MAR 16 1993

IMTB:TOM
71-0238

U.S. Department of Agriculture
ATTN: Mr. John T. Jensen
Director
6303 Ivy Lane
Greenbelt, Maryland 20770-1433

Dear Mr. Jensen:

This refers to your application dated January 29, 1993, requesting an amendment to your Quality Assurance (QA) Program Approval No. 0238 to include design and fabrication activities.

In connection with our review, we need the information identified in the enclosure to this letter. We understand that several irradiators are partially fabricated without having an NRC-approved QA program. In this regard, please describe as a separate item, how QA functions were performed to satisfy the requirements of 10 CFR Part 71 for the design and fabrication activities conducted.

This information should be provided within 45 days from the date of this letter. If you have any questions regarding this matter, you may contact Thomas Matula of my staff at (301) 504-2437.

Sincerely,

Original Signed by

Charles E. MacDonald, Chief
Transportation Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure:
As stated

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General

Reference to quality assurance (QA) requirements of 10 CFR 71 should be Subpart H rather than Appendix E.

Organization (Section I)

Provide management endorsement and commitment to the QA program through a written policy statement, signed by a U.S. Department of Agriculture official, stating that it is your policy to perform work on items important to safety in accordance with the requirements of 10 CFR 71 Subpart H as described in the QA Program and implemented by QA procedures.

Quality Assurance Program (Section II)

State that the QA program ensures activities important to safety applicable to the design, purchase, fabrication, and testing of packaging are described by written procedures and instructions and will be in place prior to engaging in these activities.

Delineate that indoctrination and training of personnel performing activities important to safety are trained and qualified to perform these activities.

Document Control (Section VI)

Identify the documents that are controlled (e.g., design and procurement documents, operating and maintenance procedures, inspection and test procedures, nonconformance and corrective action reports).

Identification and Control of Materials, Parts, and Components (Section VIII)

Describe your measures which ensure that items whose shelf life or operation times have expired are identified and precluded from use.

Nonconforming Material, Parts, or Components (Section XV)

Identify the measures taken by QA to analyze nonconformance reports to determine quality trends for appropriate management review and assessment.

Corrective Action (Section XVI)

Expand the scope of your corrective program to include suppliers and for ensuring that follow up is documented to verify that corrective actions were implemented by the supplier and are effective.

Quality Assurance Records (Section XVII)

Extend the retention time for QA records to three years beyond the date the activity ends, for which the QA Program was developed, as required by 10 CFR § 71.135.

Audits (Section XVIII)

Expand the scope of the audit program to include management and external audits. Management audits should be conducted at least once per year to assess the overall effectiveness of the implementation of the in-house QA program. External audits of the elements of major contractors' QA programs should be audited at least on a triennial basis to demonstrate implementation of QA programs having the required scope for purchases placed during the three-year period.