items. This documentation shall identify any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair".

2.2.2 In cases where the supplier does not provide documentary evidence of a USNRC-approved Quality Assurance Program or where compliance with engineering or procurement document requirements is not readily determined by receiving inspection, an individual designated by the Director of Source Operations, Safety and Transportation (DSO) shall audit the vendor for such compliance. This shall assure that the vendor has the appropriate control measures to assure that the requirements are met. The audit, if required, of suppliers during fabrication, inspection, testing, and shipment of materials, equipment and components shall be performed in accordance with written procedures to assure conformance to the purchase order requirements.

2.2.3 Records shall be maintained of the performance of vendors. These records shall contain a history of the vendor's acceptance and rejection rates for individual items. When the DSO determines that a vendor's quality performance is unsatisfactory, he, or his designee, shall notify the vendor.



2.2.4 Upon receipt, all parts, components and materials shall be identified and counted to assure that the items are properly identified and correspond with the identification on the receiving documentation. In cases where engineering documents require vendor certification, such as for material or for special processes, the items shall not be accepted from the vendor until such certification is received. All parts, materials, components, subassemblies and assemblies to which this procedure applies shall be accompanied by a copy of the Receiving Report and a copy of the Purchase Order.

**2.3 Inspection of Items**

All items to which this procedure applies shall be inspected in accordance with Quality Assurance Procedure 10.01, Inspection.

**2.4 Documentation of Inspection**

All inspections shall be documented as prescribed in Quality Assurance Procedure 10.02, Inspection Records.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 08.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Identification and Control of Materials, Parts and Components

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**1.0 Purpose**

This procedure delineates the process for identification and control of materials, parts and components.

**2.0 Procedure****2.1 Identification of Items**

2.1.1 All parts, components, subassemblies and assemblies shall be identified by a unique part number. This part number shall relate to the appropriate engineering drawing for the part. Parts, components, subassemblies and assemblies shall be identified on a tag which shall accompany the parts.

2.1.2 In cases where items have a limited shelf-life or operation time, the measures for identification and control of these materials, parts, and components shall include an expiration date, beyond which the item shall not be used. These expiration dates shall be marked on the items or on the container containing the items. Items existing beyond the expiration of their shelf-life or operation time shall be disposed.

**2.2 Identification of Accepted Parts**

Parts received from outside vendors are presented for inspection with a receiving report identifying the parts. The results of inspection shall be indicated on the receiving report. Upon acceptance, these parts shall be identified on a tag which shall accompany the parts.

**2.3 Control of Rejected Material**

Identification and control of rejected materials, parts, components, subassemblies and assemblies shall be conducted in accordance with the requirements of Quality Assurance Procedure 15.01.

**2.4 Control of Certified Material**

In cases where engineering drawings, specifications or special instructions require material certification, this material shall be delivered with the parts for inspection. The material shall not be released until the material certification is received.

**2.5 Identification of Final Assemblies**

Completed final assemblies which have been accepted by final inspection shall bear a properly completed Acceptance Tag.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 09.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Control of Special Processes

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**1.0 Purpose**

This procedure establishes the means for assuring that special processes are performed in accordance with the requirements of the applicable engineering document.

**2.0 Procedure**

2.1 As used in this manual, special processes are defined as welding, brazing, heat treating, cleaning and nondestructive testing.

2.2 Special processes shall be performed in accordance with a written procedure in accordance with the requirements of Quality Assurance Procedure 05.01.

2.3 When special processes are required, they will be identified on the applicable engineering drawing. This reference shall include the identification of the applicable written procedure and the acceptance criteria. Procedures, equipment, and personnel connected with special processes shall be qualified in accordance with the codes, standards, and/or specifications identified in the applicable engineering drawing. Qualification records of procedures, equipment, and personnel associated with special processes shall be on file, and kept current.

2.4 For special processes performed in-house, assurance that the special processes are performed in accordance with the applicable procedure must be made by an individual other than the one performing the special process. This shall be performed as described in Quality Assurance Procedure 10.01. In the case of special processes performed by outside vendors, certification must be provided by the vendors indicating that the special processes were performed in accordance with the applicable procedure.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 10.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: **Inspection**

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**1.0 Purpose**

This procedure delineates the inspection process to assure that components, parts, materials, subassemblies and assemblies conform to design criteria.

**2.0 Procedures**

2.1 All inspections described in this procedure shall be performed by an individual other than the individual performing the operations or activities being inspected.

2.2 All procured packages, spare and replacement parts, and repairs shall be inspected on a 100% basis for all attributes described on the applicable procurement specification. In cases where the procurement specification references an inspection procedure, the item shall be inspected in accordance with this inspection procedure. Inspection of incoming material, parts and components shall also conform to the requirements of Quality Assurance Procedure 07.02.

2.3 Inspection and testing of packages for radioactive material prior to use shall be conducted in accordance with Section 4 of the CIS-US, Inc. Operating & Emergency Procedures Manual. These activities shall be conducted by Radiological Technicians in accordance with that manual. The Director of Source Operations, Safety and Transportation (DSO) or his designee shall assure, by audit, that these functions are performed.

2.4 Inspection, test, and operating status will be indicated by tag, label, marking or log entry. This can be accomplished by proper completion of the shipping checklist for the package.

2.5 Status of nonconforming parts or packages shall be positively identified by a tag on the package, accompanied by a copy of the shipping checklist clearly indicating the nonconformance.

2.6 Shipment shall not be made unless all tests, certifications, acceptances, final inspections and shipping papers have been completed.



**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 11.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: **Test Control**

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**1.0 Purpose**

This procedure establishes the method for control of testing of materials and manufactured items.

**2.0 Procedure**

2.1 At the time of receipt of procured packaging, assure that results of all testing required to demonstrate that packaging will perform satisfactorily in service have been obtained from the package manufacturer. This shall include the requirements of this part and test requirements and acceptance limits contained in the package approval.

2.2 Maintained and repaired packages shall be tested in accordance with the package approval testing requirements. The specific procedure for testing shall be approved by the Director of Source Operations, Safety and Transportation. Test procedures shall include provisions for assuring that all test prerequisites are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The test results shall be documented and evaluated to assure that test requirements have been satisfied.



**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 12.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Control of Measuring and Testing Equipment

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**1.0 Purpose**

This procedure sets forth the method for control and calibration of measuring and testing equipment used for quality acceptance measurements.

**2.0 Control of Measuring and Testing Equipment**

2.1 This procedure applies to all measuring and testing equipment used for quality acceptance measurements, including linear measuring equipment, hardness testing equipment, tensile testing equipment and radiation measuring equipment.

2.2 All measuring and testing equipment to which this procedure applies shall bear a calibration tag indicating the date of most recent calibration, the due date of the next calibration and the initials of the individual performing the calibration. The calibration tag shall be supported by a properly completed calibration record.

2.3 Only measuring and testing equipment which has been calibrated within the preceding twelve months shall be used for quality acceptance measurements. Any measuring or testing equipment which has not been calibrated within the last twelve months shall be tagged out of service until calibrated.

2.4 If, at any time during use, a measuring or testing instrument appears to malfunction, the instrument shall be immediately removed from use, tagged out of service and sent for repair. The instrument shall not be put back into service until it has been recalibrated.

**3.0 Calibration of Measuring and Testing Equipment**

3.1 Radiation measuring equipment shall be calibrated in accordance with CIS-US, Inc. Operating & Emergency Procedure Number 13.

3.2 Measuring and testing equipment shall be calibrated prior to its first use at intervals not to exceed twelve months and after each instrument servicing.

3.3 Measuring and testing equipment shall be calibrated by measuring standards whose attribute is certified traceable to the National Institute for Standards and Technology or by intercomparison with measurements made by another instrument whose calibration is traceable to the National Institute for Standards and Technology.

3.4 Measuring and testing equipment shall be calibrated at sufficient number of points to demonstrate its accuracy over its useful range.



3.4.1 Linear measuring instruments must be accurate to within 10% of the minimum tolerance of dimensions to be measured using the instrument.

3.4.2 Tensile testing equipment must be accurate to within 10% of the applied force.

3.4.3 Hardness measuring equipment must be accurate to within 5% of the actual hardness measured.

3.4.4 The accuracy of radiation measuring instruments shall be as specified in CIS-US, Inc. Operating & Emergency Procedure Number 13.

3.5 When measuring and testing equipment is found to be out of calibration, the validity of previous inspection and test results shall be assessed. This assessment shall be made by the Director of Source Operations, Safety and Transportation (DSO) or his designee. When indicated by this assessment, revalidation of previous inspection and test results by means of remeasurement shall be performed. All assessments and revalidations shall be documented.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 13.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Handling, Storage and Shipping

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**1.0 Purpose**

This procedure establishes the method for handling, storage and shipping of manufactured items and radioactive material packages.

**2.0 Procedure**

2.1 In cases where special requirements for handling, preservation, storage, cleaning, packaging or shipping of items are specified in the package approval, these requirements shall be incorporated into procedures approved by the Director of Source Operations, Safety and Transportation. These procedures shall be documented in writing and controlled in accordance with the requirements of Quality Assurance Procedure 05.01.

2.2 Handling, storage and shipping of packages for radioactive material shall be conducted in accordance with the requirements of the CIS-US, Inc. Operating and Emergency Procedures Manual. These requirements include operations, tests, inspections and preparation of shipping documents. These activities shall be conducted by Radiological Technicians in accordance with that manual. These procedures shall assure that all conditions of the USNRC package approval and the US Department of Transportation shipping requirements are satisfied prior to shipment. Shipment shall not be made unless all tests, certifications, acceptances, final inspections and shipping papers have been completed in accordance with Section 4 of the Operating and Emergency Procedures Manual.

2.3 Assurance that special handling, storage and shipping is performed in accordance with the applicable procedure shall be by inspection. This shall be performed as described in Quality Assurance Procedure 10.01, Inspection.



**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 14.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Inspection, Test and Operating Status

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**1.0 Purpose**

This procedure establishes the method for indicating the inspection, test and operating status of items.

**2.0 Inspection, Test and Operating Status of Components and Assemblies**

2.1 All inspections and tests shall be documented as described in Quality Assurance Procedure 10.01, Inspection. For components, parts, subassemblies, and assemblies, the identification of the inspection status is indicated on the tag which accompanies the item.

2.2 Inspection and test status indicators may only be applied or removed by the person performing the inspection.

2.3 All nonconforming items are maintained as described in Quality Assurance Procedure 15.01, Control of Nonconforming Material, Parts and Components. Control over these items is maintained until final disposition is made as described in that procedure.

2.4 No items shall be accepted into inventory control unless it is accompanied by an inspection record. If any item is presented to inventory control without the inspection report, inventory control personnel shall notify the President immediately.

**3.0 Inspection, Test and Operating Status of Packages for Radioactive Material**

3.1 Inspection and testing of packages for radioactive material shall be conducted in accordance with Section 4 of the CIS-US, Inc. Operating & Emergency Procedures Manual. These activities shall be conducted by Radiological Technicians in accordance with that manual. The President shall assure, by audit, that these functions are performed.

3.2 Inspection, test, and operating status will be indicated by tag, label, marking or log entry. This can be accomplished by proper completion of the shipping checklist for the package.

3.3 Status of nonconforming parts or packages shall be positively identified by a tag on the package, accompanied by a copy of the shipping checklist clearly indicating the nonconformance.

3.4 Shipment shall not be made unless all tests, certifications, acceptances, final inspections and shipping papers have been completed.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 15.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Control of Nonconforming Material and Parts

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**1.0 Purpose**

This procedure establishes the method for control of nonconforming materials, parts, components, subassemblies and assemblies.

**2.0 Procedure****2.1 Identification of Nonconforming Items**

All nonconforming materials, parts, components, subassemblies and assemblies shall be labeled with Reject tags. These nonconforming items shall also be identified on a rejection notice. One copy of the rejection notice shall remain with the parts until a final disposition is made. One copy of the rejection notice shall be forwarded to the Director of Source Operations, Safety and Transportation (DSO). One copy of the rejection notice shall be maintained in the inspection file.

**2.2 Control and Disposition of Nonconforming Items**

All nonconforming items shall remain in the segregated Reject Area until one of the following actions occurs:

2.2.1 The items are deemed acceptable to be used as is by the assigned engineer. This individual shall indicate his approval of this disposition by signature on the rejection notice prior to release of the items. This disposition is reserved for items with minor variation, questionable workmanship or general appearance but the nonconformance will not affect the quality of the product.

2.2.2 The items are deemed acceptable to be used as is by the DSO. He shall indicate his approval of this disposition by signature on the rejection notice prior to release of the items.

2.2.3 The items are to be returned to the vendor. A Debit Memorandum must be prepared to accompany the release of the items.

2.2.4 The items are to be reworked. A routing tag must be prepared to accompany the release of the items. The routing tag must indicate reinspection of the items after rework.

2.2.5 The items are to be scrapped. The DSO shall indicate his approval of this disposition by signature on the rejection notice prior to scrapping the items.

**2.3 Records**

All copies of the rejection notice shall be annotated with the final disposition of the items.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 16.01

Revision: 6

Approved: David B. Reader 

Date: 6 December 1996

Subject: Corrective Action

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**1.0 Purpose**

This procedure establishes the method for initiation and documentation of corrective action when a significant nonconformance or repetitive nonconformances are noted.

**2.0 Procedure**

2.1 The Director of Source Operations, Safety and Transportation (DSO) or his designee shall periodically review inspection reports to determine the nature of the noted deficiencies and nonconformances. This review shall include reports generated from in-house inspections, equipment problem reports and field complaints.

2.2 When a significant nonconformance is noted, or when a number of repetitive nonconformances are noted, the DSO or his designee shall review the case history of the nonconformance and make an assessment of the appropriate actions. In cases where engineering action or personnel action is necessary to preclude recurrence, the DSO or his designee shall initiate this action. In the case where vendor action is required, the DSO or his designee shall inform the vendor.

2.3 In cases where conditions adverse to quality are the result of actions of outside suppliers, the supplier shall be promptly notified of the condition and instructed to conduct a review of the causes of the condition and to provide the company with a description of the corrective actions taken to prevent recurrence. These reports shall be maintained. These corrective actions shall be subsequently reviewed to verify their implementation and effectiveness. Records of these reviews shall be maintained.

2.4 The DSO or his designee shall review the results of the corrective action and its effectiveness.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 17.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Quality Assurance Records

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**1.0 Purpose**

This procedure specifies the record keeping requirements of the quality assurance program.

**2.0 Procedure**

2.1 Procurement documents, including Purchase Orders, shall be maintained in the Quality Assurance File. These records shall be maintained for a minimum of three years after the last use of the item procured.

2.2 Certification of special processes shall be maintained in the Inspection File. These certifications shall be maintained retrievable by part number. These records shall be maintained for a minimum of three years after the last use of the item procured.

2.3 Inspection records, including Shipping Checklists, receiving reports, rejection notices, test reports and final inspection reports shall be maintained in the Inspection File. These records shall be maintained retrievable by part number. These records shall be maintained for a minimum of three years after the last use of the package.

2.4 Records of calibration of measuring and testing equipment shall be maintained in the Inspection File. These records shall be maintained for a minimum of two years.

2.5 Records of package approvals (including referenced documents and drawings) shall be maintained in the Quality Assurance File. These records shall be maintained for a minimum of three years after the last use of the package.

2.6 Reports of audits and corrective actions shall be maintained by the Director of Source Operations, Safety and Transportation (DSO). These records shall be maintained for a minimum of two years.

2.7 Records of personnel training and qualifications shall be maintained by the DSO. These records shall be maintained for a minimum of three years.

2.8 Records of shipments will be maintained in the Production File. These records shall be maintained for a minimum of three years after the last shipment of a Type B radioactive material package.

2.9 Written procedures shall be maintained for a minimum of three years after the last shipment of a Type B radioactive material package. Superseded procedures shall be maintained for a minimum of three years after the procedure was superseded.

**Quality Assurance Procedure  
for Transportation of Radioactive Material**

No. 18.01  
Revision: 6  
Approved: David B. Reader   
Date: 6 December 1996  
Subject: Audits

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**1.0 Purpose**

This procedure establishes the requirements for audits conducted under the quality assurance program.

**2.0 Procedure**

2.1 Planned audits of the quality assurance program shall be conducted to provide comprehensive, independent evaluation and verification of the effectiveness of the program. The audit scope shall encompass evaluation of quality procedures and practices and the effectiveness of their implementation.

2.2 Audits shall be conducted in accordance with an audit plan and checklist which is approved in advance by the Director of Source Operations, Safety and Transportation (DSO). The audit plan shall encompass all quality activities but shall give particular attention to those areas noted as deficient in the previous audit.

2.3 Audits shall normally be conducted once every twelve months. However, unscheduled audits may be performed at more frequent intervals in specific areas as directed by the DSO.

2.4 Audits shall be conducted by personnel with no direct involvement in the performance of the activity being audited. The audit personnel shall be appropriately trained, and shall have the appropriate level of technical capability to conduct the audit.

2.5 A verbal report of audit finding, conclusions and recommendations shall be made to supervisory personnel of the activity being audited at the time of the audit. A written report containing the audit finding, conclusions and recommendations shall be prepared and presented to the DSO and to the personnel of the activity being audited. All audit reports shall include an assessment of compliance with regulatory requirements.

2.6 Responsible personnel shall review the audit report and provide a response addressing the actions being taken to correct deficiencies. This response shall be forwarded to the DSO within sixty days of receipt of the audit report.

2.7 Areas identified as deficient shall be re-audited after taking corrective action.