



# The University of Michigan

MICHIGAN MEMORIAL – PHOENIX PROJECT  
PHOENIX MEMORIAL LABORATORY FORD NUCLEAR REACTOR  
ANN ARBOR, MICHIGAN 48109-2100

21 July 2005

Document Control Desk  
Attn: Director, Spent Fuel Project Office  
Office of Nuclear Safety and Safeguards  
Mail Stop: O13D13  
Washington, DC 20555001

*Release  
docket  
71-0348*

~~Docket 71-0348, Approval No. 0348~~

**Subject: Renewal of 10 CFR Part 71 Quality Assurance Program Approval**

Sir:

The University of Michigan is submitting the enclosed 10 CFR Part 71 Quality Assurance Program for renewal.

If there are problems or questions about the information or actions in this request, please feel free to contact me via [cwbecker@umich.edu](mailto:cwbecker@umich.edu) or cell phone at 734.320.1711.

Respectfully,

*Christopher W. Becker*  
Christopher W. Becker

File: Correspondence 05-008  
Packaging and Transportation Quality Assurance Program  
C:\Documents and Settings\cwbecker\My Documents\UofM\General\Letter File\CY05\05-008.wpd

*[Faint, mostly illegible text]*

*4mss01*

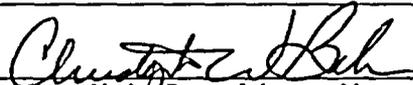


**QUALITY ASSURANCE PROGRAM**

*Packaging and Transportation of Radioactive Materials*

Rev.	Effective Date	Revision Description
0	10 Jun 1985	Original Issue
1	01 Jan 1986	Changed the organizational structure to reflect the elimination of the Reactor Supervisor position
2	01 Nov 1994	Update to reflect changes in 10 CFR 71 and the facilities Technical Specifications
3	14 July 2000	Amplified that the program applied to 10CFR 71 activities, added the FNR Technical Specifications as a reference, removed the Technical Specifications auditor as reporting to the Quality Assurance Committee, changed the audit to triennial, removed requirement that non-conforming parts be disposed of, and removed the modification request forms.
4	20 July 2005	Complete rewrite. Format to match revised format for procedures. Rewritten plan based upon plan for NASA Plumbrooke reactor facility and University of Virginia while keeping parts of original University program; Revised organizational structure to match University organizational structure for radioactive materials, hazardous materials, etc., Removed the ability to perform maintenance and repairs on licensed shipping containers,

Approval:

  
 Nuclear Reactor Laboratory Manager

*21 Jul 05*  
 Date



### Distribution

Master – PML Room 2054

Nuclear Reactor Laboratory Manager's Office

1

1



## 1. PURPOSE

- 1.1 This Quality Assurance Plan has been developed to address the Quality Assurance requirements applicable when using an NRC Licensed package for transport of radioactive material under the requirements in 10 CFR 71, Subpart H. There is no reactor fuel remaining on site, therefore, there will be no transportation of reactor fuel. No shipments will be performed under the auspices of this Quality Assurance Plan that requires the use of neutron moderation or other criticality control processes, or with thermal loads that require the use of cask cooling systems.
- 1.2 Applicability - This Quality Assurance Program is applicable to procurement, use, and maintenance of licensed packaging and services used to transport greater than Type A quantities of radioactive material in NRC licensed shipping containers. It is designed to assure the safety of the general public and the workers during packaging and transportation of the above mentioned materials, and to ensure compliance with 10 CFR 71 and the applicable transportation regulations contained in 49 CFR.
- 1.3 Scope - This Quality Assurance Plan includes a discussion of the program to be applied when shipping material in NRC licensed packages from the University of Michigan. The Quality Assurance Plan includes a discussion of the eighteen Quality Assurance Criteria of 10 CFR, Part 71, Subpart H and how they will be applied to activities at the University of Michigan.
- 1.4 The University of Michigan, the NRC Licensee and the user of the NRC licensed package, retains the responsibility for the overall effectiveness of this Quality Assurance Program. The Quality Assurance Program will be implemented through the use of controlled and approved procedures.

## 2. DEFINITIONS

- 2.1 Certificate of Compliance (CoC) - means the certificate issued by the Commission under subpart D of 10CFR71t which approves the design of a package for the transportation of radioactive material.
- 2.2 Licensed material - means byproduct, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Commission.
- 2.3 Licensed Package - means the assembly of components necessary to ensure compliance with the packaging requirements of 10CFR71 for the shipment of a quantity of licensed radioactive material greater than a Type A quantity including its radioactive contents as presented for transport. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

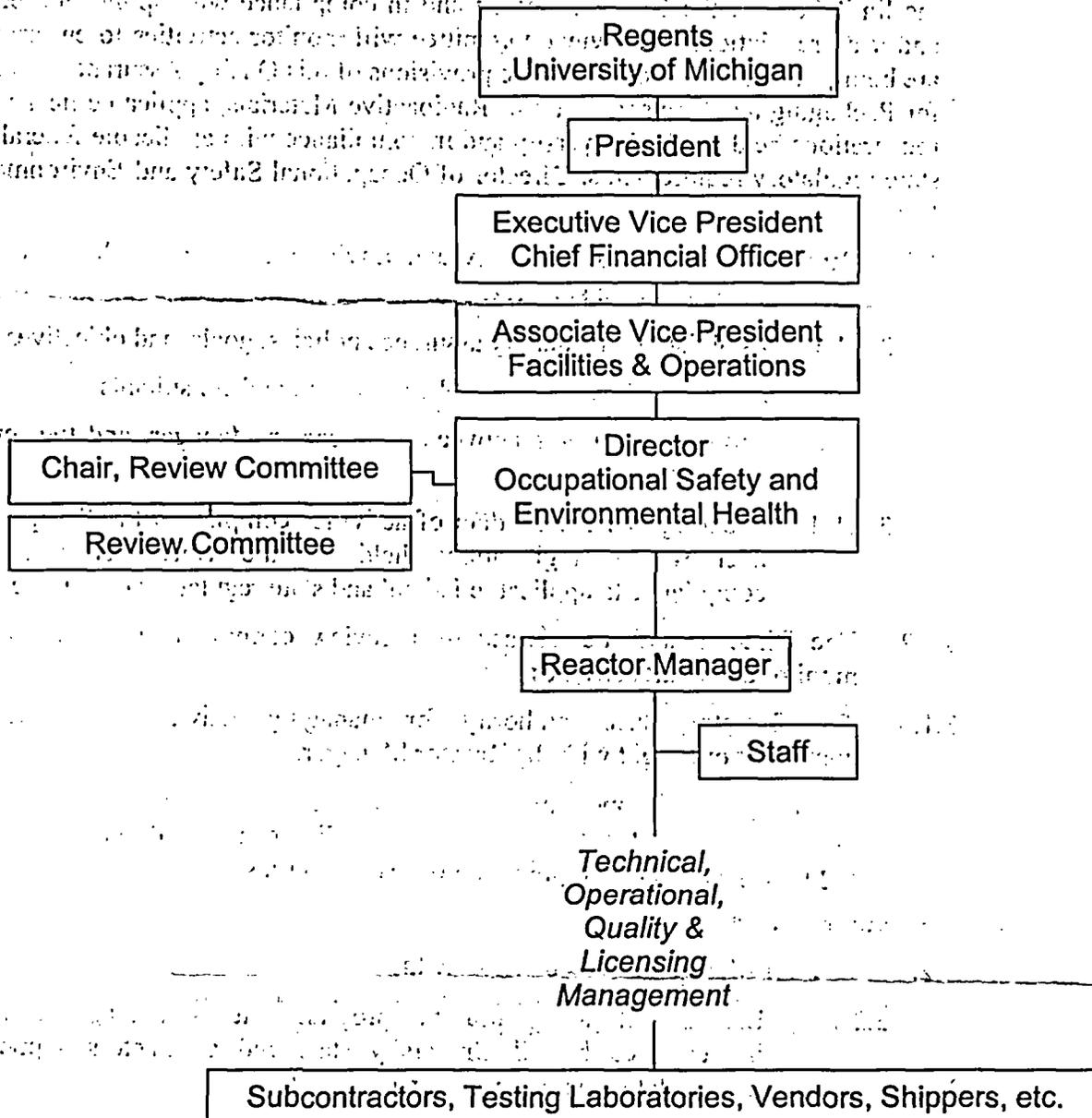
## 3. ORGANIZATION



- 3.1 The Organization is lead by the Director of Occupational Safety and Environmental Health, who will be responsible for the facility's license. The Reactor Manager is responsible for assuring that all activities are conducted within the limitations of the facility's license and in compliance with applicable federal and state regulations. A review committee will monitor activities to ensure they are being performed according to the provisions of this Quality Assurance Program for Packaging and Transportation of Radioactive Materials, applicable licenses or registrations held by the University and in compliance with applicable federal and state regulatory requirements. Director of Occupational Safety and Environmental Health
- 3.1.1 Director of Occupational Safety and Environmental Health has oversight authority and is responsible for:
- 3.1.1.1 Establishing the quality assurance policies, goals, and objectives
  - 3.1.1.2 Approval of contractors, subcontractors, and consultants
  - 3.1.1.3 Resolving conflicts between the Reactor Manager, and the review committee
  - 3.1.1.4 Ensuring that the conduct of activities complies with all applicable licenses and registrations held by the University and with compliance to applicable federal and state regulatory requirements
- 3.1.2 The Director shall be advised by a review committee that will review, monitor and audit activities.
- 3.1.3 The Director places authority for managing activities and directing contractor oversight with the Reactor Manager.
- 3.1.4 At the time of appointment to the position, the Director shall receive briefings sufficient to provide an understanding of the quality assurance and regulatory aspects of shipping radioactive materials under 10CFR 71.
- 3.2 Reactor Manager
- 3.2.1 Reactor Manager has responsibility for:
- 3.2.1.1 Ensuring all quality assurance program requirements are effectively implemented by all University staff and contractors supporting transportation activities under 10CFR71.
  - 3.2.1.2 Reporting performance to the Director and the review committee.
  - 3.2.1.3 Investigating adverse monitoring or audit findings, scheduling corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notifying the Director and each review committee member of action taken or planned or to be taken to correct conditions adverse to quality.
  - 3.2.1.4 Providing technical oversight and guidance, drawing upon other UM engineering, technical, or skilled trade resources as needed.



**Figure 1, Organization Chart for the FNR Decommissioning Project**





**Quality Assurance Program**  
*Packaging and Transportation of  
Radioactive Materials*

Revision: 04, 20 Jul 2005

3.2.1.5 Acting as interface between contractor, subcontractors, or consultants and the Director or review committee.

3.2.1.6 Coordinating contractor, subcontractor, or consultant activities.

3.2.1.7 Providing technical support to the Director and review committee.

3.2.2 The Reactor Manager shall have the authority to enforce quality assurance for activities and to shut down or suspend any operations or activities. Resumption of any activity shut down or suspended by the Reactor Manager shall require the approval of the Director or Reactor Manager.

3.2.3 At the time of appointment to the position, the Reactor Manager shall have a minimum of 6 years of nuclear experience. The individual shall have a recognized baccalaureate or higher degree in an engineering or scientific field. Education or experience that is job related may be substituted for a degree on a case-by-case basis. The degree may fulfill 4 years of the 6 years of nuclear experience required on a one-for-one time basis. The individual shall receive appropriate specific training based upon a comparison of the individual's background and abilities with the responsibilities and duties of the position. Because of the educational and experience requirements of the position, continued formal training may not be required.

#### 4. DESIGN CONTROL (10 CFR 71.107)

4.1 As a user of a licensed package, design activities will not be performed by this facility. Consequently, this criterion of 10 CFR Part 71.107 is not applicable.

4.2 Assurance that the design of the licensed package used was accomplished under control of an NRC approved QA Program will be required of the supplier of licensed package.

#### 5. PROCUREMENT DOCUMENT CONTROL (10 CFR 71.109)

5.1 The University will procure the services of vendors of licensed packages. The University will require manufacturers or vendors of licensed packages to supply appropriate certifications verifying that the designated (model and serial number) licensed package was manufactured under an approved NRC QA Program. Other available and pertinent documentation (as-built drawings, photographs, sketches, use and maintenance manuals, etc.) are to be furnished by the manufacturer or vendor with the licensed package. All pertinent documentation requirements shall be determined, including the identification of the type of verification activities required during use and maintenance of the licensed package will also be supplied with the procurement of the license package.

5.2 Procurement of required safety related replacement parts shall be in conformance with the applicable codes or standards specified for the licensed package. The procurement documents will require the necessary certification documents for purchased material under the control of vendor certified procedures and in accordance with the vendor's NRC approved QA Program. Documentation of the performance of these activities will be provided to the University. If the required



safety related replacement parts are not obtained with the required certification, THEN the University will perform or have performed the necessary testing to satisfy the certification requirement for the required safety related replacement parts. A review and concurrence of the adequacy of quality requirements will be completed and documented prior to the use of the required safety related replacement parts. This review shall determine that the quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement and testing of the required safety related replacement part is in accordance with this Quality Assurance Program and the design requirements of the replacement part.

## 6. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (10 CFR 71.111)

6.1. The University personnel shall ascertain that the licensed package, with its contents, and the preparation of the licensed package satisfies the applicable requirements of 10 CFR 71.111 and the Certification of Compliance.

6.2. The University shall prescribe activities affecting quality by documented instructions or procedures of a type appropriate to the circumstances and shall require that these instructions or procedures be followed. University written procedures shall be prepared, reviewed, and approved in accordance with University administrative procedures. Procedures and changes thereto shall be approved by the Reactor Manager. When appropriate, the University will invoke the use of vendor procedures that have been prepared, reviewed, and approved in accordance with the vendor's NRC approved QA Program.

6.3. If repair, rework, or maintenance is required to be performed on a licensed package at the University site, the work will be performed either by or under the direct supervision of the Reactor Manager or a individual designated by the Reactor Manager with similar qualifications and training. Such work will be performed in accordance with written procedures that have been prepared, reviewed, and approved in accordance with the requirements of the University or vendor's NRC approved Quality Assurance Program. The work will be coordinated with the appropriate quality assurance personnel to ensure that appropriate inspection and test points are incorporated in the procedure and that effective repairs or rework have been satisfactorily performed. Any plans for maintenance will be reviewed by designated quality assurance personnel to verify that the plans emphasize those characteristics that are most significant to safety.

## 7. DOCUMENT CONTROL (10 CFR 71.113)

7.1. Each of the shipping and packaging documents for each material shipment will receive a Quality review by a designated individual prior to the departure of the consignment from the site. Documents will be retained by the University in an auditable, retrievable manner.

7.2. Control shall be exercised over the following transportation/shipping documents:

7.2.1. Operating procedures

7.2.2. Inspection and test procedures



7.2.3 Loading and unloading procedures

7.2.4 Packaging and transport procedures

## 8. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (10 CFR 71.115)

- 8.1 Designated University personnel will take the necessary measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement requirements.
- 8.2 Documentary evidence that the licensed package conforms to the procurement specifications shall be supplied with the licensed package. Such documentation should be referenced in the certificate of compliance and should relate to the use and maintenance of the licensed package and should identify the necessary actions to be taken prior to delivery of the licensed package to a carrier for transportation. This documentary evidence shall be retained and shall be sufficient to identify the specific requirements met by the purchased material or equipment.
- 8.3 Materials, parts, and components will be stored in such a manner to preserve the integrity of the critical attributes, prevent material degradation, and to maintain traceability where required.
- 8.4 Procurement documents shall identify the applicable 10CFR71, Subpart H, requirements which must be complied with and described in the supplier's quality assurance program and will contain the University's right of access to supplier's facilities and records for inspection and audit.
- 8.5 The supplier's 10CFR71 Subpart H quality assurance program shall be reviewed and concurred with by the Reactor Manager or his designated representative, prior to initiation of activities by the program.
- 8.6 A review, by a trained individual not having direct responsibility, shall confirm that the quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed and approved as required by this Quality Assurance Program.

## 9. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (10 CFR 71.117)

- 9.1 To prevent the use of incorrect or defective materials, parts, and components, identification and control measures shall be established.
- 9.2 Non-conforming material, parts, and components will be tagged and segregated. The identification of the components and parts shall be maintained by appropriate means, either on the item or on records directly traceable to the item.
- 9.3 When replacement of limited life items is necessary, measures will be taken to preclude use of items whose shelf life or operation times have expired.



## 10. CONTROL OF SPECIAL PROCESSES (10 CFR 71.119)

10.1 Special processes will not be performed by the University. Any special processes required to effect repairs or modifications to a Licensed container are outside the scope of this Plan. Those processes will be controlled and performed only by the vendor, and will be done in accordance with the requirements of the vendor's NRC approved QA Program.

## 11. INTERNAL INSPECTION (10 CFR 71.121)

11.1 The University shall have an inspection program sufficient to guarantee the quality of the licensed package, materials and records and shall include, to the extent practicable, the following:

11.1.1 Inspection procedures, specifying the characteristics to be inspected, sampling plans, and acceptance criteria,

11.1.2 Specification of mandatory inspection hold points,

11.1.3 Procedures for identifying inspection and test status, so that only items that have passed the required inspections and tests are used, installed or operated. Nonconforming items will be clearly identified, and

11.1.4 Procedures for required in-service inspection or prior to use inspection of systems, structures or components.

11.2 Visual inspections by designated personnel will be performed upon receipt of the licensed package to ensure compliance with procurement documentation. The criteria for acceptance of each of these inspections and action to be taken if non-compliance is encountered will be specified.

11.2.1 These visual inspections should include, as applicable, an inspection of the following:

11.2.1.1 Surface conditions

11.2.1.2 Weld and structural integrity

11.2.1.3 Condition of flange or sealing faces

11.2.1.4 Gaskets and seals

11.2.1.5 Gauges, rupture disks, valves, pressure relief devices

11.2.1.6 Condition of tie-down members

11.2.1.7 Labeling and marking

11.3 The inspection program shall ensure adequate maintenance of licensed package. The vendor of the licensed package shall identify all items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item during use of the licensed package.

11.4 In process inspections by designated personnel shall be performed AND documented during the handling and loading of the licensed package to ensure that requirements in the Certificate of Compliance and Safety Analysis are satisfied.



- 11.5 Final inspections will be performed with a checklist to verify as a minimum that the following items are complied with:
- 11.5.1 Licensed packages are properly assembled
  - 11.5.2 All shipping papers are properly completed
  - 11.5.3 Licensed Package are conspicuously and durably marked as required by DOT regulations.
12. TEST CONTROL (10 CFR 71.123)
- 12.1 The licensed package's Safety Analysis or NRC Certificate of Compliance should provide for a test program to demonstrate that licensed package components will perform satisfactorily in service. The program will be identified and performed in accordance with written test procedures that are prepared, reviewed, and approved.
  - 12.2 These written procedures will incorporate the acceptance limits contained in the package approval, provisions for assuring that all prerequisites for a given test have been met, that adequate test instrumentation is available and used and that the test is performed under suitable environmental conditions.
  - 12.3 Test results shall be documented and evaluated to assure that test requirements have been satisfied prior to delivering licensed packages for transport to a carrier.
  - 12.4 The following items are included in typical tests:
    - 12.4.1 Structural integrity
    - 12.4.2 Leak tightness of the licensed package, gaskets, and seals
    - 12.4.3 Shielding integrity
  - 12.5 Test procedures will specify appropriate prerequisite and monitoring requirements, equipment to be used, personnel training requirements, and provision for data and documentation, as applicable.
  - 12.6 Records of tests shall be retained for three years.
13. CONTROL OF MEASURING AND TEST EQUIPMENT (10 CFR 71.125)
- 13.1 All instruments, gauges, and other measuring and testing devices used in activities affecting quality shall be properly controlled, calibrated (if necessary), and adjusted at specific times to maintain accuracy within necessary limits.
  - 13.2 This includes measuring and test equipment used for maintenance of safety related items.
  - 13.3 Inspection and test equipment will be tagged or labeled to indicate the calibration due date.
  - 13.4 All calibration test data shall be maintained with University records or will be readily traceable to vendor's records.



13.5 Measures will be taken and documented to determine the validity of previous inspections or tests performed when measuring and test equipment is found to be out of calibration.

#### 14. HANDLING, STORAGE, AND SHIPPING (10 CFR 71.127)

14.1 Measures will be taken to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in the licensed package to prevent damage or deterioration. The following actions will be taken when handling or storing licensed packages:

14.1.1 If a licensed package requires special handling and lifting equipment, THEN the special handling and lifting equipment should be used to move the licensed package from one station to another.

14.1.2 Special handling or storage provisions for the licensed package (e.g., shock absorbers, tags or markings to adequately protect and identify critical components) will be identified in the licensed package's Safety Analysis or NRC Certificate of Compliance and shall be followed.

14.1.3 Special protective environments (e.g., specific moisture content levels, and temperature levels) shall be specified and provided where required by the licensed package's Safety Analysis or NRC Certificate of Compliance.

14.1.4 All conditions identified in the package's NRC Certificate of Compliance for unloading the licensed package shall be followed.

14.2 When preparing a licensed package for shipment the following applicable measures will be taken:

14.2.1 Specified operations, inspections, and tests have been completed prior to delivery to a carrier.

14.2.2 NRC and DOT requirements have been satisfied prior to delivery to a carrier.

14.2.3 Necessary shipping papers have been prepared as required.

#### 15. INSPECTION, TEST AND OPERATING STATUS (10 CFR 71.129)

15.1 The status of inspections and tests performed on individual items of the licensed package, during licensed package handling, or during licensed package loading will be indicated by the use of markings such as stamps, tags, labels, or by the use of checklists, or other suitable means. These means shall provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by-passing of such inspections and tests.



**16. CONTROL OF NONCONFORMING MATERIALS, PARTS OR COMPONENTS**  
(10 CFR 71.131)

16.1 Measures shall be established to control materials, parts, or components which do not conform to specified requirements in order to prevent their inadvertent use or installation. All materials, parts, or components for use by the University which must be quality controlled will be inspected upon receipt by designated personnel. This inspection will include as a minimum:

16.1.1 Proper identification

16.1.2 Identification of any nonconforming materials, components, or parts

16.1.3 Segregation of nonconforming items

16.1.4 Evaluation and disposition of non-conforming materials, components, or parts.

16.2 Nonconforming items will be segregated in such a manner to prevent inadvertent use until proper disposition is completed. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. The acceptability of nonconforming items after designated repair or rework will be verified by designated personnel by re-inspecting or retesting the item against the original requirements. Records of such inspections, evaluations, and re-inspections and disposition will be retained.

16.3 All conditions of the NRC package approval and the DOT shipping requirements shall be satisfied prior to shipment.

**17. CORRECTIVE ACTION (10 CFR 71.133)**

17.1 Conditions that are adverse to quality, such as deficiencies, deviations, defects in material and equipment, and nonconformances shall be promptly identified. These conditions shall be reported to the Reactor Manager or other appropriate levels of management. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and prompt corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented to verify that corrective actions were implemented and effective.

**18. QUALITY ASSURANCE RECORDS (10 CFR 71.135)**

18.1 Sufficient written records shall be maintained to furnish evidence of activities affecting quality. The records shall include the following:

18.1.1 Records of use and results of reviews

18.1.2 Inspections

18.1.3 Tests

18.1.4 Audits

18.1.5 Qualifications of personnel



- 18.1.6 Maintenance
- 18.1.7 Delivery of licensed package to a carrier (including proof that applicable NRC and DOT requirements have been satisfied)
- 18.2 Shipping records required by 10 CFR and 49 CFR shall be maintained by the University in an auditable and retrievable manner.
- 18.3 Records of repairs or modifications to licensed packages will be maintained by the University. Records of activities performed only under the direct control of the vendor will be maintained by the vendor in accordance with the vendor's NRC approved QA Program.
- 18.4 Records for those quality affecting activities related to shipping licensed packages for radioactive materials will be retained for three years, in accordance with 10CFR71.91 and 10CFR71.135.

**19. AUDITS (10 CFR 71.137)**

- 19.1 Audits of the activities under this Plan begun, in progress, or completed during the year will be audited annually. An audit of the entire Packaging and Transportation Quality Assurance Program will be performed triennially. Audits shall be performed by designated qualified personnel not having direct responsibility in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, shall be taken where indicated.



## 20. REFERENCES

### 20.1 Regulatory Documentation

- 20.1.1 Title 10 of the Code of Federal Regulations (CFR) Part 71, *Packaging and Transportation of Radioactive Material*.
- 20.1.2 Information Notice 2002-35 (December 2002), *Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs*, U.S. Nuclear Regulatory Commission, Rockville, MD.
- 20.1.3 Information Notice 2004-13 (June 2004), *Registration, Use and Quality Assurance Requirements for NRC Certified Transportation Packages*. U.S. Nuclear Regulatory Commission, Rockville, MD.
- 20.1.4 Information Notice 2005-10 (April 2005), *Changes to 10 CFR Part 71 Packages*, U.S. Nuclear Regulatory Commission, Rockville, MD.
- 20.1.5 Regulatory Guide 7.10, Revision 1 (June 1986) *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, U.S. Nuclear Regulatory Commission, Rockville, MD.

### 20.2 Other

- 20.2.1 Robert R. Temps (2004) *Common Misunderstandings Noted In 1 CFR Part 71 Quality Assurance Program Submittals*, US Nuclear Regulatory Commission, Spent Fuel University Office, Rockville, Maryland.
- 20.2.2 American Society of Mechanical Engineering (ASME) NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*.

END