September 9, 2011

Ms. Julia (Shan) Marlette, M.S.
Radiation Safety Officer
Marquette General Health System
580 West College
Marquette, MI 49855-2705

Dear Ms. Marlette:

This refers to the telephone conversation between you and Colleen Casey, a materials license reviewer on my staff, on June 14, 2011. Ms. Casey contacted you to discuss an error that occurred in the original, (uncorrected version) of Amendment No. 26, to NRC License No. 21-18889-01 dated July 1, 2010, for Dickinson County Memorial Hospital (DCMH).

This amendment identified Joann M. Leahy, M.D. as an Authorized User (AU) for the use of radioactive materials in manual brachytherapy procedures permitted by Title 10 of the Code of Federal Regulations (CFR) 35.400. This error was discovered during a recent internal review of NRC License No. 21-18889-01.

The error that was identified specifically related to the training and experience documentation provided by DCMH to add Dr. Leahy to its license as an AU for manual brachytherapy procedures permitted by 10 CFR 35.400. The documentation provided was not sufficient.

We have included a detailed outline of the additional training and experience required for Dr. Leahy to become an AU for manual brachytherapy procedures permitted by 10 CFR 35.400. This outline references materials that are available on our Medical Licensing Toolkit web pages at: http://www.nrc.gov/materials/miau/med-use-toolkit.html

As a result of the error discovered, we have already issued corrected copies of Amendment Nos. 24, 25, 26, 27 and 28 to the DCMH license, which removed Dr. Leahy from the license as an AU for manual brachytherapy procedures permitted by 10 CFR 35.400.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please direct any questions you may have to me at (630) 829-9868 or to Ms. Casey at (630) 829-9841.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 21-18889-01
Docket No. 030-17318

Enclosure:
AU Guidance for 10 CFR 35.400 for Dr. Leahy

Please direct any questions you may have to me at (630) 829-9868 or to Ms. Casey at (630) 829-9841.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 21-18889-01
Docket No. 030-17318

Enclosure:
AU Guidance for 10 CFR 35.400 for Dr. Leahy

DOCUMENT NAME: G:\DNMSIII\Work in progress\LTR- Trng Clarifications to RSO for Dr Leahy Ltr DRAFT.docx
□ Publicly Available □ Non-Publicly Available □ Sensitive □ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS		RIII DNMS		RIII		RIII	
NAME	CCCasey: jm		PJPelke					
DATE	09/9/11		09/9/11					

OFFICIAL RECORD COPY

AU Guidance for Manual Brachytherapy Use in 10 CFR 35.400

1. The letter from Dickinson County Memorial Hospital (DCMH) to the NRC dated March 28, 2010, requested that Joann M. Leahy, M.D. be added to its license as an authorized user (AU) for the use of materials in Title 10 of the Code of Federal Regulations (CFR) 35.400 for manual brachytherapy. Therefore, the training and experience for Dr. Leahy is required by 10 CFR 35.490.

   The March 28, 2010, letter included a copy of Amendment No. 08 for the North Dakota license issued to Bismarck Cancer Center (BCC). North Dakota is an "Agreement State," which means that the state has legally assumed the licensing and inspection functions for the materials program under a written Agreement with the NRC.

   The BCC license authorized Joann M. Leahy, M.D. to use iridium-192 in a high dose rate remote afterloading brachytherapy device (HDR device), which is a modality authorized under the NRC – equivalent regulation in 10 CFR 35.600.

   This authorization is not sufficient under the NRC requirements to demonstrate training and experience for 10 CFR 35.490.

2. The March 28, 2010, letter also included a copy of Dr. Leahy's diploma from the American Board of Radiology (ABR) documenting her certification in the specialty of Radiation Oncology on June 7, 1990.

   This specialty board certification was not sufficient to demonstrate training and experience for 10 CFR 35.490. Please see our website listing for the specialty board certifications that NRC accepts to meet the requirements in 10 CFR 35.490 at: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

3. The NRC 313a AUS forms, submitted with the March 28, 2010, letter, were incomplete because Parts 1.3.a. and 1.3.b. were left entirely blank. These sections should have been completed with pertinent 10 CFR 35.490 training and experience information in order for Dr. Leahy's preceptor, Luther W. Brady, M.D., to have signed the forms attesting to her satisfactory completion of the requirements (as documented in Parts 1.3.a. and 1.3.b.) in 10 CFR 35.490.

   Since these sections of the forms were left blank, it negated the preceptor's attestation. Therefore, these forms were not sufficient to demonstrate training and experience for 10 CFR 35.490.

4. The copy of the BCC license for the HDR device and the ABR specialty board certification would not have qualified Dr. Leahy under 10 CFR 35.490. Therefore, it became imperative for Dr. Leahy to apply to become an AU using the "alternate pathway" under 10 CFR 35.490(b) (1), 35.490(b) (2) and 35.490(b) (3).

5. In addition to the above, if Dr. Leahy did have training in manual brachytherapy prior to achieving specialty board certification on June 7, 1990, please note that, in 10 CFR 35.59, NRC also requires that a proposed AU's training and experience be

completed within seven years of the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

In applying to become an AU in 2010, it would have been necessary for Dr. Leahy to demonstrate that she had related continuing education and experience in manual brachytherapy since the required training and experience was completed and within seven years of the date of application (March 28, 2003 – March 28, 2010).

6. In addition to the documents referenced above, NRC has published guidance in "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses (NUREG-1556, Volume 9, Revision 2." In particular, Appendices B, D, and E may be of assistance, as well as section 8.12, item 7 in the text in the front of this book.

7. A final observation and suggestion, that may warrant consideration for future licensing requests, would be to review the relevant regulation directly when preparing an application for any type of proposed authorized individual, such as an authorized user.

   For example, a review (i.e., comparison of her credentials against the regulation) of 10 CFR 35.490 directly could have helped clarify specifically where Dr. Leahy's qualifications did not appear to meet the training and experience requirements listed.