August 9, 2011

Joann M. Leahy, M.D.
[HOME ADDRESS DELETED]
[UNDER 10 CFR 2.390]

Dear Dr. Leahy:

This refers to the telephone conversation between you and Colleen Casey, a materials license reviewer on my staff, on June 15, 2011. Ms. Casey contacted you to discuss an error that occurred in Amendment No. 26, dated July 1, 2010, to NRC License No. 21-18889-01 for Dickinson County Memorial Hospital (DCMH). This amendment identified you 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 and was the result of an oversight and misunderstanding by another materials license reviewer on my staff. We apologize for this error and for any inconvenience it may have caused you.

The error that was identified specifically related to the training and experience documentation provided to add you to the DCMH 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 information you will need to address, should you plan to pursue the 10 CFR 35.400 authorization at another NRC or Agreement State licensed institution, or a permit under a broad scope license or a permit under a Master Materials license.

As a result of the error discovered, please be advised that we have issued corrected copies of the Amendment Nos. 26, 27 and 28 to the DCMH license, which removed you from the license as an AU for manual brachytherapy procedures permitted by 10 CFR 35.400. Please note that the previously issued Amendment Nos. 26, 27 and 28 to the DCMH license, that list you as an AU for the use of radioactive materials in manual brachytherapy permitted by 10 CFR 35.400, may not be used as a reference or “credential” by you, or anyone you are or become employed by, in order to become an AU for manual brachytherapy on another NRC or Agreement State license, a permit under a broad scope license or a permit under a Master Materials license.

During the June 15, 2011, telephone conversation between you and Ms. Casey, you requested copies of our regulations, forms and guidance pertaining to medical use and applications to become an AU. Copies of these materials are enclosed with this letter. In addition, these materials are all available on our Medical Licensing Toolkit web pages at:
http://www.nrc.gov/materials/miau/med-use-toolkit.html

In addition, we have enclosed an outline of the additional information you will need to submit that is specific to your training and experience for manual brachytherapy procedures permitted by 10 CFR 35.400. We have also included copies of the DCMH correspondence that was originally submitted to the NRC for your information.

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. Our fax number is (630) 515-1078.

Sincerely,

/RA/

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

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

Enclosures:
1. AU Guidance for 10 CFR 35.400 for Dr. Leahy
2. 10 CFR Part 35
3. NUREG 1556, Vol. 9, Rev. 2
4. Forms NRC 313a (AUS)
5. Specialty Board Certifications
   Accepted by NRC for Medical Uses
6. Copies of letters from DCMH to NRC
   dated March 28, 2010 and June 25, 2010

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*See previous concurrence
DOCUMENT NAME: G:\DNMSIII\Work in progress\LTR- Leahy Ltr Final RIII-11-A-0050.docx
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DATE	08/09/11		08/09/11					

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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 their 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 the attached excerpt from our website listing the specialty board certifications that NRC accepts to meet the requirements in 10 CFR 35.490.

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 your preceptor, Luther W. Brady, M.D., to have signed the forms attesting to your 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. Please see the marked-up copies of these forms (attached).

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 authorized user (AU) using the "alternate pathway" under 10 CFR 35.490(b)(1), 35.490(b)(2) and 35.490(b)(3). A copy of 10 CFR Part 35 is attached and a blank set of NRC Forms 313a AUS are attached.

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 <u>within seven years of the date of application</u> 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 above documents, 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 to you, as well as section 8.12, item 7 in the text in the front of this book.