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Name: Sandeep Bagla
Address:
6615 Jill court
Mclean,
Email: Sbagla@teamviv.com

General Comment

I have read with great interest the proposal by the nuclear regulatory commission on amending authorized user pathway for y90 microspheres. It is with great concern that I am writing to express My objection to the suggested change in the authorized user pathway. Radiologist who undergo an interventional radiology training as well as a basic radiology training including national board examination in physics and radiation safety are well prepared in the background of Radiation delivery via microspheres. It is a routine part of interventional radiology training and diagnostic radiology residency to review basic criteria for delivery, receipt and disposal of radiation safety material as well as specifically the use of microspheres with radioactive labeling.

By removing the pathway in which physicians undergo supervise training by a device manufacturer for use of the microspheres, there will be limited adoption and availability of

this advanced treatment for patients with liver dominant cancer. As an authorized user myself who is been using this product for approximately 10 years, I can speak frankly about the political nature in which training by existing authorize users will be limited. For example, if interventional radiologist would like to start a new program at a hospital and there is no existing authorize user there, he will have to approach an existing user at a different facility to become trained or signed off in something that he may already have the basic knowledge from his existing training. Why would a neighboring competitive intervention radiologist sign off on This new venture or training for the new physician when this will directly impact volumes of cases that come to his or her hospital. This is for their limited by the fact that radiology contracts are exclusive in the vast majority of hospitals and limit the competition or opportunity for other outside physicians to come in and practice interventional radiology at existing institutions. When adding i this new venture or training for the new physician when this will directly impact volumes of cases that come to his or her hospital. This is further limited by the fact that radiology contracts are exclusive in the vast majority of hospitals and limit the competition or opportunity for other outside physicians to come in and practice interventional radiology at existing institutions. When Removing this pathway for a third-party to certify training for a physician, this will impact the ability for new users to be trained with the proposal document indicates that there are a sufficient number of authorize users available for training. While this might be the case and existing programs, there are a large number of hospitals in America they do not have radiation microsphere programs and would like to offer this to their local communities. In the settings, the physicians who are trying to start new programs will be limited in their ability as they will not be able to Obtain training from other authorize users who are in the community or larger academic centers where they would like to keep those cases internally. This limitation of competition and limitation of access to advanced cancer care is something that should be strongly considered before passing this proposal.