



October 2, 2019

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

**RE: Amendment to NRC License No. 13-18881-01
Memorial Hospital**

Dear Madam or Sir:

We wish to amend our Materials License # 13-18881-01 to add Dr. Michael Hall, M.D. as an Authorized User for 10 CFR 35.1000, Yttrium-90 in SIR-spheres therapy delivery system. Dr. Hall is currently an Authorized User on our license for Yttrium-90 TheraSpheres and has completed the manufacturer training and proctoring in three patient administrations in SIR-spheres. Attached is a letter from Sirtex Medical attesting to his training and experience. His three supervised administrations were on February 28, 2019, June 5, 2019, and July 15, 2019. The Sirtex physician proctor was present for those cases and Dr. Thomas Fischback, M.D., who is an Authorized User for SIR-spheres on our license, served as Authorized User for those cases.

Also please remove the following Authorized Users from our license because they no longer practice at our facility:

John E. DePersio, M.D.
Nazar Golewale, M.D.
Gerard Duprat, Jr., M.D.

Thanks for your assistance with this license amendment request. If you have any questions or require additional information, please contact our Radiation Safety Officer, Daniel Archambeault at 574-647-7956 or by e-mail at darchambeault@beaconhealthsystem.org.

Sincerely,

Diana Custer
Vice President, Operations
Memorial Hospital

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SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 105US03

June 5, 2019

Dr. Michael Hall
Memorial Hospital
615 N. Michigan Street
South Bend, IN 46601

Dear Dr. Hall;

Re: SIR-Spheres® Yttrium-90 Resin Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on February 22, 2019, Dr. Ramana Yedavalli presented and discussed the preparation of and procedures associated with SIR-Spheres yttrium-90 (Y-90) resin microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. Dr. Ramana Yedavalli also proctored you for the administration of SIR-Spheres Y-90 resin microspheres.

Given your prior experience administering SIR-Spheres Y-90 resin microspheres at Memorial Hospital (2013-2014), I am pleased to inform you that Sirtex considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC) Program**.

Yours sincerely,

William T. Denman, MD
Global Chief Medical Officer

cc: Steve Schilt, Regional Sales Manager
TEC@sirtex.com

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Send Name Van Archaibeault Phone 574 647-7956

Company MEMORIAL HOSPITAL

Address 615 N MICHIGAN ST #-05

City SOUTH BEND State IN ZIP 46601-1039

2 Your Internal Billing Reference

3 To Recipient's Name Material Licensing Phone 630 829-9500

Company U.S. Nuclear Regulatory Commission

Address 2443 Warrenville Rd, Ste 210
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