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The Honorable Dr. Shirley Ann Jackson, Chairman
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Chairman Jackson:

The American College of Cardiology (ACC), a 24,000 member medical specialty society, has reviewed the latest revision of 10 CFR Part 35 which was made available to the public on the NRC rulemaking webpage. We wish to make specific comments on Part 35.292 that address the process of becoming an authorized user. Please reference also our letter to Chairman Jackson dated April 23.

1. We are in complete agreement with section (a) regarding specialty board certification as a pathway to achieve licensure.

We anticipate that the certification provided by the Certification Board of Nuclear Cardiology (CBNC) would fulfill the requirements of the NRC. The CBNC has already expressed its desire to work with the NRC in this approval process.

2. We strongly urge that there be a uniform policy established and recommended by the NRC relative to the requirements as listed in (c) for both Agreement and Non-Agreement states.

While we recognize the rights of Agreement states to adopt policies equal to or more restrictive than those of the NRC, having variable education requirements will create great difficulty for training programs and add tremendous administrative burden and cost to both state and Federal enforcement agencies. The current Working Group recommendation calls for 700 hours, but does not specify how many of those hours must be in classroom and laboratory training.

Our understanding is that the NRC, through its ACMUI, considers appeals and we question whether or not that mechanism would be able to handle the multiple appeals that would be forthcoming.

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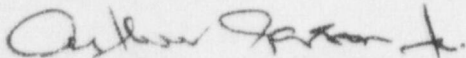
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The number could potentially be quite large and impose a sizeable financial burden upon the NRC. For this reason, we strongly urge that the NRC make every effort to obtain the concurrence of all Agreement states relative to this policy. The guaranteed safety of patients should be uniform in all states.

3. **To address further the problems identified in # 2 above, ACC recommends clarifications to the "alternative pathway " to standardize a course of basic theory/laboratory training for isotope handling and to acknowledge more clearly the concomitant clinical training implicit in the 700 hour requirement.** To accomplish these objectives, ACC recommends that (c) (1) be changed to read "Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies that include—(i) 80 hours of Classroom and laboratory training which includes [all areas listed currently in (A) through (E)]; (ii) 40 hours of supervised practical Work experience, under the supervision of an authorized user, who meets the requirements in 35.292 or 35.390 involving [all areas listed currently in (A) through (E) plus (G)] and (iii) with the remaining hours in Clinical Experience in the selection, performance and interpretation of human and research studies using reactor byproduct materials."
4. **We support the need to have a strong preceptor statement from an authorized user as documentation of experience and training as specified by the NRC.**

Thank you for this opportunity to comment further on the revisions proposed by the NRC Working Group relative to 10 CFR Part 35.

Sincerely,



Arthur Garson, Jr., MD, MPH, FACC
President

cc: Commissioner Nils J. Diaz
Commissioner Greta Joy Dicus
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Commissioner Jeffrey S. Merrifield
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