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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 Draft Guidance for Comment

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General Comment

Restricting industry involvement in training authorized users of Y-90 microsphere brachytherapy is a terrible idea and will make it extremely prohibitive for the primary treating physicians utilizing Y-90 microsphere brachytherapy, Interventional Radiologists, from becoming authorized users. The current pathway parallels many others in Interventional Radiology, Cardiothoracic Surgery, Vascular Surgery, Cardiology, and other specialties that use multiple subspecialized devices. The current pathway provides excellent training to those physicians providing the actual care for the patient. If the changes are enacted, patient care will suffer greatly. Furthermore, there is no evidence that the current NRC guidelines need to be changed. As an instructor at one of 3 TheraSphere Centers of Excellence in the US, I strongly oppose the proposed changes.

SUNSI Review Complete

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