From:

Cynthia Flannery aocrps@nemr.net

To: Date:

Thu, Dec 8, 2005 3:21 PM

Subject:

Response to Oct. 19 letter

Dear Ms. Smith:

I am writing in response to your October 19, 2005 letter and as a follow up to our telephone conversation on December 8, 2005 in which you were seeking recognition of the American Osteopathic Board of Radiology's (AOBR) certification processes by the U.S. Nuclear Regulatory Commission (NRC). There are several statements in the letter which preclude recognition of AOBR certification processes without further input from the AOBR. The issues that require attention are listed and explained below.

1. The AOBR responses to no. 3 on the training and experience for 10 CFR 35.190 and 10 CFR 35.290 provides the clarification that NRC requested, but the AOBR web site does not mention this requirement. The response indicates that candidates seeking certification must meet the specific training and experience requirements described in 10 CFR 35.190(a)(1) and 10 CFR 35.290(a)(1), but the web site information on training and experience does not list the required topics. If the provided answer is correct, the web site information needs to be revised to require that the residency program include the minimum number of hours in 10 CFR 35.190(a)(1) and 10 CFR 35.290(a)(1) in the topics listed in 10 CFR 35.190(c)(1)(ii) and (c)(1)(iii) and 10 CFR 35.290(c)(1)(ii), respectively.

An AOBR-supplied copy of referenced AOBR web site information is needed.

- 2. The AOBR responses to no. 3 on the training and experience for 10 CFR 35.390 provides the listed requirements for a physician applying for recognition as an Authorized User under the training and experience pathway, 10 CFR 35.390(b)(1). This response satisfies the certification process requirements in 10 CFR 35.390(a)(1), however, AOBR does not need to provide a breakdown of the minimum number of hours their candidates must spend in classroom and laboratory training and the minimum number of hours their candidates must spend in work experience. Please provide clarification on AOBR's letter dated October 19, 2005 regarding AOBR's training and experience requirements for candidates of 10 CFR 35.390.
- 3. The AOBR responses to no. 3 on the training and experience for 10 CFR 35.390 provides the clarification that NRC requested, but the AOBR web site does not mention this requirement. The response indicates that candidates seeking certification must meet the specific training and experience requirements described in 10 CFR 35.390(b)(1)(i) through 10 CFR 35.390(b)(1)(ii)(G)(4), but the web site does not mention the minimum number of hours of training and experience nor does it list the required topics. If the provided answer is correct, the web site information needs to be revised to require that the residency program include the minimum number of 700 hours in the topics listed in 10 CFR 35.390(b)(1)(i) through 10 CFR 35.390(b)(1)(ii)(G)(4).

An AOBR-supplied copy of referenced AOBR web site information is needed.

- 4. In our telephone conversation on December 8, 2005, you indicated that the Diagnostic Radiology residency include a 16 week rotation in clinical nuclear medicine and your October 19, 2005 letter indicates that the training and experience will be required to cover the nuclear medicine topics cited in 10 CFR 35.190, 10 CFR 35.290, and 10 CFR 35.390. Please clarify how the AOBR can ensure that all AOBR candidates meet the 700 hours of training and work experience in radiation safety in nuclear medicine in a 16 week rotation.
- 5. AOBR needs to confirm that candidates seeking certification for the 10 CFR 35.392 and 10 CFR 35.394 must meet the specific training and experience requirements listed in 10 CFR 35.392(c)(1) and (c)(2) and 10 CFR 35.394(c)(1) and (c)(2). A response on the training and experience for 10 CFR 35.392 and 10 CFR 35.394 uses has not yet been received by the NRC. The web site will also need to include this information.

An AOBR-supplied copy of referenced AOBR web site information is needed.

6. The AOBR responses to no. 3 on the training and experience for 10 CFR 35.590 provides the clarification that NRC requested, but the AOBR web site does not mention this requirement. If the provided answer is correct, the web site information needs to be revised to require that the residency program include the minimum number of hours in the topics listed in 10 CFR 35.590(b) and (c).

An AOBR-supplied copy of referenced AOBR web site information is needed.

- 7. The AOBR responses to no. 3 on the training and experience for 10 CFR 35.490 and 10 CFR 35.690 provides the listed requirements for a physician applying for recognition as an Authorized User under the training and experience pathways, 10 CFR 35.490(b)(1) and (b)(2) and 10 CFR 35.690(b)(1) and (b)(2). AOBR does not need to provide a breakdown of the minimum number of hours their candidates must spend in a structured educational program, work experience and clinical experience. AOBR's letter dated July 6, 2005 and AOBR's web site specifies the training and experience requirements that meet NRC's requirements for recognition of AOBR's certification process. Please provide clarification on AOBR's letter dated October 19, 2005 regarding AOBR's training and experience requirements for candidates of 10 CFR 35.490 and 10 CFR 35.690.
- 8. For nos. 4 and 5, the AOBR response indicates that the certification examination topics in Diagnostic Radiology. Of the listed required exam topics, only radiation safety is listed. The response does not explicitly list the additional required exam topics of radionuclide handling, quality control and the clinical use of unsealed byproduct material for which a written directive is required, listed in 10 CFR 35. 190(a)(2), 35.290(a)(2) and 10 CFR 35.390(a)(2) nor does the web site explicitly list these certification exam topics. In order for the Diagnostic Radiology certification process to be recognized for 10 CFR 35.190, 35.290, and 35.390, the exam must additionally assess knowledge and competence in radionuclide handling, quality control and the clinical use of unsealed byproduct material for which a written directive is required.

An AOBR-supplied copy of referenced AOBR web site information is needed.

9. For nos. 6 and 7, the AOBR response indicates that the certification examination in Radiation Oncology includes topics that are clinical-related. The response does not explicitly list the required exam topics in 10 CFR 35. 490(2) and 10 CFR 35.690(2) nor does the web site explicitly list these certification exam topics. In order for the Radiation Oncology certification process to be recognized for 10 CFR 35. 490 and 10 CFR 35.690, the exam must assess knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of the following: manual brachytherapy; stereotactic radiosurgery; remote afterloaders; and external beam therapy.

An AOBR-supplied copy of referenced AOBR web site information is needed that includes the required exam topics.

- Please provide clarification on the attestation requirements for the AOBR.
- 11. Please indicate when AOBR's Diagnostic Radiology and Radiation Oncology certification programs will meet (or has met) the requirements for 10 CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590 and 35.690. In responding to this request, you should consider the responses you provided to the above requests which clarify the existing program and the responses you provided which resulted in changes that have to be made to your certification process to meet the requirements in 10 CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590 and 35.690.

Review of AOBR's application for recognition will continue upon receipt of AOBR's official reply to the issues needing attention that are listed and explained above.

Communications from the AOBR associated with applying for recognition of one or more of its certification

processes should continue to be addressed to:

U.S. Nuclear Regulatory Commission ATTN: Mr. Thomas H. Essig, Chief, Materials Safety and Inspection Branch (MS T8F3) 11545 Rockville Pike Rockville, MD 20852

For further information or for questions, please contact me at (301) 415-0223, cmf@nrc.gov.

Respectfully, Cindy Flannery

Cindy Flannery, CHP, Team Leader Medical Radiation Safety Team Materials Safety and Inspection Branch Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission Mail Stop T8-F3 Washington, DC 20555 Phone: 301-415-0223

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CC: Donna-Beth Howe; Mohammad Saba; Ronald Zelac; Sandra Wastler

Mail Envelope Properties (439895C7.B39 : 17 : 35798)

Subject:

Response to Oct. 19 letter

Creation Date:

12/8/05 3:21PM

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