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STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

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December 29, 2003 (11:14AM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 16, 2003

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Rulemakings and Adjudications Staff

Re: Proposed Revision of 10 CFR Part 35, "Medical Use of Byproduct Material"

Dear Sirs:

I would like to take this opportunity to comment on the proposed revisions to 10 CFR Part 35.

I wish to applaud the Commissioner's decision to continue to require a preceptor statement for individuals who have received certification from an accepted board. I am pleased that the NRC recognizes the importance of having an individual who knows the candidate, and has worked with them, to attest to their radiation safety competence. Therefore I am strongly in favor or maintaining the preceptor statement requirement. Unfortunately, certification by an accepted board alone will no longer be adequate to become an authorized user, medical physicist, RSO or nuclear pharmacist. Initially this could be confusing to licensees, who will need to get accustomed to submitting copies of a valid preceptor statement and board certificate with their notification required by 35.14.

In 35.51(b)(1) the term "high energy" is used. There is no definition for "high energy", and this term might be interpreted differently by different states and individuals. While in Alabama we might consider energies above 0.9 MeV as high energy, how does that relate to the NRC's or another Agreement State's interpretations? Because experience with high energy, external beam therapy is essential for approval of a medical physicist, it would seem appropriate that the term be better understood.

During the Organization of Agreement States (OAS) meeting held the week of October 13, 2003, we discussed the appropriate number of hours to be deemed acceptable for the various rule sections. As you know, the rules no longer specify the number of didactic or supervised clinical and work hours necessary.

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This becomes a problem in that a certifying board could allow say five hours of didactic training to be deemed adequate to sit for an exam that will, upon successful completion, allow an individual to become an authorized user under 35.190, 35.290 and 35.390.

Exacerbating this is the fact that there are already training programs touting this change in the rules as a way to greatly lower the amount of time that a physician must be away from their practice to meet the requirements (compared to the current Subpart J 200 hours). This appears to emphasize convenience, not radiation safety.

I recommend that the NRC include a minimum acceptable number of didactic hours in the supplementary information. I recommend the following minimum acceptable didactic hours:

1) For those uses that require a written directive (i.e.35.390) a minimum of **200 hours** of didactic training should be required (out of the total of 700 hours).

2) For those uses that do not require a written directive, but still require a total of 700 hours (i.e. 35.290), I recommend a minimum of **80 hours** of didactic training be required.

3) For those uptake, dilution and excretion studies which require 60 hours of total training (i.e. 35.190), I recommend a minimum of **8 hours** of didactic training.

To arrive at these numbers I considered the relative risk to the patient, occupational worker and the public that is expected from each type of use and an anticipated eight hour class day.

Again, thank you for the opportunity to comment on this proposed rule text.

Sincerely,

David Walter

David Walter, Director
Radioactive Material Licensing
Alabama Office of Radiation Control