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General Comment

A. Tailored Training & Experience Requirements

The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board certified pathway, and for physicians certified by a medical specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct MaterialWritten Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.

For the New radiopharmaceuticals being developed (LU-177 DOTATATE/DOTATAC, Pb212 DOTATATE, LU-177 PSMA), there is no training provided to NM physicians or radiologist other then the package inserts and CME courses. Unless you have had experience treating patient's in clinical trials, there is no training provided in the NM residency training programs. Thus training for NM physicians (Residency and Fellowship) must be expanded to include more therapy experience.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

For conventional therapies (Ra223 , I-131 therapy) the training in residency and fellowship is adequate and there is enough resources
for NM physicians to be competent in managing these patients independently.
However with the new therapies being developed , the training in Residency and Fellowship must be expanded to included a minimal number
of patient treated with each new radiopharmaceutical, as well as documentation of the management of these patients complications during and AFTER
therapy. This will require additional rotations in general Internal Medicine as well as Hematology and Oncology. Many of these patients develop side effects
form the new therapies (insulinoma symptoms, hepatic encephalopathy, intractable abdominal pain, Anemia etc) which need documentation and more importantly
immediate treatment often requiring hospital admissions. Thus the current AU are not ready to treat the general public if the treating physicians have NO EXPERIENCE
dealing with the complications/side effects of these new therapies.