THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Via Federal Register Website ***June 20, 2023***

Comments to the United States Nuclear Regulatory Commission (NRC) Regarding **Docket NRC-2023-0086 Draft Regulatory Guide: Release of Patients Administered Radioactive Material**

Introduction

On behalf of The University of Texas MD Anderson Cancer Center, we appreciate the opportunity to comment on the Draft Regulatory Guide: Release of Patients Administered Radioactive Material. We commend the agency on its commitment to safety and we respectfully offer comments below.

By way of background, The University of Texas MD Anderson Cancer Center in Houston is one of the world's most respected centers focused on cancer patient care, research, education and prevention. It was named the nation's No. 1 hospital for cancer care in the U.S. News & World Report's 2021-2022 rankings. It is one of the nation's three original comprehensive cancer centers designated by the National Cancer Institute.

Comments

Regulatory guidance is used to establish methods that are acceptable to the NRC to demonstrate that the licensee has complied with relevant regulation(s). The proposed revision is overly detailed and complicated and therefore difficult to discern a minimum threshold for compliance. We request that the regulatory guide be more concrete in its guidance and refrain from including caveats about unusual situations, which can cause uncertainty in decision-making. To this end, the draft could be divided into a shorter, more succinct, and effective regulatory guidance document that states the minimum standards to assure regulatory compliance and a separate "best practices" document that could contain the extensive advice in this proposed revision. For example, the proposed revision's recommendation to maintain records in a manner that protects the patient's privacy is better suited in a document describing best practices.

We applaud the proposed elimination of internal dose for children except those being nursed, and it is a step in the right direction, as is the recommendation of dose rate constants rather than exposure rates. However, there are several proposed changes detailed below that we would request the agency reconsider.

Abandoning the occupancy factor of 0.25 as the baseline assumption for the tabular data will be a detriment to many institutions. Given that the underlying regulations have not changed, and the underlying physics has not changed, we question why institutions will now be required to justify patient releases that have been done safely for years. Shifting this burden to licensees does not improve safety or reduce doses. It simply introduces more administrative burden and may cause patients to either reconsider or delay a life-saving treatment for fear of irradiating their loved ones.

The first tier (Tables 1 and 2) is too conservative. It effectively requires nearly all licensees to use the second tier, not just for most treatments, but for some diagnostic Nuclear Medicine studies as well. The justification of an occupancy factor of unity in the Regulatory Guide is deemed to be overly conservative. Additionally, no justification is given for a separation of 1 meter between the patient and the bystander. We do not understand these recommendations. The use of a 25% occupancy factor likely predates the advent of the NRC's risk-based approach in the late 1990s, given that the limit of outpatient administrations was 30 mCi when the public dose limit was 500 mrem a year. A default 25% occupancy factor has served us well in the past and should continue to do so.

The guidance also includes potential restrictions on burial or cremation if a patient should pass away within a certain period following treatment. The agency should consider removing this statement. It is not relevant to Regulatory Guide 8.39. Unfortunately, sometimes a patient passes during or shortly after treatment, but that is never the plan, nor can be predicted. It would also be unethical to withhold a potentially life-saving treatment due to concerns related to burial or cremation. This could block access to care for certain populations or individuals based on cultural or personal burial/cremation preferences.

The discharged seed section is another area we request the agency reconsider. It states that a seed discharged by the patient once they leave the hospital will be considered a lost source and will need to be reported to the NRC. Considering that patients could potentially urinate seeds without realizing it, instructing them or their caregivers to scrutinize their outputs following implantation for some indeterminate amount of time might help satisfy this addition, but is not justified. In the event that a seed is discovered to have been dislodged, asking the patient or caregiver to retrieve the seed from the commode and return it to the licensee is a potentially harmful ask. In fact, it is one of the few times where a low-dose brachytherapy source could realistically cause harm to a bystander. Even if patients and their caregivers are properly trained to watch for and handle an excreted seed, returning it to the licensee does not provide a safety benefit to anyone.

Eliminating the three-compartment model for I-131 Na-I thyroid treatments is questionable, and we request the agency reconsider. The default parameters for the thyroid and extrathyroidal compartments are very useful to have in a regulatory document when patient-specific data are not available, and the release based upon simpler models is too onerous (and much too conservative). Our institutional experience has been that the default parameters for uptake exceed our actual patient measurements in most cases.

Additional specific comments

Page 28, the first paragraph discusses using three to five effective half-lives to determine the duration for the instruction to be followed; this could be excessive and difficult to implement in practice for some institutions. Not all institutions calculate the effective half-life for therapies.

On page 29, lutetium is spelled incorrectly.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

On page 30, we need further explanation as to how geometrical, biokinetic, or attenuation factors could be greater than unity when unity implies a point source with no attenuation and only physical decay? It would be helpful to indicate at this point that this question is answered in the appendices and in Reference 12. Regarding attenuation factors that exceed unity, it is counterintuitive, so a different name should be given to this factor. However, we are not convinced that the attenuation factor can exceed unity in a practical situation. Further analysis can be found in Appendix A.

Clinical Impact on Low-Dose Rate Brachytherapy

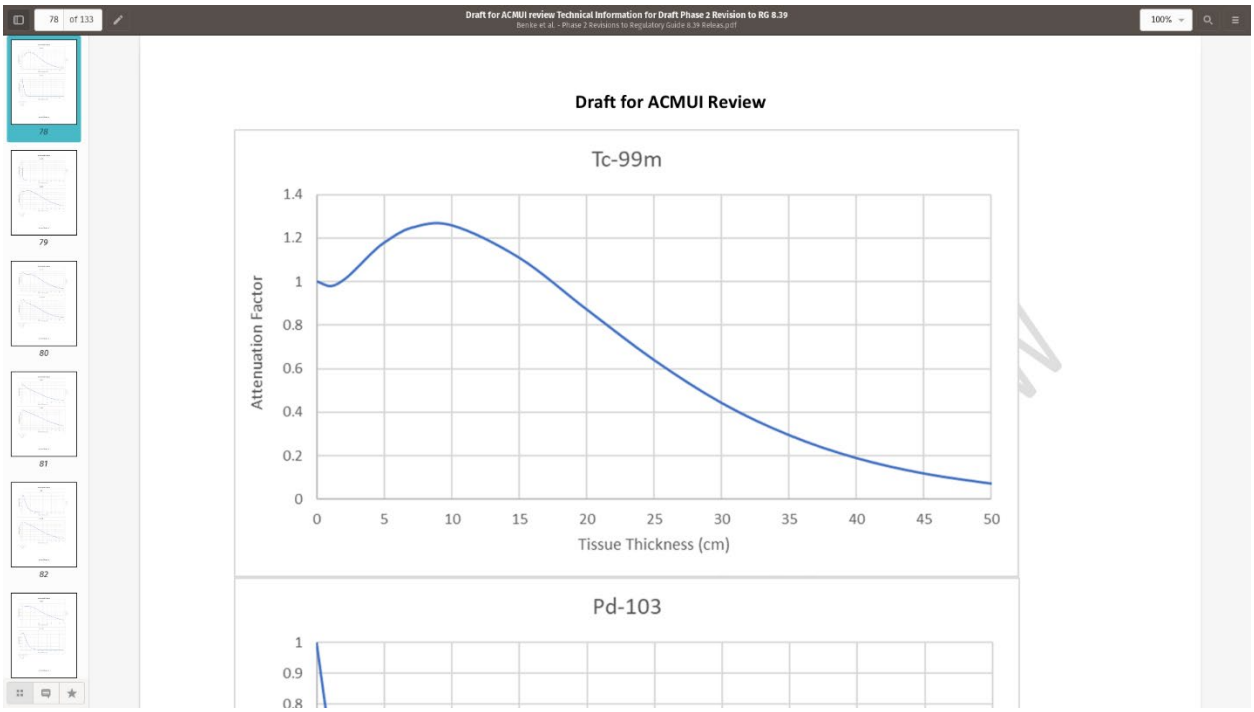
The existing NUREG 1556 patient release criteria have worked for decades, and we need further explanation as to why they need to be changed. Some institutions may consider shutting down their LDR brachytherapy programs if the proposed restrictive release criteria go into effect. This would limit available treatment options for patients, impact treatment outcomes, and make alternative treatment options unaffordable for patients.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Appendix A

On the Effect of Build-Up on the Attenuation Factor in the April 2023 Draft of RegGuide 8.39, Revision 2

The draft of NRC Regulatory Guide 8.39, Revision 2 dated April 2023 and the consultants' report from which it is derived describe situations in which moderate thicknesses of human tissue can produce an additional dose from scattered photons that exceeds the dose that is lost to attenuation of the photons within the medium. The result is that the so-called attenuation factor, F_A, can exceed unity. This is illustrated in the plot below from the consultants' report.

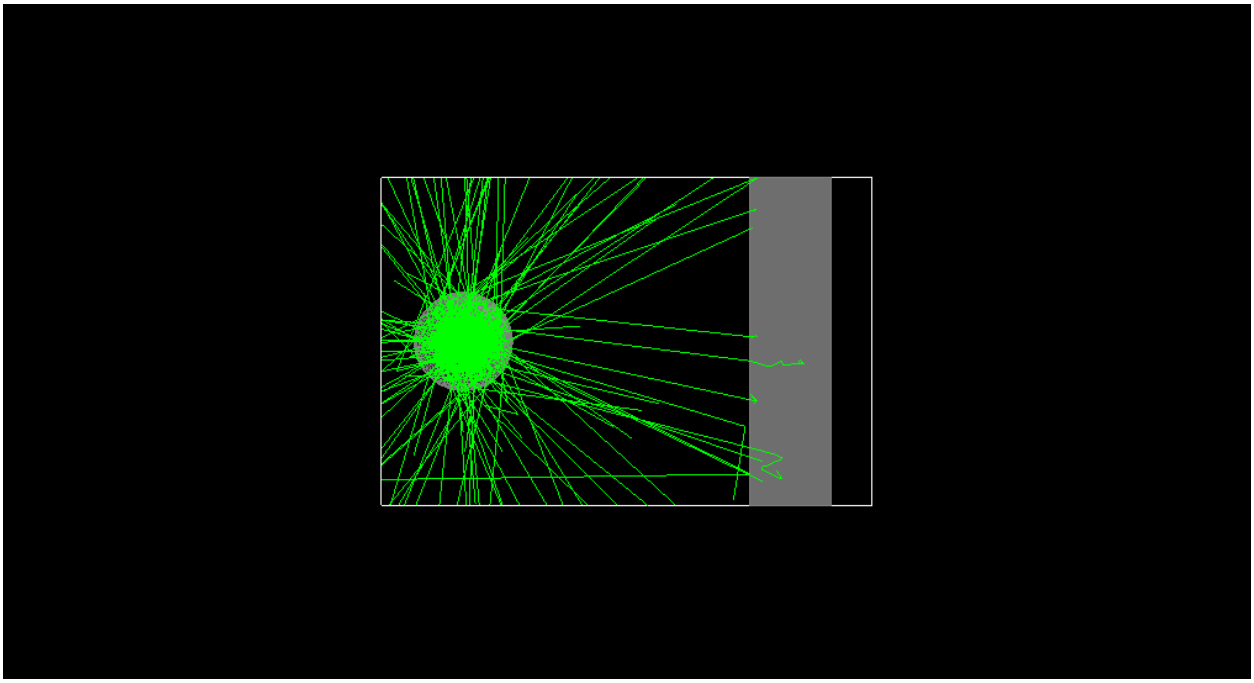


The report does not explain the underlying geometry or how they produced this, but it would involve a point source, a layer of tissue, and a small detector.

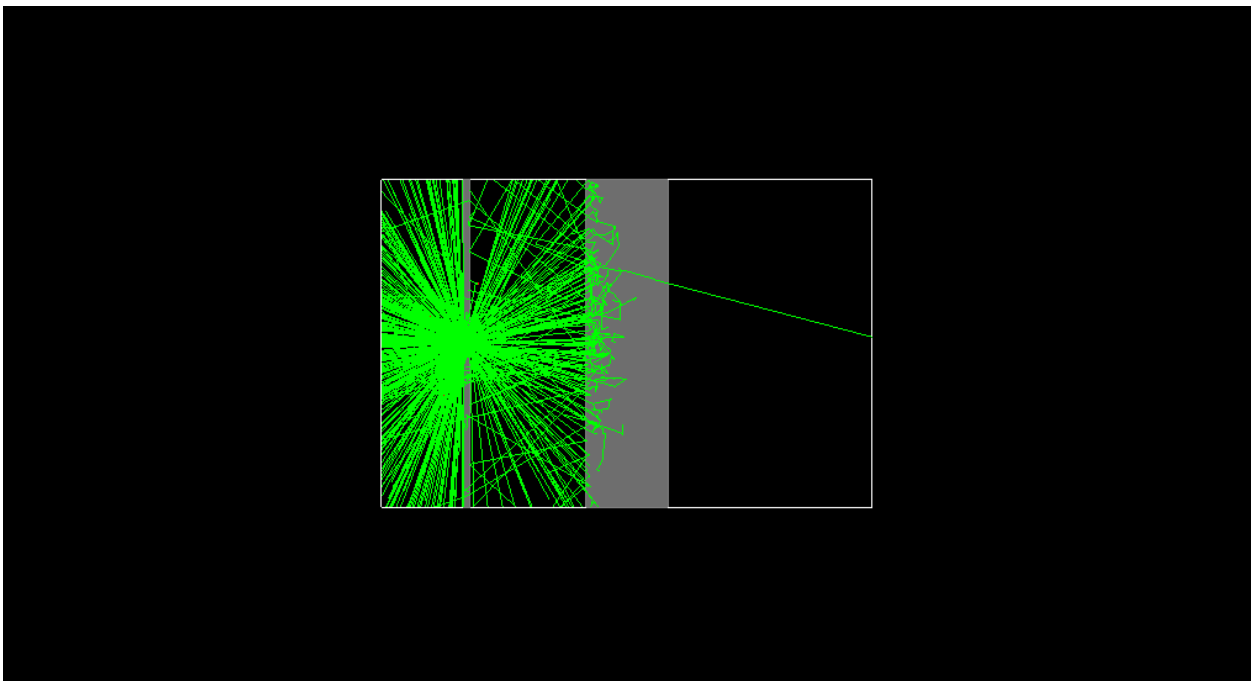
The GATE Monte Carlo software was used to perform simulations to try to replicate this result. In the first set of simulations, a point source was positioned two meters from a 50-cm thick slab of tissue 2 meters wide and 2 meters high. It extends to the edges of the so-called universe such that any particle track that leaves the universe disappears and cannot scatter back onto the tissue slab. A Dose Actor was placed in the tissue slab with voxels that are 5 mm thick. This yielded a

three-dimensional data set that is in units of gray per simulated event, which is similar to a voxel S-value in the MIRD schema. A region of interest placed over the center of the face of the slab toward the source was applied to the second and third layers of the dose data. The dose in the ROI was averaged and the ROI averages from the second and third layers were averaged to yield an estimate of the dose at a depth of 1 cm into the tissue block. This is consistent with the definition of the deep dose equivalent or DDE being the dose at a depth of 1 cm into tissue. The source consisted of the photon emissions of Tc-99m that have energies exceeding 15 keV and abundances exceeding 100 ppm. The point source was surrounded by a sphere of tissue. The radius of the tissue was varied to see the effect of tissue thickness on the dose in the tissue block. These doses were normalized by the dose with no tissue surrounding the source and the resulting transmission factors were plotted. These transmission factors are presumably the same as F_A in the Regulatory Guide.

The geometry of the first simulation is illustrated below for a sphere of tissue of radius 30 cm surrounding the source, which is two meters away from the near face of a block of tissue in which the simulated dose is deposited.

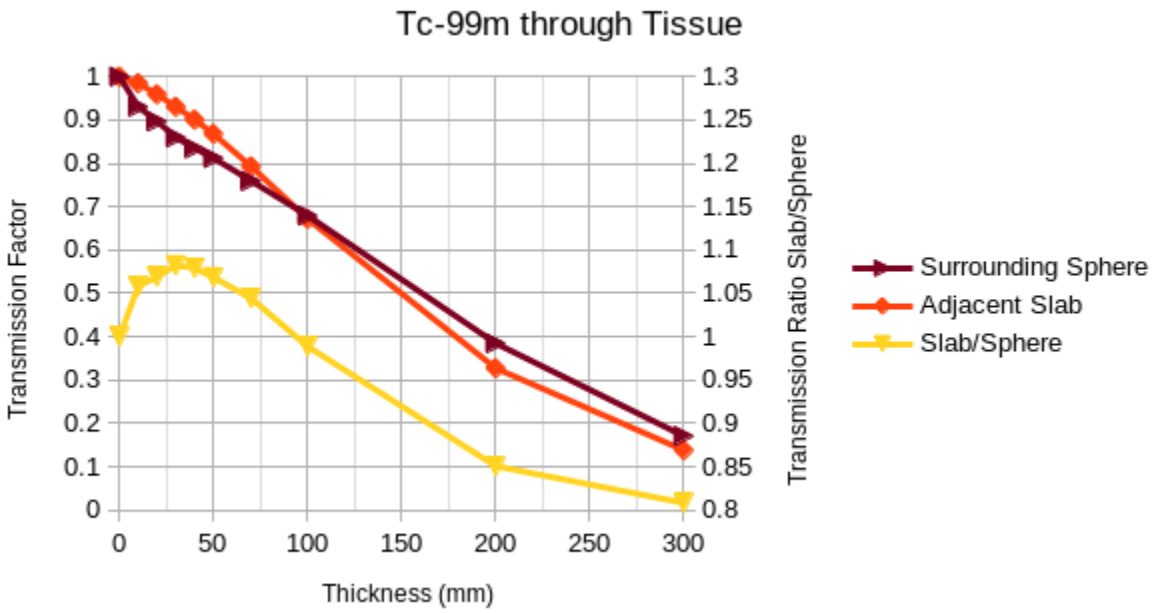


The second simulation was done after the results of the first were analyzed. A point source one meter from the near face of the tissue block was in contact with a slab of tissue of varying thickness. This is shown in the figure below.



Neither simulation produced transmission factors that exceeded unity, although the second simulation's results that are plotted in orange in the figure below appear to show a slight effect like the buildup effect that is described in the draft Regulatory Guide and the consultants' report. When one considers the ratios of the transmission factors through the slab to those through the sphere, one sees a curve, which is plotted in yellow, that bears some resemblance in shape to the F_A curves in the draft Regulatory Guide and the consultant's report. However, this is not an attenuation factor, but a modification to an attenuation factor. Additionally, the effect disappears around a thickness of 10 cm in these simulations whereas it persists until a thickness of about 18 cm in the draft Regulatory Guide and the consultants' report.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®



We conclude that the buildup factor in tissue is nowhere near as significant in our scenarios as in the consultants' report. We urge the NRC not to enshrine this buildup effect in its regulatory guidance until it has been described in more detail, including a detailed determination of how generally applicable it is, and the buildup effect has been subjected to peer review and published.