RulemakingComments Resource

From: Prisciandaro, Joann <joannp@med.umich.edu>
Sent: Friday, September 05, 2014 11:13 AM
To: RulemakingComments Resource
Subject: Re; Public comment on proposed revisions to requirements for medical uses of radioactive materials

To whom it may concern,

I would to thank you for offering the general public to provide comments on the proposed revisions to Title 10 for the Code of Federal Regulations sections 30, 32, and 35. As an Authorized Medical Physicist I would like to provide some feedback to the proposed changes specifically to section 35, on the medical use of byproduct material. I have had an opportunity to review and discuss this proposal with several of my colleagues. Please find our comments below. If you should any questions, please feel free to contact me directly.

Kind regards,
Joann Prisciandaro

1. 10 CFR 35.40 – Regarding item (b)(6)(i), changes to the pre-implant requirements for the written directive for permanent implants. The amended rule state:

> "Before implantation: The treatment site, the radionuclide, the intended absorbed dose to the treatment site and the corresponding calculated total source strength required, and if appropriate, the expected absorbed doses to normal tissues located within the treatment site;"

Overall, we are uncomfortable with the term "if appropriate." This is very subjective. In short, it should be stated whether we expected to include expected normal tissue doses or not. Otherwise, who decides if this is appropriate? Is this a clinical decision? I am concerned that an inspector may interpret this regulation differently than an AU or AMP, and could result in a potential violation of 35.40 based solely on a difference in the interpretation of this rule. We do not believe this limits needs or should be included in the written directive. There may be clinical reasons why an AU may accept a higher dose to a normal structure, especially based on its proximity of the involved tissues.

2. 10 CFR 35.490 and 35.690 – Revision to the training and experience requirements.

Based on this revision, an individual who is board certified will no longer need a preceptor attestation to become an AU or AMP. The argument for this change is that some preceptors have been reluctant to attest due to concerns related to personal liable based on possible future actions of the proposed AU/AMP. I would argue that that if someone truly has these reservations, there may be a good reason they are not willing to sign off on the attestation. Additionally, there is no clear guidance on the amount of training an individual needs in the area they are applying. Although it is stated that 500 hours of work experience under the supervision of an AU is required, this is written vaguely enough that it can and has been interpreted as 500 hours of work related to radiation therapy not specifically to brachytherapy. In reality, that is reasonable, however, it would be helpful to have some specific brachytherapy related guidance on, e.g., the number of cases the proposed AU/AMP should observe and/or perform under supervision, or the length of time they should perform these procedures under supervision.

It is also unclear how one who is board certified but beyond 7 years of the required training may seek AU or AMP status. For safety, should there not be some minimum number of cases they observe prior to obtaining AU or AMP status especially in light of the complexity of interstitial procedures such as LDR or HDR prostate.

Joann I. Prisciandaro, Ph.D., DABR
University of Michigan Hospital and Health Systems
Department of Radiation Oncology
1500 East Medical Center Dr.
UH B2 C432, SPC 5010
Ann Arbor, MI 48109