

CHAIRMAN Resource

From: Michael Stabin <stabinmg17@gmail.com>
Sent: Saturday, June 01, 2019 12:57 PM
To: Carol Marcus
Cc: Jamerson, Kellee; Cmr. Stephen G. Burns; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Subject: [External_Sender] Re: Comments for June 10th ACMUI Meeting
Attachments: Palestro.docx

Dear Ms. Jamerson (and others)

I add my comments on the proposed Reg Guide to those of Dr. Carol Marcus, in a letter to Dr. Palestro.

Michael G. Stabin, PhD, CHP
Chair, RAdiation Dose Assessment
Resource (RADAR) Committee of the
Society of Nuclear Medicine and Molecular Imaging

On Fri, May 31, 2019 at 2:30 PM Carol Marcus <csmarcus@ucla.edu> wrote:
May 31, 2019

Dear Ms. Jamerson:

Attached are my comments for the June 10 ACMUI meeting regarding draft Regulatory Guide 8.39. I wish to make comments at the meeting. I am also attaching the reference mentioned in my comments.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.

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Mike Stabin
President, RADAR, Inc.
www.doseinfo-radar.com

June 1, 2019

From: Michael G. Stabin, PhD, CHP
Chair, RADIATION DOSE ASSESSMENT
Resource (RADAR) Committee of the
Society of Nuclear Medicine and Molecular Imaging
3809 W 48th Ave
Kennewick, WA 99337

To: Christopher J. Palestro, M.D.
Zucker School of Medicine at Hofstra/Northwell
131 Grotke Road
Spring Valley, NY 10977

Re: Comments on new draft of NRC Regulatory Guide 8.39

Dear Dr. Palestro:

I am writing to express my concerns regarding the new draft NRC Regulatory Guide 8.39. I am profoundly disappointed that the scientific basis of this proposed RG contains the same scientific errors as related predecessor documents, errors that have been extensively and repeatedly refuted in the published scientific literature over many years. Your charter states that the committee:

“...provides advice, as requested by the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR), Office of Nuclear Material Safety and Safeguards (NMSS), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy.”

This advice SHOULD be based on the best scientific data currently available, or the advice is not of value. Members of the RADAR Committee have been perhaps the most active in deliberating this issue publicly, but we are certainly not the only ones. The broad consensus of the scientific community is that the science presented in previous versions of this RG, and now amazingly presented again, are in error. I will mention the specific errors that SHOULD be corrected, and provide the extensive literature basis for doing so.

The principal equation proposed for patient release, based on the completely antiquated (1970) NCRP Report No. 37, is:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-\frac{0.693t}{T_p}})}{r^2} \quad (\text{Equation 1})$$

- Where D(t) = Accumulated exposure at time t, in roentgens,
 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44),
 Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm,
 Q₀ = Initial activity of the point source in millicuries, at the time of the release,
 T_p = Physical half-life in days
 r = Distance from the point source to the point of interest in centimeters,
 t = Exposure time in days.

The fallacies in this equation are:

- 1) The assumption that the patient is a point source, with no absorption of emitted radiation by the patient's body,
 - 2) The use of a non-void period for the first 8 hours after I-131 NaI administration,
 - 3) The presumption of an occupancy factor of 0.75 for the non-void period, and
 - 4) The presumption of internal contamination of 10⁻⁵.
- In 2002, Siegel et al. made actual measurements of patients whose bodies contained I-131 Tositumomab and found that “measured dose rates were 60% (range, 37%–90%; P <0.0001) of the theoretic dose rates from a point source in air...”
 - In 2011, Willegaignon et al. monitored 90 subjects with thermoluminescent detectors after release after treatment of thyroid cancer with I-131 and found significantly lower cumulative doses than predicted by the RG equation.
 - In 2007, RADAR members Siegel, Marcus, and Stabin rationally critiqued all of the RG assumptions in the Health Physics Journal article “Licensee Over-Reliance on Conservatism in NRC Guidance Regarding the Release of Patients Treated with ¹³¹I. Health Phys. 93(6):667– 677; 2007.” It pointed out flaws in all four of the above assumptions, and showed that the correct equation to use is:

$$D(\infty) = \frac{34.6 \times 0.25 \times A \times T_{1/2} \times \Gamma \left(1 - e^{-\frac{0.693 \times \infty}{T_{1/2}}} \right)}{(100 \text{ cm})^2}$$

$$D(\infty) = 8.66 \times 10^{-4} A \times T_{1/2} \times \Gamma$$

... WITH use of the self-absorption factor of 0.6 for activity in the extrathyroidal component of I-131 retention. The treatment of a patient as an unshielded point source (for any radionuclide) is a completely unrealistic assumption, and hampers licensees' ability to release patients who will be absolutely of no hazard to anyone. All of this, with worked examples, and a FREE patient release calculator for many radionuclides, is well documented on the RADAR web site at <http://www.doseinfo-radar.com/ExposureCalculator.html>. This calculational tool is used heavily, on a daily basis, by people around the USA and the world.

It completely baffles me, as well as other members of the RADAR Committee and the scientific community, how the NRC and the ACMUI can go on for all of these years ignoring all of this relevant and well-established scientific literature that could be used to update and refine the old RG. Instead, the same clearly refuted scientific basis is repeated, and used to shackle licensees, patients and their families with unrealistic patient release criteria, as well as irrational instructions about family members needing to leave home and live elsewhere for days to weeks, for patients not to touch or be close to others, and for people to live in fear of mildly contaminated objects in their homes. The ACMUI should *take the lead* in dispelling these unscientific propositions, not be complicit in their prolonged improper imposition on the scientific community. If asked, the RADAR Committee would be very pleased to rewrite this document, using an appropriate scientific basis, and to provide appropriate numerical data and rational instructions to radionuclide therapy patients.



Michael G. Stabin, PhD, CHP
 Chair, Radiation Dose Assessment
 Resource (RADAR) Committee of the
 Society of Nuclear Medicine and Molecular Imaging

REFERENCES AND PERTINENT LITERATURE

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