

**From:** Randolph Ragland  
**To:** HealthPhysics@earthlink.net  
**Date:** Wed, Mar 30, 2005 1:42 PM  
**Subject:** Request for Additional Info: Rockingham Memorial Hospital License Renewal

Roy F. Heltzel  
Consulting Physicist  
Rockingham Memorial Hospital  
235 Cantrell Avenue  
Harrisonburg, VA 22801-3293  
NRC License No. 45-05594-01  
NRC Docket No. 03003320  
NRC Mail Control No. 135902

The Rockingham Memorial Hospital NRC Radioactive Materials License No. 45-05594-01 renewal application dated October 25, 2004, is being reviewed for completeness with respect to NUREG 1556, Vol. 9, Appendix C and the guidance presented on the NRC website:

<http://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html>

Please note that your license renewal application should represent a stand-alone package and provide sufficient information to justify licensing your facility. The license renewal process also provides licensees an opportunity to update their description of facilities, provide updated procedures, and eliminate outdated tie-downs. Base on our review of your license application dated October 25, 2004, we are requesting the following information.

1) Do you plan to continue to be licensed for Intravascular Brachytherapy (IVB)? If not, we recommend that you request removal of your authorization to conduct IVB.

2) If you do plan to continue to be licensed for IVB, please address the following issues:

To facilitate faster processing of the license application, IVB applicants are highly encouraged to address all of the points outlined below.

Authorized users should meet the training and experience requirements in either 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units" or until October 25, 2005, 10 CFR 35.940, "Training for use of brachytherapy sources."

The authorized user, interventional cardiologist/physician, and authorized medical physicist should receive the vendor training for use of the device.

Procedures should be conducted under the supervision of the authorized user, who should consult with the interventional cardiologist/physician and authorized medical physicist before initiating treatment. The procedures should be conducted in the physical presence of the authorized user or the authorized medical physicist.

The written directive should, before treatment, specify treatment site, the radionuclide, and dose.

The authorized medical physicist should perform independent measurement of source output, before the first patient treatment, using a dosimetry system that meets the requirements of 10 CFR 35.630(a).

The licensee should develop, implement, and maintain written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

The licensee should survey the patient and IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10 CFR 35.404.

In order to protect the radiation safety of patients and to reduce the risk of a medical event, an introducer sheath should be used unless such use is contraindicated for an individual patient.

In order to protect the radiation safety of patients and to reduce the risk of a medical event, a dual syringe system should be used.

“Source stepping” is permitted, if the licensee establishes appropriate procedures in writing. Source stepping procedures are not covered by the manufacturers’ instructions.

The licensee should commit to locked storage of the storage container in a secure location.

The device should be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair should be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

License authorizations should read as follows:

Authorization 6: Strontium-90

Authorization 7: Sealed sources (BEBIG Sr0.S03, AEAT SICW.2)

Authorization 8: 5 mCi per source; 800 mCi total

Authorization 9: For use in Novoste A1000 Series models for intravascular brachytherapy

The license/amendment issuance cover letter should state that source separations during treatment should be evaluated as possible medical events.

Shielding calculations are not necessary for areas outside the treatment room and device storage areas, because Sr-90 is a pure beta emitter.

Revision of the Novoste Beta-Cath™ IVB System radiation safety programs to conform to changes in this licensing guidance.

The above licensing guidance may be revised as additional experience is gained regarding the medical use of the Novoste Beta-Cath™ IVB System. A licensee already authorized to use this product that is committed by license condition to following provisions in this guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform with the revised provisions.

An applicant initially applying for authorization for the medical use of Novoste Beta-Cath™ IVB System, or a licensee applying for an amendment to conform with revisions in this guidance, may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

- (1) the revision is in compliance with the regulations;
- (2) the revision is based upon NRC's current guidance for the Novoste Beta-Cath™ IVB System 35.1000 use posted on the NRC Web site;
- (3) the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
- (4) the affected individuals are instructed on the revised program before the change is implemented;
- (5) the licensee will retain a record of each change for five years; and
- (6) the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

If you have any questions, please contact me at my listed telephone number.

Regards,

Randolph C. Ragland, Jr.  
Senior Health Physicist  
NRC Region I  
610-337-5083

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Renewal

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**From:** Randolph Ragland

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