



Demystifying NRC Release Criteria for Lu-177 PSMA Therapy Patients

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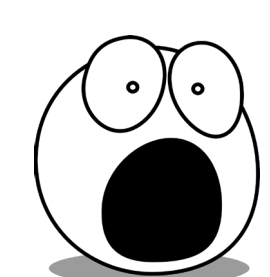
Introduction

Earlier this year, Revision 2 of the NRC Regulatory Guidance 8.39 for Release of Patients Administered Radioactive Material was published for comments. The proposed revision caused concern because the tables for automatic release based on administered activity and dose rate indicate a **four-fold reduction** from the current allowed levels for longer-lived radioisotopes. This seems to indicate that patients treated with the standard 200 mCi of Lu-177 PSMA would have to be treated as inpatients.

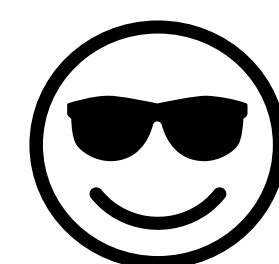
However, the proposed guidelines do still allow for outpatient therapy and are actually more flexible. The current and proposed release guidelines are further examined here.

This poster educates about the current and proposed NRC release criteria, and provides clinical examples showing how to implement them.

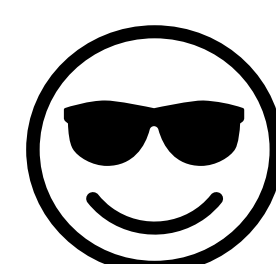
Public Discussion About Proposed Update



"The NRC Revision 2 of 10 CFR 35.75 has changed release criteria significantly. The proposed changes would lower patient release criteria to 8.6 mCi for I-131 and 110 mCi for Lu-177 (Table 1, page 11), This is obviously not going to work for our patients."



"The workaround is to always use modification factors, the easiest being [occupancy factor, self-attenuation, and effective half-life]...One just needs to document and justify the use of modifiers ...[NCRP 155 excel calculator and the patient release calculator from MIRDsoft.org (MIRDrelease)] should be helpful aids in transitioning to adoption of "patient-specific" release calculations."



"...this will change the paperwork burden such that we will have to maintain records of release for many more patients. Technically not a challenge, just a change of practice that will need to be implemented properly."

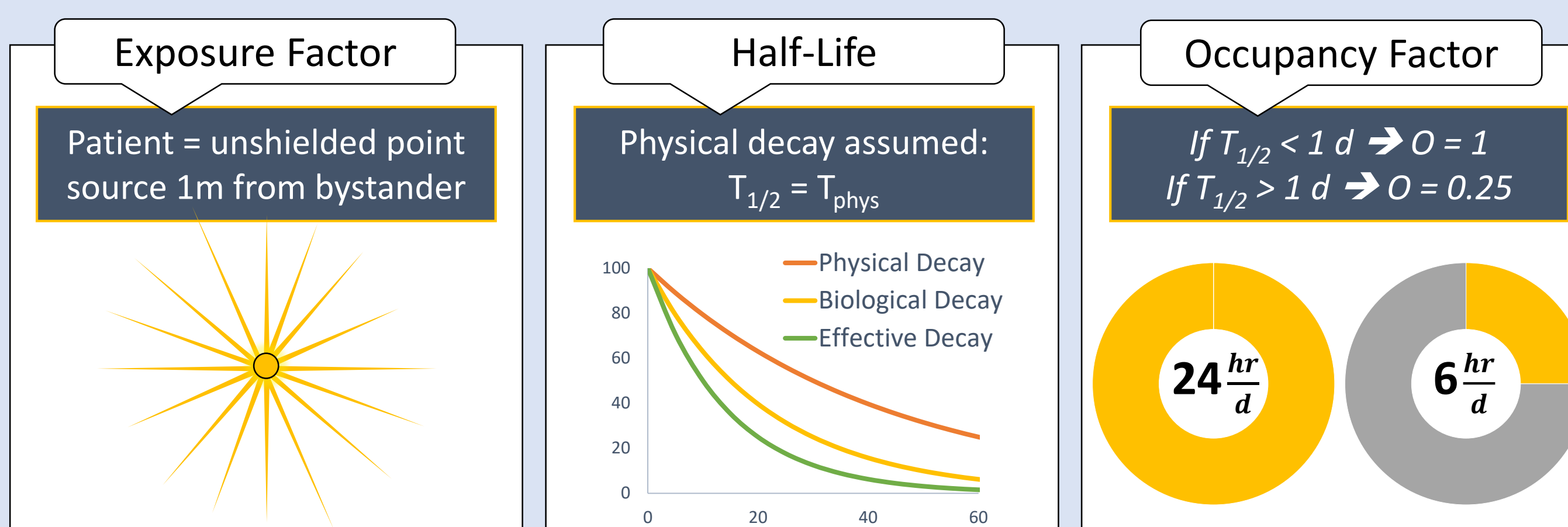
Take-Away Points

1. The NCR RG 8.39 Rev. 1 method for "Release based on administered activity" allows for immediate release of Lu-177 therapy patients based on 200 mCi administered activity.
2. The new Regulatory Guide Rev 2 (under review) will allow for "Tier 2" release of Lu-177 therapy patients given 200 mCi, given that there is documentation of modifying factors. (note, using Occupancy Factor = 0.5 allows release up to 220 mCi).
3. Release based on dose rate at 1 m could be an option for immediate release, even under more restrictive regulations

Current NRC Release Criteria

Default Assumptions:

Conservative assumptions are made to calculate administered activity and dose rate at 1m for which patients can be released, resulting in <5 mSv absorbed dose to the maximally exposed bystander.



Release Options:

Administered Activity or Dose Rate @1m

- Table 1 lists Activities and Dose Rates at or below which patients may be released, however, Lu-177 was not included in these tables...
- You can calculate Administered Activity by solving Equation 2 for Q0 (watch units!)
$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2}$$
- Then, Dose Rate is calculated using: $D@1m = \frac{Q_0 \times \Gamma}{(100 \text{ cm})^2}$
- Alternatively, Revision 2 does include Lu-177 in the tables, which you can multiply by 4 to account for the difference in occupancy factor between Rev1 and Rev2

Administered Activity	440 mCi
Dose rate @ 1 m	8.8 mR/hr

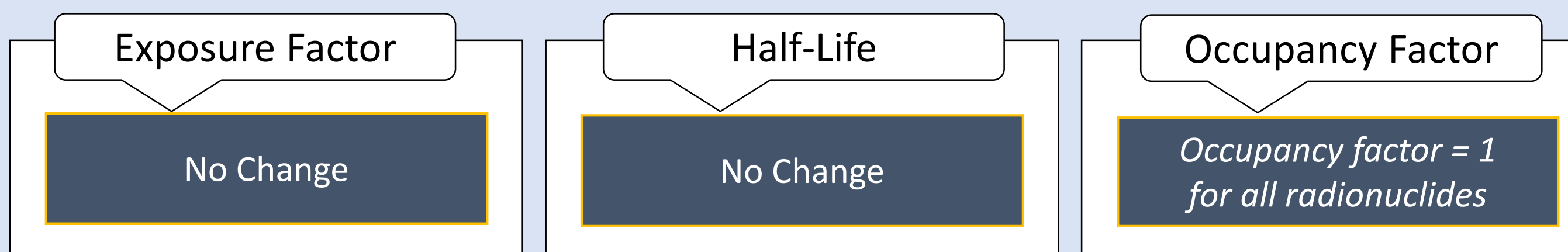
Patient-Specific

- To release a patient administered > 440 mCi of Lu-177 or with a measured dose rate of > 8.8 mR/hr @ 1m...
- Patient-Specific factors can be used in Eq. 2 to calculate $D(\infty)$
- If $D(\infty) \leq 5 \text{ mSv}$, the patient can be released*

*licensees must keep records of the basis authorizing release

Proposed NRC Release Criteria

Assumption Change!



Release Options:

Tier 1

- Occupancy factor of 1 is assumed.
- Tables 1 and 2 include administered activity and 1 m dose rate below which Lu-177 patients can be released.

Administered Activity	110 mCi
Dose rate @ 1 m	2.2 mR/hr

Also:

- The units have also been updated.
- There is a clear description of patient release after a calculated hold time.

Tier 2

- Four Modifying Factors are available:
 1. Occupancy Factor
 2. Geometry Factor
 3. Biokinetics Factor
 4. Attenuation Factor
$$Q' = \frac{Q}{F_B \cdot F_O \cdot F_G \cdot F_A}$$
 Q from Table 1
- Release based on measured Dose Rate: only occupancy factor can be used.
- Equations, explanations, and examples are clearer than in Revision 1.

Practice!
Do YOU think it's ok to release the patient?

Case 1

The table below lists administered activities for two Lu-177 PSMA patients at OHSU. Based on these administered activities, do the patients qualify for automatic release in NRC 8.39 RG Rev 1 and NRC 8.39 RG Rev 2?

Administered Activity	NRC Rev 1 Automatic Release?	NRC Rev 2 Automatic Release?
195.8 mCi	YES	NO
200.5 mCi	YES	NO

- Using 200 mCi, Equation 2 gives $D(\infty) = 2.1 \text{ mSv}$. Since this is < 5 mSv but > 1 mSv, the patient can be released with instructions.
- Revision 2 will allow for "Tier 2" release of these patients, given there is documentation of patient-specific factors such that $D(\infty) \leq 5 \text{ mSv}$.
- For example, if Occupancy = 0.5, then $D(\infty) = 4.5 \text{ mSv}$.

Case 2

The table below lists dose rates measured at 1m from Lu-177 therapy patients at OHSU. Based on these dose rates, do the patients qualify for automatic release in NRC 8.39 RG Rev 1 and NRC 8.39 RG Rev 2?

Therapy	Exposure @ 1 m	NRC Rev 1 Automatic Release?	NRC Rev 2 Automatic Release?
PSMA	1.8 mR/hr	YES	YES
PSMA	2.5 mR/hr	YES	NO
DOTATATE	1.0 mR/hr	YES	YES
DOTATATE	1.5 mR/hr	YES	YES

Case 3

A patient lives in a shared housing situation, in which they share a room and bathroom with a roommate. The roommate also helps the patient with some ADLs, and the roommate cannot relocate at all during the patient's treatment...

Q1: Is the assumption of 0.25 occupancy factor appropriate for this patient?
Q2: What would you want to know in order to make an informed decision about the safe release of this patient?

References

- [1] "NUREG-1556, Vol. 9, Rev. 2, 'Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses,' Final Report." Office of Federal and State Materials and Environmental Management Programs. [Online].
- [2] V. Shaffer, "Release of Patients Administered Radioactive Material, Revision 1." U.S. Nuclear Regulatory Commission, Apr. 2020. Accessed: Jan. 16, 2024. [Online].
- [3] K. Tapp and B. Allen, "Release of Patients Administered Radioactive Material, Revision 2." [Online]. Available:
- [4] "Society of Nuclear Medicine and Molecular Imaging (SNMMI), All Member Community," NRC Revision 2 with severe impact on Therapy. Accessed: Jan. 16, 2024. [Online].