NUCLEAR PHYSICS ENTERPRISES

INTERNATIONAL NUCLEAR CONSULTANTS

Jeffry A. Siegel, Ph.D.
President & CEO
4 Wedgewood Drive
Marlton, NJ 08053

(856) 899-9767
email: nukephysics@comcast.net

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To: The Honorable Stephen G. Burns
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Chairman@nrc.gov

The Honorable Kristine L. Svinicki
Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
CMRSVINICKI@nrc.gov

The Honorable William C. Ostendorff
Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
CMROSTENDORFF@nrc.gov

The Honorable Jeff Baran
Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
CMRBARAN@nrc.gov

Re: Concerns about NRC-funded patient release study by Dewji et al. in 2015

We are compelled to bring to your attention the attached article published in Medical Physics in 2015 authored by Dewji et al. entitled, "Estimated dose rates to members of the public from external exposure to patients with ^{131}I thyroid treatment." It is important to note that two of the article's coauthors, Sherbini and Saba, are NRC employees, and that this work was funded by the NRC.

The purpose of the study as stated in the abstract, was to compare the dose rate estimates calculated with those estimated using the simplified NRC methodology as proposed in

Regulatory Guide 8.39. The article introduces two new calculational components necessary to estimate dose rates: (1) use of a methodology for biokinetic modeling proposed by one of the article's authors (Leggett), a model originally intended for intravenous administrations of radioiodine but expected to predict equivalent dose rate estimates after oral administrations – additional unrealistic model assumptions were made involving thyroidal activity uptake and bladder voiding patterns; and (2) use of Monte Carlo simulations using the PIMAL computational phantom in various permutations to simulate three likely exposure scenarios associated with public transportation, nursing home and hotel. For the hotel scenario, incomplete assumptions were given and the cause for most concern, i.e., internal ^{131}I contamination, was not considered. Finally, the PIMAL phantom uses dated anthropomorphic body model technology; state-of-the-art medical image-based realistic phantoms are more easily deformable and much more representative of human body anatomy.

In the first place, the purpose of this study was not realized as no comparison was made between the results of this study and dose estimates that would be derived using NRC guidance methodologies as proposed in Regulatory Guide 8.39 in 1997 (the updated NUREG-1556, Volume 9, Revision 2, Appendix U published in 2008, was not mentioned). The authors believe that the Regulatory Guide methods may be too conservative, but fail to adequately and appropriately reference all the previous work, particularly our entire body of work (see references at end for a partial listing of our publications) that has so indicated, based on use of not only improved calculational approaches but also performance of actual measurements and dose validation based on data obtained from badging family members of released patients. In addition, one of these articles by Siegel, Marcus and Stabin published in 2007 in Health Physics (reference #17) was sent to the Commission by Dr. Marcus to ensure they would be aware of it. Since the authors did not compare their results to NRC methods or to the plethora of results reported in the literature, there is no way to verify if their methods or results are even correct, let alone if they would be of any use to licensees.

Secondly, the authors employed various model assumptions involving thyroidal activity uptakes and bladder voiding patterns, did not include any occupancy factors and did not address the more unrealistic assumptions made in the Regulatory Guide or NUREG regarding use of an 8-hour non-void period and its associated occupancy factor of 0.75. Thirdly, only dose rates were estimated, not integrated doses, due to exposure to released ^{131}I patients; these dose rates are of limited value, as even indicated by the authors. In the conclusion section of the abstract, it is stated that: "In estimating external dose to members of the public from patients with ^{131}I therapy, consideration must be given to (patient- and case-specific) administered ^{131}I activities and duration of exposure for a more complete estimate." This is because dose rates by themselves are essentially irrelevant to the 10 CFR 35.75 patient release regulation of maintaining integrated exposure to others so it is not likely to exceed 5 mSv. One needs additional knowledge, such as administered activity, actual biokinetic behavior in an individual patient, distance variation in patient/exposed individual interactions, occupancy factors and time duration of exposure to estimate *integrated dose*s and to ensure that the calculational methodology is somewhat accurate. Also, theoretical calculations require validation with direct

measurements. This has been done by other investigators. If you don't do a good and complete job you will end up thinking incorrectly, as the authors have done, as illustrated in the last sentence of the article: "administered ^{131}I activities for DTC can be higher than in hyperthyroid therapy, potentially yielding scenarios where the final external dose may be higher in the DTC than the hyperthyroid case." On the contrary, as we have previously reported (reference #17), a patient receiving ^{131}I for hyperthyroidism is more likely to expose individuals to larger external integrated radiation doses than a patient receiving ^{131}I for thyroid cancer if appropriate instructions are not provided, due to the much longer retention of a significant fraction of ^{131}I in the body of the hyperthyroid patient.

There are so many technical flaws with this article that we contend it provides little useful information to the radiation protection community involved in treating radionuclide therapy patients, and in fact may provide misleading information that may be potentially harmful to efforts to further the science involved with dose estimation and patient release. It is thus difficult to understand the value of this article and how licensees should view it, if at all. This article was condoned by two NRC employees who are coauthors and even more importantly, this study was funded by the NRC. Even if this article had not been NRC-funded and was authored only by Oak Ridge investigators, it would still not be acceptable, because it failed to cite the copious relevant literature and failed to demonstrate how its methods would result in an accurate, let alone any, methodology to be used reliably by licensees for patient release. At best, this article could have served to validate previous published results, but the authors did not bother to consider the need for such validation. Instead, they just presented a biokinetic model coupled with a computational phantom along with many assumptions, which are unsupported as well, to derive estimated dose rates to other individuals from exposure to released patients after ^{131}I thyroid treatment, data that are of questionable value for use in complying with the 10 CFR 35.75 patient release rule.

We believe that NRC support of such an article is an abuse of User Fees as it is unknown what this study was supposed to achieve. We would like to know who the contract manager and supervisor were as they need to be queried as to why they allowed such a wasteful expenditure of NRC funds. Further, the NRC staff involved (coauthors Sherbini and Saba) appear to not be familiar with or understand the literature or the article they have coauthored. The methodologies reported in this article are not justified or verified and only consider dose rate; however, this work appears to be acceptable to NRC, as two NRC employees are coauthors and it was NRC-funded. It gives the impression, therefore, that all prior methodologies proposed in the various versions of NRC guidance in support of the patient release rule represent a total waste of time, resources and financial expenditure by the NRC.

We have pointed out for nearly 20 years the shortcomings of NRC's methodologies proposed in guidance documents to assist licensees in complying with the 10 CFR 35.75 patient release rule. We have established a body of literature that deals with all aspects of the patient release issue (see references for listing of our publications) and created a section on our website,"RADAR" – the RAdiation Dose Assessment Resource (http://www.doseinfo-radar.com), to address these issues as well as to provide a

calculational tool for patient release that does not rely solely on NRC guidance methods. This body of work enables accurate dose estimation to others from exposure to released radionuclide therapy patients, dose estimates that have been confirmed by dose rate measurements and further validated by empirical data obtained by badging family members of released patients. These methods are more scientifically based, realistic and accurate than those proposed in NUREG-1556, Volume 9, Revision 2, Appendix U, which we have demonstrated result in doses estimates to others that are much too high due to use of extremely overconservative assumptions. **We respectfully request that the Commissioners consider making at least one of us a consultant to the Commission to help with the review of proposals and any updates dealing with any aspect of the patient release rule and to provide realistic information as needed. This will help to ensure that any potential project to be funded is carefully reviewed, analyzed and deemed to be useful before User Fees are spent unnecessarily.**

Thank you for your attention and consideration.

Sincerely,

Jeffry A. Siegel, Ph.D.
President & CEO
Nuclear Physics Enterprises,
Marlton, NJ
nukephysics@comcast.net

Carol S. Marcus, Ph.D., M.D.
Prof. of Radiation Oncology, of Molecular and Medical Pharmacology (Nuclear Medicine), and of Radiological Sciences
David Geffen School of Medicine at UCLA
csmarcus@ucla.edu

Michael G. Stabin, Ph.D.
Associate Professor of Radiology and Radiological Sciences
Department of Radiology and Radiological Sciences
Vanderbilt University
michael.g.stabin@vanderbilt.edu

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