USDA Quality Assurance Program for Packaging and Shipment of Radioactive Materials

1. General

The Department of Agriculture only uses packages that have been designed, fabricated, tested and approved for use by other persons and for which it has received certifications from DOT. Packages are retained as originally furnished by supplier and are not modified, except when damaged in which case they are restored to their original condition. If necessary, the services of the supplier are engaged. Shipments are made when it becomes necessary to transfer irradiators containing more than Type A quantities of radioactive material in the form of special form sealed sources from one laboratory to another. Such shipments, however, are made infrequently--the average being once every three years. All shipments are made with the prior approval and under the direction of the Radiological Safety Staff (RSS).

2. Organization

The final responsibility for the Quality Assurance (QA) Program for Part 71 Requirements rests with the Radiological Safety Staff. Design and fabrication, except repair, shall not be conducted under this QA Program. The Radiological Safety Officer (RSO) is responsible for overall implementation of the program, instructions and certification, document control and auditing. The qualified responsible user approved by the Radiological Safety Committee is responsible for handling, packaging, shipping, storing, inspecting and furnishing records to the RSO. See last page for organizational chart.

3. Quality Assurance Program

The Radiological Safety Committee establishes and the RSS implements the QA Program. Training, in the form of written instructions, prior to engagement for all QA functions is required. QA Program revisions will be made according to written procedures with RSS approval. The QA Program will insure that all QC procedures, engineering procedures and specific provisions of the package design approval are satisfied. The QA Program will emphasize control of the characteristics of the package which are critical to safety.

The Radiological Safety Staff will assure that all radioactive material shipping packages are designed and manufactured under a QA Program approved by the NRC and/or DOT for all packages designed or fabricated after the effective date of the QA Program. This requirement can be satisfied by receiving a certification to this effect from the manufacturer.

4. Document Control

All documents related to a specific shipping package will be controlled through the use of written procedures. All document changes will be performed according to established written procedures. The Radiological Safety Staff will insure that all QA functions are conducted in accordance with the latest applicable changes to these documents.

5. Handling, Storage and Shipping

Written safety procedures concerning the handling, loading, storage and shipping of packages for certain special form radioactive material will be followed. Shipments will not be made unless all certifications, acceptances, and final inspection have been completed. Work instructions will be provided for handling, packaging, labeling, storage and shipping operations. The Committee approved responsible user shall supervise and/or perform the critical handling, storage and shipping operations.

6. Inspection, Test and Operating Status

Inspection, test and operating status of packages for certain special form radioactive material will be indicated and controlled by written procedures. Status will be indicated by tag, label and marking. Only shipping packages as originally received (and restored if repairs are required) from supplier will be used. The responsible user, as directed by the RSS, shall inspect package prior to shipment to ensure that it is in proper condition for shipment in accordance with written procedures. The RSS will ensure that these functions are performed.

7. Quality Assurance Records

Records of package approvals (including certifications by DOT), procurement, inspections, written instructions, shipping papers and records of shipments will be maintained. Descriptions of equipment and written procedures will also be maintained. The records will be identifiable and retrievable. The records will be maintained by the Radiological Safety Staff.

8. Audits

Due to infrequency of shipments, the QA Program will be audited prior to each shipment. Results of audits will be maintained and reported to the Radiological Safety Committee. Audit reports will be evaluated and deficient areas corrected where indicated. Audit reports will be filed in the Radiological Safety Staff office as part of the quality assurance records and reviewed by a member of the Radiological Safety Committee.

9. Specific Provisions

As mentioned previously, only packages designed, fabricated, tested and approved for use by other persons and for which certifications from DOT have been received by the Department will be used. More specifically, Certificate No. USA/6125/B(U)T for AECL Gammacell 220, expiration date May 31, 1980 and Certificate No. USA/5800/B(20WC-5) for Isomedix Gammator, expiration dated June 30, 1981 and held by the Radiological Safety Staff. Our QA Program will apply to packages covered by these certificates plus any that may be obtained in the future.

RSS
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Interrelationship of QA Functions to Other Management Functions