# AAPM MPPG14a Yttrium-90 Microsphere Treatments Workshop

## Regulatory Compliance, Patient and Staff Safety

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Atlantic Health System

# Disclosures – Mary Ellen Jafari

**None**

# KEY POINTS

- Radioactive materials (RAM) license amendment required
- Authorized Users must meet NRC training and experience requirements
- Written Directive required for administration of dosages
- Comply with regulations for safe handling, surveys, and waste disposal

# Radioactive Materials (RAM) Licensing

$^{90}Y$ microspheres are considered brachytherapy by the US NRC but with special considerations due to:

- small size of spheres
- large number of microspheres administered
- Route of administration

Regulated under 10 CFR 35.1000 “Other medical uses of byproduct material or radiation from byproduct material”

# Licensing Guidance

U.S.NRC
United States Nuclear Regulatory Commission
*Protecting People and the Environment*

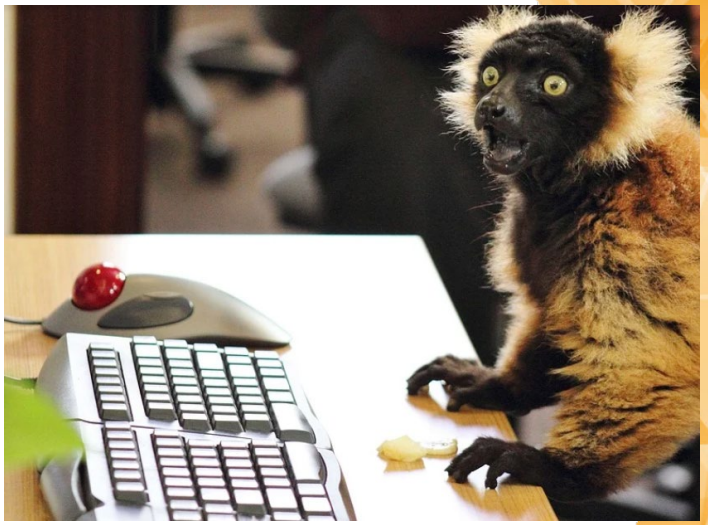
nrc.gov

**"Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance"** www.nrc.gov/docs

- Licensing
- Training and Experience
- License Commitments
- Patient Release
- Waste Disposal
- Autopsy and Cremation

# RAM License Amendment

RAM license amendment required. Must include:



- Proposed authorized users (AU) and their Training and Experience applicable to $^{90}Y$ radioembolization

- Name of RSO and their training in radiation safety, regulatory issues, and emergency procedures for $^{90}Y$ microsphere use.

# Authorized Users

A physician must be an AU for medical use under 10 CFR 35.1000, 10 CFR 35.400 or meet the training experience requirements under 10 CFR 35.390 or 10 CFR 35.490 OR:

- i) Board certification (per guidance document)
- ii) 80 hours of classroom or laboratory training in radiation physics, radiation protection, and radiation biology, including material applicable to $^{90}Y$ microspheres
- iii) Work experience under supervision of an AU for $^{90}Y$ microspheres or trained via a $^{90}Y$ microsphere manufacturer.

# Authorized Users – Clinical Cases

Clinical use training must include at least 3 hands-on patient cases for each type of $^{90}Y$ microsphere requested, conducted in the physical presence of an AU authorized for the type of $^{90}Y$ microsphere being requested.

Conditional approval can be granted with completion of 3 mock simulated cases in presence of vendor representative or authorized AU.

Must send documentation of 3 completed actual cases to regulator.

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# Radiation Safety Officer

RSO must have training specified in 10 CFR 35.50, including training in radiation safety, regulatory issues, and emergency procedures for $^{90}Y$ microsphere use.

The Muppet Show

A RSO already listed on a license that includes one type of $^{90}Y$ microsphere device does **not** require additional approval for another type o $^{90}Y$ microsphere device. Different from AUs.


Sirtex.com

bostonscientific.com

# Written Directives (WD)

Written Directive for administration is required b
10 CFR 35.40.

Vistacreate.com

WD must include the usual information but also:

- model of spheres (TheraSphere® or SIR-Spheres®)
- if appropriate for the type of spheres; “dose or activity delivered at stasis.”

Stasis is defined in the NRC guidance document as a stoppage or slowdown in the flow of blood.

Inability to complete administration due to clogging or kinking of the catheter is not stasis.

# Medical Event Reporting

kuder.com

10 CFR 35.3045(b)-(g): medical event reporting and notification requirements.

Exceptions: events caused by shunting or because of patient intervention .

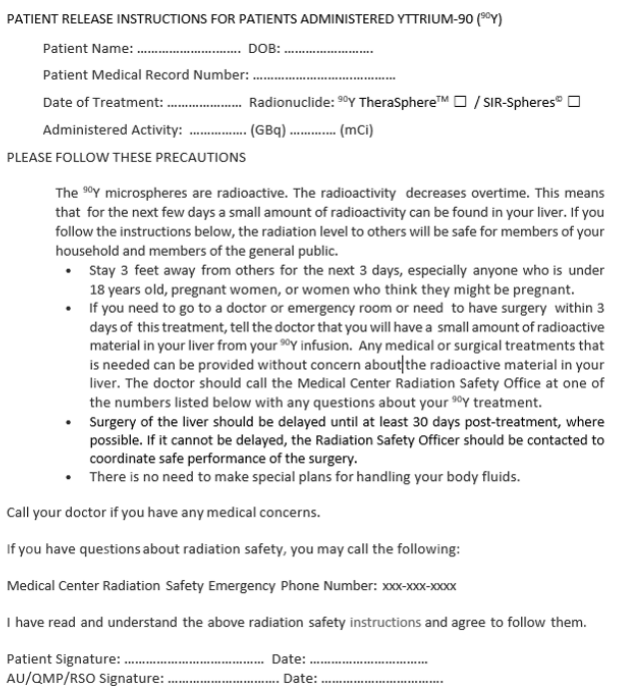
Device failures are classified as reportable medical events, even if the prescribed dose is accurately delivered to the patient.

# Patient Release

NRC regulations do not specify an activity level for the release of patients treated with $^{90}Y$ microspheres.10.CFR.35.75 applies. Patients can be released if the TEDE to another person from exposure to the patient does not exceed 5 mSv.

Studies by Zanzonico and Gulec et al showed that this level will not be exceeded for $^{90}Y$ radioembolization patients.

Patient radiation safety instructions are not required; but they are recommended.



PATIENT RELEASE INSTRUCTIONS FOR PATIENTS ADMINISTERED YTTRIUM-90 ($^{90}Y$)

Patient Name: ..... DOB: .....

Patient Medical Record Number: .....

Date of Treatment: ..... Radionuclide: $^{90}Y$ TheraSphere™ ☐ / SIR-Spheres© ☐

Administered Activity: ..... (GBq) ..... (mCi)

PLEASE FOLLOW THESE PRECAUTIONS

The $^{90}Y$ microspheres are radioactive. The radioactivity decreases overtime. This means that for the next few days a small amount of radioactivity can be found in your liver. If you follow the instructions below, the radiation level to others will be safe for members of your household and members of the general public.

- Stay 3 feet away from others for the next 3 days, especially anyone who is under 18 years old, pregnant women, or women who think they might be pregnant.
- If you need to go to a doctor or emergency room or need to have surgery within 3 days of this treatment, tell the doctor that you will have a small amount of radioactive material in your liver from your $^{90}Y$ infusion. Any medical or surgical treatments that is needed can be provided without concern about the radioactive material in your liver. The doctor should call the Medical Center Radiation Safety Office at one of the numbers listed below with any questions about your $^{90}Y$ treatment.
- Surgery of the liver should be delayed until at least 30 days post-treatment, where possible. If it cannot be delayed, the Radiation Safety Officer should be contacted to coordinate safe performance of the surgery.
- There is no need to make special plans for handling your body fluids.

Call your doctor if you have any medical concerns.

If you have questions about radiation safety, you may call the following:

Medical Center Radiation Safety Emergency Phone Number: xxx-xxx-xxxx

I have read and understand the above radiation safety instructions and agree to follow them.

Patient Signature: ..... Date: .....
AU/QMP/RSO Signature: ..... Date: .....

Zanzonico PB, Binkert BL, Goldsmith SJ. Bremsstrahlung Radiation Exposure From Pure Beta-Ray Emitters. *J Nucl Med*. 1999;40(6):1024-1028.

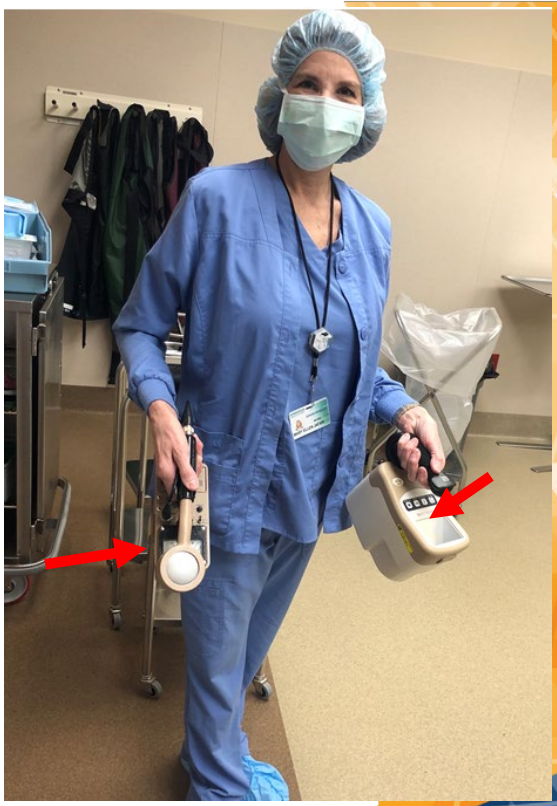
Gulec SA, Siegel JA. Posttherapy Radiation Safety Considerations in Radiomicrosphere Treatment with 90Y-Microspheres. *J Nucl Med*. 2007;48(12):2080-2086

# Instrumentation and Surveys

Licensees are required to determine and record the activity of each dosage before medical use. Calibrate dose calibrator for use with $^{90}Y$.

Surveys are required for all areas where $^{90}Y$ microspheres are prepared for use or administered per 10 CFR 35.70GM meter is sufficient for surveys.

Recommend ionization type meter for quantitative measurement of the exposure rate from the microsphere vial, waste container, and patient.



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# Staff Safety

Procedure room door must be posted with appropriate radiation warning signs.

Use personal dosimeters to show compliance with 10 CFR 20.1201.

Nursing staff caring for the patient after the procedure, prior to release, should maintain a distance of at least 3 feet from the patient's liver, preferably providing all care from the patient's left side.


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# Radioactive Waste

$^{90}Sr/^{90}Y$ generator: carrier free $^{90}Y$

Reactor produced $^{90}Y$: several ppm long lived impurities

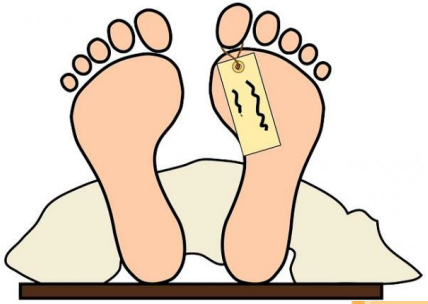
Store waste until exposure rate indistinguishable from background.

May need to hold the waste for an extended time or transfer the $^{90}Y$ microspheres to an authorized recipient pursuant to requirements in 10 CFR Parts 20 and 30.

| Isotope | Half life |
|---|---|
| $^{91}Y$ | 57.5 d |
| $^{88}Y$ | 106.6 d |
| $^{57}Co$ | 270.9 d |
| $^{152}Eu$ | 3.6 y |
| $^{154}Eu$ | 8.8 y |
| $^{60}Co$ | 5.27 y |

Metyko J et al. Health Physics: November 2012 - Volume 103 - Issue 5S - p S204-S208

# Autopsy and Cremation



Pixabay.com

$^{90}Y$ microspheres are permanent implants. 64 hr $T_{½}$

If autopsy or cremation is necessary shortly after treatment, see guidance in:

- NCRP Report No. 155, “Management of Radionuclide Therapy Patients,” December 2006;
- NUREG-1556, Vol 9,Rev. 3, App N, “Model Emergency Procedures.”

# Updates in NRC Guidance Document


subr.edu

- NRC has issued at least 10 versions since 2002.

- Licensees committed to a previous version must request and receive a license amendment to follow a new revision.

- Licensee can request incorporation of a change process into their license, to permit future changes to radiation safety programs without a license amendment.

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# Thank you for attending my presentation.

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