UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 2 1 1989

AD11-1

MEMORANDUM FOR: Darlene Huyer, Chief, NUDOCS/IRM

FROM: Anthony N. Tse, RDB/DRA/RES

SUBJECT: REGULATORY HISTORY DOCUMENTS FOR A PROPOSED AMENDMENT

Copies of the subject documents are enclosed for the proposed amendment, "Palladium-103 for Interstitial Treatment of Cancer," which are to be included in the NUDOCS. This amendment was prepared in response to a petition for rulemaking PRM-35-7. As requested by Michael Lesar of the Regulatory Publications Branch/ADM, the designator "AD11-1" was placed in the upper right-hand corner of each document, including this transmittal memorandum.

Also enclosed for your information is a copy of the index of the documents for the proposed amendment. Please let me know if you have any questions.

Anthony N. Tse
Regulation Development Branch
DRA/RES

Enclosures:
1. Index
2. Copies of documents

cc (w/encl. 1):
M. Lesar, ADM

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AD11-1

REGULATORY HISTORY - INDEX

FOR A PROPOSED AMENDMENT

"PALLADIUM-103 FOR INTERSTITIAL TREATMENT OF CANCER"

DATE	FROM	TO	SUBJECT
12/20/88	WMcDonald	EBeckjord	PRM filed by Theragenics
01/12/89	EBeckjord	PNorry	Fast-track processing
01/19/89	ATse	Cognizant individuals	Draft proposed rule for comment
02/14/89	EBeckjord	Office Directors	Proposed rule for office concurrence
03/23/89	EBeckjord	VStello, Jr.	Proposed rule for approval
Undated	NA	NA	Federal Register notice
Undated	NA	NA	Regulatory Analysis
04/07/89	EBeckjord	Congressional Committees	Letters to Congressional Committees
05/08/89	OLinton, American College of Radiology	Secretary	Public comment (Only one comment letter was received)

End

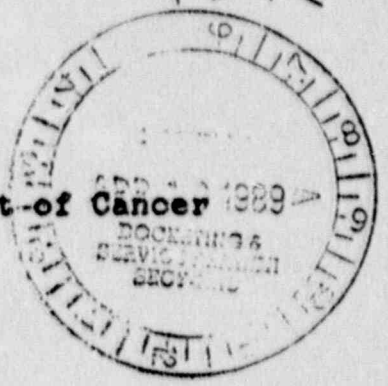
DOCKET NUMBER
PROPOSED RULE PR 35
(54FR13892)

[7590-01] AD11-1

PDR

Copy to Secy--
Original sent to the
Office of the Federal Register
for publication

NUCLEAR REGULATORY COMMISSION



10 CFR Part 35

RIN: 3150-AD11

Palladium-103 for Interstitial Treatment of Cancer

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the medical uses of byproduct material. The proposed regulation would add palladium-103 as a sealed source in seeds to the list of brachytherapy sources permitted for use in treatment of cancer. Under current NRC regulations, users must have their licenses amended before they may use palladium-103. The proposed rule, developed in response to a petition for rulemaking (PRM-35-7), would reduce the regulatory burden on medical use licensees who plan to use the sealed source. An evaluation of the potential radiation hazards to hospital personnel and the public showed that there would be minimal risk if the sealed source is used in accordance with the manufacturer's radiation safety and handling instructions.

DATE: Comment period expires (30 days from the date of publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm weekdays.

published in FR on 4-6-89

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FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301)492-3797.

SUPPLEMENTARY INFORMATION:

Petition for Rulemaking

On November 30, 1988, Theragenics Corporation submitted a petition for rulemaking, PRM-35-7, which was docketed on December 9, 1988. The petitioner requests that the NRC amend its regulations to add palladium-103 as a sealed source in seeds for the interstitial treatment of cancer to the list of sealed sources currently permitted in 10 CFR 35.400 for use in brachytherapy. A copy of the petition may be obtained from the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petitioner enclosed a document from the Food and Drug Administration (FDA) of the Department of Health and Human Services that allows the marketing of palladium-103 as a sealed source in seeds. The petitioner stated that, under current NRC regulations, licensees who are users of palladium-103 must go through the cumbersome process of having their licenses amended before using the product and that amending 10 CFR 35.400 in the manner suggested would eliminate this cumbersome process.

In supporting the petition, the petitioner submitted several documents, including a letter from the FDA, a safety evaluation report from the State of Georgia, the package insert, and product literature.

The letter from the FDA stated that, under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended, marketing

the device (palladium-103 as a sealed source in seeds) would be permitted subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act until such time as the device has been classified as either a Class I, II, or III device under Section 513.

In March 1986, Theragenics, an "Agreement State" licensee of the state of Georgia, submitted information on the radiation safety properties of palladium-103 to Georgia in order to obtain a "Certificate of Registration." Such a certificate is necessary for Theragenics to manufacture and distribute palladium-103 seeds to specific licensees. The information on these safety properties included the design and construction, prototype testing, conditions of normal use, labelling, external radiation levels, solubility in body fluids, and quality control and assurance. After reviewing the information and determining the adequacy of the radiation safety properties of the source, the State of Georgia issued a Certificate of Registration to Theragenics on September 22, 1986. This certificate summarized the submitted radiation safety information and specified additional limitations and conditions on the use of the source. This certificate was amended in its entirety on June 6, 1988 to include a minor design improvement made by Theragenics.

Following its determination that the radiation safety properties of the source are adequate, the State of Georgia sent NRC a copy of the certificate to include in the Registry of Source and Device Designs that is maintained by the NRC. The NRC reviewed the certificate for consistency with other certificates in the Registry and added palladium-103 to the Registry on October 29, 1986, and again in June 1988 to cover the design improvement. This action, in effect, granted a premarketing approval of the sealed source and permitted the use of palladium-103 provided that the user's license was amended to include that sealed source.

Conclusion

The NRC has evaluated the petition and supporting information and proposes to grant the petition. The NRC has determined that the addition of palladium-103 as a sealed source in seeds to the list of sealed sources specified in 10 CFR 35.400 would not cause additional risk to hospital personnel or the public because the radiation safety and handling instructions for palladium-103 are similar to the instructions for the brachytherapy sources currently listed in Section 35.400. This action would reduce the regulatory burden to the users of palladium-103 seeds (about 700 potential users) as well as to the NRC staff. Most users would not have to follow the present requirement of submitting individual license amendment applications in order to be able to use palladium-103 as a sealed source in seeds for the interstitial treatment of cancer (if their license permits the use of any brachytherapy sources specified in 10 CFR 35.400). A user whose license only permits the use of specified brachytherapy sources would still be required to submit a license amendment application. A reduction in the number of license amendment applications would reduce the expenditure of NRC staff resources in reviewing and granting or denying the requested license amendments.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork

Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0010.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street, Lower Level, NW, Washington, DC. Single copies of the draft regulatory analysis may be obtained from Dr. Anthony N. Tse (See FOR FURTHER INFORMATION CONTACT heading).

The NRC requests public comments on the draft regulatory analysis. Comments may be submitted to the NRC (See ADDRESSES heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The proposed rule would add the use of palladium-103 as a sealed source in seeds in 10 CFR 35.400. This action would reduce the regulatory burden on medical use licensees planning to use the sealed source because most users would not have to follow the present requirement of submitting a license amendment application in order to use palladium-103 as a sealed source in seeds for the interstitial treatment of cancer (if the license permits the use of any brachytherapy sources specified in 10 CFR 35.400).

The NRC has adopted size standards that classify a hospital as a small entity if its annual gross receipts do not exceed $3.5 million, and a private practice physician as a small entity if the physician's annual gross receipts are $1.0 million or less. Although some NRC medical use licensees could be considered "small entities," the number is estimated to be a very small percentage of the total number of licensees and does not constitute a substantial number for purposes of the Regulatory Flexibility Act. However, the proposed rule would have a positive economic impact on about 700 licensees.

Backfit Analysis

The NRC has determined that a backfit analysis is not required for this proposed regulation because the amendment does not constitute a backfit as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C 553, the NRC is proposing to adopt the following amendment to 10 CFR Part 35.

1. The authority citation for Part 35 is revised to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20(a) and (b), 35.21(a) and (b), 35.22, 35.23, 35.25, 35.27(a), (c) and (d), 35.31(a), 35.49, 35.50(a)-(d), 35.51(a)-(c), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.120, 35.200(b), 35.204(a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610(a) and (b), 35.615, 35.620, 35.630(a) and (b), 35.632(a)-(f), 35.634(a)-(e), 35.636(a) and (b), 35.641(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27(a) and (c), 35.29(b), 35.33(a)-(d), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406(b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

2. In § 35.400, paragraph (g) is added to read as follows:

§ 35.400 Use of sources for brachytherapy.

* * * * *

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

Dated at Rockville, Maryland, this 28th day of March, 1989.

For the Nuclear Regulatory Commission.

Victor Stello, Jr.,
Executive Director for Operations.