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To: [RulemakingComments_Resource](#)
Subject: Proposed Medical Rules Amendments Comments
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Attachments: [Part 35 Comments 11-6-2014.pdf](#)

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STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

November 6, 2014

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

Re: Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR Parts 30, 32 and 35 (FSME-14-078)

Secretary,

The Alabama Office of Radiation Control is pleased to provide the following comments regarding the referenced proposed amendments.

35.433(a)(2) The NRC added a definition of the term "Ophthalmic physicist." However, the definition refers to "an individual who meets the requirements of §35.433(a)(2)..." The term 'ophthalmic physicist is not used in 35.433. Recommend changing the text in 35.433(a)(2) to read:

"An individual named as an ophthalmic physicist who:

- (i) Holds a masters..."

35.3045 This rule section does not meet the criteria to be assigned a compatibility "B" designation. All medical events are local events and are not transboundary, regardless of their significance. Even multiple events with a common root cause are considered local events. For example, an authorized medical physicist performs SR-90 eye applicator outputs using flawed equations in their spreadsheet. They perform these outputs for six different medical facilities, one NRC licensee, and five different Agreement State licensees. As a result medical events occur at all of the facilities. This is considered a separate medical event at each of the six

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licensees, and each licensee will be required to submit a medical event report to their licensing authority. Only if multiple medical events occur at a single licensee that result from the same root cause can it be handled as a single medical event. I believe the correct compatibility designation should be "C".

Medical events are to be reported in NMED, so NRC does receive notice of all such events that meet the NRC medical event criteria. This assures that specified information, required to properly complete the NMED entry, is acquired by the regulating agency.

Assigning this a compatibility "B" designation limits the flexibility of the Agreement States to properly address issues in their states that include a wide range of radiation safety concerns from both machine produced and radioactive material radiation. If it is the intent of the NRC to assure that all Agreement State agencies have, at a minimum, the NRC's medical event thresholds, then a compatibility designation "C" is appropriate. If it is the intent of the NRC to try and force Agreement State agencies, which currently have lower thresholds in their description of a medical event, to raise their thresholds to a higher level, I recommend against that idea. Such a decision would not appear to be in the best interest of radiation safety. It is also difficult to justify given the small number of medical events compared to the total number of patient studies performed.

Thank you for the opportunity to comment on these proposed rules. If you have any questions, please feel free to contact me at 334-206-5391.

Sincerely,



David Walter, Director
Office of Radiation Control