AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Office of Administration
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Submitted by electronic mail to Katherine.Tapp@nrc.gov

Re: Draft Regulatory Guide: Release of Patients Administered Radioactive Material [Docket ID NRC-2023-0086]

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments on the draft regulatory guide (DG-8061) titled "*Release of Patients Administered Radioactive Material*." AAPM appreciates this opportunity to provide feedback directly to the U.S. Nuclear Regulatory Commission (NRC) with respect to the proposed revision of Regulatory Guide (RG) 8.39, a widely used guidance document for patient release.

EXECUTIVE SUMMARY

AAPM applauds the NRC's efforts and intentions behind the DG-8061 revisions to RG 8.39. The nuclear medicine field continues to grow and incorporate more uses of radioisotopes at an astonishing pace. Updating the guide to be inclusive of new isotopes and procedures, as well as being robust enough for future uses, is absolutely necessary. The goal of overhauling the existing guidance to be more clear, simplified, and explicit is also to be commended.

Though the ambitions are admirable, this draft guidance raises several concerns. AAPM's remarks are organized in five separate sections. The below list summarizes the general themes from each section:

I. Overly Conservative—The proposed revision is overly conservative in calculating bystander doses. Most significantly is the extra factor of 4 being introduced unnecessarily by changing the default occupancy factor from 0.25 to 1. This will likely lead to unintended consequences

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 9,000 medical physicists.

relating to patient outcomes, access to care, healthcare costs, and may undermine RG 8.39 as the standard reference on patient release.

II. Objective and Scope—SECY-18-0015 set a great target for this revision to simplify, clarify, and build the guidance around current scientific knowledge. Instead, DG-8061 brings forth added complexity and a new methodology that the scientific community has yet to test or accept.

III. Methodology—We do not see a clear rationale for creating a new methodology. Both the previous RG 8.39 and NCRP 155 are sufficiently conservative and widely accepted. Instead, DG-8061 could have instructed on the application of these established methods rather than what was proposed.

IV. Patient Instructions—Patient instructions and their behaviors resulting from that instruction are shown to be a highly variable factor for doses to individuals in routine proximity to the patient. If the patient instruction sections can be enhanced for clarity, it stands to achieve higher adherence by patients and far higher dose reductions than the changes in methodology, table values, and patient specific factors.

V. Editorial Items and Language Choice—DG-8061 contains several errors and cases of unclear language. There are many corrections needed throughout the guide beyond those identified in our detailed comments. A rigorous editorial review is highly recommended before finalizing this document.

The changes proposed in DG-8061 will most certainly ensure anyone following the First-Tier approach will remain in compliance with the regulatory requirements around patient release. However, the modifications provide a marked departure from using industry experience and scientific methods to risk-inform regulatory processes. We strongly advise that the NRC must make a substantial course correction with this revision by implementing stakeholder comments, making it clearer and simpler, and creating practical guidance as opposed to this overly conservative approach. If not, the agency jeopardizes its credibility and support from the regulated community for future issues.

SPECIFIC COMMENTS

I. Overly Conservative

A major point made by NRC SECY 18-0015 is that the current RG 8.39 could result in the underestimation of doses. However, by reviewing the SECY's cited study, "Patient Release Following Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations" (Dewji and Hertel, 9/25/2017, ML17262A909), there is no statement or implication that RG 8.39 underestimates doses. In fact, it shows that the current method, employing a point source approximation at 1 meter separation, overestimates the dose by a factor approaching 2.

The authors of that review, Dewji and Hertel, substantiate this further by reviewing more than two decades worth of literature. In that review, studies evidenced actual dose measurements of family members are far below regulatory limits on average, and that the doses received were typically a fraction of what was predicted by the existing RG 8.39 methods.

Occupancy Factors—DG-8061 admits that the justification for an occupancy factor of unity is meant to be a conservative assumption. Additionally, the literature review discussed above demonstrated that the existing RG 8.39 methodology is sufficiently conservative, which uses an occupancy factor of 0.25. Shifting from 0.25 to 1 for a default occupancy factor unnecessarily ratchets up the conservatism by a factor of 4. The default 0.25 occupancy factor served us well in the past; there is no reason to believe it will not continue to do so. If the occupancy factors must be adjusted, then a

simpler and more straight forward method for selecting a value, with descriptions of what factors and how to account for them, is essential.

The First-Tier (Tables 1 and 2) establishes values that build margins upon margins, and multiplies it even further, making the tables impractical for use in any real setting. This layering of safety margins will cause many licensees to use the Second-Tier, not only for treatment but even for some diagnostic studies. Very few of the facilities using this revised RG 8.39 have dedicated medical physics staff, and even fewer possess nuclear medicine physicists. Publishing guidance that by default forces Second-Tier patient-specific dose calculations is non-ideal and introduces complexity. DG-8061's overly conservative approach will lead to indirect harm to the nuclear medicine industry and most importantly to the patients who rely on these services.

During the NRC's presentation on July 20, 2023, NRC staff and their contractor made several statements that began with "the medical physicist can…". Unfortunately, this assumption is not valid for the reasons discussed above, and few facilities conducting these procedures will have access to dedicated medical physics support. The remarks made at this meeting demonstrate a disconnect between what the NRC regards as licensee capabilities and what they are in truth.

For clinics lacking physicist support, they may be inclined to avoid performing procedures if the First-Tier isotope activities are exceeded. This could limit patient access to lifesaving and rapidly evolving radiopharmaceuticals. The overly conservative approach in DG-8061 imposes an unintended barrier to the advancement and expansion of these technologies. For facilities that proceed, they may do so but only by hospitalizing patients. There is no real scientific or safety basis for this.

DG-8061's overly conservative guidance to hospitalize patients imposes unnecessary harm, all to chase the possibility of an extremely small safety gain. The concept of as low as reasonably achievable (ALARA) would suggest the negative costs incurred by the proposed DG-8061 are too high for the dose sparing achieved, thus it is not reasonable. Negative consequences of pushing increased hospitalizations include:

- Patients will be subjected to financial toxicity. This may discourage them from seeking or completing treatments. Not getting appropriate care for a patient is much worse of an outcome than the small radiation risks to a bystander.
- Patients to bear additional distress and discomfort of not being allowed timely and realistic discharge times to their private residences.
- Some hospitals or clinics may opt-out of providing the treatments, hindering access to care.
- Other facilities may reduce the administered activity to be below release thresholds, causing suboptimal care for patients.
- Hospital beds will be occupied by radiation patients, reducing overall capacity for other patients requiring more critical attention for hospitalization.
- Further inflation of already ballooning healthcare costs.
- Radiation protection staff and hospital personnel will be further stretched to manage, survey, respond to patients or their rooms.
- Extra administrative burden could distract personnel from priorities of actual consequence.
- Additional training to the nursing and house staff will be necessary to alleviate possible fears of working around radioactive patients.

II. Objective and Scope

DG-8061 misses what was perhaps the best goal set forth in SECY-18-0015, which states:

"The staff determined that the guidance in RG 8.39, as well as the equations and parameters contained/ referenced in the guide, should be updated, simplified, and made more clear and explicit. A comprehensive update incorporating current scientific knowledge and patient instruction enhancements would lead to a more accurate estimate of public doses from released patients…"

The revised RG 8.39 fails to make the process simpler, clearer, or more explicit. In fact, it arguably makes patient release decisions more confusing for licensees. While an update may be merited, this is a complete replacement of the previous methods. Weighing current scientific knowledge, AAPM does not support the creation of a new method and suggests the NRC utilize existing national standards, such as the National Council on Radiation Protection and Measurements (NCRP) Report No. 155, *Management of Radionuclide Therapy Patients*. More on method selection is discussed in the next section, III. Methodology.

If the intention of this regulatory guidance is to establish a minimum standard that assures licensee compliance with the regulation, then the details of this revision make it hard to discern that minimum. DG-8061 should be more concrete in its guidance instead of adding caveats about unusual situations, such as internal dose to the bystander when the patient is incontinent. Another example of unnecessary discussion is the advice to keep records in a manner that protects the patient's privacy. While this is an essential practice to comply with other federal laws, it is not pertinent to radiation control regulations.

A shorter, more succinct regulatory guide document could better accomplish the minimum standard to assure regulatory compliance. Separate patient-specific, case-by-case, or "best practice" considerations would be reserved for the document's appendices. Appendices could then contain the extensive advice that goes beyond the minimum. This approach would still offer technical resources to facilities taking on the Second-Tier approach. DG-8061 does succeed in expanding the isotope lists to include accelerator produced radionuclides. It also provides helpful considerations for public transportation, hotel stays, and for funeral arrangements that may closely follow a procedure.

III. Methodology

The NRC fell short for using current scientific knowledge to drive this revision of RG 8.39. There was no rationale to create an all-new methodology. NCRP 155 provides reliable, conservative, and accepted ways of calculating bystander doses following administration of radioisotopes. NCRP 155 also includes a spreadsheet program to aid in determining patient release criteria and instructions. Regardless of the changes made in Revision 2 of RG 8.39, providing users with supporting spreadsheets and calculation tools would be welcomed, and the tools would prove useful for navigating patient release criteria.

AAPM is concerned that the approach incorporated in DG-8061 is not well tested and has no established track record. The proposed method is not scientifically peer reviewed or tested in any real-world settings. To our knowledge, not even the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) has condoned its use. The ACMUI commented that:

"*Patient-Specific Modifying Factors and Methods presented… are overly complex and require an unrealistic level of knowledge of extended patient behavior following release. While this calculational methodology is an admirable academic exercise, it is not practical for licensees to use for authorizing and documenting patient release using patient specific factors.*"

It is worth noting that the revised guidance will still only be guidance. Licensees and agreement states can pursue different patient release methods, such as NCRP 155 or the past RG 8.39. Given the original RG 8.39 provides adequate and conservative approaches to achieving patient release, individuals may decide to continue using it instead of what is presented in DG-8061 (to avoid an overly conservative and complex approach). While options are provided by the regulatory framework,

it does not benefit the National Materials Program to publish a regulatory guide that is undesirable for implementation.

Separation Distance—The decision to set 1 meter between the patient and the bystander appears to be an arbitrary value for the default input parameters. There could be further discussion as to why this was selected as the default value.

AAPM agrees with certain aspects of DG-8061's methodology, for instance eliminating the internal dose for all but children being nursed by the patient, and the use of dose rate constants rather than exposure rate constants.

Biokinetic Factor—It would be worth pointing out to readers of this guidance document that the assumed value of unity for the biokinetic factor (F_B) can be updated relatively soon after administration. A more realistic, yet still conservative value, can be achieved by taking dose rate measurements after the patient's initial void. Discussion of using the patient's measured dose rates over time would help in establishing a more accurate value of F_B.

Eliminating the three-compartment model for I-131 Na-I thyroid treatments is a step backward. AAPM recommends including *Table B-1. Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments* from the original RG 8.39. This table and its use should be made more prominent than hiding the concept down in *Example D* of *Appendix C*. Specifically, the default parameters for the thyroid and extrathyroidal compartments are very useful to have in a regulatory document when patient-specific data is not available, and release based upon simpler models is too onerous (and too conservative). AAPM members' institutional experience shows that the default parameters for uptake exceed that of actual patient measurements in the majority of cases.

On page 30, the revision suggests the geometry, biokinetic, and attenuation factors could be greater than unity. This does not make sense when unity implies a point source with no attenuation and only physical decay. The discussion on page 30 would benefit by highlighting the explanations can be found in the appendices and in Reference 12.

Attenuation Factors—Regarding attenuation factors that exceed unity, it is counterintuitive; perhaps a different name should be given to this factor. One AAPM member examined if the attenuation factor might exceed unity in a practical situation but could not show evidence of its plausibility. Their report of on this investigation is enclosed, but the conclusion was such that the buildup factor in tissue is not nearly as significant as described in Reference 12. AAPM urges the NRC not to formally recognize this buildup effect in regulatory guidance until it can be described in more detail, including an extensive determination of how generally applicable it is. More importantly, the effect should be subjected to and pass peer review in a publication process before it is further referenced in regulatory documents.

IV. Patient Instructions

The ACMUI submitted many constructive comments with respect to the draft revision; unfortunately, the NRC dismissed ACMUI's recommended changes regarding specific patient instructions. The rationale for the rejection was that:

> *"The patient instructions and precautions were updated in Revision 1. While editorial changes are acceptable, changing significant content or scope is outside the scope of this revision."*

Outright dismissal of any comment, let alone on patient instructions, is not productive to the overall goal this regulatory guide and of the NRC. Skipping over identified enhancement opportunities for RG 8.39, while it is open and in review, is shortsighted. As a draft, all content should be fair for comment, even if it is not the target of this particular revision.

AAPM supports the ACMUI recommendations and request that they be addressed with this revision:

- *ACMUI Comment: Pg 22, Patient Instructions a-l: Suggest replacing the patient instructions al with the following to be more clear, concise, and consistent with the Patient Precaution section.*
- *ACMUI Comment: Pg 24, Section 4.2.4 Patient Precautions, b. (1): Change sentence to read "Encourage the patient not to prepare or share food with others and to use separate dishware and eating utensils."*
- *ACMUI Comment: Pg 24, Section 4.2.4 Patient Precautions, b.: Delete items (3), (4), and (5) as they are excessive, arbitrary, and not likely to reduce exposure to others.*
- *ACMUI Comment: Pg 25: Delete first full paragraph "The licensee may encourage patients to have available plastic bags, disposable gloves and wipes before treatment," as this is redundant with the previous statement in this section.*

The literature review by Dewji and Hertel demonstrated the critical role of release instructions, and that emphasis and clear communication regarding the most impactful behaviors post-release are significant. They showed that behaviors of patients and those around them have a higher correlation to bystander doses than the actual activity administered. That said, patient release instructions, language, and methods for clear delivery to patients and their families should be a top priority for licensees and regulators.

V. Editorial Items and Language Choice

Below are a substantial number of editorial and language selection comments. Due to the volume identified, it indicates the internal NRC review of DG-8061 received poor attention to detail. A thorough review for accuracy, consistency, practical structuring, and clear language needs to be conducted prior to finalizing this revision to RG 8.39.

Breastfeeding—For questionnaire and instruction purposes, saying only “breastfeeding” may not be sufficient. One extreme case that a member shared was when a woman answered “no” to an I-131 instruction and release questionnaire that asked if they were breastfeeding. Later, local children presented with reduced thyroid function, and it was determined that the patient was pumping and storing milk to be dispensed as a wet-nurse service to her community. Terminology (i.e., breastfeeding vs. lactating, feeding vs. storing vs. discarding) should be looked at carefully by all licensees, and it is worth highlighting in the guidance that confusion around simply saying “breastfeeding” could occur.

“Release of a Patient After a Hold Time”—AAPM supports the ACMUI’s comments regarding the holding a patient in Sections 1.3 and 3.3, namely about the use of this language and concept. Currently, it is not a standard practice in the United States and the lengths of time it suggests would not be practical for many licensees.

Page 4 and 5, it is recommended to use consistent terms such as "Sources Separated from the Patient". However, in the Table of Contents (Page 4) it is referred to as “Material Separated from the Patient”. Later in the document the section is named “6. Sources Separated from the Patient". It is also referenced as “Sources” in the "Reason for Revision" (Page 5).

Page 5, Background: change “…that a license provide…” to “…that a license provides…”.

Page 8, remove the word "in" from "..., but in that individual may be human research subject as well...".

Page 8, change "...the second tier provides a method licensees can use to gather and use patient-specific information..." to "...the second tier provides a method licensees can use to gather patient-specific information...".

Page 9, change "The basic activity threshold Q is calculated by replacing A0 with Q:" to "The basic activity threshold Q is calculated by replacing A0 in equation 1 with Q:"

Page 10, change "...infants or children who continue to breastfeed..." to "...infants or children who continue to be breastfed...".

Page 12, the sentence "...if the patient-specific modification of the activity threshold is such that the TEDE is calculated by using an occupancy factor less than 0.25 at 1 m..." should be rewritten more clearly.

Table 2 (Page 13), footnote “a” suggests some of the values are below background or measuring capabilities. This is not helpful and requires that each person must determine this for themself. It would be better for the NRC to label these according to what standard radiation equipment and practices exist to date.

Table 2, footnote “e” is not referenced anywhere in the table. We assume there would be some isotopes this should be attached, such as C-14, to and recommend it be reevaluated.

Table 2, footnote “f” discusses alpha-emitters, but it is attached to positron-emitters in the table. This needs reviewed.

Page 13-14, ensure consistent capitalization when referring to tables and figures. For example, "...Release activities in column 1 of table 1..." (Page 13) and "Unlike activity threshold (see Table 1) ..." (Page 14).

The section on "breastfeeding patients" appears before the section on "patient-specific dose calculations" in the previous version of the guide, but it has been moved afterwards in the current version. However, the page numbers and contents have not been completely revised accordingly. This has resulted in inconsistencies, such as the order of equations not being properly arranged. For example, Equation 4 is followed by Equation 7 (Page 15), and Equations 5 and 6 are placed after Equation 12 (Page 18-19), the statement "Section 3.3 provides a calculation licensees may use..." (Page 17) should be revised to "Section 2.3" to ensure accurate referencing.

Page 17, the sentence "When the measured dose rate at 1 m exceeds the patient-specific measured dose rate threshold (A0 > M'rel)..." indicates that M'rel (dose rate) can be compared to A0 (activity of the radionuclide), which might not be correct.

Page 18, change "...for a breastfeeding infant or child..." to "...for a nursing infant or child...".

Table 3 (Page 20), columns listing values in GBq and mCi have several errors due to inconsistent equivalents between GBq and mCi. Note that 1 GBq ≈ 27 mCi, but in the table there are cases where 2 GBq is listed as equivalent to 40, 50, and 60 mCi. Every value in every table needs to be evaluated for correct and consistent conversion factors.

Table 4 (Page 21) is calculated to 5 decimal places and 3 significant figures. This does not follow how the values are established in Table 3.

Page 21, change footnote in Table 4 “...on most restrictive..." to "...on the most restrictive...".

Table 4, I125 OIH and I131 OIH are not usually available or at least have not been for a long time.

Table 4, the typical administered activity for I-123 NaI is 0.1-0.4 mCi not 0.01 mCi.

Table 4, the footnote and table values for I125 are confusing because no explanation is provided. I125 NaI is not used for nuclear medicine purposes. We suspect this is a convoluted effort to account for I123 that often contains up to 10% I125 contamination. This might be improved by stating the footnote as, “Could be as high as 10% of the activity of I123 that is administered. This is due to contamination of I125 byproduct while producing I123.”

Page 22, the sentence "...the patient can be released without dose-minimizing instructions Q'ins" is difficult to understand. Should it be revised to "...is relying on instructions..."?

Page 23, the sentence "However, a patient-specific occupancy factor can be used to modify the measurement threshold measured dose rates are independent of occupancy" appears to be incorrectly written.

Page 24 mentions that 10 CRF 35.75 applies to Ac-225 among other radionuclides, yet Ac-225 is not in Tables 1 and 2. Perhaps include them in the tables' lists of isotopes with reference to the footnote and a value of "—" instead of placing alpha-emitting isotopes exclusively in the footnote of "d" or "f".

Page 28, the sentence "Try to maximize your distance from others as much as possible two meters (6.56 feet)" seems to be incorrectly written.

On page 29, lutetium is spelled incorrectly.

Page 42 and Page 43, the reference to "section C.1" in the main body on Page 42 and "section B.3" on Page 43, which is in the appendix, can cause confusion. It is suggested to specify it as "Appendix section B.3" to provide clarity.

"Page 43, it is challenging to follow equations B3-B7 without reading through the example cases. It is recommended to provide a specific definition for ""instruction period"" as the period following instruction after traveling home. Occupancy factor discussion is confusing, some members reported challenges with the equations initially, especially the concept of the "instruction period", but the example cases later did help.

Page 44, the sentence "For the basic dose assessment described in section 1" should be clarified to "section C.1" for accuracy.

Page 45, add a space in "...$F_G$to..." at the bottom of the first paragraph.

SUMMARY

AAPM appreciates the opportunity to comment on this important regulatory guide's revision. While the rationale for revising the guide identifies many opportunities, the proposed revision in DG-8061 leaves substantial room for improvement. Should it be allowed to move forward as written, we fear the guide will lose utilization and relevance in the nuclear medicine community. Additionally, it could drive many unintended consequences, largely due to the extreme levels of over conservatism introduced.

We hope that the NRC seriously considers the comments submitted by AAPM while making any final changes to RG 8.39. If we can provide any additional information, please contact AAPM's Senior Government Relations Manager, David Crowley (david@aapm.org).

Sincerely,

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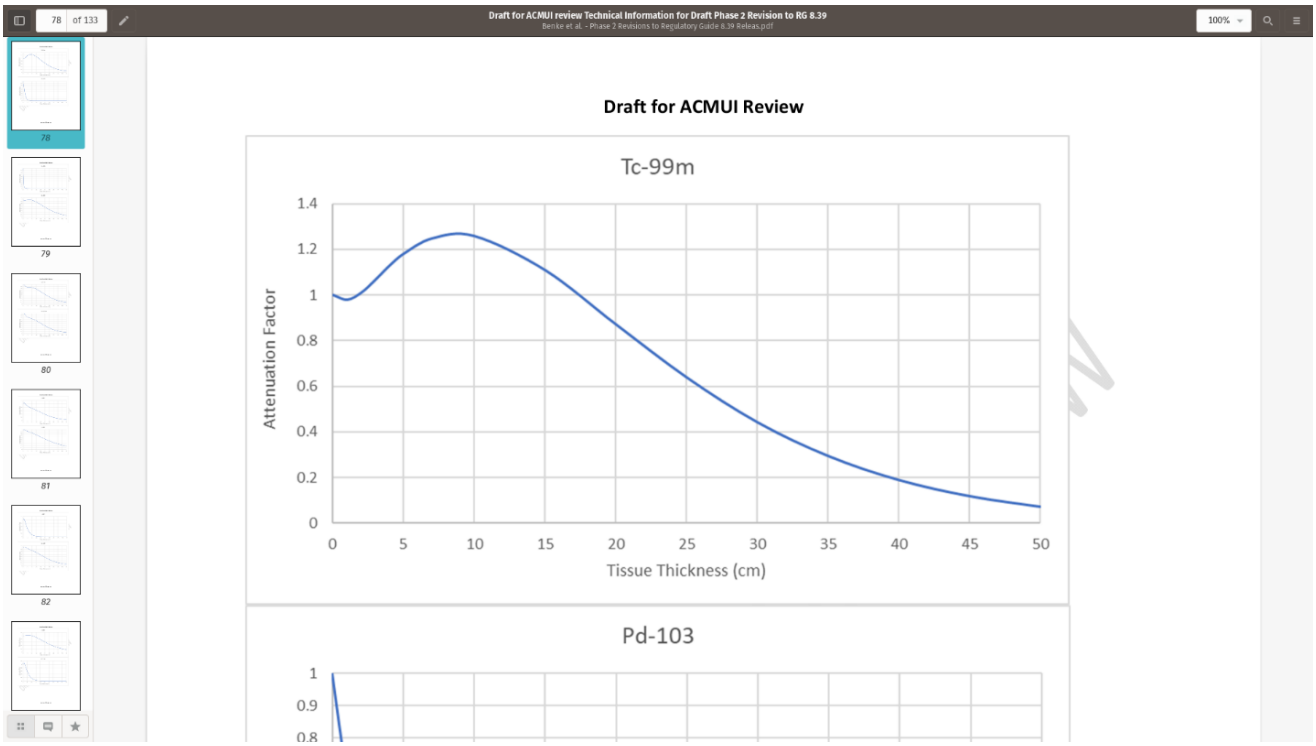
Enclosure 1—On the Effect of Build-Up on the Attenuation Factor Presented in DG-8061 (Wendt)

ENCLOSURE 1:

On the Effect of Build-Up on the Attenuation Factor Presented in DG-8061

Richard E. Wendt III, PhD, FAAPM

The draft of NRC Regulatory Guide 8.39, Revision 2 that is dated April, 2023 along with 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.

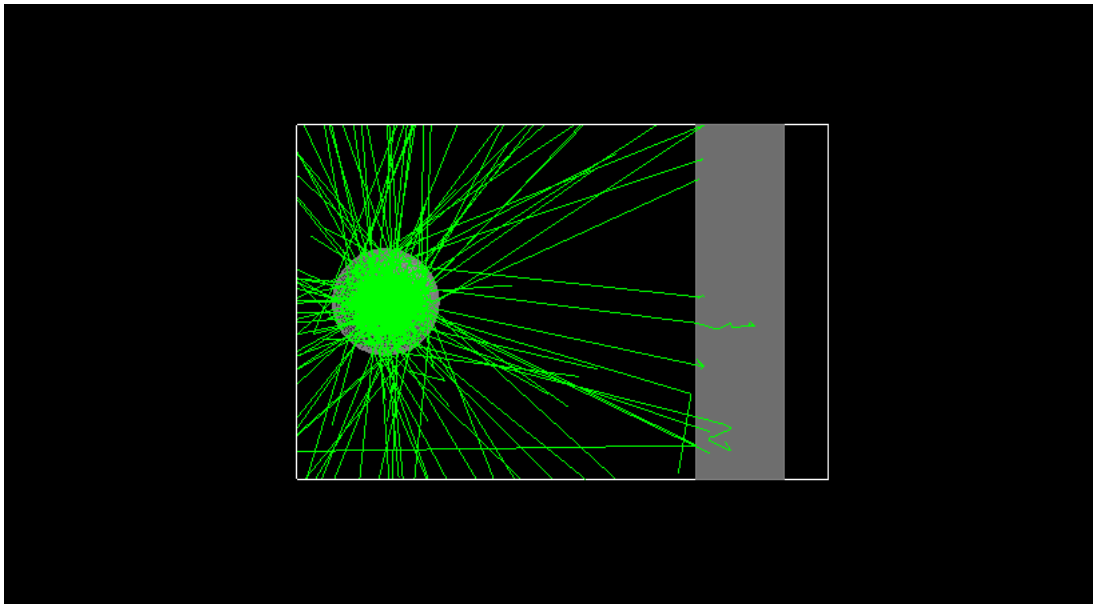


The consultants' report does not describe the geometry of how they came up with this, but it presumably would involve a point source, a layer of tissue, and a small detector.

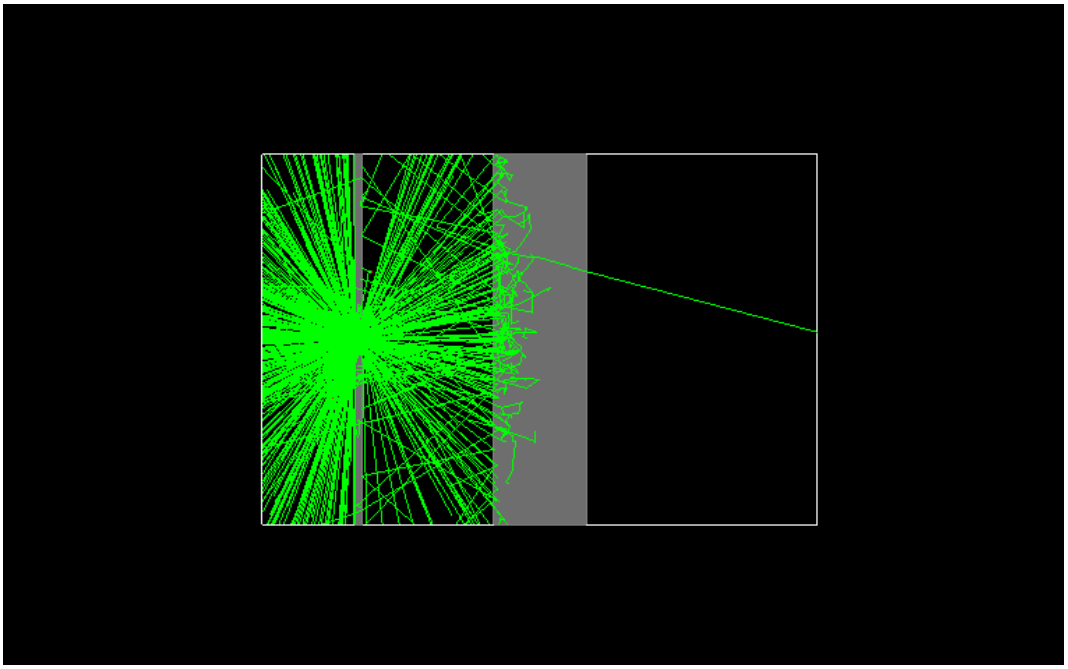
The GATE Monte Carlo software was used to perform simulations to try to replicate this result. In the first set of simulations, a point source was positioned two meters from a 50-cm thick slab of tissue that is 2 meters wide and 2 meters high. It extends to the edges of the so-called universe such that any particle track that leaves the universe disappears and cannot scatter back onto the tissue slab. A so-called 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 very similar to a voxel S-value in the MIRD schema. A region of interest that was placed over the center of the face of the slab that was toward the source was applied to the second and third layers of the dose data. The dose in the ROI was averaged and then 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 in order 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 presumably are the same as F_A in the RegGuide.

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.

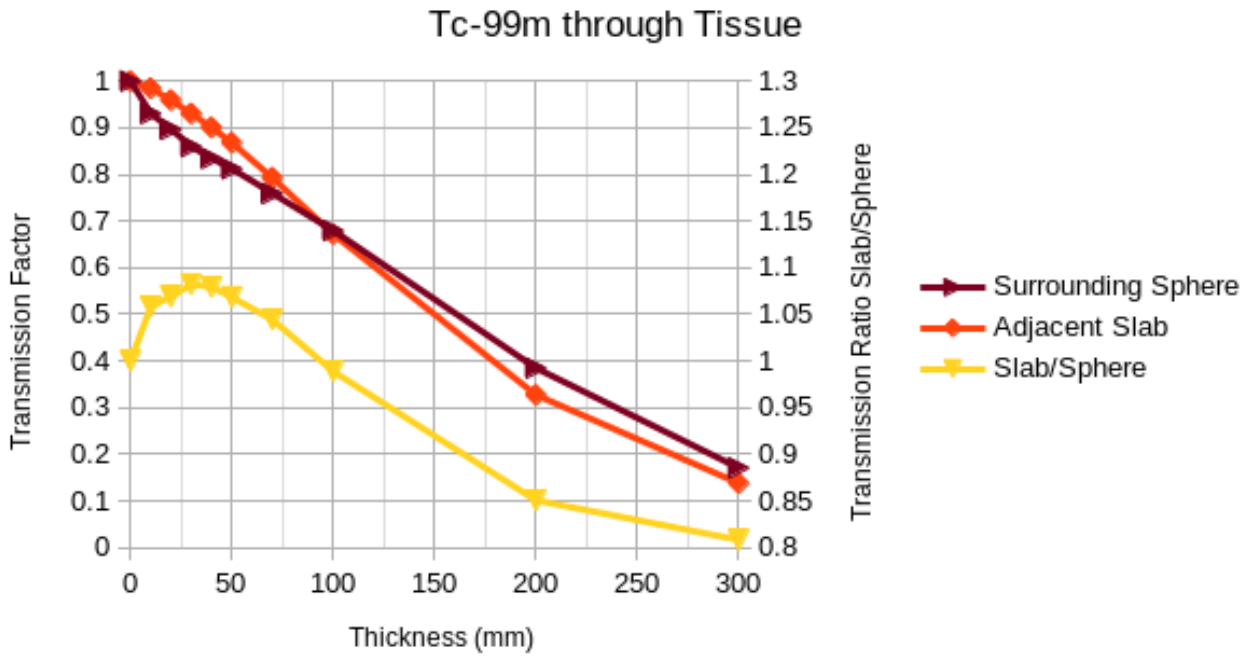


The second simulation was done after the results of the first were analyzed. In it, a point source one meter from the near face of the tissue block was in contact with a slab of tissue of varying thickness. This is shown in the figure below.



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 similar to the buildup effect that is described in the draft RegGuide and in 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 RegGuide and in the consultant's report. However, this is not an attenuation factor, but rather a modification to an attenuation factor. What is more, 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 RegGuide and in the consultants' report.



We conclude that the buildup factor in tissue is not nearly so significant in our scenarios as it is in the basis of 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 it has been subjected to peer review and published.