

April 14, 2004

E. Lynn McGuire, Director  
National Health Physics Program (115HP/NLR)  
Department of Veterans Affairs  
Veterans Health Administration  
2200 Fort Roots Drive  
Little Rock, Arkansas 72114

Dear Mr. McGuire:

This is in response to your letter dated September 5, 2003, in which you requested the NRC review and approve your proposed criteria for evaluating recentness of experience under 10 CFR 35.59, and NHPP Form 313A.

The NRC has determined that it cannot, at this time, approve your request for reviewing recentness of training and the NHPP Form 313A, based upon the information you submitted. Currently, if an individual's training and experience was obtained more than 7 years before the date of the application and the individual is not currently identified on a medical use license or permit as an authorized user, the NRC will determine, on a case-by-case basis, with input from the Advisory Committee on the Medical Use of Isotopes (ACMUI), as necessary, whether the individual's "related continuing training and experience," as documented on NRC Form 313A, is adequate to meet the requirements of 10 CFR 35.59. In addition, it should be noted that the Supplementary Information for section 35.59 (67 FR 20294 and 20346) states that the continuing training and experience requirements are reviewed on a case-by-case basis with input from the ACMUI.

As explained below, the criteria (c) and (d) described in your submittal are deficient as a means of determining if recentness of training and experience requirements in 10 CFR 35.59 are met. Also, Form 313A should be modified as noted.

Criterion (c) recommends approving recentness of training if an individual had completed a residency or other training program within the 7 years preceding the date of application. This criterion is inadequate because it requires only that the individual has completed a residency program or "other training program" within the last 7 years. It does not clarify whether the residency program is relevant to the proposed medical use (e.g., meets the residency program requirements in 10 CFR 35.490, "Training for use of manual brachytherapy sources") or provide an adequate description of the "other training program" to assure it addresses the elements in the regulations for a specific medical use (e.g., the elements in 10 CFR 35.290(c)(1)).

Criterion (d) recommends approving recentness of training if there is a NHPP Form 313A preceptor statement. This criterion is inadequate because it does not clearly indicate that the authorized user (preceptor) is certifying that the training and experience in each element was satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user for the authorized medical uses.

When an individual's training and experience was obtained more than 7 years before the date of the application and the individual is not currently identified on a medical use license or permit as an authorized user, the NHPP should continue to instruct its permittees to use NRC Form 313A to document each individual's training over the last 7 years and provide supplemental information such as documentation of the individual being listed on a license or permit during the last 7 years.

The NHPP should continue to submit such documentation to the NRC for its review on a case-by-case basis. This does not preclude the NHPP from revising its proposed program for reviewing recentness of training by addressing the items described above, and resubmitting it to the NRC for additional review and consideration.

If you have any questions, please feel free to contact me at (630) 829-9854.

Sincerely,

/RA/

Kevin G. Null  
Sr. Health Physicist

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