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 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 that 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 the 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, if adopted, 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 proposes to adopt this alternative.

6. IMPLEMENTATION

Implementation involves adding palladium-103 as a sealed source in seeds for interstitial treatment of cancer in 10 CFR 35.400.

Otha W. Linton
Associate Executive Director

May 8, 1989

Secretary
U.S. Nuclear Regulatory Commission
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Attention: Docketing and Service Branch

To Whom It May Concern:

The following comments are filed on behalf of the 20,000 members of the American College of Radiology (ACR) and the 3,000 members of the American Society of Therapeutic Radiology and Oncology (ASTRO) in response to the proposed rule Palladium-103 for interstitial treatment of cancer published in the April 16 Federal Register, Page 13892.

The ACR and ASTRO support the proposed rule that would add Palladium-103 as a sealed source in seeds to the list of brachytherapy sources permitted for use in treatment of cancer. This would indeed alleviate burdensome current NRC regulations that require users to amend their licenses before using Palladium-103. The ACR and ASTRO agree that adding Palladium-103 to the list of sealed sources would not cause additional risk to hospital personnel or the public, as the radiation safety and handling instructions for this source are similar to instructions for other brachytherapy sources.

We appreciate the opportunity to be able to comment on this proposed rule.

Sincerely,

Otha W. Linton
Associate Executive Director

OWL/pgm