

SGTB:MG  
71-9011

JUN 10 1991

Advanced Medical Systems, Inc.  
ATTN: Ms. Sherry J. Stein  
121 North Eagle Street  
Geneva, OH 44041

Dear Ms. Stein:

This refers to your application dated May 16, 1991, as supplemented May 17, 1991, requesting renewal of Certificate of Compliance No. 9011 for the Model No. E-MEH-00-0004 package. The Certificate of Compliance will not be deemed to have expired until the application has finally been determined.

In connection with our review, we need the information identified in the enclosure to this letter.

This information should be provided within 30 days from the date of this letter. Additional information requested by this letter should be submitted in the form of revised pages. If you have any questions regarding this matter, we would be pleased to meet with you and your staff.

Sincerely,

Original Signed by

Charles E. MacDonald, Chief  
Transportation Branch  
Division of Safeguards  
and Transportation, NMSS

Enclosures: As stated

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Operating Procedures

1. Revise the operating procedures to include procedures for loading the cobalt-60 source into the teletherapy head, and for loading and securing the teletherapy head in the overpack. The procedures should require that the plug assembly, the plug assembly bolts, and other components be inspected for damages prior to loading. Torque requirements for the plug assembly bolts and overpack bolts should also be specified.
2. Revise item 1.3 of the operating procedures to include only authorized contents and containers. Note that the contents and containers in items 1.3.1.1, 1.3.1.3 and 1.3.2 are not authorized. Also, the container specified in items 3.4 and 3.5 is not authorized.
3. Revise the operating procedures to include provisions for assuring that the package surface contamination levels are within the limits specified in 10 CFR §71.87(i)(1). Item 3.1 of the operating procedures does not satisfy the requirements of 10 CFR §71.87.
4. Revise the operating procedures to include opening instructions which are in compliance with the requirements of 10 CFR §71.89.
5. Provide operating procedures for shipment of an empty package. The procedures should address the requirements of 49 CFR §173.427. Also, the procedures must include:
  - a. a test made prior to shipment which verifies that a source is not present in the teletherapy head, and
  - b. verification that the shutter is locked.

Maintenance Program

Provide a maintenance program which would ensure continued performance of the packaging. The program should include periodic testing, inspection and replacement schedules, as well as criteria for replacement and repair of components and subsystems on an as-needed basis.