

**From:** [Gabriel, Sandra](#)  
**To:** [Best, Karin](#)  
**Cc:** [Woods, Ellen](#)  
**Subject:** Request for additional information in response to AOBR request for recognition under 35.394  
**Date:** Friday, February 06, 2015 3:57:00 PM

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February 6, 2015

Roy M. Teng, D.O., Chair  
c/o Karin Best, Certification Manager  
American Board of Osteopathic Radiology (AOBR)  
142 East Ontario Street, 4<sup>th</sup> Floor  
Chicago, IL 60611

Dear Dr. Teng:

This is in response to the AOBR's letter to the NRC dated December 19, 2014 requesting recognition of the AOBR board certification process in Diagnostic Radiology under the requirements of 10 CFR 35.394 -- Training for oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). Additional information is needed in order for the NRC to approve this request. Each item below briefly states the issue, then specifies in **bold** the information to be provided:

- 1) AOBR's request described the Basic Standards for Residency Training in Diagnostic Radiology—American Osteopathic Association and American Osteopathic College of Radiology, which became effective in July 2012, and listed portions of the requirements. We noted that the information provided does not exactly correspond to NRC requirements. Most of the deviations concern the NRC authorized user qualifications in 10 CFR 35.290. In a letter to the NRC dated July 15, 2014, the AOBR provided a website location of AOBR requirements for certification in Diagnostic Radiology related to NRC authorized user qualifications in 10 CFR 35.290 and 35.392: <http://www.aobr.org/wp-content/uploads/2013/10/requirements-nrc-diagnostic-radiology-website.pdf>. With one minor exception (discussed in item 3, below), the information at this website corresponds to the NRC requirements. This website appears to be active, however it has not been updated to include NRC authorized user requirements for 35.394.

**Please provide the website location of AOBR requirements for certification in Diagnostic Radiology that fully correspond to all NRC authorized user requirements under 10 CFR 35.290(a), 35.392(a), and 35.394(a). Also describe how residency programs and certification applicants will be made aware of the location of this website.**

- 2) The first paragraph of AOBR's request noted that the title of 10 CFR 35.394 is "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)". Many of the subsequent references in the request used the term "oral administration of I-131" without indicating the chemical form.

**Please confirm that all AOBR training requirements for oral administration of**

**I-131 are for the chemical form sodium iodide.**

- 3) 10 CFR 35.394(c)(2) requires work experience to be supervised by an authorized user (AU) who meets the requirements in 10 CFR 35.57, 35.390, or 35.394, or equivalent Agreement State requirements. The current AOBR request appears to be more restrictive, in that it does not include supervision by AUs who meet the requirements in 10 CFR 35.57. 10 CFR 35.57 is the section of the regulations that allows a physician that met previous AU requirements to continue to be an AU for that use without having to meet the current requirements. Omitting supervision by AUs who meet the requirements in 10 CFR 35.57 means that all supervising AUs must meet the current AU requirements.

Note that 10 CFR 35.290(a) and 35.392(a) also allow supervision by AUs who meet the requirements in 35.57. Your request and website at <http://www.aobr.org/wp-content/uploads/2013/10/requirements-nrc-diagnostic-radiology-website.pdf> do not appear to include supervision for 10 CFR 35.290 or 35.392 by AUs who meet the requirements in 35.57, which may be unnecessarily restrictive.

**Please clarify whether the AOBR requirements for certification in Diagnostic Radiology allow work experience under 10 CFR 35.290, 35.392, or 35.394 to be supervised by an authorized user who meets the requirements of 10 CFR 35.57.**

- 4) 10 CFR 35.394(c)(3) requires a written attestation that the individual has satisfactorily completed the requirements of 10 CFR 35.394(c)(1) and (c)(2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses under 35.300. The attestation must be signed by a preceptor authorized user who meets certain requirements. The AOBR's current request from the AOBR did not fully describe the written attestation requirement.

**Please confirm that the AOBR requirements for certification in Diagnostic Radiology include obtaining a written preceptor attestation in accordance with the requirements of 10 CFR 35.394(c)(3).**

- 5) AOBR's request noted that the current version of the Basic Standards for Residency Training in Diagnostic Radiology became effective in July 2012. It also stated that, upon NRC approval, the first examination will be offered in May 2015. Upon approval, the NRC website will list the initial date of issuance of certificates designating eligibility for AU status for 35.394.

**Please provide the first date on which certificates will be issued that designate eligibility for AU status for 35.394.**

- 6) The AOBR's request noted that time-limited certificates have been issued since 2012 and all recipients must participate in Osteopathic Continuous Certification (OCC) to maintain board certification.

**Please confirm the duration for which a time-limited certificate is valid. After the expiration of a time-limited certificate, what is the method that an NRC license reviewer may use to confirm that an individual meets the OCC**

**requirements and continues to hold certification?**

- 7) The NRC now posts on its web site copies of sample certificates for recognized board certification processes for each recognized time frame. For all recognized boards except AOBR, the sample certificates can be viewed from the links on the web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. This allows licensees and regulators to confirm the expected appearance of a certificate.

**Please provide a copy of a sample AOBR certificate for Diagnostic Radiology that will be issued following NRC recognition of eligibility for AU status for 35.394. The sample certificate should include fictional name and date information, with a watermark stating "Not Valid."**

- 8) In a letter to the NRC dated July 15, 2014, you stated that the new AOBR Certification Manager, Karin Heffron, is authorized to correspond with the NRC on behalf of the AOBR. The current AOBR request listed "Karin Best" as Certification Manager.

**Please confirm that Karin Best is authorized to correspond with the NRC on behalf of the AOBR.**

Please respond to the items listed above by formal letter within 30 days. The letter should acknowledge the board's commitments to and responsibility for the completeness and accuracy of the information provided to the NRC. The NRC will continue review of the AOBR's request upon receipt of this letter.

Please note that our organization names and address have changed. Please mail the letter to:

Director  
Division of Material Safety, State, Tribal and Rulemaking Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Attention: Chief, Medical Safety and Events Assessment Branch, Mail Stop T-8E18

For delivery services requiring a street address, mail to:

Director  
Division of Material Safety, State, Tribal and Rulemaking Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
11545 Rockville Pike  
Rockville, MD 20852-2738  
Attention: Chief, Medical Safety and Events Assessment Branch, Mail Stop T-8E18

For further information or any questions, please contact me at (301) 801-3889 or [sandra.gabriel@nrc.gov](mailto:sandra.gabriel@nrc.gov). Please note that I typically work Tuesday through Thursday of each week and will be away until February 12.

Thank you,  
Sandy Gabriel, Ph.D.  
Health Physicist  
NRC Medical Radiation Safety Team