



Office of the Vice Chancellor  
for Administrative Services

University of Missouri-Columbia

319 Jesse Hall  
Columbia, MO 65211-1250

PHONE 573-882-4097  
FAX 573-884-4847

March 9, 2012

Ms. Colleen Carol Casey  
U.S. Nuclear Regulatory Commission  
Region III - Nuclear Materials Safety Division  
2443 Warrenton Road  
Lisle, Illinois 60532-4352

**SUBJECT: Request for amendment No. 111 to University of Missouri-Columbia Broad Scope License No. 24-00513-32, Docket No. 030-02278, to add Yttrium-90 ( $Y^{90}$ ) microspheres for permanent implant therapy**

Dear Ms. Casey,

The purpose of this letter is to request an expedited approval of an amendment to the University of Missouri's NRC Radioactive Materials License (RML) 24-00513-32 (current amendment No. 110), issued to the Curators of the University of Missouri-Columbia, to add  $Y^{90}$  for use in microspheres for manual brachytherapy permanent implantation. The University has identified a patient who is a candidate for this treatment modality.

Our Radiation Safety Committee's (RSC) Medical Quorum (MQ) is in the process of reviewing documents, procedures, training, and experience related to one of our medical authorized users for compliance with 10 CFR 35.1000 "Other Medical or Radiation from Byproduct Material" and the October, 2011 "Microsphere Brachytherapy Sources and Devices" licensing guidance. We expect conditional approval to be granted at the next meeting of the RSC MQ. This amendment request is being submitted in advance of that date to provide the NRC with time for review before we arrange for the manufacturer to provide supervised hands-on training and administration of the  $Y^{90}$  microspheres to the patient.

Specifically, the University of Missouri-Columbia requests that RML No. 24-00513-32 be amended to revise the following:

Insert and modify Item 6. "Byproduct, source, and/or special nuclear material (page 4 of 11).

**NN. *Any byproduct material permitted by 10 CFR 35.1000***"

Insert and modify Item 7. "Chemical and/or physical form" (page 4 of 11).

**NN. *"Microspheres"***

Insert and modify Item 8. "Maximum amount that licensee may possess at any one time under this license" (page 4 of 11).

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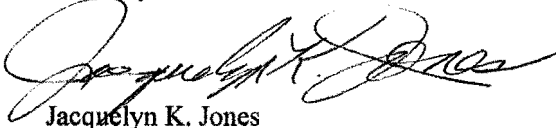
**NN. "5000 millicuries"**

Insert and modify Item 9. "Authorized Use" (page 5 of 11).

**NN. "Any manual brachytherapy sources used for the permanent implantation as permitted by 10 CFR 35.1000"**

If possible, we are asking that the amendment request be finalized before March 31, 2012. If additional information is needed, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacquelyn K. Jones". The signature is fluid and cursive, with the first name being the most prominent.

Jacquelyn K. Jones  
Vice Chancellor of Administrative Services

**Attachment**

cc: S. Jurisson, MU RSC Chair  
S. Westgate, MU RSC Medical Quorum Chair  
M. Kotlas, MU EHS Director  
J. Crawford, MU RSO

## Crawford, Jack

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**From:** Trent, Neil J.  
**Sent:** Thursday, March 08, 2012 9:20 AM  
**To:** Crawford, Jack  
**Cc:** Singh, Amolak; Lunceford, Kevin R.; Creamer, Angela A.  
**Subject:** FW: Y90

**Importance:** High

Jack,  
Please see communication from our Radiologist Dr. Mendez.  
Neil

**From:** Mendez-Castillo, Alejandro  
**Sent:** Tuesday, March 06, 2012 4:57 PM  
**To:** Trent, Neil J.  
**Subject:** Y90  
**Importance:** High

Neil,

This is to stress the importance of expediting the addition of Y90 to our current license as we continue to see patients in great need of radioembolization using this radioactive beads. There is at least one candidate that oncology has requested assessment for this procedure as he seems to be a perfect candidate for it. I cannot schedule clinic appointments to see the patient and do appropriate assessment without knowing for sure that the beads will be available.

I hope this helps in accelerating the process.

Thanks,

***Alejandro Méndez-Castillo, M.D.***  
Assistant Professor of Clinical Radiology  
Director, Division of Vascular & Interventional Radiology  
University of Missouri Health Care  
Columbia, Missouri 65212



## Casey, Colleen

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**From:** Crawford, Jack [crawfordw@missouri.edu]  
**Sent:** Friday, March 09, 2012 1:45 PM  
**To:** Casey, Colleen  
**Subject:** Request for amendment No. 111 to RML 24-00513-32 Docket 030-02278 to add Y90 Microsphere with 5 curie limit  
**Attachments:** Signed MU RML 240051332 Amendment No.111 for Adding Y90 Microspheres with 5 curie limit request 03.09.12.pdf

Ms. Casey (Colleen),

Attached is our license amendment No. 111 requesting that the NRC add to our RML 24-00513-32 line item NN. for Y<sup>90</sup> microspheres for use in permanent implant therapy with a 5 curie possession limit.

We are following the guidelines as outlined in the licensing guidance and 10 CFR 35.1000 for submission to our RSC MQ for their review and approval.

As discussed earlier we are requesting an expedited review (April 16<sup>th</sup> or sooner) as a patient has been identified as being eligible and benefitting from this therapy modality. An email communication from a physician indicating that is included in this amendment packet.

Please let me know what else you might need to support this request.

Regards

Jack Crawford  
Assistant Director EHS  
Radiation Safety Officer  
Laser Safety Officer  
Adjunct Instructor NSEI  
University of Missouri  
# 8 Research Park Development Building  
Columbia Mo 65211-3050  
Phone: 573-882-0931  
Fax: 573-882-7940