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July 23, 2009

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U.S. Nuclear Regulatory Commission
ATTN: Mr. Robert Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Mail Stop: T8E24
11545 Rockville Pike
Rockville, MD 20852

Re: Request for Modification of Recognized Status for the American Board of Radiology (ABR) in Diagnostic Radiology

Dear Mr. Lewis:

We are writing on behalf of the American Board of Radiology (ABR) to apply for an amendment to ABR's specialty board recognition under the provisions in the Training and Experience (T&E) requirements of 10CFR Part 35. Currently, the NRC has granted recognition of ABR's certification of its Diagnostic Radiology diplomates under the requirements of sections 35.290 and 35.392 (oral administration of I-131 in quantities ≤ 33mCi). Beginning with ABR certificates issued in June 2011, the ABR seeks additional NRC recognition for section 35.394 (oral administration of I-131 in quantities > 33mCi). The ABR instructions to Diagnostic Radiology training programs regarding the relevant training requirements can be found in the attached letter to program directors. ABR certificates are valid for ten years.

The ABR examines approximately 1300 candidates each year in Diagnostic Radiology. Diagnostic Radiology candidates complete the 700 hours of required T&E by having four 4-week clinical rotations on Nuclear Medicine in ACGME-approved Diagnostic Radiology residency programs. In addition, 80 hours of classroom and laboratory training as well as pertinent work experience as specified in 35.392, and now 35.394, are required. Some of the didactic instruction may occur while the candidates are on the clinical rotations in nuclear medicine, and some may occur at other times within the overall 4-year training program in Diagnostic Radiology. Candidates complete and submit to ABR procedure logs related to their participation in I-131 therapy as per sections 35.392 & 35.394, and the compliance of their overall training with NRC requirements is attested to by training program directors prior to their admission to the ABR examination.

Gary J. Becker, M.D., Executive Director
Robert R. Hattery, M.D., Senior Advisor to the Executive Director

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Radiologic Physics: Richard L. Morin, Ph.D.

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Subspecialty Certification: Janet L. Strife, M.D.

The candidates' mastery of the relevant topics of training as specified in section 35.394 is assessed by the two-part written and oral examination process currently in place and already recognized by the NRC for sections 35.290 & 35.392. These examinations are standardized and psychometrically validated annually. Many of the topics currently covered in the examination as part of the requirements of 35.392 training are also generally relevant to section 35.394 requirements. In addition, this portion of the examination has been expanded to include specific testing relevant to the oral administration of I-131 in quantities $>33\text{mCi}$ as per section 35.394.

The ABR has certified candidates in areas related to nuclear medicine since nuclear medicine became relevant clinically in the 1950s - 60s (the ABR was formed in 1934). Until recently this has included NRC recognition of ABR certification for section 35.394. Over the past few years, the shrinking pool of clinical practitioners qualified to become Authorized Users under section 35.394 has raised concerns in the medical community regarding restricted patient access to such crucial care. ABR has responded to these concerns by reinstating the necessary training requirements as specified in section 35.394 as a prerequisite for its examination process, effective in 2011. A recent poll of Diagnostic Radiology training programs indicates that this training can be provided in the programs. Indeed, many programs have been providing this training and experience to their residents all along. In addition, ABR's consultations within the Diagnostic Radiology community have met with both approval and encouragement of this initiative, including endorsements from the American College of Radiology and the ACGME Residency Review Committee in Diagnostic Radiology. ABR diplomates have an excellent safety record over the years in the administration and control of radionuclides used for medical purposes. Accordingly, we hope that the NRC will respond favorably to ABR's request for additional specialty board recognition for section 35.394. The ABR hopes for your prompt and favorable reply. Of course, should the NRC have comments or concerns, we wish to hear back promptly regarding those as well.

Sincerely,

 

N. Reed Dunnick, MD
President

Gary J. Becker, MD
Executive Director

cc: Milton J. Guiberteau, MD
Cindy Flannery



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July 23, 2009

To: Diagnostic Radiology Program Directors and Department Chairs

From: Gary J. Becker, MD, Executive Director
Milton J. Guiberteau, MD, ABR Trustee and Category Chair, Nuclear Radiology

RE: Training Requirements for I-131 therapies under 10 CFR 35.394

In recent years, a decline in the number of authorized users (AUs) who can provide high-dose (>33mCi) I-131 therapy under 10 CFR 35.394 has created a demand for specialists who are so-trained and authorized. To address this urgent need, the ABR has applied to the NRC for approval to grant AU-eligible status to residents who are properly trained and examined in this therapy beginning in 2011.

By submitting this application the ABR has committed to requiring that candidates for diagnostic radiology certification receive the training required in section 35.394. In addition, ABR will require attestation from training programs regarding completion of this training, as well as a log (for each candidate) of completion of 3 cases of oral administration of I-131 therapy in amounts greater than 33mCi in addition to the 3 cases of oral administration of I-131 therapy in amounts less than or equal to 33mCi. Whether approval is given by the NRC or not, the ABR feels strongly enough about maintaining an adequate pool of AUs that we are updating our training requirements to include these therapies. Our future exams will contain content specific to 10 CFR 35.394.

A survey of diagnostic radiology training programs was recently conducted by the ABR to inquire about their ability to provide such training to their residents based on their current nuclear medicine program. Of the 150 diagnostic radiology training programs that responded to the survey, 136 said they currently provide such training to their residents. Of the 14 programs that do not currently provide this training, 9 would be able to implement this training in the future, or are affiliated with a program that could provide the training. Thus, we believe that implementing this requirement is feasible, and should be done by 2011 in order to meet the urgent need for authorized users in both low- and high-dose I-131 therapies.

We encourage your program to continue to train your residents in these I-131 therapies, or begin training them as soon as it is feasible in preparation for the 2011 implementation date. Residents who are properly trained and who pass the ABR NRC examination will be well-positioned to become authorized users.

Gary J. Becker, M.D., Executive Director

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