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

NOV 22 1989

AD11-2

MEMORANDUM FOR: Darlene Huyer, Chief, NUDOCS/IRM

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

SUBJECT: REGULATORY HISTORY DOCUMENTS FOR A FINAL AMENDMENT

Copies of the subject documents are enclosed for the final 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 "AD11-2" 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 final 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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REGULATORY HISTORY - INDEX

FOR A FINAL AMENDMENT

"PALLADIUM-103 FOR INTERSITTIAL TREATMENT OF CANCER"

DATE	FROM	TO	SUBJECT
07/06/89	ATse	Cognizant individuals	Draft final rule for comment
08/21/89	EBeckjord	Office Directors	Final rule for office concurrence
09/19/89	EBeckjord	JTaylor	Final rule for approval
Undated	NA	NA	Federal Register notice
Undated	NA	NA	Regulatory Analysis
10/19/89	EBeckjord	Congressional Committees	Letters to Congressional Committees
11/03/89	SBahadur	HCooper, Theragenics Corporation	Letter to the petitioner

End

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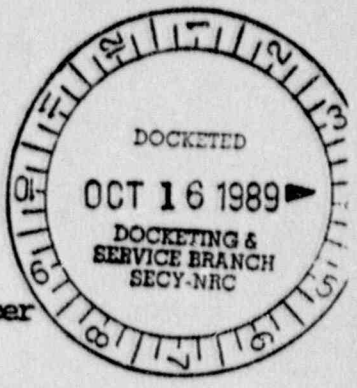
DOCKET NUMBER
PROPOSED RULE PR 35
(54 FR 13892)

[7590-01]

NUCLEAR REGULATORY COMMISSION



10 CFR Part 35

RIN NO. 3150-AD11

Palladium-103 for Interstitial Treatment of Cancer

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical uses of byproduct material to add palladium-103 as a sealed source in seeds to the list of brachytherapy sources permitted for use in the treatment of cancer. Under current NRC regulations, users must have their licenses amended before they use palladium-103. This amendment, promulgated in response to a petition for rulemaking (PRM-35-7), will 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.

EFFECTIVE DATE: (Insert the date of publication)

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.

8910180242 7pp.

Published in the Federal Register on 10-12-89 as 54 FR 41819

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 requested 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. 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. Class I devices require general controls, that is, registration and good manufacturing practices. Class II devices require performance standards in addition to general controls. Class III devices require prior FDA approval of a Pre-Market Approval application, performance standards, and general controls. In January 1988 (53 FR 1554), FDA classified radionuclide brachytherapy sources as Class II devices. This permits Theragenics to continue marketing the palladium-103 seeds.

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, labeling, 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 minor design improvement. This action, in effect, granted a premarketing approval of the sealed source and permitted the use of palladium-103, provided the user's license was amended to include that sealed source.

Proposed Amendment and Public Comment

After considering the petition, the NRC published a proposed amendment granting the petition for a 30-day public comment period (54 FR 13892, April 6, 1989). One comment letter was received. The comment letter, submitted by a medical professional organization, supported the petition. The letter stated that "this would indeed alleviate burdensome current NRC regulations that require users to amend their licenses before using palladium-103."

Conclusion

The NRC has determined that the addition of palladium-103 as a sealed source in seeds to the list of sealed sources specified in § 35.400 will not cause additional risk to hospital personnel or the public because the radiation safety and handling instructions to be used for palladium-103 are the same as the instructions used currently for the brachytherapy sources listed in § 35.400. This action will reduce the regulatory burden to the

users of palladium-103 seeds (about 700 potential users) as well as to the NRC staff. Most users will not have to follow the present requirement of submitting individual license amendment applications in order 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 § 35.400). A user whose license only permits the use of specified brachytherapy sources will still be required to submit a license amendment application. But for most licensees this rule will eliminate the license amendment application process and the review and approval process for the NRC. Thus, the NRC is amending § 35.400 to add palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final amendment 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 amendment.

Paperwork Reduction Act Statement

This final amendment does not contain any new or amended information collection requirements 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 regulatory analysis on this amendment. The analysis examines the costs and benefits of the alternatives considered by the NRC. The analysis concludes that the adoption of the amendment will not increase the risk to the public health and safety but will reduce the cost to the medical use licensees who plan to use palladium-103 sealed sources. Interested persons may examine a copy of the regulatory analysis at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Single copies of the regulatory analysis may be obtained from Dr. Anthony N. Tse (See FOR FURTHER INFORMATION CONTACT heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this amendment does not have a significant economic impact on a substantial number of small entities. This amendment adds the use of palladium-103 as a sealed source in seeds in 10 CFR 35.400. This action will reduce the regulatory burden on medical use licensees planning to use the sealed source by eliminating the requirement of submitting a license amendment application. 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 that would fall into this category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

Backfit Analysis

The NRC has determined that a backfit analysis is not required for this amendment because the action 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 552 and 553, the NRC is adopting the following amendment to 10 CFR Part 35.

PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

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 26th day of September, 1989.

For the Nuclear Regulatory Commission.

James M. Taylor,
Acting Executive Director for Operations.

AD11-2
PDR

REGULATORY ANALYSIS

10 CFR PART 35

PALLADIUM-103 FOR INTERSTITIAL TREATMENT OF CANCER

1. STATEMENT OF PROBLEM

10 CFR 35.400, "Use of Sources for Brachytherapy," lists specific radioactive sealed sources that may be used for treatment of cancer in brachytherapy. In December 1988, the NRC received a petition for rulemaking filed by Theragenics Corporation dated November 30, 1988 (docketed PRM-35-7) to amend 10 CFR 35.400.

The petitioner requested that the NRC amend its regulations to add palladium-103 as a sealed source in seeds for interstitial treatment of cancer to the list of sources specified in 10 CFR 35.400. The petitioner stated that, under the present regulation, users of palladium-103 must go through the cumbersome process of amending their licenses before they can use the product and that amending 10 CFR 35.400 would eliminate this cumbersome process.

2. OBJECTIVES

NRC's objectives are to protect the health and safety of workers and the public in the licensing of byproduct materials for medical uses. The Food and Drug Administration permitted marketing of Theragenics' palladium-103 seeds under Section 510(k) of the Federal Food, Drug and Cosmetic Act as amended. The State of Georgia, an "Agreement State" which licenses Theragenics, performed safety evaluations of the use of palladium-103 and issued a Certificate of Registration. Subsequently, the NRC reviewed the certificate for consistency with other certificates in the Registry of Source and Device Designs and added palladium-103 to the Registry. This action, in effect, granted a premarketing approval of the source and would permit the use of the source provided the user's license was amended to include the source.

3. ALTERNATIVES

There are only two alternatives:

(1) Maintain the status quo, i.e., a licensee seeking to use palladium-103 must first apply for and obtain a license amendment permitting its use; and

(2) Amend 10 CFR 35.400 to include palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

4. CONSEQUENCES

In terms of the public health and safety, both alternatives would permit the use of palladium-103 as a sealed source in seeds for brachytherapy, thus, there would be essentially no difference between the two alternatives.

In terms of cost, alternative 2 would be less burdensome for both the medical use licensees and the NRC. Alternative 2 would eliminate the amendment application process for most licensees who plan to use the sealed source and the review and approval process for the NRC.

5. DECISION RATIONALE

Since Alternative 2 would result in less burden to the medical use licensees and the NRC staff while providing the same level of protection of the public health and safety, the NRC is adopting this alternative.

6. IMPLEMENTATION

The amendment is effective on the date of publication in the Federal Register.