COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352
(630)-829-9841 FAX: (630) 515-1259

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? YES. **July 20, 2004**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Tom Kumpuris, M.S., consultant for Bay Regional Medical Center		1-800-321-2207

SUBJECT

License No.: 21-18585-01 **Control No.: 313471**

Response dated 9/9/04

SUMMARY

We have reviewed your application dated June 22, 2004, and your letters dated April 28, 2004, and June 22, 2004, requesting renewal of and an amendment to your byproduct materials license and find that we need additional information as follows:

Please note that we voided control number 313347 assigned to your letter dated April 28, 2004, and combined that review into the renewal under control number 313471. This was done for the sake of licensing economy and to give your requests a more timely review.

(1) OK. Please note that we cannot verify that the I-125 sealed sources named under 10 CFR 35.400 are in the Sealed Source and Device Registry. Please provide us with the SSDR certificates themselves, available from the vendors or online, or with the SSDR certificate numbers. Verify certs given - OK.

2. OK. It appears that the only material you wish to possess and use under 10 CFR 35.400 will be the iodine-125 sources, as no other sources are mentioned in your application. If this is correct, please confirm in your response.

3. OK. Please note that an internal interpretation of 10 CFR 35, especially 35.24(b), has resulted in our being unable to continue the multiple-RSO arrangement currently on your license. Hereafter you may have only one RSO for the entire radiation safety program. No assistant RSO's, alternate RSO's or ~~program~~-specific RSO's can be continued on the renewed license. Dr. Singh

Therefore, please indicate which of the 2 current RSO's you wish to have as the sole RSO, Dr. Singh or Mr. Langrill.

4. OK, NA We cannot authorize your current barium-133 BEACON sources and devices as a line item as the authorization for this material is now captured by 10 CFR 35.500, which will appear on the renewed license as a new line item. This is for your information only and no response is required.

5. Please provide copies showing the final disposition of the waste materials associated with use of the materials in 10 CFR 31.11. Please provide a close-out survey for the areas where these materials were used. This information will be necessary to delete the authorization for materials in Part 31.11 from the specific license.

6. In order to authorize strontium-90 for use in the Novoste Beta Cath Model A1000 devices for intravascular brachytherapy please provide appropriate, complete, concise responses to the information requested on our website for materials in Part 35.1000, copy attached. We cannot add this authorization to your license without the requested information.

7. For your facility diagrams, please advise us of the scale used for the diagrams or provide the actual room dimensions and state whether each room is a restricted area or unrestricted area as defined in 10 CFR 20.1003. It would also be helpful to include the direction of north and the locations of lockable doors.

ACTION REQUIRED

Extend 8/24/04.

Submit the requested information within 20 calendar days (by COB August 10, 2004) by **referencing control number 313471.**

Upon receipt of your response we will resume our review. Address your written response to my attention at the above address to facilitate proper handling. **PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.**

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	July 20, 2004

Licensing Guidance Novoste and Guidant Intravascular Brachytherapy (IVB) Systems

Licensing Guidance for Intravascular Brachytherapy (IVB) Systems

On this page:

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Licensing Guidance for the Novoste Beta-Cath™ IVB System

Remarks: Certain training and physical presence guidance is included for consideration because IVB is a new technology, and the devices deliver high dose rates (greater than 1200 rads per hour). For license application requirements, see 10 CFR 35.12(d).

- Below are some recommended areas that licensees are encouraged to address, in order to obtain license authorization for the use of the Novoste Beta-Cath TM Intravascular Brachytherapy system. To facilitate faster processing of the license application, 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, 2004, 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 prior to initiating treatment. The procedures should be conducted in the physical presence of the authorized user or the authorized medical physicist.
- The written directive should, prior to treatment, specify treatment site, the radionuclide, and dose.
- The authorized medical physicist should perform independent measurement of source output, prior to 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.

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- 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 website;
(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 5 years; and
(6) the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, 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.

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5 OF 5,

Licensing Guidance for the Guidant Galileo™ and Galileo III IVB System

TRANSMISSION VERIFICATION REPORT

TIME : 07/20/2004 03:43
NAME : US NRC RIII DNMS
FAX : 6305151259
TEL :

DATE,TIME	07/20 03:42
FAX NO./NAME	17346629224
DURATION	00:01:39
PAGE(S)	05
RESULT	OK
MODE	STANDARD ECM

NRC FORM 386 (RIII)
(2-2002)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 Warrenville Road, Suite 255
Lisle, Illinois 60532-4351

TELEFAX TRANSMITTAL

DATE: 7/20/04 NUMBER OF PAGES: 5
(including this page)

SEND TO: TOM KUMPURIS

LOCATION: MPC

FAX NUMBER: 734-662-9224 ☐ ***VERIFY BY CALLING SENDER***

FROM: COLLEEN CASEY
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE Please call me to discuss upon receipt - but I will be out until late afternoon on Thurs. 7/22/04

NRC FORM 386 (RIII)
(2-2002)

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REGION III
801 Warrenville Road, Suite 255
Lisle, Illinois 60532-4351

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Thank you.

Colleen Carol Casey

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contai information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address , by U.S. Mail. Thank you.