

24 June 2022

Secretary, US Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Rulemaking and Adjudications Staff

TO WHOM THIS MAY CONCERN,

I am writing in response to Docket ID NRC-2017-0031 to support a proposed rule that would amend Appendix B to 10 CFR part 30 used to determine decommission funding requirements for specific sealed and unsealed radioactive material. Professionally, I am an Authorized Nuclear Pharmacist, owning and operating independent commercial Nuclear Pharmacies in North and South Carolina. These pharmacies have been providing Nuclear Medicine patient doses for 30 years. Upon request from area hospitals and physicians, Shertech Pharmacy secured sufficient resources and training to make available Ga68 DOTATATE upon FDA approval to our customer base. The Agreement State licensing amendment for the GA68 generator triggered 10 CFR 30.35 requirements for obtaining confirmation of expired generator take back by the manufacturer along with posting financial decommissioning assurance based on referencing NRC Licensing Guidance, July 2019 specific to Ge68/Ga68 pharmaceutical grade generator.

The NRC agreed with ACMUI in providing exemption for these Ga68 generators from establishing a decommission plan, but failed to exempt the requirement for placement of funding and instead of a specific plan, required a Standby Trust be put in place to administer funds to the appropriate State agency. This set of requirements adds more financial burden to an already high cost of entry into the Ga68 isotope distribution and product addition to the pharmacy formulary - \$ 100,000 for a 50 mCi Ga68 generator, \$ 225,000 for either a letter of credit or surety bond. One percent (1%) is the usual annual bank charge for issuing a Letter of Credit (another \$ 2,250) and there is a 2% charge for the bank to establish a Standby Trust to administer these funds (another \$ 4,500). As pointed out, there is a steep financial barrier to enter this Ga68 market.

To add to the difficulty factor, not all banks maintain a Trust Department anymore for liability reasons. Even Bank of America, as large as they are, claims to not have a Trust Department. Additionally, many banks turn down the opportunity of issuing a Letter of Credit when they discover the reason for seeking credit involving something "nuclear" along with requiring the named beneficiary being a "Bureau of Radiological Health". The compliance difficulty is high and the financial burden and backing difficulty is even higher. For a small business entity to set aside and "park" \$ 225,000, it not only affects the cash flow of the business but inhibits overall business growth including payroll, capital equipment repair/replacement, new product acquisition and so on.

Shertech Pharmacy has had possession of a Ga68 generator for almost 3 years without any detectable elution breakthrough of Ge68. We have housed and shipped back to the manufacturer two expired generators without incident. We have provided over 1500 Ga68 patient doses without incident. My future concern is with the FDA approval of Ga68 PSMA and other Ga68 labeled products that there will be a possession need for greater than 100 mCi of Ge68 and our small business could NOT afford to set aside \$ 1.125 million and continue to provide diagnostic radiopharmaceutical doses to patients. We are already struggling in this post-Covid business recovery period having to leave the \$ 225,000 untouched and not available for current business needs.

Since Ge68/Ga68 generators will be the only technically “unsealed” radionuclide that these commercial nuclear pharmacies will possess with a half-life over 120 days, I would ask the NRC to complete the “specific exemptions” section and include decommission funding with the same exception made for decommission planning. A guidance will need to be issued in order for the Organization of Agreement States (OAS) to adopt the NRC position in this matter. I would also like to thank the Commission for expediting this process as there are several Ga68 PSMA providers of those products poised to enter the market along with several more Ga68 labeled molecules under FDA review.

Respectfully submitted,

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President/Owner

Shertech Pharmacy Charlotte
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Shertech Laboratories

From: [Rick Sheriff](#)
To: [RulemakingComments Resource](#)
Subject: [External_Sender] Docket ID NRC-2017-0031 comments
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Attachments: [NRC decommission fund letter.docx](#)

Please find attached comments that I would like to submit in response to the proposed rule amending Appendix B, 10 CFR part 30 specific to decommission funding requirements. Thank for the opportunity to provide my voice to this very impactful issue to commercial nuclear pharmacies.

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