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TITLE: PRM-032-003 - 56FR51182 - ADVANCED MEDICAL SYSTEMS, INC.'S PETITION FOR RULEMAKING (MANUFACTURE AND TRANSFER OF ITEMS CONTAINING BYPRODUCT MATERIAL)

CASE REFERENCE: PRM-032-003

56FR51182

KEY WORD: RULEMAKING COMMENTS

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PROPOSED RULE: PRM-032-003 OPEN ITEM (Y/N) N

RULE NAME: ADVANCED MEDICAL SYSTEMS, INC.'S PETITION FOR RULEMAKING (MANUFACTURE AND TRANSFER OF ITEMS CONTAINING BYPRODUCT MATERIAL)

PROPOSED RULE FED REG CITE: 56FR51182

PROPOSED RULE PUBLICATION DATE: 10/10/91 NUMBER OF COMMENTS: 2

ORIGINAL DATE FOR COMMENTS: 12/09/91 EXTENSION DATE: / /

FINAL RULE FED. REG. CITE: 59FR17286 FINAL RULE PUBLICATION DATE: 04/12/94

NOTES ON PET. REQUESTED NRC AMEND REGS. APPLYING TO MANUFACTURERS & TRANSFE
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F RULE IERS OF REPLACEMENT PARTS. PET. DENIED BY EDO. FILE LOCATE ON P1.

TO FIND THE STAFF CONTACT OR VIEW THE RULEMAKING HISTORY PRESS PAGE DOWN KEY

HISTORY OF THE RULE

PART AFFECTED: PRM-032-003

RULE TITLE: ADVANCED MEDICAL SYSTEMS, INC.'S PETITION FOR RULEMAKING (MANUFACTURE AND TRANSFER OF ITEMS CONTAINING BYPRODUCT MATERIAL)

PROPOSED RULE SECY PAPER:	PROPOSED RULE SRM DATE: / /	DATE PROPOSED RULE SIGNED BY SECRETARY: 10/04/91
FINAL RULE SECY PAPER:	FINAL RULE SRM DATE: / /	DATE FINAL RULE SIGNED BY SECRETARY: 03/28/94

STAFF CONTACTS ON THE RULE

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CONTACT2: JOE MATE	MAIL STOP: NLS-129	PHONE: 492-3795

DOCKET NO. PRM-032-003
(56FR51182)

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.'S PETITION FOR RULEMAKING (MANUFACTURE AND TRANSFER OF ITEMS CONTAINING BYPRODUCT MATERIAL)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
07/19/91	06/28/91	LTR STEIN TO CHILK W/RESUBMITTAL OF 7/2/90 RULEMAKING PETITION
10/07/91	10/04/91	PETITION FOR RULEMAKING: NOTICE OF RECEIPT PUB. ON 10/10/91 IN 56FR51182
11/18/91	11/12/91	COMMENT OF DEPARTMENT OF THE AIR FORCE (LAWRENCE DONOVAN, MAJOR, USAF) (1)
12/09/91	12/03/91	COMMENT OF ILLINOIS DEPARTMENT OF NUCLEAR SAFETY (STEVEN C. COLLINS, CHIEF) (2)
04/11/94	03/28/94	FEDERAL REGISTER NOTICE ON DENIAL OF PETITION FOR RULEMAKING PUBLISHED ON 4/12/94 AT 59 FR 17286.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 32

[Docket No. PRM-32-3]

Advanced Medical Systems, Inc. - Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM-32-3) from Advanced Medical Systems, Inc. The petitioner requested that the NRC amend its regulations because it believed that the requirements of Part 32, which are applicable to original manufacturers and suppliers, were not equally applicable to manufacturers and suppliers of replacement parts. The petition is being denied because current regulations apply equally to manufacturers and suppliers of both original and replacement parts, ensuring the integrity of these parts; therefore, no additional requirements addressing the regulation of manufacturers and suppliers of replacement parts are necessary. Further, current regulations address service and maintenance of sources and devices possessed and used under an NRC license, including replacement parts, whether manufactured or supplied by the original manufacturer or supplier or some other manufacturer or supplier. Therefore the amendments suggested by the petitioner are not necessary.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and the NRC's letter to the petitioner are available for public

inspection or copying in the NRC Public Document Room, 2120 L Street NW, (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Naiem S. Tanious, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3878.

SUPPLEMENTARY INFORMATION:

The Petition

In a letter dated June 28, 1991, Advanced Medical Systems, Inc. (AMS) filed a petition for rulemaking with the NRC. The petition was docketed by the Commission on July 19, 1991, and was assigned Docket No. PRM-32-3. The petitioner requested that the NRC amend its regulations because it believed that the requirements of Part 32, which are applicable to original manufacturers and suppliers, were not equally applicable to manufacturers and suppliers of replacement parts. The petitioner has suggested two alternatives for accomplishing this objective. The first alternative is to insert the necessary language regarding manufacturers and suppliers of replacement parts into each appropriate section of Part 32. The second alternative would revise the purpose and scope provisions of § 32.1 to include manufacturers and suppliers of replacement parts.

Basis for Petitioner's Request

The petitioner identified itself as an original teletherapy equipment manufacturer. As such, it has a definite and direct interest in the health and safety of the public who may use or be treated by equipment it manufactures.

According to the petitioner, it appears that the requirements of Part 32 are being interpreted as applying only to manufacturers and suppliers of original equipment and not to manufacturers and suppliers of replacement parts, devices, products, or sources designated for units originally manufactured or transferred by others. In the petitioner's view, lack of specific requirements applicable to manufacturers and suppliers of replacement parts, devices, products, or sources, can lead to use of inferior quality replacement parts which in turn can cause malfunction or failure of devices, in particular teletherapy equipment, and thereby risk of overexposure. Advanced Medical Systems cited two incidents as examples of this problem: Access No. M49250, Anderson Memorial Hospital, Anderson, South Carolina; and Access No. M49324, St. Mary's Medical Center, Saginaw, Michigan.

Public Comments on the Petition

A notice of receipt of the petition for rulemaking was published in the Federal Register on October 10, 1991 (56 FR 51182). Interested persons were invited to submit written comments concerning the petition. The comment period closed December 9, 1991. The NRC received comments from the State of

Illinois, Department of Nuclear Safety, and the Department of the Air Force, Headquarters Air Force Office of Medical Support.

The State of Illinois, Department of Nuclear Safety, stated that the Department fully supports development of the rule proposed in the petition. The Department further stated that the integrity of NRC evaluated devices (NRC or an Agreement State evaluate for safety any devices containing radioactive materials) may be compromised significantly if nonstandard replacement parts are used during the life of the device. While the Department agreed that the issue of replacement components needs to be addressed, it was concerned with the use of the term "replacement sources and devices" in the wording of §§ 32.74, 32.110 and 32.210 as suggested by the petitioner. The Department believed that all sources and devices must be evaluated by the NRC or an Agreement State, whether or not they are considered "original" or "replacement" equipment. Therefore, the Department did not believe it is necessary to distinguish between original or replacement sources or devices. The Department was in favor of the petitioner's suggested alternative to modify § 32.1, Purpose and Scope.

The Headquarters Air Force Office of Medical Support, Department of the Air Force, opposed the rule language proposed by the petitioner, as written, although it agreed with the petitioner's intent to ensure that the safety and effectiveness of devices not be compromised because original parts are replaced by inferior ones. They did not agree that all replacement parts should be subject to the requirements of 10 CFR Part 32. They stated that NRC review and approval should apply to replacements of parts or components that are essential to the proper and safe operations of a device. The Air Force gave examples of parts (such as panel screws and covers) that conform to

industry standards. These, the Air Force stated, should not be subject to the proposed requirements. The Air Force voiced concern that the petition, as written, may serve to restrict competition and would lead to greater expense which would have to be recouped through higher medical costs from patients, or, in the case of the Air Force, from taxpayers.

NRC Action on the Petition

The NRC reviewed the petition, the public comments, and the two cases (incidents) cited by the petitioner as supporting evidence for filing this petition. The NRC also reviewed its regulations pertinent to the petition.

Shortly after the NRC received correspondence[1] from AMS about the two cases, the NRC advised[2] AMS of its intention to investigate these incidents, especially with regard to the quality of service and replacement parts used in servicing the teletherapy units. From October to December 1989, the NRC conducted a thorough investigation which included three onsite inspections: Atom Mechanical Company, Cleveland, Ohio (The servicing company that conducted the maintenance and replacement of parts in the two cases), St. Mary's Medical Center, Saginaw, Michigan, and Picker International, Highland Heights, Ohio (The company that manufactured the teletherapy units at Anderson Memorial Hospital and at St. Mary's Medical Center). The NRC also referred the case of

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[1]Three letters dated June 20, August 8, and August 25, 1989, to Hugh L. Thompson, Jr., Deputy Executive for Nuclear Materials Safety and Safeguards & Operations Support, NRC, from Sherry Stein, Director, Regulatory Affairs, Advanced Medical Systems, Inc.

[2] By a letter dated September 15, 1989 from Robert M. Bernero, Director, Office of Nuclear Material Safety and Safeguards, NRC, to Sherry Stein, Director, Regulatory Affairs, Advanced Medical Systems, Inc.

Anderson Memorial to the State of Maryland, because the company that serviced the teletherapy unit there, Atom Mechanical Company, is an authorized user on the Neutron Products, Inc. license, and Neutron Products is located in the State of Maryland, an Agreement State.

The incident at Anderson Memorial Hospital was caused by a broken spring in a teletherapy unit which failed to retract the source into the OFF position following a cobalt-60 cancer treatment. The hospital technologist promptly retracted the source manually. According to the hospital report, the technologist received very little additional exposure over expected monthly exposure, as evidenced by the individual's radiation film badge reading. Moreover, according to the same report the delivered daily dose to the patient was less than the prescribed daily dose, i.e., no patient overexposure for that treatment, because the technologist acted promptly. In its communication with NRC (prior to filing the petition), AMS stated that it was concerned about the quality of the replacement springs used in the teletherapy machine.

The incident at St. Mary's Medical Center was caused by the failure of a microswitch. The failure of the switch prevented a timing device from operating properly, to automatically terminate the treatment. No misadministration occurred because the subsequent treatment times were adjusted and the total delivered dose did not differ from the total prescribed dose. Neutron Products, Inc. was called to repair the machine.

The NRC investigation and subsequent inspections revealed several violations. Enforcement action was taken by the NRC against Atom Mechanical for violation of Part 21 requirements, and against St. Mary's Hospital and Picker International for violations of Part 35 and Part 30 requirements,

respectively[3]. Moreover, the State of Maryland determined from its own investigation that the incident at Anderson Memorial Hospital resulted from a failure of the part, i.e., breakage of the return spring. No enforcement action was taken by the State of Maryland.

Under current NRC regulations, persons authorized under a specific license to use devices containing byproduct material (e.g., use of teletherapy equipment under a Part 35 specific license) ultimately are responsible for the safe use of these devices, and for assuring that such devices are properly maintained. Suppliers of sources or devices containing byproduct material, whether they are an original manufacturer or a manufacturer of replacement sources or devices, must be licensed under Parts 30 or 32 or an appropriate Agreement State license, and also have responsibility for the safety of the sources or devices that they supply or replace. Service or repair, which would include the replacement of parts or components of medical or industrial sources or devices that present a risk of radiation exposure from the failure of certain parts, such as the teletherapy devices discussed as examples in this petition, may be performed only by qualified persons authorized under an NRC or Agreement State license (cf. § § 35.605, and 39.43(e)). Some generally licensed devices may be serviced by general licensees who are authorized to perform limited service work if sufficient information about the service work (e.g., procedures, training, expected dose, etc.) is submitted by

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[3] Specifically, Atom Mechanical Company was found to be in violation of 10 CFR 21.21 (October 16, 1989), St. Mary Medical Center was found to be in violation of 10 CFR 35.59(g), 10 CFR 35.605, 10 CFR 35.630(a), 10 CFR 35.615(d)(4), 10 CFR 35.632(a), and 10 CFR 35.634(a) (October 17 and 26, 1989), and Picker International, Inc. was found to be in violation of 10 CFR 30.3 (subsequent to inspections that occurred on October 26 and November 9, 1989). Inspection reports are available for review in the NRC Public document room.

manufacturer or initial distributor and accepted by the NRC. However, these devices typically are not mechanically complex and do not present the same risk of significant radiation exposure. Moreover, the NRC has no record of failure of these devices leading to a radiation exposure attributable to defective replacement parts or improper servicing. Finally, under the provisions of Part 21, the supplier of any basic component[4], whether or not a licensee of NRC or an Agreement State, is also responsible for the quality of the component, whether it is original or replacement.

Reasons for Denial

The NRC has examined the petition (1) in light of its regulations and policies for both general and specific licensees, and (2) in view of the cases cited by the petitioner in support of the petition. The NRC is denying the petition because current regulations apply equally to manufacturers and suppliers of both original and replacement parts, ensuring the integrity of these parts; therefore, no additional requirements addressing the regulation of manufacturers and suppliers of replacement parts are necessary. Further, current regulations address service and maintenance of sources and devices possessed and used under an NRC license, including replacement parts, whether manufactured or supplied by the original manufacturer or supplier or some other manufacturer or supplier.

[4] A "basic component" is defined in Part 21 as one,"....in which a defect could create a substantial safety hazard."

Accordingly, the petition for rulemaking is denied.

Dated at Rockville, Maryland this 28th day of March, 1994.

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, IL 62704
(217) 785-9900

THOMAS W. ORTCIGER
DIRECTOR

JIM EDGAR
GOVERNOR

December 3, 1991

2

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Re: Advanced Medical Systems, Inc.: Receipt of Petition for Rulemaking; 10 CFR Part 32; Docket No. PRM-32-3.

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the above-identified petition for rulemaking. The petition requests a change to 10 CFR Part 32 that would require manufacturers and suppliers of replacement parts to follow the same provisions that apply to original equipment suppliers and manufacturers.

The Department fully supports development of such a rule. Devices containing radioactive material are typically evaluated for safety by the NRC or an Agreement State. The integrity of the original evaluated device may be compromised significantly if non-standard replacement parts are used during the life of the device.

The petition for rulemaking proposes two alternatives to amending 10 CFR Part 32. The first alternative suggests changing various sections of Part 32 to include the words "replacement part or products" or "replacement device." The Department agrees that replacement components need to be addressed, however, we are concerned about the term "replacement sources and devices" used in Sections 32.74, 32.110 and 32.210. All sources and devices must be evaluated by the NRC or an Agreement State, whether they are considered "original" or "replacement" equipment. The Department does not believe it is necessary to distinguish between original or replacement sources or devices.

The second alternative proposed (a single amendment to 10 CFR 32.1) is a simple, straightforward approach to defining the scope of the regulations. The Department is in favor of the Second Suggested Alternative.

In general, the Department agrees with the petitioner's concerns about replacement components in evaluated devices. Since many of these devices do not have absolute end-of-life dates, it is important that they be repaired with components equivalent to those evaluated with the original device. If you have any questions regarding these comments, do not hesitate to call me or Kathy Allen at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

SCC:KAA

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE OFFICE OF MEDICAL SUPPORT
BROOKS AIR FORCE BASE, TEXAS 78235-5000

12 NOV 1991

(1)

REPLY TO
ATTN OF: SGPR

SUBJECT: Comments on Petition for Rulemaking, Docket No. PRM-32-3

TO: Secretary of the Commission,
U.S. Nuclear Regulatory Commission
ATTN: Docketing and Service Branch
Washington DC 20555

1. While we agree with the petitioner's intent to ensure that the safety and effectiveness of a device not be compromised as a result of use of inferior parts, we do not agree that all replacement components need be subject to requirements of 10 CFR 32. The requirement to demonstrate IAW 10 CFR 32 review procedures that replacement parts or components are of equivalent or superior quality to that used by the original manufacturer in obtaining NRC review and approval should apply only to replacements for parts or components (including software) essential to the proper and safe operation of the device. Parts or components for which no specifications are established in the original submission; e.g., panel screws, electrical connectors, wires or parts which are installed for aesthetics such as trim panels or covers should not be subject to the proposed requirements. Further, if the original manufacturer's specification for a part is limited to an industry consensus standard; e.g., specifies no. 14 screw or AWG wire gauge, conforms to ANSI XYZ, it should be left to the user to ensure the replacement component meets the specifications.

2. We are concerned that the proposal, as written, may serve to restrict competition and would lead to unnecessary expenses which would have to be recouped through higher medical care costs from patients, or in the case of the Air Force, taxpayers.

3. Please call us if you have any questions. We can be reached at (512) 536-3331.

Lawrence Donovan

Lawrence Donovan, Major, USAF, BSC
Chief, Licensing Actions
USAF Radioisotope Committee
Office of the Surgeon General

cc: HQ USAF/SGP

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
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[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 32

[Docket No. PRM-32-3]

Advanced Medical Systems, Inc.;

Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking dated June 28, 1991. The petition, which was filed with the Commission by Advanced Medical Systems, Inc., was docketed by the Commission on July 19, 1991, and has been assigned Docket No. PRM-32-3. The petitioner requests that the NRC amend its regulations that apply to the manufacturers and transferors of certain items containing byproduct material to specify that these provisions apply to the manufacturers and suppliers of replacement parts as well as the manufacturers and transferors of the original units.

12/9/91

DATE: Submit comments by (60 days after publication). Comments received after this date will be considered if it is practical to do so but the Commission is able to ensure consideration only for comments received on or before this date.

Pub. 10/10/91
56FR51182

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write: Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW, Lower Level, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background

On June 28, 1991, Advanced Medical Systems, Inc. (AMS) filed a petition for rulemaking with the Commission. Pursuant to 10 CFR 2.802, this petition was docketed by the Commission on July 19, 1991, and has been assigned Docket No. PRM-32-3. Advanced Medical Systems originally sent this petition to the NRC in a document dated July 2, 1990. However, this document was never received by the NRC. Therefore, the petitioner resubmitted the petition, without change, for consideration by the NRC.

The NRC has established requirements governing the issuance of specific licenses to persons who manufacture or initially transfer items containing

byproduct material for sale or distribution under 10 CFR Part 32. NRC regulations in 10 CFR Part 21 require directors and responsible officers of firms and organizations that build, operate, or own NRC-licensed facilities or conduct NRC-licensed activities to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard.

The petitioner is an original equipment manufacturer licensed under 10 CFR Part 32. The petitioner has a definite and direct interest in the health and safety of the public who may use or be treated by equipment it manufacturers.

According to the petitioner, it appears that the requirements of Part 32 are being interpreted as applying only to manufacturers and suppliers of original equipment and not to manufacturers and suppliers of replacement parts, devices, products, or sources designated for units originally manufactured or transferred by others. The petitioner is concerned that equipment originally manufactured and transferred under an NRC license may be serviced by a third party who may use inferior replacement parts that were not manufactured in accordance with the licensing requirements of Part 32.

The Petitioner's Request

The petitioner suggests that Part 32 be amended to clarify that the regulations in question apply to the manufacturers and suppliers of replacement parts as well as to the manufacturers and suppliers of original equipment. In addition to the potential health and safety benefits of this action, the petitioner believes that the number of incidents reported under Part 21 might be reduced by specifically applying the requirements of 10 CFR Part 32 to the manufacture and distribution of replacement parts.

The petitioner requests that the NRC amend Part 32 so that its requirements specifically apply to manufacturers and suppliers of replacement parts or products. The petitioner has suggested two alternatives for accomplishing this objective. The first alternative would be to insert the necessary language into each appropriate section of Part 32. The second alternative would be to revise the purpose and scope provisions of §32.1 so that the requirements of the part would apply to the manufacture and transfer of replacement parts.

The Petitioner's Proposal

The specific amendments suggested by the petitioner are presented below. The NRC has inserted the appropriate amendatory language and structure for these amendments and corrected several minor editorial errors.

The First Suggested Alternative

1. In §32.1, the introductory text of paragraph (a) is revised to read as follows:

§32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution, and persons who manufacture or initially transfer replacement parts, devices, products or sources designed for units originally manufactured or initially transferred by others to:

* * * * *

2. In §32.14, the introductory paragraph is revised to read as follows:

§32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in §30.15 of this chapter, including replacement parts or products, or to initially transfer for sale or distribution such products containing byproduct material (including replacement parts or products) for use pursuant to §30.15 of this chapter will be approved if:

* * * * *

3. In §32.15, paragraphs (a)(1), (c)(1), and (d) are revised to read as follows:

§32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) * * *

(1) Maintain quality assurance practices in the manufacture of the part of product, or the installation of the part into the product including replacement parts or products:

* * * * *

(c) * * *

(1) Any part or product including a replacement part or product which has been tested and found defective under the criteria and procedures specified in the license issued under §32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under §32.14; or * * * * *

(d) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Replacement parts, products and byproduct material must all be labeled or marked.

4. In. §32.16, paragraph (a) is revised to read as follows:

§32.16 Certain items containing byproduct material; Records and reports of transfer.

(a) Each person licensed under §32.14 or §32.17 including manufacturers of replacement parts or products shall maintain records of transfer of material and report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy of the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

* * * * *

5. In §32.51, the introductory text of paragraphs (a), (a)(2), and (a)(3), and paragraphs (a)(2)(i) and (a)(2)(ii) are revised to read as follows:

§32.51 Byproduct material contained in devices for use under §31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material, including replacement parts or products, to persons generally licensed under §31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

* * * * *

(2) As indicated, the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device, including replacement devices, to provide reasonable assurance that:

(i) The device or replacement device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage, and use of the device or replacement device, the byproduct material contained in the device or replacement device will not be released or inadvertently removed from the device or replacement device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in §20.101(a) of this chapter; and

* * * * *

(3) Each device including replacement devices bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

* * * * *

6. In §32.74, the introductory text of paragraph (a) and paragraphs (a)(2)(ii), (a)(2)(iv thru viii), (a)(3), and (b)(1) are revised to read as follows:

§32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material, including replacement sources, devices, parts and products, to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§35.400 and 35.500 of this chapter will be approved if:

(2) * * *

(ii) Details of design and construction of the source, device or replacement source or device;

* * * * *

(iv) For devices containing byproduct material, including replacement devices, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices, including replacement sources and devices, meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibration sources and devices, including replacement sources and devices;

(vii) Legend and methods for labeling sources and devices, including replacement sources and devices, as to their radioactive content:

(viii) Instructions for handling and storing the source or device, including replacement sources and devices, from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device, or replacement source and device, or attached to a permanent storage container for the source or device, or replacement source and device: Provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or replacement source and device; or to the permanent storage container for the source or device, or replacement source and device, contains information on the radionuclide quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device, or replacement source and device), to persons licensed to use byproduct material identified in §§35.58, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987, may be used until March 30, 1989.

(b)(1) In the event the applicant desires that the source or device, including replacement sources and devices, be required to be tested for leakage of radioactive material at intervals longer than six months, he/she shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source, device or replacement source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

* * * * *

7. In §32.110, paragraph (a) is revised to read as follows:

§32.110 Acceptance sampling procedures under certain specific licenses.

(a) A random sample shall be taken from each inspection lot of devices, including replacement devices, licensed under §§32.14, 32.53, or 32.61 of this part for which testing is required pursuant to §§32.15, 32.55 or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

* * * * *

8. In §32.210, paragraphs (a), (c) thru (e) and the introductory text of paragraph (f) are revised to read as follows:

§32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device, including replacement sources and devices, containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

* * * * *

(c) The request for review of a sealed source or device, including replacement sources and devices, must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device or replacement device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards to provide reasonable assurance that the radiation safety properties of the source or device or replacement source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device, including replacement sources and devices, using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source, including replacement sources and devices, are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate or registration acknowledges the availability of the submitted information for

inclusion in an application for a specific license proposing use of the product or replacement product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product or replacement product in accordance with--

* * * * *

The Second Suggested Alternative

1. In §32.1, the introductory text of paragraph (a) is revised to read as follows:

§32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution (including those persons who manufacture replacement parts, devices, or sources designed for units originally manufactured or initially transferred by others) to:

* * * * *

Dated at Rockville, Maryland, this 4th day of Oct 1991.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

DOCKET NUMBER
PETITION RULE PRM 32-3
(56FR51182)

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 4332-135 ATC UI FAX (216) 466-0186

June 28, 1991

Samuel J. Chilk,
Secretary, Docketing and Service Branch
Mail Stop 16G15
United States Nuclear Regulatory Commission
Washington, DC 20555

RE: RESUBMITTAL OF JULY 2, 1990 RULEMAKING PETITION

Dear Mr. Chilk,

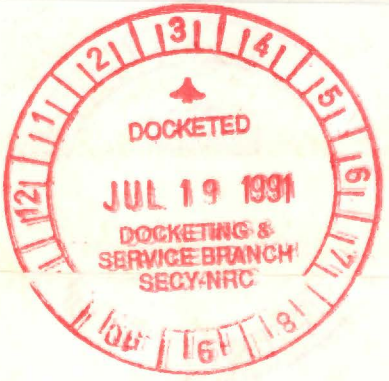
It has come to our attention that the enclosed Petition for Rulemaking Pursuant to 10 CFR Section 2.802, submitted on July 2, 1990, does not currently appear on your docket. We are therefore resubmitting it for review.

Thank you for your prompt assistance in this matter.

Sincerely,

Sherry J. Stein

SHERRY J. STEIN
Director of Regulatory Affairs



encl.

U.S. NUCLEAR REGULATORY COMMISSION
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July 2, 1990

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Chief, Docketing and Service Branch

RE: Petition for Rulemaking Pursuant to 10 CFR §2.802

Gentlemen:

Whereas it is understood that all NRC licensees are held responsible for safety and prudent use of nuclear materials, it appears that 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material", is being interpreted as applying only to manufacturers and suppliers of original equipment and not to manufacturers and suppliers of replacement parts, devices, products, or sources designated for units originally manufactured or initially transferred by others.

Whereas every licensee who replaces a part in any teletherapy machine or any mechanism which uses licensed nuclear material is subject to the requirements of 10 CFR Part 21, a clarification to 10 CFR Part 32 might cut down the number of incidents reported pursuant to Part 21.

Advanced Medical Systems, Inc., as an original equipment manufacturer, has a definite interest in the health and safety of the public utilizing and being treated by its equipment which has been serviced by third party organizations using inferior replacement parts. AMS first became aware of this problem through a series of U.S. Pharmacopeia reports including, for example, Access No. M49324 which concerned St. Mary's Medical Center in Saginaw, Michigan and Access No. M49250 which concerned Anderson Memorial Hospital, Anderson, South Carolina.

The proposed modification to the text of 10 CFR Part 32 would strengthen its effectiveness by removing any question with respect to its applicability to <u>all</u> manufacturers and transferrers.

Two alternatives have been prepared. Either would adequately resolve the issue of whether 10 CFR Part 32 applies to manufacturers and suppliers of replacement parts, devices, products, or sources designated for units originally manufactured or initially transferred by others.

AMS has conferred with the NRC staff prior to the filing of this petition.

Sincerely,

Sherry J. Stein

SHERRY J. STEIN
Director of Regulatory Affairs

SJS/mz
Enclosures

PROPOSED MODIFICATIONS TO 10 CFR §32

§32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing by-product material for sale or distribution, including those persons who manufacture replacement parts, devices, products or sources designed for units originally manufactured or intially transferred by others to:

§32.14 Certain items containing byproduct material; Requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products including replacement parts or products specified in §30.15 of this chapter or to initially transfer for sale or distribution such products including replacement parts or products containing byproduct material for use pursuant to §30.15 of this chapter will be approved if:

§32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a)(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product including replacement parts or products:

(c)(1) Any part or product including replacement parts or products which has been tested and found defective under the criteria and procedures specified in the license issued under §32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under §32.14; or

(d) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Replacement parts, products and byproduct material must also be labeled or marked.

§32.16 Certain items containing byproduct material; Records and reports of transfer.

(a) Each person licensed under §32.14 or §32.17 including manufacturers of replacement parts or products shall maintain records of transfer of material and report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy of the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

§32.51 Byproduct material contained in devices for use under §31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices including replacement parts, products or devices containing byproduct material to persons generally licensed under §31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

(a)(2) As indicated, the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device including replacement devices to provide reasonable assurance that:

(i) The device or replacement device can be safely operated by persons not having training in radiological protection:

(ii) Under ordinary conditions of handling, storage, and use of the device or replacement device, the byproduct material contained in the device or replacement device will not be released or inadvertently removed from the device or replacement device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in §20.101(a) of this chapter: and

(a)(3) Each device including replacement devices bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

§32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material including replacement sources, devices, parts and products to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§35.400 and 35.500 of this chapter will be approved if:

(a)(1)(ii) Details of design and construction of the source, device or replacement source or device;

(a)(2)(iv) For devices including replacement devices containing byproduct material, the radiation profile of a prototype device;

(a)(2)(v) Details of quality control procedures to assure that production sources and devices including replacement sources and devices meet the standards of the design and prototype tests;

(a)(2)(vi) Procedures and standards for calibration sources and devices including replacement sources and devices;

(a)(2)(vii) Legend and methods for labeling sources and devices including replacement sources and devices as to their radioactive content:

(a)(2)(viii) Instructions for handling and storing the source or device including replacement sources and devices from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or replacement source or device or attached to a permanent storage container for the source or device or replacement source or device: Provided, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(a)(3) The label affixed to the source or device or replacement source or device; or to the permanent storage container for the source or device or replacement source or device, contains information on the radionuclide quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device or replacement source or device to persons licensed to use byproduct material identified in §§35.58, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(b)(1) In the event the applicant desires that the source or device including replacement sources and devices be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source, device or replacement source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

§32.110 Acceptance sampling procedures under certain specific licenses.

(a) A random sample shall be taken from each inspection lot of devices including replacement devices licensed under §§32.14, 32.53, or 32.61 of this part for which testing is required pursuant to §§32.15, 32.55, or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

§32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device including replacement sources and devices containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

(c) The request for review of a sealed source or a device including replacement sources and devices must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device or replacement device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device or replacement source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device including replacement sources and devices using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source including replacement sources and devices are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate or registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product or replacement product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product or replacement product in accordance with--

§32.1 Purpose and scope.

This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution, including those persons who manufacture replacement parts, devices, our sources designed for units originally manufactured or intially transferred by others.