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Nuclear Reactor Program

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26 February 2007

Attn: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Re: Quality Assurance Program for Radioactive Material Packages
Docket No. 71-0331

Please renew the Quality Assurance Program for Radioactive Material Packages for our facility. A copy of the previously approved document is enclosed for your reference. There have been no changes since the last approval date.

If you have any questions regarding this correspondence or require additional information, please contact Gerald Wicks at 919-515-4601 or wicks@ncsu.edu .

I declare under penalty of perjury that the forgoing is true and correct. Executed on 26 February 2007.

Ayman I. Hawari, Ph.D.
Director, Nuclear Reactor Program
North Carolina State University

Enclosures: Quality Assurance Program for Packaging and Transportation of Radioactive Material, Revision 3

UMSSOI

Control No. 0541	Type of Change:	[ ] DC [ ] PC [ ] MC [ ] IC [X Other Quality Assurance Program for Packaging and Transportation of Radioactive Material
	Status:	[ ] New [X] Revision
Title: Quality Assurance Program for Packaging and Transportation of Radioactive Material		
Effective Date: 26 Feb 2002		
Revision: 3	Effective Pages: 1 through 13	
Originator: Gerald Wicks	Date: 18 Sep 2001	

APPROVAL

Gerald Wicks — Associate Director, NRP — 30 Nov 2001 — Date

Bernard W. Wehring — Chair, Reactor Safety and Audit Committee — 30 Nov 2001 — Date

Jim C Rink — Chair, Radiation Safety Committee — 13 Dec 2001 — Date

COMMENTS

QUALITY ASSURANCE PROGRAM for PACKAGING and TRANSPORTATION OF RADIOACTIVE MATERIAL

1.0 Quality Assurance Requirements

Quality Assurance Program (QAP) requirements to be met by North Carolina State University (NCSU) Nuclear Engineering Department (NED) as stated in Title 10 Code of Federal Regulations Part 71 (10 CFR 71) Subpart H are established by this document. The QAP is applicable to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety used in the transportation of radioactive materials (RAM). Quality Assurance (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control (QC), which includes those QA actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

Each of the applicable criteria given in Subpart H and any specific provisions that are applicable to activities conducted by the NED, including procurement of packaging, shall be established, maintained, and executed in this QAP. Applicable criteria shall be applied in a graded approach, i.e. to an extent that is consistent with its importance to safety. Safety control will be commensurate with the radioactivity and the form of the material being shipped. The three most likely materials to be shipped by the NED in increasing order of QA requirements are (1) fresh fuel (unirradiated), (2) Type B quantities, and (3) large quantities of activity and spent fuel assemblies. The graded approach to safety control will be applied to each shipment through the use of supporting documents (procedures, instructions, checklists, etc.) and training to the degree required to be certain the shipment will be accomplished safely. Training sufficient to meet 49 CFR requirements will be completed by affected personnel.

Before the use of any package for the shipment of licensed RAM subject to 10 CFR 71 Subpart H, approval of the QAP shall be obtained from the Nuclear Regulatory Commission (NRC). The QAP shall be filed with the NRC Office of Nuclear Material Safety and Safeguards (NMSS) and shall include a discussion of which requirements of 10 CFR 71 Subpart H are applicable and how they are satisfied.

The QAP is applicable to packaging owned by another party and for which NCSU is registered as an authorized user. The NED does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the NED to undertake any or all of these QA functions, the QAP will be revised accordingly.

This is the only NRC approved QAP that is established, maintained, and executed which satisfies 10 CFR 71 Subpart H. 10 CFR 50 Appendix B is not applicable to the NED or NCSU.

The NED does not own or directly use radiographic exposure devices regulated under 10 CFR 34 or equivalent agreement state requirements. Use of such radiographic exposure devices would be contracted with a licensed party and overseen by the NCSU Radiation Safety Division or the NED Reactor Health Physicist in accordance with approved procedures. If in future it becomes prudent for the NED to own or perform radiography with such devices, an appropriate license will be obtained by the NED which will include a program for transport container inspection and maintenance.

2.0 Quality Assurance Organization

NCSU through the NED shall retain and exercise responsibility for the QAP applicable to the packaging and containers in which RAM will be shipped. Work related to the QAP may be delegated to contractors, consultants, or agents by the NED. All work performed for the QAP, whether by the NED or others, shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the QA functions.

The QA function of assuring that an appropriate QAP is established and executed shall be met by:

1. The Reactor Health Physicist in the NED will serve as the QAP Manager (QAPM) and shall be the person responsible for preparing the QAP and supporting documents. The QAPM shall coordinate operations performed under the QAP and supporting documents.

2. NRP staff and the NCSU Radiation Safety Division for review of the QAP and supporting documents.

3. Director, Nuclear Reactor Program (NRP), for supervision of the work performed by the NRP staff.

4. Reactor Safety and Audit Committee (RSAC) and NCSU Radiation Safety Committee (RSC) for review and approval of the QAP and supporting documents. Documents for reactor related activities are approved by the RSAC. Documents for activities other than those related to the reactor are approved by the RSC.

The QA function of verifying, by procedures, that activities affecting the safety-related functions have been performed correctly shall be met by:

1. Adherence to the approved QAP and supporting documents and by use of check, inspection, and witness points at critical steps in supporting documents.

2. Having at least one person performing QA/QC and inspection functions for shipments of RAM made under the QAP. QA/QC and Inspection personnel shall not participate in the actual physical receipt of the packaging, loading, and preparation for shipment or serve as Audit personnel. QA/QC and Inspection personnel may include NED staff, NRP staff, NCSU Radiation Safety Division staff, RSAC members, or RSC members.

3. Having at least one individual audit shipment(s) of RAM made under the QAP. RSAC shall audit reactor related activities and RSC or the NCSU Radiation Safety Division shall audit activities other than those related to the reactor. Audit personnel shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment, or serve as QA/QC and Inspection personnel.

Other QA organization requirements include:

1. Allowing personnel performing the work or QA/QC and inspection functions under this QAP the authority to halt operations and to refer safety matters to the QAPM for resolution. Workers, personnel performing QA/QC and inspection functions, the Director, NRP, or the QAPM may recommend or provide possible solution(s) to problems. If the QAPM is not able to satisfactorily resolve the matter, the Head of NED shall be consulted. The RSAC or the RSC may also be consulted for problem resolution by either the QAPM, Director NRP or Head of NED.

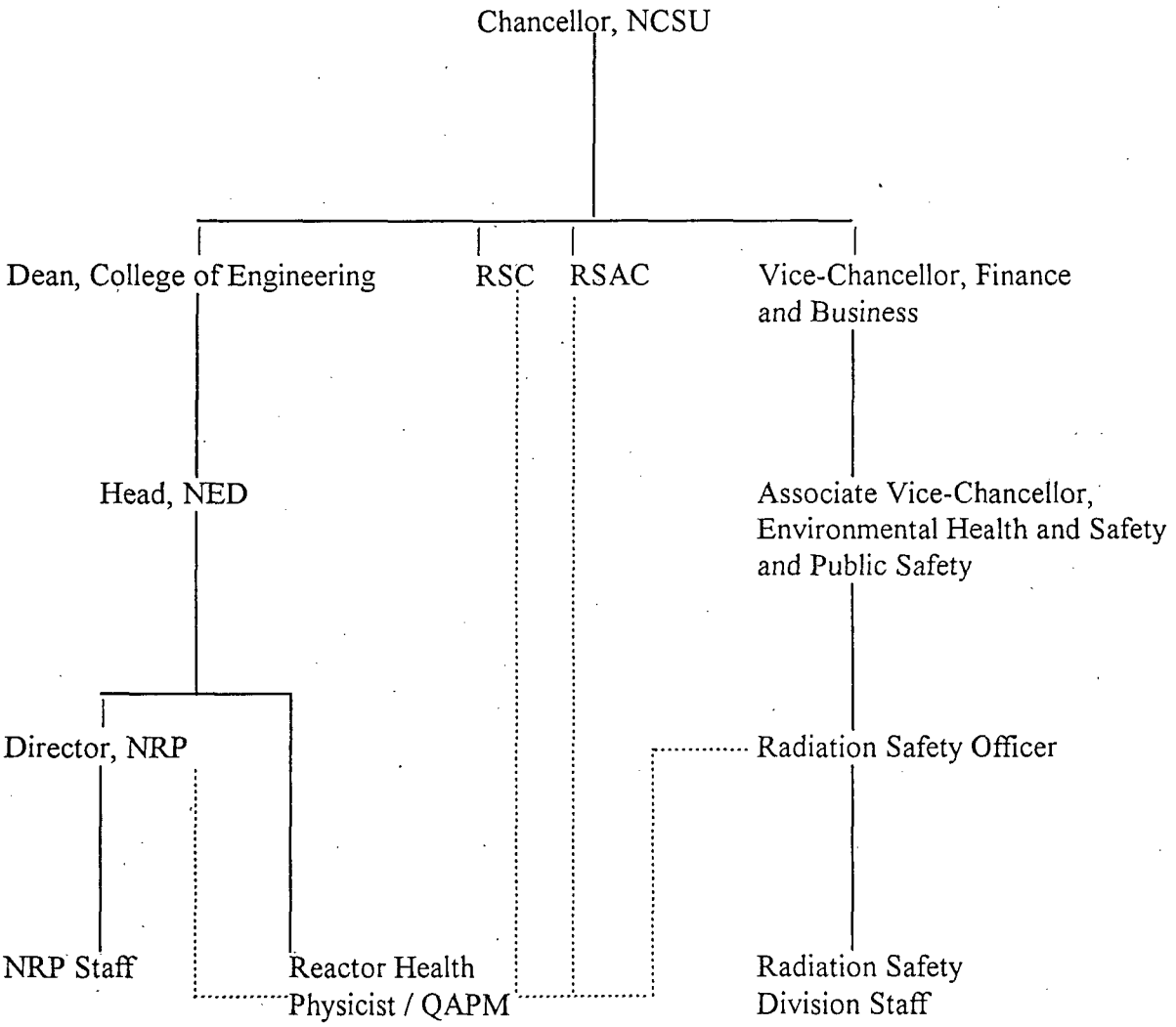
2. Allowing the QAPM the authority to cease operational functions with justifiable cause and directing continuance of the operation only upon resolving the cause for the cessation of activities.

3. Verification of solutions to problems by the workers, QA/QC and Inspection personnel, and/or the QAPM and by use of approved supporting documentation, as necessary.

4. Maintaining the QAP organization as depicted in Figure 1, indicating the reporting and communication lines.

FIGURE 1

Quality Assurance Program Organizational Chart



NCSU is North Carolina State University
NED is Nuclear Engineering Department
NRP is Nuclear Reactor Program
QAPM is Quality Assurance Program Manager
Reporting Line ————

RSC is Radiation Safety Committee
RSAC is Reactor Safety and Audit Committee

Line of Communication .....

3.0 Quality Assurance Program

This QAP will be established, maintained, and executed by the NED as required by 10 CFR 71 Subpart H for any applicable license while the license is in effect. The QAP and any supporting procedures and instructions shall be documented. The QAP shall be implemented in accordance with those documents during the period in which the packaging is used.

The QAP applies to the following materials and components:

1. Procurement of packaging for fissile materials or Type B packaging, i.e. RAM other than fissile material in excess of Type A quantities, including the design, fabrication, assembly, and testing of such packaging by a vendor approved for those activities by the NRC. Design, fabrication, assembly, and testing of the packaging by the NED is not permitted by this QAP.

2. Shipment of fissile materials (e.g. irradiated reactor fuel or new, unirradiated reactor fuel).

3. Shipment of RAM other than fissile material in excess of Type A quantities.

4. Shipment of any RAM in Type B packaging. Other shipments of RAM are performed in accordance with approved procedures and manuals written to meet requirements given in applicable federal and State of North Carolina regulations (e.g. 10 CFR 20, 10 CFR 30, 10 CFR 70, 49 CFR, 15A NCAC 11).

Major organizations and personnel and their functions in the QAP are listed below:

1. Head, NED is responsible for the QAP. The NED includes the NRP and QAPM. If the QAPM is not able to satisfactorily resolve safety problems, the Head, NED shall be consulted. The RSAC or the RSC may also be consulted for problem resolution by either the QAPM, Director, NRP or Head, NED.

2. QAPM is responsible for preparing the QAP and supporting documents, such as procedures and checklists. The QAPM coordinates operations performed under the QAP and supporting documents. The QAPM resolves any safety questions related to shipments of RAM made under the QAP and supporting documents. The QAPM has the authority to cease operational functions with justifiable cause and shall direct continuance of the operation only upon resolving the cause for the cessation of activities.

3. NRP is responsible for shipment of RAM and fissile material made at the PULSTAR nuclear reactor under the QAP.

4. RSAC is responsible for review and approval of reactor related documents and audit of RAM shipments made under the QAP that involve activities performed at the PULSTAR nuclear reactor. RSAC members may serve as QA\QC and inspection or Audit personnel.

5. RSC is responsible for review and approval of documents and audit of RAM shipments made under the QAP that involve activities other than those made at the PULSTAR nuclear reactor. RSC members may serve as QA/QC and inspection or Audit personnel.

6. NCSU Radiation Safety Division is responsible for providing assistance to the QAPM and for ensuring that State of North Carolina licensing requirements are met. NCSU Radiation Safety Division members review the QAP and supporting documents, may serve as QA/QC and inspection or Audit personnel.

7. Director, NRP exercises overall supervision of the work performed by NRP staff under the QAP and any supporting documents, including problem identification and resolution.

8. QA/QC and Inspection personnel are appointed to ensure that the actions required by the QAP and supporting procedures are being followed. QA/QC and Inspection personnel shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment, or serve as Audit personnel. QA/QC and Inspection personnel may raise questions and concerns and have the authority to halt operations for activities conducted under the QAP and shall refer those matters to the QAPM for resolution. Personnel performing QA/QC and inspection functions may suggest possible solution(s) to problems.

9. Audit personnel are appointed to review documentation of shipments made under the QAP. Audit personnel shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment; or serve as QA\QC and Inspection personnel. Audit personnel may raise questions and concerns on activities conducted under the QAP and shall refer those matters to the QAPM for resolution. Personnel performing audit functions may suggest possible solution(s) to problems.

The activities and quality of materials and components identified in the QAP shall be controlled to an extent consistent with their importance to safety and as necessary to assure conformance to the approved design of each individual package used to ship RAM.

Activities affecting quality shall be accomplished under controlled conditions and include the use of appropriate equipment, suitable environmental conditions (such as adequate cleanliness), and assurance that all prerequisites have been satisfied. Special controls, processes, test equipment, tools, and skills shall be taken into account to attain the required quality. This requirement is primarily met by the preparation, review, and approval of and adherence to the QAP and supporting documents,(such as procedures, instructions, and checklists).

Other considerations for supporting documents include:

1. Information provided from the packaging provider, e.g. packaging documentation and certification.

2. Safety measures commensurate with the shipment.

3. Complexity and use of the package and its components, the impact of malfunction or failure of items, design and fabrication complexity or uniqueness of items, surveillance over processes and equipment, inspection and testing of items, and quality history and degree of standardization of items.

4. Qualification or certification of equipment and personnel, (e.g. equipment rating and personnel training) including proficiency testing of personnel (e.g. use of equipment, mock-up training).

5. Handling instructions (e.g. package assembly and loading, unloading and opening of the package, transport and storage).

6. Required records and forms.

7. Other requirements of the QAP and applicable regulations

Based upon the information accumulated on the packaging and the activity to be performed, required supporting documents are prepared by the QAPM and validated if possible. The supporting documents are then reviewed and approved before being used. The supporting documents are then used by affected personnel to control the activities and to attain the required quality.

The status and adequacy of the QAP and supporting documents are reviewed by the QAPM, NRP staff, and the NCSU Radiation Safety Division:

1. Every five years.
2. Following major regulatory changes.
3. Prior to executing the QAP or a supporting document.

Changes to the QAP are reviewed by the NRP staff and are reviewed and approved by the RSAC and RSC. Documents and procedures supporting the QAP are reviewed by the NRP staff and are reviewed and approved by the RSAC for reactor related activities or by the RSC for activities other than those related to the reactor.

4.0 Package Design Control

The QAP is applicable to packaging owned by another party used by the NED. The NED does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the NED to undertake any or all of these QA functions, the QAP will be revised accordingly. Only approved packaging shall be used for RAM shipments. Changes to approved packaging or conditions of use are not permitted.

5.0 Procurement Document Control

The QAP is applicable to packaging owned by another party used by the NED. Arrangements for use of this packaging are made by the NED. Only approved packaging shall be used for RAM shipments. The packaging supplier will be required to furnish evidence of compliance with 10 CFR 71 Subpart H, packaging documentation required by 10 CFR 71, and/or the Certificate of Compliance (CoC) for the packaging. The packaging supplier shall be requested to furnish other information (tools, equipment, checklists, etc.) that would facilitate the safe handling and use of the packaging and satisfactory evidence that the packaging was designed, fabricated, and tested, etc., in accordance with an approved QAP. The requests and receipts will be documented by the NED.

6.0 Instructions, Procedures, and Drawings

Instructions, procedures, and drawings will be prepared and documented for actions affecting quality. Sufficient detail in describing the sequence of events essential to achieving the desired quality objective will be provided. These supporting documents are reviewed and approved before being used. These supporting documents are then used by affected personnel to control the activities and to attain the required quality. Quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished shall be included in the supporting documents. Changes shall be made so that these supporting documents shall conform and be consistent with the degree of safety control required for the RAM to be shipped. Applicable supporting documents shall be reviewed prior to use by affected personnel, including radiation safety measures and actions to be taken in the event of an undesired occurrence. Mock-up (dry run) training for proficiency and familiarity with complicated evolutions shall be performed, as necessary. Package unloading procedures shall be the responsibility of the consignee. If required, arrangements for transportation of the RAM shipment by a firm possessing a NRC approved transportation security plan shall be made by the NED. This plan shall be verified as fulfilling the specific requirements of the RAM shipment to be made. For irradiated reactor fuel, special attention shall be given to the planning for the transportation of the shipment, including the provisions for security guards, communications, and training as stated in 10 CFR 73 and 49 CFR.

7.0 Document Control

The QAP and supporting documents are prepared by the QAPM and reviewed by the NRP staff and NCSU Radiation Safety Division. Changes to the QAP reviewed and approved by the RSAC and RSC. Documents and procedures supporting the QAP and are reviewed and approved by the RSAC for reactor related activities or by the RSC for activities other than those related to the reactor. The status and adequacy of the QAP and supporting documents are reviewed by the QAPM, NRP staff, and the NCSU Radiation Safety Division prior to being used. Working copies of valid, approved documents are distributed by the QAPM for use by authorized personnel at the location where the prescribed activity is being performed.

8.0 Control of Purchased Material, Equipment, and Services

The NED is responsible for the following:

1. Measures to assure that material, equipment, and services purchased directly or through contractors and subcontractors conforms to the procurement documents shall be established. Provisions for source evaluation, selection, and objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of the products on delivery shall be included, as appropriate.

2. Documentary evidence that the material and equipment conforms to the procurement specifications before installation or use of the material and equipment shall be available. Such documentary evidence shall be sufficient to identify specific requirements met by the purchased material and equipment and shall be retained for the life of the package to which it applies.

3. Assessment of the effectiveness of the control of quality by contractors and subcontractors shall be made at intervals consistent with the importance, complexity, and quantity of the product or services purchased.

9.0 Identification and Control of Materials, Parts, and Components

The NED does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the NED to undertake any or all of these QA functions, the QAP will be revised accordingly. Only approved packaging shall be used for RAM shipments. Changes to approved packaging are not permitted. Approved supporting documentation and/or documentation provided by the packaging supplier will be followed for use of the packaging. Items used in the assembly of the package are specified in the supporting documents and, if necessary, recorded to ensure that incorrect or defective items are not used.

10.0 Control of Special Processes

The NED does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the NED to undertake any or all of these QA functions, the QAP will be revised accordingly. If a special process is required for use of the supplied packaging, e.g. welding a container lid, then qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements will be specified in the approved supporting documentation and/or documentation provided by the packaging supplier.

11.0 Internal Inspection

The NED does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the NED to undertake any or all of these QA functions, the QAP will be revised accordingly. Approved supporting documentation will include witness, inspection, and hold points at critical steps, as necessary, to be performed by personnel other than those performing the work or personnel performing the audit functions. Direct or indirect monitoring methods (electronic monitoring, measurements, tests and exams, etc.) may be used as specified in the approved supporting documentation by management, QA/QC and Inspection personnel, and Audit personnel.

12.0 Test Control

Testing of packaging at NCSU shall be limited that necessary to demonstrate that the packaging will function satisfactorily while loaded with the RAM being shipped from NCSU. Approved procedures specifying the tests to be performed and acceptance criteria shall be used. The approved procedures shall follow the pertinent requirements of the package approval. The approved procedures shall identify the testing equipment needed, provide for verification of calibration, and conclude with a statement of test results obtained. Test results shall be reviewed and accepted prior to making the RAM shipment. Documentation of testing and the results obtained shall be included in the RAM shipment records. Testing stated or implied herein shall not replace or negate the testing required to obtain NRC or DOT certification of the packaging.

13.0 Control of Measuring and Test Equipment

Measuring and testing under this QAP shall be limited to that necessary to verify that the package is ready and safe for use. Those items of equipment necessary for measurement and testing will be identified and the calibration maintained to the required accuracy, purpose, stability, and other conditions affecting measurement. Measuring and test equipment are calibrated at regular,

specified intervals and calibration records are maintained. Portable radiological survey instruments are calibrated as required by 10 CFR 20. Prior to use for RAM shipments made under this QAP, calibration status and operability of measurement and test equipment shall be determined and included in the shipment records and/or approved supporting documents.

14.0 Handling, Storage, and Shipping

Special handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration shall be requested of the packaging supplier and included in approved supporting documentation. Special protective environment requirements shall be provided by the packaging supplier and specified in the approved supporting documents, as necessary. Additionally, particular attention will be given to advance agreement on the package receipt and on advance notification of the shipment. Approved supporting documents will include steps for coordination with state and federal officials, as necessary. Approved supporting documents will also identify any necessary shipping papers and notices to be included in the shipment.

15.0 Inspection, Test, and Operating Status

Markings (e.g.tags, labels, stamps, cards, etc.), affixed to packaging by the supplier to show evidence of satisfactory testing and operational status will not be removed or obliterated. Markings shall be affixed to packaging by the NED, as necessary, that have been:

a. Inspected or tested in accordance with approved supporting documents to preclude inadvertent bypassing of inspections

b. Identified in accordance with approved supporting documents to prevent inadvertent operation of packaging components.

16.0 Nonconforming Materials, Parts, or Components

Approved supporting documentation shall include information, as necessary, which:

a. Prevents inadvertent use or installation of materials, parts, or components that do not conform to the package requirements.

b. Identifies, documents, segregates, indicates disposition, and notifies affected organizations for nonconforming materials, parts, or components.

c. Provides criteria for the review and acceptance, rejection, repair, or rework of nonconforming materials, parts, or components.

17.0 Corrective Action

Conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, shall be reported by personnel to the QAPM for resolution. The QAPM has the authority to cease operational functions with justifiable cause and shall direct continuance of the operation only upon resolving the cause for the cessation of activities. Corrective actions must address the cause of the adverse conditions and preclude repetition. Identified conditions adverse to quality, the cause of the condition, and corrective actions taken shall be documented by the QAPM and reported to the Director, NRP.

18.0 Quality Assurance Records

Sufficient records shall be kept to describe the activities affecting quality. Records shall include approved supporting documents and closely related specifications, such as required qualifications of personnel, procedures, and equipment. Also, copies of shipping papers, results of inspections and tests, and audits that were completed shall be included in the records, as required. The QAPM files and stores necessary records in locations allocated by the NED. Records are kept for a minimum of 3 years beyond the last date in which the activity was performed. If any portion of an approved supporting document is superseded, the superseded material shall be retained for 3 years after it is superseded. Additionally, records are retained as stated in the reactor facility license or State of North Carolina broad scope license issued to NCSU, as applicable.

19.0 Audits

Transportation of RAM from the NED is expected to be infrequent. Accordingly, the audit function will be different than those for routine shipments or other operations. Audits will occur prior to, during, and shortly after the RAM shipment. Beforehand, the audit will be concerned with the preparation and planning for the RAM shipment to be certain the appropriate degree of safety control has been identified and adequately considered; that the necessary documents have been properly reviewed and approved and that qualifications for personnel and equipment have been met. During the preparation of the shipment, the audit objective will be to ensure that required safety measures are being adequately implemented. After the RAM shipment is made, the audit objective will be to make certain that the records have been properly completed, assembled, and prepared for storage. Audit personnel will not be selected from the individuals who performed the RAM shipment or QA\QC and inspection functions. Written documents will be prepared to assure a thorough check and verification of the actions being audited. The results

of the audit(s) will be given to the Head NED, Director NRP, QAPM, and RSAC Chair or RSC Chair, as appropriate. Deficiencies will be corrected before proceeding with operations related to the shipment or the storage of records. Audit findings that require notification of NCSU and NED management, carriers, receivers, and regulatory agencies will be made, as necessary. If necessary, follow-up actions and reaudit of deficient area shall be taken where indicated.