

PUBLIC SUBMISSION

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

COMMENT (65)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

As of: 1/29/19 8:38 AM Received: January 27, 2019 Status: Pending_Post Tracking No. 1k3-97xa-o25c 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-0071

Comment on FR Doc # 2018-23521

Submitter Information

Name: Charles Peterson

Address: United States,

Email: cbiledo@gmail.com

General Comment

I would like to submit the attach file regarding this subject.

Attachments

NRC Training Comments

Reference: Nuclear Regulatory Commission(NRC) Advisory Committee On the Medical Uses of Isotopes (ACMUI) Subcommittee On Training and Experience Requirements for All Modalities Subcommittee Draft Interim Report February 19, 2018

If I understand this report that consideration is being given to shortening the AU training hours to administer parenteral radionuclide therapy.

Shortening training hours is totally inappropriate. Instead consideration at some point should be given to expanding the numbers of hours in view off the wide variety of this type of therapy that is in the development pipeline around the world. Ever year I attend many nuclear medicine meetings around the world including Japan, Korea, China, Myanmar, India, Malaysia, Singapore, Australia, Europe and USA (2). It is very impressive the amount of research that is taking place around the world to develop new radionuclide therapy, many which will become routine clinical therapies going forward. We are just at beginning of this revolution in therapy which will become a world standards of care. As more of these therapies come online it will require a whole new skill set and experience to appropriate use these therapies in clinical practice. This is becoming a much more sophisticated field of medicine and will require more training and experience for the physician supervising this therapy. Dr. C S Bal, Director of Nuclear Medicine and PET, at AMIS medical center in New Delhi, India has actually established a fellowship to train current and future nuclear medicine physicians to meet the expected increased demand for radionuclide therapies.

Therapy is only half the equation, there is also the diagnostic part of this clinical field that has to be taken into consideration when determining training requirements. The physician engaging in radionuclide therapies also needs to be competent in interpreting the PET and nuclear medicine scans that are the basis for the radionuclide therapies. The whole new concept of theranostics and

personalized medicine is based on physicians being competent in both diagnosis and in radionuclide therapy. This is not the place to further expand on these concepts but they have to be clearly understood before discussing shortening training hours.

The suggestion that there are not enough trained AUs to provide easy clinical access for patients to the current demand for radionuclide therapies is a bogus argument as far as I am concerned but I will let others with more current knowledge than I have make those arguments. If only taking into the consideration the demand for radionuclide therapy for neuroendocrine tumors the current number of AUs in Radiology and Nuclear Medicine departments should be more than adequate to treat this population of patients. According to the NIH there are 12000 new cases of neuroendocrine tumors found each year. That is only 240 new cases on average for each state. Not all will need radionuclide therapy but that would represent less than one therapy needed on average a day. Not a big problem with the current number of AUs now or in the near future. As more radionuclide therapies of this nature become standard clinical practice the demand will go up but as this type therapy gets more complexed, AUs may need more training/experience to provide quality care to patients.

I just read a NRC document SECY-18-0084 dated August 28, 2018
SUBJECT; STAFF EVALUATION OF TRAINING AND EXPERIENCE
REQUIREMENTS FOR ADMINISTERING DIFFERENT
CATEGORIES OF RADIOPHARMACEUTICALS IN RESPONSE TO
SRM-M170817

It is clear from this document the 200 hours of basic radiation training should not be shortened. The only area where we can harm patients in the use of radionuclides in the care of patients is in oral, parenteral and topical application of these agents that are alpha and beta emitters. AUs have to be well trained in the safety aspect of these radionuclides. However, the new approved radiotherapy agents (Lu-177) for patient care require a much higher level of experience in using. As it has been said "this is not your grandfather's Buick" the new radiotherapies are not your routine I-131 therapy that has

relatively low risks as it is rapidly excreted from the body except for the focal accumulations in thyroid tissue and thyroid cancer and requires limited patient preparation and followup. The newer radionuclide therapy agents require a higher level of patient preparation, monitoring during therapy and an ability to interpret the follow up diagnostic scans to determine effectiveness and if more therapy is required. If there is any change in training requirement it should be more supervised training in the use of these newer radionuclide therapies that are currently approved and are in the pipeline to become clinically useful. Contrary to past practices this clinical training should be well documented and the person certifying this training should know that in signing this federal documentation that it is subject to the federal laws regarding falsification. From personal observation I can state that the hours of certified training most radiology resident receive cannot be documented if they were legally required to prove this training.

From 1 March to 3 March 2019 the Theranostic World Congress meeting will take place on Jeju Island Korea. I would strongly recommend someone from the committee attend to get an update on the current status of this field and get an insight where it is headed.

In summary the issue of training for AUs rest on having a clear understanding of the new radionuclide therapies that are approved (one) and the one in the pipeline that can be expected to be approved in the future. The I-131 therapy model is not the one that should be used. The new radionuclide therapies require a much high level of knowledge and experience. Commerical interests and speciality groups that are focus on the monetary returns of these therapies are not the expertise to consult regarding training to use these new therapies.

I would also suggest getting in contact with the current world leaders in this field to get their opinion on training requirements for this rapidly expanding field. Suggested contacts:

Andrew Scott, MD, Director of the Department of Molecular Imaging and Therapy, Austin Health, and Head, Tumor Targeting Laboratory, Olivia-Newton John Cancer Research Institute, Melbourne, Australia

Also his article in the JNM should be reviewed - 2018 SNMMI Highlights Lecture: Oncology and Therapy

Dr. Richard Baum Central Clinic Bad Berka Germany He is a recognized leader in the development of theranostic research and therapies.

Dr. C S Bal, Director of Nuclear Medicine and PET, C/O Aiims Hospital, Ansari Nagar-Aiims, Delhi - 110029 India He has developed a nuclear therapy fellowship.

