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General Comment

See attached file(s)

Attachments

Comments on NRC Docket NRC-2023-0086 DG8061(RG8-39r2)-081923 RPLieto

August 19, 2023

Office of Administration
Mail Stop: TWFN–7–A60M,
U.S. Nuclear Regulatory Commission,
Washington, DC 20555–0001,
ATTN: Program Management, Announcements and Editing Staff

RE: Docket ID NRC–2023–0086 Comments on Draft Regulatory Guide 8.39 Rev.2 (also called Draft Guide 8061)

I am a nuclear medical physicist with over 35 years experience in nuclear medicine and as a radiation safety officer in large healthcare systems. I appreciate the opportunity to comment on the draft regulatory guide (DG), DG–8061, "Release of Patients Administered Radioactive Material," by the U.S. Nuclear Regulatory Commission (NRC) announced in the April 21, 2023, *Federal Register* (Docket ID NRC-2022-0218; 88 FR 24495).

All my experience has been in NRC regulated states and involved working with the medical staff administering and patients receiving radionuclide therapies. I am disappointed and concerned by the major change in methodology to calculate doses for patient release with radionuclides. This changed methodology will increase the complexity of determining and documenting patient release and cause licensees to make significant changes in their procedures to release patients who have received radionuclide therapies.

Summary: To avoid adverse impacts on licensees and patients of certain therapies, the NRC is strongly recommended to retract, reevaluate, and revise the draft calculational modifications and guidance in DG-8061 and reduce licensee compliance burden by more realistic baseline assumptions in the guidance and simpler implementation. Some of the reasons for this recommendation are in the following paragraphs.

This draft DG has failed to follow the directions of the NRC in their 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 clearer and more explicit.* The context of this was to address such things as the need to update for NARM radionuclides that had come under NRC authority, restrictions if any for public transport/ hotel stays, additional realistic occupancy factors, release to funeral directors, and more recently release of patient waste into landfills. This is not an update but a replacement methodology made more complex and intentionally ignores a national standard in NCRP 155, which could have been an excellent template to expand the existing guidance document and made more flexible for newer radionuclides. DG 8061 certainly is not simpler or clearer.

When looking at the background for the revision of RG 8.39, it is erroneous to believe that the methodology was inadequate. The intent for revision was initiated to update the existing RG 8.39 to incorporate updated patient instructions, add NARM radionuclides because of new NRC authority invested by the Energy Policy Act in 2008, released patients needing to use motel/hotel for personal or travel reasons, using public transport. The methodology to calculate reasonable and realistic dose estimates for release was not in question; only the numerical values of the factors going into the estimate needed review and possible realistic improvement

and updating for new or NARM radionuclides. This revision seems to have a fixation on accuracy of the calculations with a minimum of restrictions, which is not the realistic situations for which this guidance is used.

There is a serious problem with the Appendices and their single, unique reference. These sections rely on a single reference of NRC contractor-developed information contained in RCD Radiation Protection Associates, RCD-21-181-0. The contractor revising the RG 8.39 wrote this "reference" as only a draft "Research Information Letter Report". It was never peer reviewed and has not been approved by the ACMUI for whom it was written.
Even more disturbing is licensees were not made aware that this singular reference is supposed to be part of the current public review and comment period of the DG8061. Yet, this was never identified by the NRC. It is has never heard of a draft document review where the references are supposed to be reviewed for appropriateness and accuracy. It is very suspicious why the sole, major reference for doing calculations was not identified as lacking review and approval and it was expected that this would occur during public comment.
SECY-18-005 goes on to say *"A comprehensive update incorporating current scientific knowledge and patient instruction enhancements would lead to a more accurate estimate of public doses from released patients, resulting in better licensee decisions regarding when it may release patients following radioactive material administrations, as well as enhancing the patient's understanding of how their behavior, including following the provided instructions, affects the radiation exposure to other individuals."* Nowhere in this statement does it mention changing the methodology. Also, how can the NRC say this revision is based on current scientific knowledge when the primary reference is a single document that has never been peer-reviewed, never been published in the scientific literature, and was not approved by the ACMUI to whom it was addressed!! This is unbelievably bad science!

The ACMUI made many constructive comments and concerns with the draft revision, many which were not accepted. Members of the regulated community and the public were not informed of the NRC's response to the ACMUI review until the mid-August just before this comment deadline despite its earlier generation. All recommended changes regarding the pages addressing specific instructions were dismissed stating, "*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.*" This is not productive and unacceptable. This a draft and only guidance. All of it is available for comment on improvement. The ACMUI provides the medical expertise and representation of the regulated community and their patients. The NRC and its contractor need to give due consideration to all items regardless if they involve changes in Revision 1. Licensees, ACMUI, and public warned the NRC when they announced their two-step revision process that it could very likely create serious conflict. NRC was told explicitly establishing precautions without knowing the final methodology/process could be problematic. Obviously, that is the case. We support the ACMUI recommendations and request that they be properly readdressed.

DG 8061 has established baseline conditions of dose calculations for conservatism and realism assuming the patient is a point source, nearest exposed person is at one meter for 24 hrs. [occupancy factor = 1.0], and no biological elimination. This is not realistic but is extremely overconservative. DG-8061 will be very problematic to implement because using unrealistic baseline conditions, many more patients will require individualized calculations to be

released. During the second webinar while going through calculational examples, the NRC and its contractor repeatedly stated, "The medical physicist can do ..." clearly assuming that a medical physicist is available to do this individualized calcs for each patient. That is a false assumption. Very few licensees have NM physicists. NRC needs to assess what the magnitude of this increase may be, and how this demand will be met, especially in this time of national understaffing in the radiological specialties. The NRC needs to make the patient release process simpler and easier not more complex.

Agreement States will still be given option on adopting this revision, thus creating a national smorgasbord of acceptable methodologies, i.e., current RG 8.39 or the proposed DG-8061 or NCRP 155. This must be addressed to have uniformity of guidance or significant differences will be occurring across geographic borders. A strong recommendation is to consider updating RG 8.39 methodology using NCRP 155 as template and incorporating scientifically valid tables and factors from DG -8061.

A major premise made in NRC SECY 18-0018 is that the current RG 8.39 results in underestimation of dose estimates. This is totally false. In NRC document, "*Patient Release Following Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations*," (ADAMS Accession No. ML17262A909), cited in the SECY, it never states or implies the RG results in underestimates. In fact, it explicitly states that employing the point source method overestimates the dose by at least a factor of 2 (and could be as high as 10X). This overestimate has been substantiated in the literature for more than twenty years:

> Comparing Dose Rates Near a Radioactive Patient Evaluated Using Various Source Models Point, Line, Cylinder, and Anthropomorphic Phantoms. Liu, Yi-Ching; Lee, Kuo-Wei; Sheu, Rong-Jiun. Health Physics 109(1):p 69-77, July 2015
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> Comparison of Measured and Calculated Dose Rates Near Nuclear Medicine Patients. Yi, Y.; Stabin, M.G.; McKaskle, M.H.; Shone, M.D.; Johnson, A.B. Health Physics 105(2):p 187-191, August 2013
>
> Correction Factors For More Accurate Estimates Of Exposure Rates Near Radioactive Patients: Experimental, Point, And Line Source Models. Willegaignon, J; Guimarães, Maria I. C.; Stabin, Michael G.; Sapienza, Marcelo T.; Malvestiti, Luiz F.; Marone, Marília M. S.; Sordi, Gian-Maria A. A. Health Physics 93(6):p 678-688, December 2007.
>
> The Nuclear Medicine Patient as a Line Source: The Source Length Is Certainly Not the Patient Height, But It Is a Reasonable Approximation. Broggio, David. Health Physics 123(3):p 208-217, September 2022.
>
> Calculating the Absorbed Dose from Radioactive Patients: The Line-Source Versus Point-Source Model. Jeffry A. Siegel, Carol S. Marcus and Richard B. Sparks.Journal of Nuclear Medicine September 1, 2002, 43 (9) 1241-1244.
>
> Assessment of the Point-Source Method for Estimating Dose Rates to Members of the Public from Exposure to Patients with 131I Thyroid Treatment. Dewji, Shaheen Azim; Bellamy, Michael; Hertel, Nolan; Leggett, Richard; Sherbini, Sami; Saba, Mohammad; Eckerman, Keith. Health Physics 109(3):p 233-241, September 2015.

Moreover, the literature shows that actual measurements of family members employing the current guidance demonstrate that dose limits are not exceeded and supporting the conservatism of the current methodology for dose estimates.

Measurement of Radiation Exposure in Relatives of Thyroid Cancer Patients Treated With 131I. Ramírez-Garzón, Y.T.; Ávila, O.; Medina, L.A.; More. Health Physics. 107(5):410-416, November 2014.

Radiation dose to family members of hyperthyroidism and thyroid cancer patients treated with 131I Get access. G. S. Pant, S. K. Sharma, C. S. Bal, Rakesh Kumar, G. K. Rath. Radiation Protection Dosimetry, Volume 118, Issue 1, April 2006, Pages 22–27.

External Radiation Dose to Owners of Canines Treated with (117mSn) Radiosynoviorthesis for Osteoarthritis. Smith, Chad A.; Krimins, Rebecca A, Health Physics. 123(2):128-132, August 2022.

Recommended Restrictions After 131I Therapy: Measured Doses in Family Members
Mathieu, Isabelle; Caussin, Jacques; Smeesters, Patrick. Health Physics. 76(2):129-136, February 1999.

Outpatient Treatment with 131I-Anti-B1 Antibody: Radiation Exposure to Family Members. Rutar, R., Augustine, S., et.al. J Nucl Med 2001; 42:907–915

Hold Time -- Nuclear medicine resources are at a premium. This has existed since before the Covid crisis. Release of patients after a hold time based on patient-specific “biological removal” is not a practical option or a realistic scenario. Although it is an interesting educational exercise, it is resource and time intensive option that is a wasteful use of those limited resources. At best it would provide a only a rough estimate of a “hold time” and patient release based measured dose rate would still be required. Addition considerations are exposure to ancillary medical staff, security, and have an unused, accessible empty room for such a unique purpose. Did NRC do any assessment to verify what, if any, frequency this is done? This whole section should be removed from guidance. Such an “option” is undesirable because of the impact upon licensee resources, ALARA concerns, and security.

Many problems have been found with several tables that indicate a poor attention to details of accuracy, consistency, practical implementation, and editing. Some of the problems that have been found are the following:

- The table of contents do not match their page numbers for several items. As an example, “Breastfeeding Patients” appears on page 18 but the table of contents specifies page 15.

Table 2, Patient Thresholds

- Many values are below background or measuring precision. This is referenced in footnote “a”, but this is not helpful and requires that each user of the table has to determine this for themself. This is totally unnecessary and useless and irrelevant.
- Footnote “e” is not referenced anywhere in the table.
- Footnote “f” discusses alpha-emitters, but it is attached to positron-emitters in the table!

Table 3, Breastfeeding

- there are several errors due to inconsistent equivalents between GBq and mCi. For example, 2 GBq is given the equivalent of 40, 50, and 60 mCi.
- Rather than providing the true equivalent value, an inexplicable rounding technique is used which creates errors of around 10%. For example, 1000 mCi is stated as equivalent to 40 GBq when it is by definition 37 GBq. This is done throughout the table. Yet, for Table 4 entries are calculated to 5 decimal places and 3 significant figures.

Table 4, Breastfeeding Interruption

- Info is very confusing regarding the radioiodines. I125 OIH and I131 OIH are not and have not been available for a long time.
- The typical administered activity for I-123 NaI is 0.1-0.4 mCi not 0.01.
- The footnote and table values for I125 are very confusing. I125 NaI is not used for nuclear medicine purposes. Because no explanation is provided. It is suspected this entry is a very convoluted, poorly described effort to account for I123 that is often produced with up to 10% I125 contamination. The footnote might be improved by stating as, "10% of the activity of I123 that is administered (to consider contamination)." It might be more straightforward to have two entries for NaI I123: 1) carrier free I123; 2) I123 + 10% NaI I125.

Where else are there errors or inconsistency in the tables that we did not identify? The NRC must review and confirm for all the tables the accuracy and precision of all the entries and footnotes.

Accordingly for the above stated reasons, the NRC is strongly recommended to retract, reevaluate, and revise the draft calculational modifications and guidance in DG-8061 and reduce licensee compliance burden by more realistic baseline assumptions and simpler implementation in the guidance. I appreciate the opportunity to comment and hope that the NRC addresses the recommendations and comments.

Respectfully,

Ralph P. Lieto

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