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Docket: NRC-2017-0094
Patient Release Program

Comment On: NRC-2017-0094-0004
Patient Release Program; Extension of Comment Period

Document: NRC-2017-0094-DRAFT-0077
Comment on FR Doc # 2017-11027

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4/11/2017
82 FR 17465

General Comment

See attached file(s)

91

Attachments

NorCal_CarciNET_NRC

SUNSI Review Complete**Template = ADM - 013****E-RIDS= ADM-03****Add= DB Home (DBH)**



June 23, 2017

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Docket ID NRC-2017-0094,
Patient Release Program Requirements

Dear Chairman Svinicki:

NorCal CarciNET Community appreciates the opportunity to provide comments on the Nuclear Regulatory Commission's current patient release requirements. NorCal CarciNET Community is a patient community based in Northern California representing over 450 Neuroendocrine Tumor (NETs) patients in the San Francisco Bay Area and over 1,500 NETs patients and their caregivers in the United States.

We support the Society of Nuclear Medicine and Molecular Imaging's letter of June 10, 2017 to the Commission¹ regarding patient release programs. The issue of patient access for treatment is critical for our community and we believe that an in-patient requirement for upcoming nuclear medicines therapy for NETs would limit access to a very promising new treatment option for patients. As Calais and Turner² showed, exposure from the outpatient administration of Lu177 Dotatate for NET patients is in the 0.4-0.5 mSv range much less than the 1mSv range suggested.

We appreciate the opportunity to comment on this topic as it impact our care. Please feel free to reach out to us for any further comment or discussion.

Very sincerely,

Josh Mailman
President, NorCal CarciNET Community

¹ http://snmmi.files.cms-plus.com/docs/hpra/Non_Searchable_Folder/SNMMI_NRC_patient_release_2017_FINAL.pdf

² Calais PJ1, Turner JH. Radiation safety of outpatient 177Lu-octreotate radiopeptide therapy of neuroendocrine tumors. Ann Nucl Med. 2014 Jul;28(6):531-9. doi: 10.1007/s12149-014-0843-8. Epub 2014 Apr 1.