

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

F-04

Date: 2/3/04

FEB 09 2004

Mail and E-mail to: Tom Essig, Chief
MSIB, NMSS

From: John Madera, Chief
MLB, Region III



Licensee: Department of Veterans Affairs (DVA)

License Number: 03-23853-01VA

Docket Number: 030-34325

Control Number: N/A

Letter dated: January 8, 2004 (attached)

Enforcement Action being held in abeyance: () Yes (x) No

Suggested change in licensing procedure (enclosed): None

Problem/Issue:

The Department of Veterans Affairs (DVA), a Master Materials Licensee (MML), received the attached amendment request from the Eastern Colorado Health Care System, a permittee under the MML. Since the permittee is requesting approval of criteria for approving authorized users to perform certain IVB procedures that deviates from current NRC licensing guidance, the DVA has submitted it to NRC for review.

The Colorado VA is proposing training criteria for approving cardiologists to use the Novoste IVB device. In summary, they are proposing to approve cardiologists as authorized users of the Novoste Beta-Cath unit that meet the following:

- a. 24 hours of classroom and laboratory training; and
- b. manufacturers training on the Novoste device; and
- c. supervised clinical training from an authorized user in the treatment of 5 patients; and
- d. written certification of completion of training.

Event Details: N/A

Action Requested:

Please review the enclosed documentation and indicate whether this amendment request can be approved.

Recommended Action and Alternatives: () Approve or (X) Reject

The proposed criteria is significantly less than the NRC training requirements described in 10 CFR 35.690 or 35.940, which is referenced on NRC's web site as acceptable training for Novoste devices.

Please note that in its letter to the NRC, the DVA has requested that if we reject the alternate criteria, then Colorado VA's submittal be treated as a petition to modify the NRC's IVB licensing guidance and/or Part 35.

TARs addressing similar issues (subject and date): N/A

Background documents (identify those not sent electronically):

Headquarters Reviewer: N/A

Regional Inspector: Kevin Null

Reviewer Code: R2

Reviewer Phone Number: X 9854

Request Needed by: March 31, 2004



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

JAN 08 2004

In Reply Refer To: 598/115HP/NLR

Kevin G. Null
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Mr. Null:

Per NRC License 03-23853-01VA, we are enclosing a letter from a VHA permittee requesting approval of alternate criteria for approving authorized user physicians to perform intravascular brachytherapy (IVB). The approval of these alternate criteria would provide a pathway for cardiologists to be designated as IVB authorized users.

The request is reasonable and would not degrade the safety of IVB procedures. Approval of the request would likely decrease the cost of patient care and expedite patient treatments. We note the proposed revised training requirements are similar in concept to those of 10 CFR 35.392 and 35.394. These sections permit physicians, who will be performing a limited subset of 10 CFR 35.300 procedures, to be approved as authorized users with reduced training requirements.

However, the request is contrary to NRC's IVB licensing guidance posted on the NRC Web site; therefore, the NHPP does not have the authority to approve the request. We request you treat the enclosed document as an amendment request. Should the amendment request be denied, we request you treat the enclosure as a petition to modify the NRC's IVB licensing guidance and/or 10 CFR 35.

Sincerely,

A handwritten signature in black ink that reads "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

ATTACHMENT 1

JAN 12 2004



DEPARTMENT OF VETERANS AFFAIRS
EASTERN COLORADO HEALTH CARE SYSTEM

December 4, 2003

Mr. Lynn McGuire
National Health Physics Program
2200 Fort Roots Drive (115HP)
Building 101, Room 208E
North Little Rock, AR. 72114

Medical Center &
Nursing Home
1055 Clermont St.
Denver, CO
80220
303-399-8020

Nursing Home
2600 Oakshire Lane
Pueblo, CO
81001
719-295-7279

In Reply Refer To: 554/115

Dear Mr. McGuire:

OUTPATIENT
CLINICS

622 Del Sol Dr.
Alamosa, CO
81101
719-587-6800

13001 E. 17th Pl.
P.O. Box 6327
Aurora, CO
80045
303-724-0190

25 N. Spruce St
Colo. Springs, CO
80905
719-327-5660

1100 Carson Ave.
Suite 104
La Junta, CO
81
719-384-5195

155 Van Gordon
Suite 395
Eakewood, CO
80228
303-914-2680

201 Kendall Dr.
Lamar, CO
81052
719-336-5972

4112 Outlook Blvd.
Pueblo, CO
81008
719-553-1000

SUPPORT
OFFICES

531 Lewis Street
La Junta, CO
81050
719-384-4632

507 Bent
P.O. Box 390
Las Animas, CO
81054
719-456-6086

1300 Fortino Blvd.
Pueblo, CO
81008
719-553-1000

The VA Eastern Colorado Health Care System, Medical Center is requesting to amend its radioactive materials permit, number 05-01401-02 to establish alternate requirements for a physician to become an authorized user for intravascular brachytherapy (IVB). As the VA Medical Center's use is limited to the Novoste Beta Cath™ Device the alternate requirement would be limited to those Novoste Beta Cath Devices approved by the Food and Drug Administration.

On October 21, 2002 the Nuclear Regulatory Commission issued a Regulatory Issues Summary¹ formally identifying intravascular brachytherapy as a modality under 10 CFR 35.1000. Section 10 CFR 35.1000 was established as part of a major revision of 10 CFR 35 published in the Federal Register² and becoming effective on October 24, 2002. In that notice it stated that³ "...the training and experience will be evaluated on a case-by-case basis with input from the ACUMI and individuals who have been involved with the development of the technology, as needed, and other input as appropriate."

The VA Medical Center currently has three authorized users for IVB. These authorized users meet the requirements of 10 CFR 35.940 and are contracted through the University [of Colorado] Hospital. The amendment⁴ allowing the use of the Novoste Beta Cath unit which requires using 10 CFR 35.940 requirements for approving authorized users of IVB was granted by the Nuclear Regulatory Commission on July 3, 2001. This amendment request would not supercede the previous approval as the VA Medical Center desires to retain this option (i.e., meeting 10 CFR 35.940 requirements) for approving authorized users for IVB. It is assumed that all authorized users under the requested alternate training and experience requirements would be cardiologists.

If approved, this amendment requests would add the following alternate requirements for approving authorized user of IVB.

- (1) Complete 24 hours of classroom and laboratory training applicable to the medical use of the applicable to the Novoste Beta Cath device and obtain written certification of completion of the training. The training must include:
 - a. Radiation physics and instrumentation;
 - b. Radiation protection
 - c. Mathematics pertaining to the use and measurement of radioactivity and
 - d. Radiation biology.

- (2) Complete any training for authorized users, cardiologists or user of the Novoste Beta Cath device provided by the manufacturer and obtain written certification of completion of the training.
- (3) Complete supervised clinical training in the Novoste Beta Cath device under the supervision of an authorized user at a medical institution, clinic or private practice that includes the use of the Novoste Beta Cath device for the treatment of 5 individuals. This supervised training must involve:
 - a. Examination of each individual to be treated
 - b. Procedures/Calculations to determine appropriate dose to be administered;
 - c. Administration of dose;
 - d. Follow-up and review of each individual's case history;
 - e. Checking survey meters for proper operation;
 - f. Visual checks of unit to insure source return;
 - g. Using administrative controls to avoid medical events involving the use of the Novoste Beta Cath system;
 - h. Use of emergency procedures in case of a failure for sources to deploy, return or an apparent loss of source or sources.

As is our current practice, either the Radiation Safety Officer, a medical physicist or other person fully capable of handling a lost source problem or other radiation safety emergencies will be required to be present for all procedures as well as the authorized user.

The following is provided as justification for the request.

- (1) The Nuclear Regulatory Commission has, within its current regulations, alternate and less rigorous requirements for authorized users of specific limited applications of the use of radioactive material in medicine. Approved alternate and less rigorous requirements include those for oral administration of sodium iodide I-131 for the treatment of thyroid carcinoma and hyperthyroidism (10 CFR 35.394 and 35.392) and ophthalmic use of Sr-90 (10 CFR 35.491)
- (2) In the use of the Novoste Beta Cath device to treat coronary arteries, location of treatment is determined by the Cardiologist. The catheter is placed for treatment by the Cardiologist. The diameter of the coronary artery is determined by the Cardiologist. The diameter of the coronary artery is used by the authorized user to determine the dose to be delivered and the dwell time of the sources. With the Beta Cath transfer device both the dose to be delivered and the dwell time are standardized and are based on the single variable of the diameter of the coronary artery.
- (3) Oncologist are specialist in the treatment of cancer. Cardiologist are specialist in the treatment of heart and supporting arteries. Current guidance does not require the Radiation Oncologist to be physically present if a medical physicist is, during the actual procedure. However for the Radiation Oncologist to have a billable service, the Radiation Oncologist must be physically present. Therefore, if authorized users are limited to individuals who

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To Lynn McGuire

meet the requirements meant for a Radiation Oncologist (10 CFR 35.940) there is either an unnecessary cost to the patient or the Radiation Oncologist is required to take significant responsibility for a procedure without compensation.

If you have any questions or need further information please do not hesitate to call our Radiation Safety Officer, Peter Vernig at 303.399.8020 extension 2447.

Sincerely,



E. Thorsland, Jr.
Director, Eastern Colorado HCS

References

1. NRC Regulatory Issue Summary 2002-19, "New Modalities to be Regulated Under 10 CFR 35.1000, October 21, 2002.
2. 2001 Federal Register, Vol. 67, No. 79, Wednesday, April 24, 2002 pp 20249-20397.
3. Ibid Page 20321.
4. Amendment 52 to Materials License # 05-1401-05, Docket # 30-01234, signed July 3, 2001 by Anthony D. Gaines.