PUBLIC SUBMISSION

SUNSI Review Complete
Template = ADM-013
E-RIDS=ADM-03
ADD=Sarah Lopas

COMMENT (31)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

As of: 1/15/19 10:27 AM
Received: January 14, 2019
Status: Pending_Post
Tracking No. 1k3-97oo-6leb
Comments Due: January 29, 2019
Submission Type: Web

Docket: NRC-2018-0230
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0029
Comment on FR Doc # 2018-23521

Submitter Information

Name: Jeffry Siegel

General Comment

ADDITIONAL Comments Re: Training and Experience Requirements for
Different Categories of Radiopharmaceuticals
Docket ID NRC20180230

Jeffry A. Siegel, PhD
President & CEO, Nuclear Physics Enterprises

To further clarify my previous comments and better focus the discussion, I respectfully submit the following.

The NRCs FRN re Training and Experience Requirements for Different Categories of Radiopharmaceuticals misses the mark. The NRC is requesting input on whether it should establish tailored T&E requirements for essentially only two different categories of radiopharmaceuticals for which a written directive is required. But since the NRC has already established such tailored requirements, the input should address whether further tailoring is required or whether 35.392 and 35.394 for only Na131I use is inappropriate and should be deleted from the regulations.

I will limit my comments to the alternate pathway currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394. The NRC has already established tailored T&E requirements pursuant to 10 CFR 35.392 and 35.394 for only the oral administration of Na131I in dosages 33 mCi or in dosages >33 mCi, respectively. Only 80 hours of training are required together with an unspecified number of clinical experience hours. These account for two of the four categories of use specified in 10 CFR 35.390 that requires 700 hours of

T&E (i.e., at least 200 hours of training and somewhat less than 500 clinical experience hours). Note that the two categories for oral Na131I administration, are for that specific agent, not categories at all. Given these current distinct requirement options, should a physician wish to limit his/her practice to only oral Na131I use, it is obvious which path (35.392/394 vs. 35.390) they would choose.

Further tailoring, which is what the NRC is contemplating, would therefore be confined to the other two current dosage categories pursuant to 10 CFR 35.390, namely, parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide. These two categories actually do contain various specific radiopharmaceuticals. Therefore, should specific radiopharmaceuticals in these two categories be placed into their own requirement(s), such as a new codified 10 CFR 35.395, if their radiation safety profiles justify a reduced T&E that is appropriate and sufficient to protect public health and safety or should they remain all lumped together in 35.390?

Since all therapeutic radiopharmaceuticals do not pose the same risk, it follows that their use should not be subjected to, and limited by, identical T&E requirements, or requiring physicians seeking limited AU status to have the same fundamental T&E required of physicians seeking full AU status for oral Na131I and all parenteral administrations. This latter mandate would entirely rule out the ability to attain limited AU status, if justified.

NRC apparently believes limited AU status is justified, at least for oral Na131I, although this is a questionable position. Important considerations to ascertain appropriate and sufficient T&E for a given radiopharmaceutical to ensure the radiation protection for patients and workers, in addition to NRCs only two specified criteria of parenteral administration and radionuclide under 35.390, should include: how supplied, ease of administration, intended administered activity level, half-life, impurity/radiocontaminant levels, route of elimination from the body, waste disposal, potential dose to others, potential for internal contamination, and patient release issues.

Tailoring may increase the complexity of regulatory oversight, but when justified, should be of minor concern, as it would be a more risk-informed approach and of great benefit to patients and their treating physicians. Restricting physicians access to, and ability to use an FDA-approved and commercially available agent by imposing unwarranted and unduly burdensome T&E regulations that are not reflective of the radiation risks involved, is detrimental to them and their patients, conflicts with NRC guidelines of minimizing intrusion into medical judgments and is most assuredly not risk informed.

Each radiopharmaceutical must therefore be objectively assessed to understand its associated radiation risks and the level of T&E necessary it may be more or less than currently codified. This assessment is necessary for NRC to arrive at a meaningful decision as to whether it is appropriate for a physician to attain essentially full or limited AU status before being able to administer a given therapeutic agent. If this is not done, the NRC cannot reliably regulate the T&E of physicians for medical uses and therefore should not do so.