
From: pbyrne@mpcphysics.com
Sent: Thursday, June 07, 2018 9:36 PM
To: RulemakingComments Resource
Subject: [External_Sender] Petition for Rulemaking
Attachments: PetitionForRulemaking060718.docx

NRC,
Please accept the attached Petition for Rulemaking in regards to 10 CFR 35.65.

Sincerely,
Patrick J. Byrne

June 7, 2018

Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, DC, 20555-001
Attn: Rulemakings and Adjudications Staff

RE: Petition for Rulemaking

To whom it may concern:

I am requesting that 10 CFR 35.65 be considered for rulemaking to give medical licensees flexibility in their maintenance of an adequate quality control program. As the regulation is currently written, licensees may utilize any amount of Tc-99m for check, calibration, transmission, and reference use. The use of unsealed byproduct material with a half-life less than 120 days is only allowed in individual amounts up to 15 mCi (10 CFR 35.65(c)). As the practice of nuclear medicine has evolved since the introduction of this regulation and the Commission has taken over the regulation of accelerator produced materials, the regulation as it is currently written poses a hinderance to certain licensees. Specifically, there are facilities that only utilize positron emitting isotopes and they may need quantities of positron emitters greater than 15 mCi in order to test their scan equipment and dose calibrators. Additionally, as new radiopharmaceutical therapies are approved, some utilizing quite large activities, facilities may need various non-Tc-99m isotopes in quantities greater than 15 mCi for developing accurate dose calibrator calibration and geometry factors.

I propose revising 10 CFR 35.65 to delete paragraph (e) and to revise paragraph (c) to state: "Any byproduct material with a half-life not longer than 120 days in amounts as needed." The combination of these two changes will allow licensees to be flexible when testing and calibrating their radiation detection and measurement equipment as they see fit.

Thank you in advance for your consideration.

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