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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Draft Guidance for Comment

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Comment on FR Doc # 2017-24129

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Submitter Information

Name: Anonymus Anonymous

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General Comment

The use of Y-90 microspheres is currently being licensed by the NRC under 10 CFR 35.1000, Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Subpart K was created by the NRC to accommodate medical emerging technologies, and microspheres are assigned an inspection program code 02240 (Medical Therapy - Other Emerging Technology) in accordance with NRC Inspection Manual Chapter 2800. Y-90 microspheres have been used in the United States for the past 10 years so its designation as a medical emerging technology is no longer applicable. The Y-90 microsphere technology has reached maturity and should no longer be considered an emerging technology (35.1000) in licensing space. The NRC should allow the Y-90 microsphere to be licensed under 10 CFR 35.300 (use of unsealed byproduct material requiring a written directive). In addition, the NRC needs to develop a pathway for 35.1000 emerging technologies to be moved out from 35.1000 to other existing regulatory uses in Part 35 (35.300, 34.400, etc.) once the technology reaches maturity and based on a certain number of years of operational experience.

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Add= L. Dimmick (LCDA)