PUBLIC SUBMISSION

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

COMMENT (58)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

As of: 1/29/19 7:53 AM
Received: January 26, 2019
Status: Pending_Post
Tracking No. 1k3-97wr-b6ur
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-0064
Comment on FR Doc # 2018-23521

Submitter Information

Name: Josh Mailman
Submitter's Representative: Josh Mailman
Organization: NorCal CarciNET Community

General Comment

See attached file(s)

Attachments

NorCal CarciNET Response NRC-signed

NorCal CarciNet

May Ma
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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

Dear Ms. Ma:

NorCal CarciNET Community is a non-profit whose mission is to help those with neuroendocrine tumors (NETs) and carcinoid to share challenges and experiences, learn about prognosis and treatments, find information, and improve communications between the medical community, patients and caregivers. We hold monthly meetings and an annual patient symposium that is attended by 350 people as well as streamed live by 500 more. Over 2,000 individuals follow us via newsletter and our online presence.

We would like to thank the commission for being concerned about access and availability of nuclear medicine therapy in the US. For several decades, NETs patients were required to travel thousands of miles or out of the country to receive treatment using radionuclide treatment. Many were not able to make these journeys as they did not have the health or the resources required.

In response to the commission's four main questions regarding patient access and availability for patients with NETS, it is our observation that:

1. There is **no shortage** in the number of Authorized Users (AUs) for medical uses under 10 CFR 35.300.
2. There is **adequate** Geographic coverage of AUs where sufficient demand for therapy exists.
3. Current NRC regulations on AU Training & Education (T&E) requirements **do not** limit patient access to procedures involving radiopharmaceuticals.
4. Current NRC regulations on AU T&E requirements **do not limit research and development** in nuclear medicine.

Background / Rationale

As the commission is aware, the U.S. Food and Drug Administration approved 177Lu DOTATATE for treatment of neuroendocrine tumors on January 26, 2018, In the first year of commercial availability, over 1,000 treatments at over 100 locations were performed in the US. In the not too distant future the US will lead the world in the number of these types of radionuclide therapy performed.

The NET patient community is grateful to no longer need to fly overseas in order to receive this treatment, and for most patients to be able to be treated where they are seen for treatment for their disease.

The patient community would welcome even greater access to treatment; however, we do not think that this should come at the expense of safety and training. Our patients' main concerns are if the center they are considering is adequately trained and if they are doing enough therapies to be experienced in the delivery and the safety of the treatment.

In polling we conducted with our community earlier this month, we found that nearly three quarters of the respondents had no concept of what an AU is and half of them did not feel that we have adequate information to make an informed decision of how many hours of training should be required to become an AU. Of those that did express a preference, one third suggested more training while two thirds thought that the current four month training should be maintained.

The commission has asked for comment regarding if a lack of AUs was causing a delay of treatment throughout the country. Our nationwide poll highlighted the top 3 reasons we hear from patients time and time again regarding delays in treatment of over 30 days: 1) Insurance Coverage, 2) Lack of adequate facilities to support the workflow, 3) Lack of finished product.

With clear treatment guidelines being released by the National Comprehensive Cancer Network and the North American Neuroendocrine Tumor Society, we believe insurance coverage delays will be reduced. We are also encouraged that many centers that could only support a workflow of 1 or 2 patients a week have already increased to 3 or 4 by bringing on more staff or reallocating clinic space to the practice of nuclear medicine therapy. We are also encouraged that over time the suppliers will be able to meet and better predict demand.

To increase the numbers of medical professionals interested in nuclear medicine research and practice, we believe that the commission, industry and the nuclear medicine community should be focusing on funding research in nuclear medicine, expanding infrastructure, and providing incentives for recruitment opportunities. We believe this will result in expanding the geographic footprint of where therapies can be offered.

We do not wish to see reduced training requirements for AUs in order to expand treatment availability as this could lead to an accident that would harm patients.

We need to attract the best and brightest into the field of nuclear medicine as the number of nuclear medicine therapies increases. This should not be done by easing requirements but by promoting outreach and potential investment by and in the nuclear medicine community.

We thank you for the opportunity to comment on this area of great concern to patients.

Sincerely,

Josh Mailman
President
NorCal CarciNET Community