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August 28, 2017
RA 17-0099

ATTN: Document Control Desk
Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Docket Nos. 71-0598 and 50-482: Changes to the Wolf Creek Nuclear Operating Corporation Quality Assurance Program for Radioactive Material Packages

Reference: Correspondence dated August 28, 2015, from P. Silva, USNRC, to A. C. Heflin, WCNO

To Whom It May Concern:

In accordance with 10 CFR 71.1(a), 10 CFR 71.106(b) and the Reference, Wolf Creek Nuclear Operating Corporation (WCNO) hereby reports changes made to the WCNO Quality Assurance Program for Radioactive Material Packages since August 28, 2015. The changes made to the WCNO Quality Assurance Program for Radioactive Material Packages since August 28, 2015 are documented in procedure AP 31-001, "Packaging for Transporting Type B and Fissile Quantities of Radioactive Materials Quality Program Requirements," Revision 6, which was released on March 16, 2017. This procedure is enclosed.

The attached summary of the changes made to the WCNO Quality Assurance Program for Radioactive Material Packages since August 28, 2015 documents that these changes do not reduce the commitments in this quality assurance program. This letter contains no commitments. If you have any questions concerning this matter, please contact me at (620) 364-4204.

Sincerely,

Cynthia R. Hafenstine

CRH/rlt

Q004
NM5520
NM55
NRR

Attachment: Summary of Changes Made to the Wolf Creek Nuclear Operating Corporation
Quality Assurance Program for Radioactive Material Packages Since August 28,
2015

Enclosure: Procedure AP 31-001, "Packaging for Transporting Type B and Fissile Quantities
of Radioactive Materials Quality Program Requirements," Revision 6.

cc: K. M. Kennedy (NRC), w/a, w/e
B. K. Singal (NRC), w/a, w/e
N. H. Taylor (NRC), w/a, w/e
Senior Resident Inspector (NRC), w/a, w/e

Summary of Changes Made to the Wolf Creek Nuclear Operating Corporation Quality Assurance Program for Radioactive Material Packages since August 28, 2015

Steps Changed in Procedure AP 31-001, Rev. 6	Date of Changes to Procedure AP 31-001, Rev. 6	Description of Changes to Procedure AP 31-001, Rev. 6	Regulatory Basis for Determining that Changes to Procedure AP 31-001, Rev. 6 do not reduce QA Program commitments
3.1.4	3-16-2017	Changed the title of the reference to procedure AP 20A-008, "QA Surveillance and Station Monitoring Program."	10 CFR 71.106 (b): Non-substantive editorial change
3.1.5	3-16-2017	Added a reference to procedure AP 20A-010, "Conduct of Performance Assessment."	10 CFR 71.106 (b): Non-substantive editorial change
4.1 through 4.10	3-16-2017	Sequence of definitions changed to place all definitions in alphabetical order.	10 CFR 71.106 (b): Non-substantive editorial change
4.3	3-16-2017	Enhanced definition of "Criticality Safety Index."	10 CFR 71.106 (b): Editorial clarification
4.4	3-16-2017	Enhanced definition of "Fissile Material."	10 CFR 71.106 (b): Editorial clarification
4.7	3-16-2017	Enhanced definition of "Packaging."	10 CFR 71.106 (b): Editorial clarification
4.8	3-16-2017	New step that enhanced the definition of "Transport Index."	10 CFR 71.106 (b): Editorial clarification
4.10 in revision 5	3-16-2017	Deleted definition of "Fissile Radionuclides."	10 CFR 71.106 (b): Editorial clarification
4.11.1 in revision 5	3-16-2017	Deleted step with information about "Transport Index."	10 CFR 71.106 (b): Editorial clarification
6.3.1	3-16-2017	Changed step title to "Quality Assurance Organization."	10 CFR 71.106 (b): Editorial clarification
6.3.3	3-16-2017	Changed step title to "Package Design Control."	10 CFR 71.106 (b): Editorial clarification
6.3.10	3-16-2017	Changed step title to "Internal Inspection."	10 CFR 71.106 (b): Editorial clarification
6.3.12	3-16-2017	Changed step title to "Control of Measuring and Test Equipment."	10 CFR 71.106 (b): Editorial clarification
6.3.13	3-16-2017	Changed step title to "Handling, Storage and Shipping Control."	10 CFR 71.106 (b): Editorial clarification
6.3.15	3-16-2017	Changed step title to "Nonconforming Materials, Parts and Components."	10 CFR 71.106 (b): Editorial clarification

Summary of Changes Made to the Wolf Creek Nuclear Operating Corporation Quality Assurance Program for Radioactive Material Packages since August 28, 2015

Steps Changed in Procedure AP 31-001, Rev. 6	Date of Changes to Procedure AP 31-001, Rev. 6	Description of Changes to Procedure AP 31-001, Rev. 6	Regulatory Basis for Determining that Changes to Procedure AP 31-001, Rev. 6 do not reduce QA Program commitments
6.3.18.1.a	3-16-2017	Replaced "surveillance" with "assessment"	10 CFR 71.106 (b): Editorial clarification
6.3.18.2	3-16-2017	Replaced "surveillance" with "assessment"	10 CFR 71.106 (b): Editorial clarification
6.3.18.8	3-16-2017	Replaced "observation" with "surveillance"	10 CFR 71.106 (b): Editorial clarification
6.3.18.9	3-16-2017	Replaced "surveillance" with "assessment"	10 CFR 71.106 (b): Editorial clarification
6.3.18.10	3-16-2017	Replaced "surveillance" with "assessment" and replaced "observation" with "surveillance"	10 CFR 71.106 (b): Editorial clarification



AP 31-001

PACKAGING FOR TRANSPORTING TYPE B AND
FISSILE QUANTITIES OF RADIOACTIVE
MATERIALS QUALITY PROGRAM
REQUIREMENTS

Responsible Manager

MANAGER QUALITY

Revision Number	6
Use Category	Information
Administrative Controls Procedure	Yes
Management Oversight Evolution	No
Program Number	31

DC5 03/16/2017

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 1 of 19

TABLE OF CONTENTS

<u>SECTION</u>	<u>TITLE</u>	<u>PAGE</u>
1.0	PURPOSE	2
2.0	SCOPE	2
3.0	REFERENCES AND COMMITMENTS	2
4.0	DEFINITIONS	3
5.0	RESPONSIBILITIES	4
6.0	PROCEDURE	6
7.0	RECORDS	19
8.0	FORMS	19

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 2 of 19

CAUTION

Revisions to this program are required to be reviewed in accordance with 10CFR50.54(a)(3). Changes to this program may be made provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the program description that do reduce the commitments must be submitted to the NRC for review and approval prior to implementation.

1.0 PURPOSE

- 1.1 This Special-Scope Quality Program establishes the quality requirements for those components and activities required for the packaging and transporting of Type B quantities of radioactive materials and fissile materials.
(Reference 3.1.2)

2.0 SCOPE

- 2.1 This procedure establishes Special-Scope Quality Program requirements for those activities:
- 2.1.1 Associated with design, fabrication, assembly and testing of packaging used to transport Type B radioactive and fissile materials; and
 - 2.1.2 For procurement, use, and documentation of maintenance and/or repair of packaging used to transport Type B radioactive and fissile materials.
- 2.2 WCNOG will not conduct any maintenance and/or repair of Type B and fissile material packaging. In the event of needed repair or maintenance, the supplier shall perform the activities under their NRC approved QA program.
- 2.3 Type B packaging, where the package identification number includes either .../B(), .../B()F or B, are not acceptable for use at Wolf Creek Generating Station (WCGS) **IF** the fabrication of the packaging was completed later than August 31, 1986.
- 2.4 Shipments using DOT specification containers shall be allowed under the general license of 10CFR71.20.

3.0 REFERENCES AND COMMITMENTS

3.1 References

- 3.1.1 10CFR50 Appendix B "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 3 of 19

- 3.1.2 10CFR71 "Packaging and Transporting of Radioactive Material"
- 3.1.3 USNRC IE Information Notice 86-86, dated 10/10/86.
- 3.1.4 AP 20A-008, QA Surveillance and Station Monitoring Program
- 3.1.5 AP 20A-010, Conduct of Performance Assessment

3.2 Commitments

- 3.2.1 None

4.0 DEFINITIONS

- 4.1 Activity: When activity or activities are used in this procedure, it means a non-hardware function is to be performed.
- 4.2 Carrier: A person engaged in the transportation of passengers or property by land or water as a common, contract or private carrier or by civil aircraft.
- 4.3 Criticality Safety Index (CSI): The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 10 CFR 71.22, 71.23, and 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the over pack, freight container, consignment or conveyance.
- 4.4 Fissile material: The radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural uranium or depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.
- 4.5 Nonconformance: A deficiency in characteristic, documentation or procedure which renders the quality of material, item or component unacceptable or indeterminate.
- 4.6 Package: Packaging together with its radioactive contents as presented for transport.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 4 of 19

- 4.7 Packaging: The assembly of components necessary to ensure compliance with the packaging requirements. 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.
- 4.8 Transport index (TI): The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).
- 4.9 Type B Packaging: Packaging which shall meet the general packaging requirements and all the performance standards for both normal (10CFR71.71) and accident (10CFR71.73) test conditions.
- 4.10 Type B Quantities of Radioactive Materials: A quantity of radioactive material greater than Type A quantity. Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed the A1 value for special form radioactive material or A2 value for normal form radioactive material, where A1 and A2 values are given in 10CFR71, Appendix A.

5.0 **RESPONSIBILITIES**

- 5.1 The Manager Quality is responsible to ensure the necessary 10CFR50 Appendix B quality assurance program requirements are developed for packaging and transporting of Type B quantities of radioactive materials and fissile materials activities requiring additional quality program requirements. He is also responsible to ensure these quality assurance program requirements are implemented by performing audits or evaluations as required by upper tier documents or performance indicators, which ever is applicable.
- 5.2 WCNOC department heads, managers and supervisors are responsible to ensure WCNOC personnel and contractors performing packaging and transporting of Type B quantities of radioactive materials and fissile materials activities have received the required training and are qualified to perform these activities.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 5 of 19

- 5.3 WCNOC department heads, managers and supervisors are responsible to ensure approved procedures used in packaging and transporting of Type B quantities of radioactive materials and fissile materials activities are provided to WCNOC personnel and contractors and that these procedures contain the quality requirements necessary to ensure satisfactory completion of the special-scope activity.
- 5.4 WCNOC personnel and contractors have the responsibility for implementing Quality Program requirements identified in procedures, work instructions, program documents and license commitments.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 6 of 19

6.0 PROCEDURE

- 6.1 This special scope program ensures that packaging and transporting of Type B quantities of radioactive materials and fissile materials are in conformance with the applicable regulatory requirements.
- 6.2 The extent to which each applicable criterion of 10CFR50 Appendix B is applied to the packaging and transporting of Type B quantities of radioactive materials and fissile materials quality assurance program to ensure that applicable regulatory and design bases requirements are maintained consistent with their effect on nuclear safety is defined in the Section 6.3.

6.3 10CFR50 APPENDIX B REQUIREMENTS

6.3.1 Quality Assurance Organization

1. Duties and responsibilities of personnel implementing packaging and transporting of Type B quantities of radioactive materials and fissile materials quality assurance program shall comply with Section 5.0 and shall be delineated in program descriptions, procedures and instructions to the extent necessary to ensure the special-scope activity is satisfactorily accomplished.
2. Duties and responsibilities for implementation of this program may be delegated to individuals and organizations outside WCNO. This delegation shall be in writing with WCNO maintaining the overall responsibility for the delegated activity.

6.3.2 Quality Assurance Program

1. This Special-Scope Quality Program provides assurance that activities pertaining to packaging and transporting of Type B quantities of radioactive materials and fissile materials are performed with specified equipment and under suitable environmental conditions.
2. Personnel performing special-scope activities shall have received the necessary training and be appropriately qualified. This training shall be documented and the documentation retained as described in approved procedures and instructions.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 7 of 19

6.3.3 Package Design Control

1. Design activities are not performed by WCNOG, however, WCNOG shall ensure that the Type B package vendor's QA program included appropriate measures to control design activities.

6.3.4 Procurement Document Control

1. Controls shall be established to ensure that applicable regulatory requirements, design bases and other requirements necessary to ensure quality are included or referenced in procedures for procurement of equipment and services.
2. Procedures shall also provide controls for the review and approval of procurement specifications as well as revision control of the procurement documents.
3. Changes to technical and quality requirements in procurement documents shall have the same degree of control as the original.
4. Procurement documents for equipment and services shall include:
 - a. Provisions for specifying technical, quality documentation and records requirements;
 - b. Extending applicable procurement document requirements to lower tier suppliers;
 - c. Specifying special requirements such as reporting defects and nonconformances, documentation requirements, applicable acceptance criteria and receipt inspections;
 - d. Requirements for manufacturers and/or suppliers of packaging to supply certifications verifying that the designated packaging (model and serial number) was manufactured and tested under the control of an NRC approved QA program;
 - e. Require replacement parts be procured under the suppliers NRC approved QA Program;
 - f. Requirements for supplying WCNOG information for meeting the reporting requirements of 10CFR71.95 and 10CFR21; and
 - g. Requirements for other pertinent documentation to be furnished with the packaging (e.g., maintenance, repair, modification of documentation records, Certificate of Compliance, as-built drawings, photographs, sketches, use and maintenance manuals).
5. Fissile material (e.g., new fuel assemblies) shall be returned to the supplier/vendor in accordance with established procurement procedures.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 8 of 19

6.3.5 Instructions, Procedures and Drawings

1. Special-Scope activities, including functional and administrative activities affecting quality or nuclear safety, shall be accomplished using procedures, instructions and drawings approved prior to use.
2. Procedures, instructions, checklists, drawings and specifications, and changes thereto, used in Special-Scope activities shall be reviewed, approved in accordance with approved procedures.
3. Procedures, instructions and checklists shall contain the necessary controls and the applicable quantitative or qualitative acceptance criteria to ensure the satisfactory completion of the special-scope activity.
4. Procedures and instructions shall be sufficiently detailed so that qualified individuals may perform the required activity without direct supervision.
5. Procedure revisions which involve a change to Technical Specifications or an unreviewed safety or environmental question shall be referred to the Plant Safety Review Committee for review and approval.
6. The following specific clarifications to instructions, procedures and drawing requirements shall be applied by WCNOG:
 - a. WCNOG shall not conduct any repair, rework or maintenance to a supplier's Type B or fissile material package. These activities shall be conducted by the supplier in accordance with their NRC approved QA Program;
 - b. WCNOG shall be responsible for ensuring that proper documentation of required maintenance or repair/rework is available; and
 - c. Measures shall be established to ensure that loading and unloading of Type B and fissile materials into/from packaging is controlled.
7. WCNOG shall implement the supplier's closure procedures to ensure proper sealing of the Type B and Fissile material containers. The procedure shall include verification:
 - a. That a gasket or sealing material is in place on the closure device,
 - b. That the closure device is properly aligned on the container,
 - c. Of the tightening or affixing of the closure device to container has been accomplished, and

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM	AP 31-001
Information Use	REQUIREMENTS	Page 9 of 19

- d. That pressure testing has been performed when required.
- 8. Measures shall be established to ensure that, prior to departure of the package from WCGS, the Type B or fissile material package is:
 - a. The proper package for the contents and in good condition;
 - b. Adequately secured within or on the transport vehicle in proper shipping configuration;
 - c. Properly sealed;
 - d. In compliance with Department of Transportation (DOT) and NRC regulations;
 - e. Identified by model and license registration numbers;
 - f. Adequately sealed with provisions for expansion for any system containing liquid;
 - g. Provided any moderator or neutron absorber, if required, and is in proper condition; and
 - h. Provided, when required, an operable pressure relief device which is properly set.

6.3.6 Document Control

- 1. Personnel and organizations participating in activities affecting quality shall be made aware of and use proper and current instructions, procedures, specifications and drawings for the performance of special-scope activities.
- 2. Participating organizations shall comply with procedures for control and maintenance of documents and document changes to preclude the use of outdated or inappropriate information.
- 3. Document control measures identified in procedures shall include:
 - a. Identification of positions or organizations responsible for the release, distribution and control of documents and changes;
 - b. Establishing and updating distribution lists;
 - c. Coordination of the control of documents;
 - d. Ascertaining that proper documents (including current revisions) are available at field locations; and
 - e. Changes to documents are reviewed and approved by the same organization that performed the original review and approval or an equivalent organization using equivalent criteria.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 10 of 19

6.3.7 Control of Purchased Material, Equipment and Services

1. Controls shall be established in approved procedures to ensure that Type B and fissile material packaging conform to procurement document requirements.
2. Controls of items and services shall include:
 - a. Evaluation and selection of suppliers,
 - b. Placing the supplier on the Supplier Information List (SIL),
 - c. Source Inspection,
 - d. Surveillance or audit of supplied items or services, and
 - e. Examination, test or inspection of items at delivery.
3. Prior to the first use of a package by WCNOG, the package identification number, as specified on the package approval, and WCNOG's name and license number shall be submitted to the NRC. (Reference 10CFR71.17)
4. WCNOG shall establish measures to ensure packaging received at the WCGS is accompanied by documentation required by the purchase order. As a minimum, such documentation shall:
 - a. Be a copy of the Certificate of Compliance,
 - b. Relate to the use of the packaging, and
 - c. Identify necessary actions to be taken prior to delivery of the licensed material to a carrier.
5. When required, documented evidence that items conform to procurement requirements shall be available at the site and reviewed by responsible personnel prior to installation or use.
6. Nonconformances will be processed in accordance with 6.3.15.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 11 of 19

6.3.8 Identification and Control of Materials, Parts and Components

1. Approved procedures providing for identification and control of material, parts and components shall require that only correct and acceptable material, parts and components are received, and installed.
2. These procedures require traceability be maintained from initial receipt through use in accordance with procurement documents or other applicable drawings or specifications.
3. Physical identification of items shall be used to the maximum extent possible. Identification may be on the item or records traceable to the item.
4. In lieu of physical identification, physical separation or procedure controls may be employed.
5. When required by codes, standards or specifications, procedures shall provide for traceability of materials, parts or components to specific inspection or test records.

6.3.9 Control of Special Processes

1. WCNOG shall not perform maintenance and/or repair activities on Type B or fissile material packaging.
2. Any special processes required for the supplier to repair or rework the packaging shall be established and controlled in accordance with the supplier's NRC approved QA program.

6.3.10 Internal Inspection

1. Controls for inspection shall be established and documented to verify conformance with applicable instructions, procedures and drawings that specify inspection requirements, acceptance limits and inspection responsibilities.
2. Inspections, examinations, measurements and tests shall be accomplished in accordance with instructions or procedures at each work operation where it is necessary to verify quality.
3. Such inspections, including the final inspection prior to departure of the shipment, shall be performed by individuals qualified within their respective area of responsibility who did not perform or directly supervise the activity being inspected.
4. If mandatory inspection hold points are required, these hold points shall be designated in appropriate procedures, instructions or drawings.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 12 of 19

5. Specific inspections to be addressed shall be the visual inspections, at time of receipt and prior to departure, of Type B and fissile material packaging to ensure compliance to procurement documents and supplier's closure procedures.
6. If inspection is impossible or disadvantageous, indirect control by monitoring process methods, equipment or personnel shall be provided.
7. Both inspection and process monitoring shall be provided when control is inadequate without both.
8. Qualifications of personnel performing or evaluating results of inspections and examinations shall meet applicable license commitments, codes and standards appropriate to the discipline involved.
9. Records of inspection and test results shall identify the person recording data as well as the person approving inspection and test results. Deviations, their cause and any corrective action completed or planned shall also be documented.
10. The individual operating the test equipment shall also be identified for those tests where special training is required on the operation and/or interpreting the readings of test equipment.

6.3.11 Test Control

1. WCNOG shall establish measures to ensure appropriate acceptance tests have been conducted prior to transporting Type B packaging and fissile material containers from WCGS. The basis for this acceptance shall be identified (e.g., Certificate of Compliance, maintenance and operational manuals furnished by the packaging manufacturer).

6.3.12 Control of Measuring and Test Equipment

1. Controls shall be established in approved procedures to ensure that tools, instruments, test equipment and measuring devices used for tests, calibrations and measurements are of the proper range and type and are identified, controlled, calibrated, adjusted and maintained at specified intervals or prior to use.
2. Calibrations shall be against acceptance standards having documented traceability to nationally recognized standards. If no national standard exists, the basis for calibration shall be documented.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 13 of 19

3. Some commercially available measuring and test devices (e.g. rulers, tape measures, manometers, etc.) are not calibrated but provide adequate accuracy for an application without calibration and control measures.
4. Methods and intervals of calibration for installed instruments and control devices shall be specified and documented based on the type of equipment, required accuracies and conditions affecting calibration.
5. When calibration, testing or measuring devices are found to be out of calibration, an evaluation shall be performed and documented indicating the validity and acceptability of parameters or equipment previously calibrated, measured or tested with these devices.
6. Calibration, measuring or testing devices consistently found out of calibration shall be repaired or replaced.

6.3.13 Handling, Storage and Shipping Control

1. Fissile material shall be packaged in the suppliers NRC approved container in accordance with this QA Program.
2. Approved procedures shall be in effect to control handling, storage (including segregation) and shipping of Type B and fissile material packaging to prevent damage, deterioration, inadvertent use or loss.
3. These procedures shall take into account requirements of instructions, procedures and drawings applicable to specific items including those provided by equipment suppliers.
4. All conditions identified in the package Certificate of Compliance when loading or unloading shall be adhered to.
5. All conditions including specified operations, inspections and tests shall be completed prior to delivery to a carrier.
6. All necessary shipping documents shall be prepared.
7. Critical, sensitive, perishable or high-value articles will be handled, stored, shipped, packed and preserved in accordance with specific, approved methods.
8. Special tools or equipment used for handling material, parts and components shall be inspected and tested in accordance with approved procedures to verify handling tools and equipment are adequately maintained.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 14 of 19

9. Items under warehouse control shall be subjected to shelf life and preventative maintenance programs, when specified, to ensure acceptability for use.

6.3.14 Inspection, Test and Operating Status

1. Controls shall be established in approved procedures to require the status of inspections and tests performed be indicated by the use of markings such as stamps, tags, labels, routing cards, logs or other suitable means, including physical segregation.
2. Establishing traceability from the item to documentation indicating the status of inspections and tests is acceptable method of maintaining inspection and test status for the item.
3. Identification of the status of nonconforming items from inspections of tests is identified in section 6.3.15.

6.3.15 Nonconforming Materials, Parts and Components

1. Warehouse and "in-plant" nonconformances are identified, documented, controlled, dispositioned and corrected in accordance with approved procedures and provide for the notification of affected parties to prevent their inadvertent use or installation.
2. Controls of "in-plant" and warehouse nonconforming items shall be accomplished in accordance with approved procedures.
3. "In-plant" and warehouse nonconforming items shall be promptly identified and controlled to prevent their inadvertent use or installation.
4. Any person identifying a deficiency in characteristic, documentation or procedure which renders the quality of an item unacceptable or indeterminate shall report the nonconformance in accordance with approved procedures.
5. Recommended dispositions specifying methods to correct or accept nonconforming items shall be documented by responsible station personnel in accordance with approved procedures.
6. Engineering shall review and approve recommended "use-as-is" or "repair" dispositions which affect the design basis or constitute a deviation from engineering requirements.
7. Unacceptable recommended dispositions shall have an alternate disposition specified by the designated engineering organization.
8. When the disposition of a nonconformance is "rework" or "reject", designated station staff shall provide the disposition.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 15 of 19

9. The organization responsible for correcting the nonconforming item or activity shall implement the approved disposition.
10. Nonconforming items shall be corrected in accordance with an approved disposition. Repair and rework shall be accomplished using documented and approved procedures and instructions.
11. Repaired or reworked items shall be reinspected, as appropriate, to ensure that critical attributes possibly affected by the nonconforming condition are acceptable.
12. Control of nonconforming items in the warehouse shall be accomplished in accordance with approved procedures.
13. Tags or labels of prominent size and color attached to items when practical.
14. When it is impractical to apply tags or labels, documentation traceable to the item shall be used to identify nonconforming conditions.
15. When possible, nonconforming items shall be placed in segregated storage areas.
16. These segregated storage areas shall be clearly identified as containing nonconforming material, parts and components and shall have access controlled to prevent entry by unauthorized individuals.
17. Documentation for supplier-generated nonconformances with a disposition of "use-as-is" or "repair" shall be submitted to Engineering for concurrence.
18. Correction of nonconforming warehouse items and associated close-out of the nonconformance is accomplished as described below.
 - a. Recommended dispositions specifying methods to correct or accept nonconforming items shall be documented by responsible personnel in accordance with approved procedures.
 - b. Engineering shall review and approve recommended "use-as-is" or "repair" dispositions which affect the design basis or constitute a deviation from engineering requirements. Unacceptable recommended disposition shall have an alternate disposition specified by the designated engineering organization.
19. Nonconformances shall be evaluated for reportability in accordance with 10CFR71.95, "Reports", and required reports submitted to the NRC.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 16 of 19

6.3.16 Corrective Action

1. Non-hardware conditions adverse to Quality shall be identified, reported, corrected and documented in accordance with approved procedures. WCNOG and contractor personnel are able to identify non-hardware conditions adverse to quality in accordance with approved procedures.
2. Included is the identification of the cause of significant conditions adverse to quality, as defined in approved procedures, and corrective actions to prevent recurrence of significant conditions adverse to quality.
 - a. Significant conditions adverse to quality is defined in approved procedures.
3. Follow-up verification of identified significant conditions adverse to quality will also be performed as described in approved procedures to verify completion and effectiveness of corrective action.
4. Reports for significant conditions adverse to quality shall be reviewed and evaluated to determine if an operating abnormality, deviated from expected performance, or an unanticipated deficiency in design that affects nuclear safety has occurred.
5. Approved procedures will identify documents to be analyzed to determine if significant adverse conditions may be developing. A report of the analysis shall be issued, at an interval specified by approved procedures, to appropriate levels of management and applicable organizations.
6. A Trend Analysis Program shall be implemented in accordance with approved procedures, which analyzes identified documents.
7. The purpose is to analyze those assigned documents for significant adverse conditions which may be developing.
8. A trend report will be issued at an interval specified by approved procedures to appropriate levels of management.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 17 of 19

6.3.17 Quality Assurance Records

1. Approved procedures or program documents shall specify the requirements and responsibilities for identification, preparation, collection, storage and maintenance of records.
2. Records shall be legible, complete, and identifiable to the specific items or activities and be readily retrievable.
3. Record retention periods shall be identified and be of sufficient duration to be of value in:
 - a. Demonstrating safe station operation;
 - b. Reconstructing significant events in station history;
 - c. Determining the cause of accidents or malfunctions; and
 - d. Inspecting, maintaining, reworking, repairing, replacing, modifying, Type B and fissile material packaging.
4. The requirements for storage and maintenance of records shall be identified in approved procedures, program documents and shall be consistent with Technical Specifications and license commitments.
5. Quality Assurance records shall include as a minimum:
 - a. Records of package use;
 - b. Results of reviews, inspections, tests, audits, monitoring of work performance and any required materials analyses;
 - c. Records showing evidence of delivery of a package to a carrier;
 - d. Records showing compliance with NRC and DOT requirements for Type B and fissile material shipments; and
 - e. Records showing that a package was ultimately accepted for disposal at a facility licensed to receive radioactive materials in the type, quantity and form shipped.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 18 of 19

6.3.18 Audits

1. Planned and documented audits shall be performed in accordance with approved procedures to verify compliance to activities affecting quality.
 - a. Once every 24 months an audit or assessment of the Packaging for Transporting Type B and Fissile quantities of Radioactive Materials Quality Program Requirements shall be scheduled and performed in accordance with approved procedures.
 - b. Vendor audits shall be performed as a minimum of once every three (3) years as required by Regulatory Guide 1.144, except where commitments require more frequent audits.
2. The audit or assessment shall verify those activities for the procurement and use of packaging used in the transport of radioactive materials.
 - a. Vendor auditing shall establish that the design was accomplished under control of an NRC approved QA program.
 - b. Vendor audits shall ensure adequate procurement controls during the procurement of replacement parts.
3. Scheduled audits are not mandatory if no activities associated with the packaging and transport of Type B radioactive materials has been scheduled or occurred during the 24-month period. In that instance, the evaluation may be performed in conjunction with the scheduled audit of the Process Control Program.
4. Supplemental or additional audits may be conducted when:
 - a. Significant changes are made in functional areas,
 - b. It is suspected that the quality of an item may be in jeopardy,
 - c. An evaluation of the Special-Scope Program effectiveness is considered necessary, or
 - d. It is necessary to verify effectiveness of corrective actions.
5. Audits shall include, as a minimum, verification that policies, procedures, regulations and license provisions have been implemented and are effective.
6. Those leading the performance of audits shall be certified as a Lead Auditor in accordance with approved procedures.

Revision: 6	PACKAGING FOR TRANSPORTING TYPE B AND FISSILE QUANTITIES OF RADIOACTIVE MATERIALS QUALITY PROGRAM REQUIREMENTS	AP 31-001
Information Use		Page 19 of 19

7. Audit team members may be from the audited organization; however, they shall not:
 - a. Be permitted to audit activities for which they have immediate responsibility or
 - b. Report to a management representative who has immediate responsibility for the activities being audited.
8. A QA Surveillance is a limited scope QA oversight function that is typically conducted on short notice (i.e., not usually scheduled) and provides feedback on specific concerns or activities of interest to QA or WCNO Management.
9. A QA Assessment is a QA oversight function that is typically scheduled in advance and provides feedback on specific concerns or activities of interest to QA or WCNO management. A QA Assessment may be comprehensive enough to satisfy an entire audit element.
10. QA Audit, QA Assessment, and QA Surveillance reports are made available to
 - a. Management of the evaluated organization,
 - b. Management responsible for the evaluated program or activity,
 - c. Other management as deemed necessary.
11. Periodic reviews of the audit program shall be performed to ensure that audits are accomplished in accordance with program commitments.

7.0 RECORDS

7.1 None

8.0 FORMS

8.1 None