Authorized Users for Y-90 Microspheres

Ashley Cockerham

Professional Education Manager – Americas

Sirtex Medical, Inc.

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Disclosure

- Employee of Sirtex Medical, Inc.

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Authorized User (AU)

- Physician named on a radioactive material license who meets specific NRC/State requirements and is responsible for the medical use of Y-90 microspheres.
  - The AU may or may not be the physician administering Y-90 microspheres
    - “two doc model” – radiation oncologist (RO) or nuclear medicine (NM) physician is the AU
    - “one doc model” – IR is the AU

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RO only

AU Evolution - 2002

Microsphere Brachytherapy Sources and Devices

Licensing Guidance - TheraSphere and SIRSphere Yttrium-90 Microspheres

Y-90 microspheres are manual brachytherapy sources used for permanent brachytherapy implantation therapy.

Authorized users must meet the training and experience requirements of either 10 CFR 35.490 or, until October 25, 2004, 10 CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system.

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NM & RO

AU Evolution - 2007

Microsphere Brachytherapy Sources and Devices

REVISED SEPTEMBER 2007

Questions should be directed to: Ashley Tull (301) 415-5294 or
Ronald Zelac (301) 415-7635

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

The authorized user (AU) must meet the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490. The AU should have successfully completed training in the operation of the microsphere delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. Additionally, the AU should have successfully completed supervised work experience including at least three cases for each type of Y-90 microspheres for which the individual is seeking AU status. The microsphere-specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The applicant must provide documentation for all of the above training and experience.

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AU Evolution - 2008

Microsphere Brachytherapy Sources and Devices

REVISED AUGUST 2008

Questions should be directed to: Ashley Tull (240) 888-7129 or
Ronald Zelac (301) 415-7635 or
MedicalQuestions.Resource@nrc.gov

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Training and Experience

The NRC staff has evaluated these devices and determined that the following requirements are necessary to ensure the protection of public health and safety. These requirements will be imposed by license condition.

The authorized user for Y-90 microspheres (AU) must meet the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490. Additionally, the AU must have successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The additional Y-90 microsphere specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by either:

pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or

pathway 2) a Y-90 microsphere manufacturer. The clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* simulated cases and a commitment that each individual will complete the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, the licensee's commitment will include submitting documentation to the appropriate NRC Regional Office within 30 days of when these three patient cases have been completed.

In addition, the applicant shall commit to provide training in the manufacturer's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

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IR, NM, RO

AU Evolution - 2011

Microsphere Brachytherapy Sources and Devices

REVISED JANUARY 2011

Questions should be directed to: Ashley Cockerham (240) 888-7129 or
Ronald Zelac (301) 415-7635 or
MedicalQuestions.Resource@nrc.gov

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Consistent with the direction in 10 CFR 35.1000, the NRC has evaluated these devices and determined that licensees must use Y-90 microspheres in accordance with the following requirements, which will be incorporated into the license either through license condition or through incorporation by reference to licensee submittals that include commitments consistent with these requirements. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, L, and M.

Training and Experience

NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the use of Y-90 microspheres. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

The authorized user for Y-90 microspheres (AU):

A) meets the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490 or the guidelines for interventional radiologists as follows:

1)
   a) American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or
   b) Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and

2) has 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received in accordance with Item A.1. in:
   a) Radiation physics and instrumentation;
   b) Radiation protection;
   c) Mathematics pertaining to the use and measurement of radioactivity;
   d) Radiation biology; and

3) has work experience under the supervision of an AU for Y-90 microspheres or a Y-90 microsphere manufacturer representative involving:
   a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
   b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
   c) Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;
   d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
   e) Using administrative controls to prevent a medical event involving the use of byproduct material;
   f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
   g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and

B) has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The additional Y-90 microsphere specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by either:

pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or

pathway 2) a Y-90 microsphere manufacturer. The clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

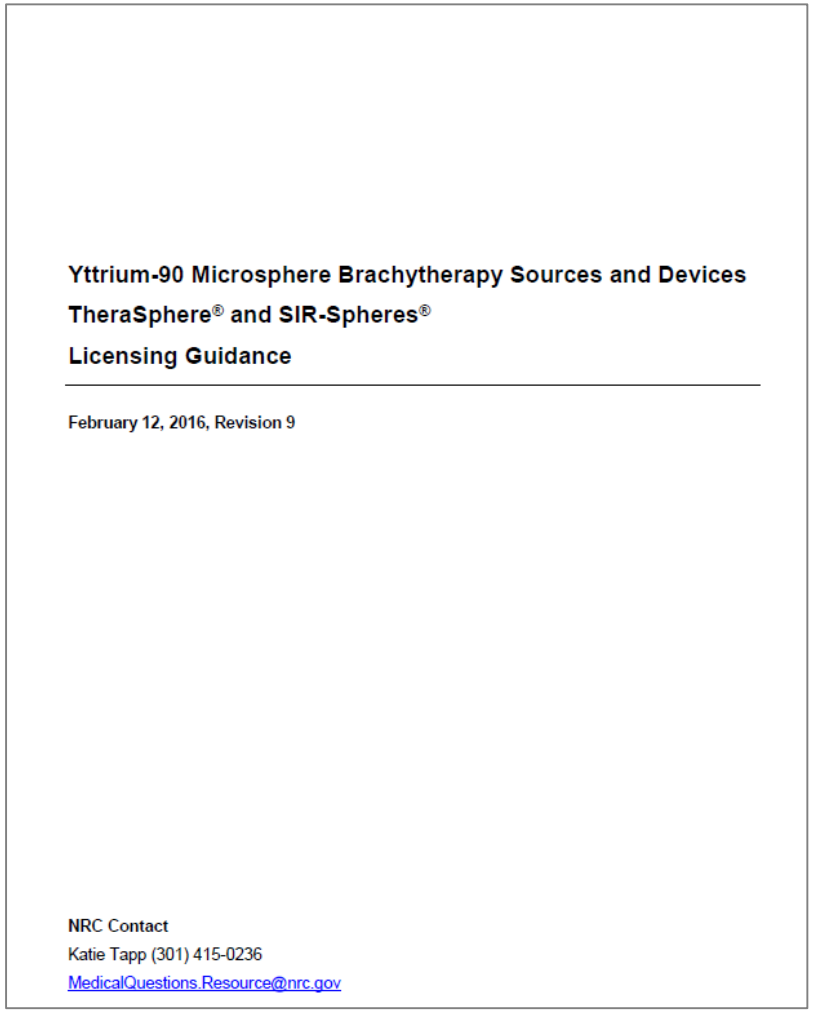
The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

In addition, the applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

AU Evolution Summary

- 2002 - RO only with vendor training
- 2007 – RO and NM with training and supervised cases by another AU or the vendor
- 2008 – RO and NM with training and supervised cases by another AU or vendor (manufacturer *in-vitro* pathway created)
- 2011 – RO, NM and IR
- 2016 – *current version*



Yttrium-90 Microsphere Brachytherapy Sources and Devices
TheraSphere® and SIR-Spheres®
Licensing Guidance

February 12, 2016, Revision 9

NRC Contact
Katie Tapp (301) 415-0236
MedicalQuestions.Resource@nrc.gov

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IR ①

AU Criteria for IRs

- ABR/AOBR diagnostic radiology certification and IR subspecialty certification

OR

- Diagnostic radiology residency (3 yrs) and IR fellowship (1 yr)

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IR ②

AU Criteria for IRs

- 80 hours of classroom and lab training for radioactive material, including Y-90 (i.e. nuc med rotations)
  - Radiation physics and instrumentation
  - Radiation protection
  - Mathematics for measuring radioactivity
  - Radiation biology

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IR ③

AU Criteria for IRs

- Work experience* under another AU or Y-90 manufacturer
  - Ordering, receiving, unpacking…radiation surveys
  - Performing quality control procedures and checks on radiation measuring instruments
  - Evaluating patients for activity to administer
  - Calculating and measuring activity to administer
  - Preventing medical events
  - Controlling contamination and decontaminating
  - Following up and reviewing patient history for Y-90 microspheres

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*specific to each type of Y-90 microsphere

IR ④

AU Criteria for IRs

- Training in operation of delivery system, safety procedures, and clinical use*

- <u>Clinical Use Options</u>

  Pathway 1 – AU to AU: 3 patient cases

  Pathway 2 – Y-90 manufacturer: 3 *in-vitro* cases and 3 patient cases

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*specific to each type of Y-90 microsphere

IR ①-④

Summary of AU Criteria for IRs

1. Diagnostic radiology + IR
2. 80 hours of nuc med training, incl Y-90
3. *Work experience from AU or Y-90 manufacturer
4. *Training in operation of delivery system, safety procedures, and clinical use

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*specific to each type of Y-90 microsphere

Multi-Disciplinary Team Approach

- AU should consult, as necessary, with individuals with expertise in:
  - Cancer management
  - Catheter placement
  - Radiation dosimetry
  - Safe handling of unsealed radioactive material

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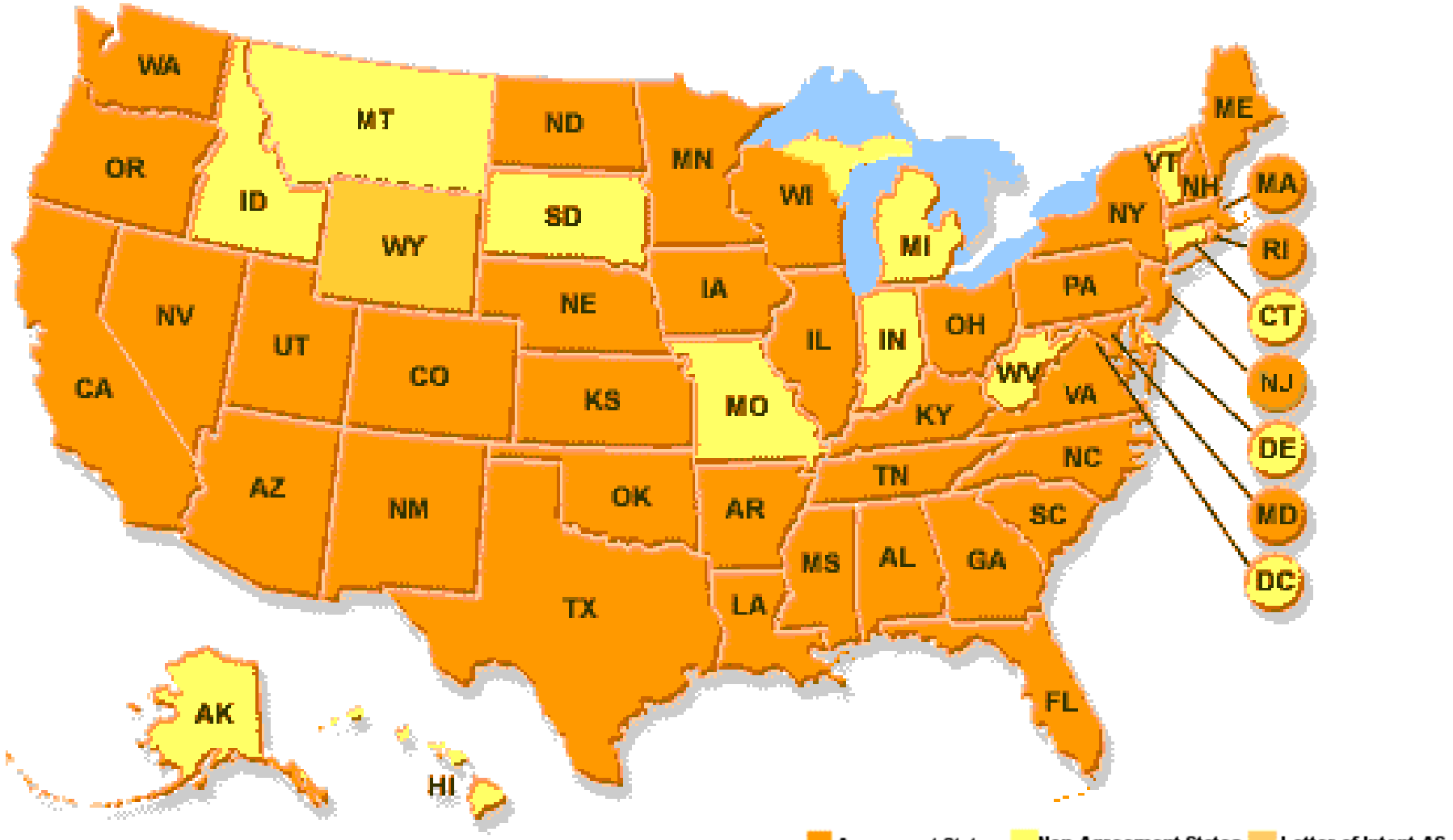
NRC vs Agreement States



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