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Board Counsel  
Pennsylvania State Board of Pharmacy  
P.O. Box 69523  
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RA-STRegulatoryCounsel@pa.gov  
Reference No. 16A-5419 (Compounding)

Dear Board,

Thank you very much for the opportunity to comment on the draft rules on nuclear pharmacy sterile compounding.

**§ 27.1 Definitions**

Compounding – The definition of compounding should be modified to include that compounding does not include reconstitution of a drug product pursuant to a manufacturer's directions.

**§ 27.602 Substances and components**

A pharmacist solely using a commercially manufactured, FDA approved drug product in the course of their compounding will not have COAs for these FDA approved drugs. Please consider this scenario.

**§ 27.608 Protective apparel**

"For a sterile compounding operation involving one or more aseptic manipulations, sterile gowning components are necessary as required by the USP." Please be aware that not all of the gowning components required by USP<797> are sterile.

**§ 27.608 Label information required**

Not all pharmacies possess DEA licenses (such as radiopharmacies) and do not possess nor dispense controlled substances. The requirement in (b) to include the "DEA number of the pharmacy" should be reevaluated.

**§ 27.625 Product testing and examination**

A pharmacist solely using a commercially manufactured, FDA approved drug product in the course of their compounding should not need to perform pH testing of solutions.

Thank you again for allowing us to provide these comments prior to the publication of the proposed rule.

Sincerely,

Richard L. Green, R.Ph., BCNP  
Chair, BPS Specialty Council on Nuclear Pharmacy  
Nuclear Pharmacist on NRC's Advisory Council on the Medical Uses of Isotopes  
Director of Radiopharmacy Practice  
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