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May 2, 2018

Douglas R. Bollock, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission

Dear Mr. Bollock:

The Commonwealth of Virginia's Office of Radiological Health appreciates the opportunity to respond to your request for input on 10 CFR Part 35.390, "Training for use of unsealed byproduct material for which a written directive is required." We believe this to be a very important topic as we have some significant concerns with Part 35.390 that are likely to become more challenging for the NRC, the Agreement States, and the medical community at large.

In our opinion, the NRC, working in close cooperation with the Agreement States, has an opportunity to re-examine the entire regulatory basis for all 10 CFR Part 35 based training requirements for authorized users. In other words, we believe that we have a rare opportunity to determine just what the regulators' role should be in this regard, without the constraints of previous rules and policies, to the extent possible. We also believe that this effort should involve as many stakeholders as possible, including individuals and organizations not traditionally involved in NRC regulatory activities. Such individuals and organizations may help the NRC to understand that there are alternative approaches to regulating hazardous materials that do not involve prescriptive requirements focused on inputs (like training hours) but rather help the NRC focus on evaluating outcomes (like successfully passing a rigorous examination). We strongly believe that past practices and approaches should not be the starting point when trying to determine the best path forward. If the NRC truly wants to understand how best to assess knowledge, then key stakeholder groups would seem to be those that have expertise in education rather than nuclear medicine or radiation safety.

Our specific responses to your questionnaire follow:

1. We believe that the fundamental knowledge components needed to administer any radiopharmaceutical licensed under 10 CFR 35.390 have been addressed. However, we have identified some minor edits we would like to offer for your consideration:
   - 1.c.iv. - We suggest that "aprons" be replaced with "L blocks."
   - 1.c.v. - We suggest that this item be removed.
   - 1.c.xiii. - We suggest that this section be re-worded to state "Radiation protection for patients." Further, the fourth bullet should be re-worded to state "Proper operation of radiopharmaceutical therapy delivery systems" and the fifth bullet should be eliminated as it is essentially a repeat of 1.c.vii.

2. We believe that all of the topics listed in question number "2" should be removed. This additional granularity is not only redundant to the list of topics outlined in question number "1," but encroaches on regulating the practice of medicine. As regulators, we should do all that we can to clearly delineate our radiation safety role from anything involving the clinical care of patients.

3. We believe strongly that the question of how physicians should acquire the knowledge necessary to safely possess and administer radiopharmaceuticals should not be our focus as regulators. In a performance based regulatory environment, it is our opinion that our focus should be solely on whether or not physicians possess that knowledge. That is, it is unnecessary for us, as regulators, to "count hours." When asked, no one seems to know how the number of required training hours was determined. The number of required training hours in the current regulations seems entirely arbitrary.

4. We believe that we, as regulators, do not have the knowledge or experience necessary to answer the question of how best to evaluate a physician's knowledge. At best, we may have some insights into this topic, but we simply do not know. As stated earlier, we believe that the NRC, in conjunction with the Agreement States, should engage others who possess this highly specialized, education-focused knowledge and experience.

Thank you again for the opportunity to provide you with our insights on this very important topic. We stand ready to participate in this effort moving forward. If you have any questions or desire additional information or clarification, please contact me by phone at (804) 864-8151 or email at steve.harrison@vdh.virginia.gov, or Mike Fuller, Radioactive Materials Program Director, by phone at (804) 864-8168 or email using michael.fuller@vdh.virginia.gov.

Sincerely,

Steven A. Harrison, MA, MEP
Director, Office of Radiological Health
Virginia Department of Health