

# PUBLIC SUBMISSION

**As of:** 1/30/19 11:20 AM  
**Received:** January 29, 2019  
**Status:** Pending\_Post  
**Tracking No.** 1k3-97yh-cilf  
**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-0110

Comment on FR Doc # 2018-23521

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## Submitter Information

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

COMMENT (102)  
PUBLICATION DATE:  
10/29/2018  
CITATION: 83 FR 54380

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## General Comment

See attached file(s)

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## Attachments

2019 01-29 MSK Comments on Training and Experience Requirements FINAL



Memorial Sloan Kettering  
Cancer Center

*Submitted electronically via regulations.gov*

January 29, 2019

Daniel S. Collins  
Director, Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Re: NRC-2018-0230, Training and Experience Requirements

Dear Mr. Collins:

Memorial Sloan Kettering Cancer Center (MSK) appreciates the opportunity to respond to the Nuclear Regulatory Commission (NRC)'s solicitation (83 F.R. 54380) of comments on its training and experience (T&E) requirements, specifically, whether the NRC should establish tailored T&E requirements for authorized users (AUs) for different categories of radiopharmaceuticals for which a written directive is required under [10 C.F.R. 35.300](#) (i.e., a *limited* AU status). These comments reflect the consensus of the membership of the MSK Committee on Radiation (COR), whose charge includes assessing and ensuring compliance with radiation safety guidelines, as well as the opinion of the MSK Department of Radiology and Molecular Imaging and Therapy Service (formerly known as the Nuclear Medicine Service). In brief, MSK is strongly opposed to any such tailored T&E requirements, and more specifically, to any *reduction* in the T&E requirements for AUs of radiopharmaceuticals for which a written directive is required (most notably, therapeutic radiopharmaceuticals).

Since its inception, the field of nuclear medicine has had an outstanding record of patient, personnel, and public safety while contributing in important ways to patient care and medical science – thanks in part to the extensive technical and clinical training required of AUs. The field is now transitioning to an increasingly therapeutic discipline, with the introduction of targeted radionuclide therapies (including, for

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NCI-designated Comprehensive Cancer Center

example, radioimmunotherapy, alpha-particle therapy, and lutetium-177 peptide/“small-molecule” therapy of neuroendocrine and prostate cancers). These important advances will demand even greater technical as well as medical expertise among nuclear medicine physicians, as the higher activities used for and the complexity of such procedures introduce additional potentially significant radiation risks for patients and the general public. Particularly in rural and other settings where technical support (in physics, radiation safety, and radiopharmacy) may not be immediately available, the AU must deal independently with such complex issues as radiation dosimetry, assay and dispensing of therapeutic levels of radiopharmaceuticals, and safe and compliant application of patient release criteria and radioactive waste disposal. Thus, adequate T&E of AUs in the basic science as well as clinical aspects of nuclear medicine in general, and radionuclide therapy in particular, are becoming more, not less, important. Any reduction in T&E requirements for AUs and the resulting diminution of relevant scientific and clinical expertise is therefore extremely ill-advised.

MSK joins with nuclear medicine and other health professionals and professional organizations nation-wide in strongly opposing any reduction in T&E requirements for AUs for any categories of radiopharmaceuticals for which a written directive is required. Instead, we urge the retention of the current standards, which we believe will continue to effectively protect the safety of patients, personnel, and the public. Again, we appreciate the opportunity to offer our comments on the T&E requirements for AUs. If we can serve as a resource to you on this or other issues, please do not hesitate to call on us.

Respectfully submitted,



Pat Zanzonico, PhD  
Chair, Committee on Radiation



Lawrence Dauer, PhD  
Vice-Chair, Committee on Radiation  
Corporate Radiation Safety Officer



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