4731.0420 QUALITY ASSURANCE REQUIREMENTS.

Subpart 1. **Program requirement.**

A. A licensee who uses a general license under part 4731.0406, 4731.0409, 4731.0410, or 4731.0411 must establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this part.

B. As used in this subpart, "quality assurance" 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, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

C. Before the use of any package for the shipment of licensed material subject to this part, a licensee must obtain the commissioner's approval of its quality assurance program. The licensee must file a description of its quality assurance program, including a discussion of which requirements of this part are applicable and how they will be satisfied.

D. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of part 4731.4090, subpart 2, items A to C, or an equivalent requirement of the NRC or an agreement state, is deemed to satisfy the requirements of subpart 1 and part 4731.0406, subpart 2.

Subp. 2. **Quality assurance organization.**

A. A licensee is responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but must retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

B. The quality assurance functions are:

(1) assuring that an appropriate quality assurance program is established and effectively executed; and

(2) verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions important to safety have been correctly performed.

Subp. 3. **Quality assurance program.**

A. The licensee must document the quality assurance program by written procedures or instructions and carry out the program according to those procedures throughout the period during which the packaging is used. The licensee must identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

B. The licensee, through its quality assurance program, must provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to ensure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee must ensure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality and the need for verification of quality by inspection and test.

C. The licensee must base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) the impact of malfunction or failure of the item to safety;

(2) the design and fabrication complexity or uniqueness of the item;

(3) the need for special controls and surveillance over processes and equipment;

(4) the degree to which functional compliance can be demonstrated by inspection or test; and

(5) the quality history and degree of standardization of the item.

D. The licensee must provide for the indoctrination and training of personnel who perform activities that affect quality, as necessary to ensure that suitable proficiency is achieved and maintained. The licensee must review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program that a participating organization is executing.

Subp. 4. **Changes to quality assurance program.**

A. A quality assurance program approval holder must submit a description of a proposed change to its commissioner-approved quality assurance program that will reduce commitments in the program description as approved by the commissioner. The quality assurance program approval holder shall not implement the change before receiving commissioner approval. The description of a proposed change to the commissioner-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of this part.

B. Each quality assurance program approval holder may change a previously approved quality assurance program without prior approval from the commissioner if the change does not reduce the commitments in the quality assurance program previously approved by the commissioner. Changes to the quality assurance program that do not reduce the commitments must be submitted to the commissioner every 24 months. In addition to quality assurance program changes involving

administrative improvements and clarifications, spelling corrections, and nonsubstantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(1) the use of a quality assurance standard approved by the commissioner that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

(2) the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities or, alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) the elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards that the quality assurance program approval holder has committed to on record; and

(5) organizational revisions that ensure persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

C. Each quality assurance program approval holder must maintain records of quality assurance program changes.

Subp. 5. **Handling, storage, and shipping control.** The licensee must establish measures to control, according to instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

Subp. 6. **Inspection, test, and operating status.**

A. The licensee must establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary, to preclude inadvertent bypassing of the inspections and tests.

B. The licensee must establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Subp. 7. **Nonconforming materials, parts, or components.** The licensee must establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked according to documented procedures.

Subp. 8. **Corrective action.** The licensee must establish measures to ensure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition that is adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition that is adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

Subp. 9. **Quality assurance records.** The licensee must maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by subpart 4, and closely related specifications, such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and that designates factors such as duration, location, and assigned responsibility for the records. The licensee must retain these records for three years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee must retain the superseded material for three years.

Subp. 10. **Audits.** The licensee must carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and determine the effectiveness of the program. The audits must be performed according to written procedures or checklists by appropriately trained personnel who do not have direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

Statutory Authority: *MS s 144.1202; 144.1203*

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