

# PUBLIC SUBMISSION

<b>As of:</b> 1/30/19 10:23 AM <b>Received:</b> January 28, 2019 <b>Status:</b> Pending_Post <b>Tracking No.</b> 1k3-97y1-st5p <b>Comments Due:</b> January 29, 2019 <b>Submission Type:</b> 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-0098

Comment on FR Doc # 2018-23521

## Submitter Information

**Name:** Martin Allen-Auerbach

**Address:**

11000 Kinross Ave, Suite 244

Los Angeles, CA, 90095

**Email:** mauerbach@mednet.ucla.edu

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

COMMENT (92)  
 PUBLICATION DATE:  
 10/29/2018  
 CITATION: 83 FR 54380

## General Comment

Re: Docket ID NRC-2018-0230 Los Angeles, CA, January 28th 2019

Dear Madame/Sir,

We read with great concern that the U.S. Nuclear Regulatory Commission is currently considering creating alternate pathways for physicians without dedicated nuclear medicine training and board certification to become limited authorized users for the administration of radionuclide therapies.

We, the UCLA Radiation Safety Committee, are deeply concerned about this development. As the general policy-making and regulating body for activities at UCLA that involve the use of materials and machines producing ionizing radiation we are regularly confronted with incidents that involve the therapeutic use of radioactive pharmaceuticals.

From our experience it is very clear that care involving systemic delivery of ionizing radiation requires in depth understanding

of physics, instrumentation, radiobiology and radiation protection pertaining to radiopharmaceuticals. In addition advanced skills in interpretation of scintigraphic and hybrid imaging (SPECT, SPECT/CT and PET/CT), which form an essential part of the evolving Nuclear Medicine aspect of Theranostics, are essential for being able to safely and adequately perform therapies with radioactive pharmaceuticals.

It is our strong opinion that the proposed alternate pathway being considered by the NRC would result in dangerously inadequate care being delivered by alarmingly insufficiently trained authorized users. It is unimaginable that the medical and regulatory community would allow complex surgeries, chemotherapies or brachytherapies to be performed by non-specialty physicians after two weeks of training.

We would also like to point out, that, to a large extent the push to allow limited authorized users appears to originate from lobbying efforts by pharmaceutical companies standing to gain financial profit by expanding the market for established and emerging radiopharmaceutical treatments with very high profit margins (treatment courses usually run in the 10s of thousands of dollars).

The official NRCs Safety Culture Policy Statement reads The Commission defines Nuclear Safety Culture as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. The proposed changes for creating alternate pathways for physicians to become limited authorized users constitutes the opposite of what the NRC sets out as their policy. As such the UCLA Radiation Safety Committee strongly opposes the proposed changes.

Respectfully,

Martin Allen-Auerbach, MD

Chair UCLA Radiation Safety Committee

---

## Attachments

NRC comment Docket ID NRC-2018-0230

Re: Docket ID NRC-2018-0230

January 28<sup>th</sup> 2019, Los Angeles, CA

Dear Madame/Sir,

We read with great concern that the U.S. Nuclear Regulatory Commission is currently considering creating alternate pathways for physicians without dedicated nuclear medicine training and board certification to become limited authorized users for the administration of radionuclide therapies.

We, the UCLA Radiation Safety Committee, are deeply concerned about this development. As the general policy-making and regulating body for activities at UCLA that involve the use of materials and machines producing ionizing radiation we are regularly confronted with incidents that involve the therapeutic use of radioactive pharmaceuticals.

From our experience it is very clear that care involving systemic delivery of ionizing radiation requires in depth understanding of physics, instrumentation, radiobiology and radiation protection pertaining to radiopharmaceuticals. In addition advanced skills in interpretation of scintigraphic and hybrid imaging (SPECT, SPECT/CT and PET/CT), which form an essential part of the evolving Nuclear Medicine aspect of Theranostics, are essential for being able to safely and adequately perform therapies with radioactive pharmaceuticals.

It is our strong opinion that the proposed alternate pathway being considered by the NRC would result in dangerously inadequate care being delivered by alarmingly insufficiently trained authorized users. It is unimaginable that the medical and regulatory community would allow complex surgeries, chemotherapies or brachytherapies to be performed by non-specialty physicians after two weeks of training.

We would also like to point out, that, to a large extent the push to allow limited authorized users appears to originate from lobbying efforts by pharmaceutical companies standing to gain financial profit by expanding the market for established and emerging radiopharmaceutical treatments with very high profit margins (treatment courses usually run in the 10s of thousands of dollars).

The official NRC's Safety Culture Policy Statement reads "The Commission defines Nuclear Safety Culture as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment". The proposed changes for creating alternate pathways for physicians to become limited authorized users constitutes the opposite of what the NRC sets out as their policy. As such the UCLA Radiation Safety Committee strongly opposes the proposed changes.

Respectfully,



Martin Allen-Auerbach, MD

Chair, UCLA Radiation Safety Committee