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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 Draft Guidance for Comment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

Submitter Information

Name: Ramana Yedavalli

Address:

6201 Wildwood Lane
 Burr Ridge, IL, 60527

Email: ryedavalli@hotmail.com

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General Comment

Taking away the alternate pathway makes the ability to become much more difficult. Likely the majority of AUs who practice were only able to become AUs because of this alternate pathway. To say that the manufacturer's representative is no longer an adequate resource to ensure quality makes no sense. It makes the path much more difficult and adds nothing to patient safety. In addition, one cannot even start a Y-90 program anyway unless you have taken the Society of Interventional Radiology's intensive yttrium-90 course. The vast majority of trainees coming out of fellowship will have been exposed to yttrium-90 therapy, but they still cannot become authorized users in their own right unless they have taken the course and been appropriately proctored as attending physicians. Taking away the alternate pathway does nothing but make the process more onerous and does nothing to add to patient safety. This seems, to me, to be a roadblock that is being placed to help other medical specialties at the

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Add=L. Dimmick (red)

expense of interventional radiology. I strongly object to this and I want to be on record with my objection.