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Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

Comment On: NRC-2017-0215-0001

Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres;
Draft Guidance for Comment

Document: NRC-2017-0215-DRAFT-0115

Comment on FR Doc # 2017-24129

82 FR 51655
11/7/2017

Submitter Information

(174)

Name: David Reindl

Government Agency Type: State

Government Agency: Wisconsin Department of Health Services

General Comment

See attached file(s)

Attachments

STC-17-078 Wisconsin Comments

SUNSI Review Complete
Template = ADM - 013
E-RIDS= ADM-03
Add= Lisa Dimmick (lcdl)



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January 8, 2018

Lisa Dimmick
U.S. Nuclear Regulatory Commission
Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

RE: Comments on FEDERAL REGISTER NOTICE – YTTRIUM-90 (Y-90) MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® (STC-17-078)

Dear Ms. Dimmick,

The State of Wisconsin, Radioactive Materials Program has reviewed the above document and submits the following comments:

1. On page 5, in the leak test section, delete the following: "The small size and large number of Y-90 microspheres make leak testing, as required by 10 CFR 35.67(b), impractical. Further, if leak testing were practical, licensees would not be required to leak test individual microspheres."
2. On page 9, the words "in most cases" should be deleted from the last sentence in the first paragraph.
3. On page 9, in the first sentence of the second paragraph, Wisconsin recommends clarifying what "in the process" means. Wisconsin also suggests limiting the continued use of the alternate pathway for physicians who have completed an in-vitro simulated case by the date when this revision to the Y-90 microsphere guidance is published.
4. Wisconsin supports the elimination of the alternate pathway for authorized users.

Sincerely,

David Reindl
Nuclear Engineer
Radioactive Materials Program
State of Wisconsin