71-0354

Advanced Medical Systems, Inc.

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December 16, 1993

Mr. John P. Jankovich, Section Leader
Quality Assurance Section
Source Containment and Devices Branch
Division of Industrial and
Medical Nuclear Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

RE: Response to Your Letter Dated December 6, 1993

Dear Mr. Jankovich:

1A QA 2000 1.0 was revised in its entirety with the revision approved on July 8, 1993.

1B Please clarify your request since, as indicated by the procedure, QA 2000 1.0 relates to compliance with 10 CFR Part 71. As you know, AMS does not manufacture or sell overpacks, only repairs are performed on existing overpacks. Further, as indicated by the organizational chart, the Radiation Safety Officer oversees quality control of radioactive shipments (i.e., transportation). The Radiation Safety Officer does not report to the Engineering Manager, both are members of the management team. The Radiation Safety Officer, however, has the final and ultimate say regarding radioactive materials, including transportation of same.

1C Please remember that AMS does not design, manufacture, or sell overpacks. The quality assurance program is designed to ensure that existing overpacks are properly repaired and only those in good condition are used. The management team is, as indicated, comprised of the Engineering Manager, Radiation Safety Officer, and Director of Regulatory Affairs. The Director of Regulatory Affairs handles auditing of the QA program, since QA individuals cannot audit themselves and audits should be unbiased, training (although job specific training is ordered under the auspices of the Engineering Manager), and procedural updates to ensure that charges are properly documented. QA procedures relating to design (not performed), fabrication (not performed), and maintenance of the overpacks are part of QA. Final inspection of the overpacks in preparation for shipment are performed under the auspices of the Radiation Safety Officer, who has final say on the approval of an overpack for shipment to a customer.

2.0A Quality control is another term for quality assurance. Further, the individuals who share QA responsibilities, the management team comprised of the Engineering Manager, RSO, and Director of Regulatory Affairs, all receive copies of updates.

2B Yes

NTOF 1/0

C Please remember that AMS does not manufacture overpacks. All items purchased, manufactured, or used by AMS in the service of its overpacks are subject to QA control. AMS' program emphasizes control of the characteristics of the package which are critical to safety. This does not, however, mean that there are no controls for items which are not critical to safety.

D Given the fact that AMS neither designs, manufactures, nor sells overpacks, and simply maintains existing overpacks for its own use, we do not understand what you mean by "influences of cost and schedule". Further, please remember that the Radiation Safety Officer has final and ultimate say regarding shipments of radioactive materials. Please clarify this statement so that we may properly respond.

4 Procurement documents generated (and reviewed) by QA personnel are reviewed by the Engineering Manger as an additional check.

6 Please clarify this request since in some instances the department wishing to make the change is not the best qualified to review it, i.e., an engineering change requested by purchasing should be reviewed and approved by engineering.

As indicated by 6.2.1, all changes and revisions are reviewed by the Isotope Committee and approved by the chairman.

7.0 Director is correct. Again, since AMS neither manufactures, designs, nor sells overpacks, and the Radiation Safety Officer has final and ultimate say regarding shipments of radioactive material, please indicate what you mean by "influences of cost and schedule".

10.0 In the event that original design or inspection requirements have been superseded, modifications, repairs, and replacements are inspected according to the most current requirements.

14 QA 1014 A & B provides this information (see 10.1.1 for QA 1014 reference). QA 1014 is already on file.

15 See QA 1000 for specifics. QA 1000 3.1-3 governs recovery inspection, 4.1 governs inprocess Inspection Policy, 5.1 governs final acceptance.

Upon receipt of your clarification as requested above, we will be happy to respond further.

Sincerely,

SHERRY J. STEIN
Director of Regulatory Affairs

SJS/cs