Tennessee Valley Authority, 1101 Market Street, Chattanooga, Tennessee 37402-2801

April 22, 2004

2/25/04

69 FR 8706

(2)

Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Gentlemen:

TENNESSEE VALLEY AUTHORITY (TVA) - COMMENTS ON DRAFT REGULATORY GUIDE DG-7004, "STANDARD FORMAT AND CONTENTS OF PART 71 APPLICATIONS FOR APPROVAL OF PACKAGING FOR RADIOACTIVE MATERIAL" - PROPOSED REVISION 2 TO REGULATORY GUIDE 7.10 (VOL. 69, NO. 37, *FEDERAL REGISTER (FR)* 8707, DATED FEBRUARY 25, 2004)

TVA appreciates the opportunity to comment on the subject draft regulatory guide published in the *FR* dated February 25, 2004 (69 *FR* 8707) and titled "Standard Format and Contents of Part 71 Applications for Approval of Packaging for Radioactive Material."

TVA's comments are provided in the enclosure.

If you have any questions, please contact Terry Knuettel at (423) 751-6673.

Sincerely,

Mark J. Burzynski

Mark J. Burzynski
Manager
Nuclear Licensing

Enclosure
cc (Enclosure):
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

E-RIDS=ADM-03
Cadc=J. Pearson (JSP)

Template=ADM-013

ENCLOSURE

COMMENTS ON DRAFT REGULATORY GUIDE DG-7004, "STANDARD FORMAT AND CONTENTS OF PART 71 APPLICATIONS FOR APPROVAL OF PACKAGING FOR RADIOACTIVE MATERIAL" - PROPOSED REVISION 2 TO REGULATORY GUIDE 7.10 (VOL. 69, NO. 37, *FEDERAL REGISTER* 8707, DATED FEBRUARY 25, 2004)

Establishing Quality Assurance Programs for Packaging
Used in Transport of Radioactive Material

PROPOSED	COMMENTS
The proposed DG-7004, Section: B. Discussion, Changes to Approved QA Program Description [page 4, 2nd paragraph, 2nd sentence] states: "Any changes to the approved QA program plan description require NRC approval prior to implementation."	*The NRC did not use this opportunity in the regulations and regulatory guide to make changes that would have (according to IN 2002-35 Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs, dated December 20, 2002) reduced regulatory burden and increased efficiency by providing a method similar to the provisions of 10 CFR 50.54(a)(3) and (4) for making changes to QA programs.*
The proposed DG-7004, Section: C. Regulatory Position, Subsection 1.2, Top Management Endorsement of a QA Program [page 6, 2nd paragraph, 1st sentence] states: "The policy statement should also identify the individuals who have been delegated authority for: • Implementing and revising the provisions of the described QA program and • Regularly assessing the scope, status, implementation, and effectiveness of the QA program."	*Company policy statements can accomplish the goal of designating authority by identifying functional and positional responsibilities versus identifying "individuals," as stated.*

<table>
<tr><th>PROPOSED</th><th>COMMENTS</th></tr>
<tr><td></td><td></td></tr>
<tr><td>The proposed DG-7004, Section: C. Regulatory Position, Subsection 2.1, General Guidance on QA Programs, [page 6, 1st paragraph, 3rd sentence] states: "For example, someone using a general license solely for the transportation of radioactive material in packages...would be expected to address regulations governing activities such as procurement, shipping, and handling....Elements common to all QA programs...quality organization and program, corrective action, QA records, and audits."</td><td>A matrix identifying the user vs. design and fabricator governing activities with the applicable RG section would be helpful. For example a general user should, as a minimum, address the following:

<table><tr><th>DG 7004</th><th>Quality Activity</th><th>Regulation</th></tr><tr><td>1.0</td><td>QA Organization</td><td>71.103</td></tr><tr><td>2.0</td><td>QA Program</td><td>71.105</td></tr><tr><td>4.0</td><td>Procurement Document Control</td><td>71.109</td></tr><tr><td>13.0</td><td>Handling, Storage, and Shipping Controls</td><td>71.127</td></tr><tr><td>16.0</td><td>Corrective Action</td><td>71.133</td></tr><tr><td>17.0</td><td>QA Records</td><td>71.135</td></tr><tr><td>18.0</td><td>Audits</td><td>71.137</td></tr></table>
With the understanding that parts of the requirements for procedures, documentation, etc., would apply to the main activities identified above.</td></tr>
<tr><td>The proposed DG-7004, Section: C. Regulatory Position, Subsection 10.2.3, Final Inspection, [page 17, 2nd paragraph, lead-in sentence & 7th bullet] states: "For packaging use, checklists should be established to ensure that inspections are performed to verify the following:
• Measures are established to ensure that an individual designated by the user of packages signs the shipping tags or indicators prior to authorization for shipping."</td><td>1. Is the requirement of 71.121 Internal Inspections applicable to general license that use the package for transport of radioactive material?

2. The user designates a qualification for performing activity by position (Radwaste Shipper) rather than by individual.</td></tr>
</table>

PROPOSED	COMMENTS
The proposed DG-7004, Section: C. Regulatory Position, Subsection 17.4, Receipt, Retrieval, and Disposition of Records, [page 22, 1st sentence] states, in part: "Measures should be established to provide a receipt control system, including identification of individuals in each organization responsible…"	*Identification of responsible individual or group is adequate.*
The proposed DG-7004, Section: C. Regulatory Position, Subsection 18.1, Elements of an Audit Program, [page 23, 2nd paragraph, 2nd sentence] states: "The frequency of audits should be based on the importance of the activity to safety; however, each activity should be audited at least once each year."	*This guidance contradicts itself, in that if an item is not important to safety there is no reason to audit once each year. The frequency needs to be determined by the importance to safety, as stated, which would mean that the requirement to audit "each year" is not needed.*
The proposed DG-7004, Section: C. Regulatory Position, Subsection 18.2, Scheduling of Audits, [page 23, 2nd paragraph & 3rd paragraph, 3rd sentence] states in part: "Internal audits….should be audited at least annually or at least once within the life of the activity, whichever is shorter…. Management audits should be conducted at least once every 12 months."	*Scheduling of audits should be based on the activities importance to safety, i.e., at least once during the license cycle or five year period for internal and management audits.*