Response to Public Comments on Draft Regulatory Guide DG-8057, "Release of Patients Administered Radioactive Material" Proposed Revision 1 of Regulatory Guide 8.39

On July 26, 2019, the NRC published a notice in the Federal Register (84 FR 36127) announcing that Draft Regulatory Guide 8057 (DG-8057, proposed Revision 1 of Regulatory Guide 8.39) was available for public comment. The public comment period ended on September 26, 2019. The NRC received comments from the individuals and organizations listed below. The bracketed identifiers at the end of each comment relate to the annotations that the NRC applied to the received comment documents. Annotated versions of the received comment documents are available in the Agencywide Document Access and Management System (ADAMS) under the indicated accession numbers. The following table shows the public comments and NRC staff's responses.

The NRC received comments from the following:

Ms. Carol Wen Dated: August 5, 2019 ADAMS Accession No.: ML19219A112	Carol S. Marcus, Ph.D. csmarcus@ucla.edu 1877 Comstock Avenue Los Angeles, CA 90025-5014 Dated: August 2, 2019 ADAMS Accession No.: ML19239A031	Clark Snelgrove clarksnel@gmail.com 1158 S 220 W Orem, UT 84058 Dated: August 23, 2019 ADAMS Accession No.: ML19235A304
Thomas Morgan Ph.D., CHP tom.morgan@versantphysics.com Versant Medical Physics and Radiation Safety 116 S. Riverview Dr. Kalamazoo, FL 49004 Dated: August 28, 2019 ADAMS Accession No.: ML19241A189	Edwin M. Leidholdt Veterans Health Administration 2200 Fort Roots Drive North Little Rock, AR 72114 Dated: August 15, 2019 ADAMS Accession No.: ML19253A037	James Grice Colorado Department of Public Health and Environment james.grice@state.co.us 4300 Cherry Creek Drive S Denver, CO, 80246-1530 Dated: September 18, 2019 ADAMS Accession No.: ML19261B908
Peter Crane kinderhook46@yahoo.com 6545 27th Avenue Northwest Seattle, WA, 98117 Dated: September 21, 2019 ADAMS Accession No.: ML19267A063	Geraldine McGinty mpeters@acr.org American College of Radiology Dated: September 25, 2019 ADAMS Accession No.: ML19275F869	Craig Little, Ph.D. President, Health Physics Society agencyliaison@hps.org Dated: September 26, 2019 ADAMS Accession No.: ML19275F872

Terry Derstine Organization of Agreement States Chair Radiation Protection Program Manager Pennsylvania Department of Environmental Protection Southeast Regional Office 2 E. Main Street Norristown, PA 19401 Dated: September 25, 2019 ADAMS Accession No.: ML19275F879	Daniel Miron, CHP dmiron@mpcphysics.com W176S8019 Joel Drive Muskego, WI, 53150 Dated: September 25, 2019 ADAMS Accession No.: ML19275F884	Cynthia McCollough, PhD, FAAPM, FACR, FAIMBE President American Association of Physicists in Medicine Dated: September 26, 2019 ADAMS Accession No.: ML19275F887
David Reindl david.reindl@wi.gov Wisconsin Department of Health Services P.O. Box 2659 Madison, WI, 53701-2659 Dated: September 26, 2019 ADAMS Accession No.: ML19275F890	Josh Mailman President NorCal CarciNET Community Dated: September 26, 2019 ADAMS Accession No.: ML19275F896	Caitlin Kubler Associate Director, Health Policy and Regulatory Affairs, Society of Nuclear Medicine and Molecular Imaging ckubler@snmmi.org Dated: September 26, 2019 ADAMS Accession No.: ML19275F904 ML19275F910
Aria Razmaria arazmaria@mednet.ucla.edu Department of Molecular and Medical Pharmacology David Geffen School of Medicine at UCLA 200 Medical Plaza, Suite B114 Los Angeles, CA 90095 Dated: September 26, 2019 ADAMS Accession No.: ML19275F910	Christine Pepper Chief Executive Officer National Funeral Directors Association 13625 Bishops Dr Brookfield, WI 53005 Dated: September 11, 2019 ADAMS Accession No.: ML19298A002	

Commenter	Comment Category	Specific Comments	NRC Resolution
Carol Wen	Specific	On page 14 of the practice guideline it states there is no hazard to any member of the family arising from sites where the patient sits, what the patient has touched, or what the patient cooks. Internal exposure of family members from items contaminated by patient salvia or urine must be prevented. Disposable plates and utensils are not only unnecessary but, if used, can trigger sensitive waste facility alarms; dishes and utensils should not be shared before washing. It is unnecessary to wash the patient's laundry separately.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are items that should be considered by the licensee and used on a case by case basis. Each treatment is unique and therefore we cannot determine how long a patient should follow any of the precautions. This should be determined by the licensee. The NRC staff will review the Society of Nuclear Medicine (SNM) "Practice Guideline for Therapy of Thyroid Disease," and modify Section C.2.3.2 in Regulatory Guide (RG) 8.39 as appropriate during phase 2 (phase 2 work for RG 8.39 scheduled for completion by 2023).
Carol Wen	Point of Clarification	The Society of Nuclear Medicine & Molecular Imaging has published a procedure standard named The SNM Practice Guideline for Therapy of Thyroid Disease with 131I 3.0. A copy of this practice guideline is attached. The draft Regulatory Guide has a list of precautions and measures on page 15 and 16. Some of the precautions and measures contradict with the above statement provided in the Nuclear Medicine Practice Guideline. For example, on page 16, (2) encourage the patient not to prepare or share food with others. (4) encourage patients to use disposable eating utensils. (6) encourage the laundering of a patients clothing separately from other household members clothing. Also if these are recommended, for how long should the patient not prepare food, use disposal eating utensils, or laundry separately?	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that "should" be considered by the licensee. If the license uses these instructions, they should use their judgment and provide them to the patient on a case by case basis based on the treatment. Each treatment is unique. The NRC staff will review the SNM Practice Guideline for Therapy of Thyroid Disease and modify Section C.2.3.2 in RG 8.39 as appropriate during phase 2 (phase 2 work for RG 8.39 scheduled for completion by 2023).

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Carol Wen	Point of Clarification	On page 15 of the draft Regulatory Guide, it states emphasize the importance of keeping an adequate distance from others, especially children and pregnant woman. The word children here means anyone who is less than 18 years old, correct?	The NRC staff agrees with the comment, but no changes were made to the guidance in response to this comment. The word “child” or “children” in this context refers to a minor, which is an individual under the age of 18.
Carol S. Marcus	Specific	P.6 bullet 7: This is an utterly preposterous section. For radionuclides with a half-life that is less than or equal to one day, it is actually easier, not more difficult, to justify an occupancy factor of 0.25 and perhaps less, because the patient is in the nuclear medicine clinic and their contacts can be controlled. In addition, it is virtually impossible for reasons of pharmacokinetics, biochemistry, and dosimetry that a therapy radiopharmaceutical with a half-life of one hour or less and moderate to strong gamma radiation accompanying most or all disintegrations will ever be developed. The NRC staff does not appear to understand enough nuclear medicine to realize this.	No change was made to the guidance in response to this comment. An evaluation of potential updates for the occupancy factor will be done during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	P.8 Section 1.1: This whole section is ridiculous. In the first place, keeping calculations for NRC inspection makes no sense because the NRC staff does not understand how to do these calculations and can't check anything. Second, it is likely these days that many or most calculations are done using the RADAR interactive dose calculator. So go check RADAR, but quit bothering the physicians with this asinine paperwork.	No changes were made to the guidance in response to this comment. The potential inclusion of RADAR will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	P.11 Table 2: I don't think that Ag-111, Au-198, I-125, Re-186, Re-188, Sc-47, Se-75, Sn-117m, or Yb-169 have been used in decades. On the other hand, F-18, N-13, 0-15, Ga-68, Lu-177, I-124 and Ra-223 are missing from the table. Doesn't the NRC know what radionuclides are being used in nuclear medicine?	No change was made to the guidance in response to this comment. An evaluation of which radionuclides may be added or removed will be done during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

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Carol S. Marcus	Specific	P.12 Paragraph 1: The regulatory limit is 500 mrem, not 100 mrem. The NRC is fraudulently stating that the dose to a nursing infant must be under 100 mrem. The NRC ought to know Its own regulatory limit.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The purpose of Table 3 is to provide activities that could exceed 100 mrem and therefore would require the licensee to provide instructions to the patient pursuant to NRC regulations.
Carol S. Marcus	Specific	P.12 and 13, Table 3: The ACMUI subcommittee report submitted newly calculated breastfeeding interruption limits. It also included a reference to older limits being used at Memorial Sloan Kettering Cancer Center. That reference is not to be substituted for the newer calculations submitted by the subcommittee (basically Pat Zanzonico's subcommittee calculations). In addition, some values in DG-8057 do not correspond to the subcommittee's calculations. For example, I-123 MIBG should not be 24 hours. It should be "no interruption". Ga-67 and Zr-89 do not state to what they are attached. Lu-177 is not used as a diagnostic agent. As a therapeutic agent, the interruption should be for 27 days, not complete cessation. For Zr-89 whatever, it should read 21 days, not 28 days. Ga-68 octreotide should read Ga-68 all radiopharmaceuticals, and it should read no interruption, not 4 hours. 1-124 Nal should read 28 days, not complete cessation. Note that all these NRC errors err on the conservative side, even though the calculations themselves are very conservative. But they are blamed on the subcommittee report, not the NRC staff. The most egregious problem is that the NRC has failed to include the 500 mrem calculations, all of which are in the subcommittee report. The ACMUI voted unanimously to include the 500 mrem calculations, but the NRC staff ignored them.	No changes were made to the guidance in response to this comment. Further analysis on Table 3 for the recommended duration of interruption of breastfeeding will be performed during phase 2 of the RG update. Phase 2 revision is going to be completed in 2023.

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Carol S. Marcus	Specific	P. 13 Footnote b, at the end, the NRC states, "For Tc-99m radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single 24-hour interruption period is recommended. Although this time interval may be longer than necessary for some Tc-99m labeled radiopharmaceuticals, it is compliant with the 0.1-rad dose limit and simplifies the guidance, thereby avoiding confusion and reducing the likelihood of error." First, the limit is 0.5 rad, not 0.1 rad. Second, suggesting that physicians are too dumb to read a number for a specific radiopharmaceutical off a table and are prone to making errors doing so is insulting and ridiculous. Although NRC staff can't copy numbers correctly into a table, physicians are a lot smarter. The 0.5-rad limit for each Tc-99m radiopharmaceutical should be included so no one is unnecessarily conservative.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The regulatory threshold for a patient to receive instructions is 100 mrem and not 500 mrem.
Carol S. Marcus	Specific	P. 14 Paragraph 3: The NRC cautions against the volatility of 1-131 Nal. This was only an issue in past years when the NRC made a rule forbidding adding any chemical to an FDA-approved radiopharmaceutical. All American manufacturers of 1-131 Nal, as solution or capsules, were made extremely basic and EDT A was added to chelate metal ions that might contribute to volatility. This decreased the volatility from 10-15% (roughly) to 10 exp -6 for the solution and 10 exp-5 for the capsules (measured in several radiopharmacies). FDA did approve a Nal-131 from France that was not stabilized against volatility. The FDA assumed the radiopharmacy would take care of it. In fact, the radiopharmacies were taking care of it until NRC passed this foolish rule. Volatile 1-131 N al was all over the place until the rule was rescinded after much	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. In Section C.2.3, second paragraph, the NRC added the word "potential" before the word "volatility."

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		effort (it took about five years of hard work). At present, and for many years, all preparations of 1-131 NaI are stabilized against volatility, and therefore volatility is no longer a problem.	
Carol S. Marcus	Recommendation	P .15 Item e: Competent nuclear medicine physicians know enough to not give I-131 NaI to dying patients. It doesn't do any good and leaves us with a radioactive corpse. Once in a great while a patient given I-131 NaI dies of something other than thyroid cancer (for example, a heart attack), but this is extremely unusual. Competent nuclear medicine physicians need to then measure the exposure rate from the corpse at a meter with an ion chamber, and then do the calculations and decide about burial or cremation, and whether the body needs to be stored in the morgue before either procedure. It's not difficult. Usually at least several days have gone by from I-131 NaI administration to death, and most of the I-131 has been excreted.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. An event was reported to the NRC staff last year in which an individual was cremated, and the crematorium was not aware that the individual had received radioactive therapy. The location was contaminated. This section will remain as a reminder to consider this scenario as possible.
Carol S. Marcus	Specific	P. 16 (1): Children and pregnant women may receive up to 500 mrem just like other adults, and in almost all cases may remain at home. If the child is very young and requires a great deal of care, then another caregiver needs to be present. But they can be in the same household.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.3.2(a) was modified to read: "Or can another individual come and take care of the children and any pregnant household member in their home?"
Carol S. Marcus	Specific	P.16 (2): If the patient is making food for others, explain that I-131 comes out in sweat and give the patient multiple pairs of disposable gloves that can be reused after rinsing. It might not be practical to try to stop the patient from cooking for others.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.3.3 was modified to read: "If choosing to prepare food for others, consider using gloves while cooking."

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Carol S. Marcus	Specific	P.16 (3): No data have ever been shown to require separate bathrooms. I-131 as iodide is soluble in water, so using the sink, the shower, or the toilet should not preclude others from using the same facility. A few loose atoms here and there are not important.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. For ALARA purposes, it is in the patient's and others' interest to be cautious with the bathroom usage.
Carol S. Marcus	Specific	P.16 (4): No data have ever been shown that requires separate washing, in a sink or a dishwasher. Do not encourage the patient to use disposables, because these ends up in garbage dumps that may be monitored for radioactivity and although the levels of radioactivity are not dangerous, the people who run garbage dumps don't understand that and there can be problems.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that should be considered by the licensee. The license should use judgement with the instructions needed for the patient on a case by case basis based on the treatment.
Carol S. Marcus	Specific	P.16 (6): No data have ever been shown that requires separate washing of clothing. While numerous nuclear medicine documents throughout the years have promoted separate washing of eating utensils and clothing, and the use of separate bathrooms, and the NRC may reference these, none have ever shown data supporting such advice.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that should be considered by the licensee. The license should use judgement with the instructions needed for the patient on a case by case basis based on the treatment.
Carol S. Marcus	Specific	P.16 last paragraph: It is not necessary to dwell on measures to limit contamination of objects and surfaces. This contamination level has been measured and is very low and not a problem.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that should be considered by the licensee. The license should use judgement with the instructions needed for the patient on a case by case basis based on the treatment.

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Carol S. Marcus	Recommendation	P.17 Patient Instructions: a, b, and d are not necessary, and in c remove disposable kitchen utensils. In i, omit preparing food, but state that if preparing food it's a good idea to wear disposable gloves.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that should be considered by the licensee. The license should use judgement with the instructions needed for the patient on a case by case basis based on the treatment.
Carol S. Marcus	Recommendation	P .17 Paragraph 2: In the event a patient becomes pregnant around the time of I-131 N al administration, 5 rem is too low a dose for reporting. A dose like this may occur with a dose of l-131 Nal for hyperthyroidism. But this is too low a dose to have an effect on the embryo (Schwulst SJ and Son M: Diagnostic imaging in pregnant patients with suspected appendicitis. JAMA 322(5):455-456, 2019). All the NRC accomplishes is making the patient fearful. A dose of 50 rem would be a scientifically more reasonable reporting limit, if we need one at all. What can NRC do about it?	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. RG 8.39 does not address dose limits. Dose limits are set in 10 CFR Part 20 and 10 CFR Part 35.
Carol S. Marcus	Specific	P.18 2.3.4: No paperwork documenting patient acknowledgement of instructions is necessary. The contents of 2.3.4 is not a regulatory requirement, and this extensive paperwork is an excessive burden with no value.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. While paperwork documentation of the acknowledgement of instructions is not a regulatory requirement, the NRC still recommends this for the both the licensee and patient. NRC's regulatory experience has shown that there is a regulatory benefit from documenting the instructions that are provided to the patient.
Carol S. Marcus	Specific	P.18 2.4: The Authorized User (AU) Physician should be handling this, rather than the RSO (who is often another physician). Autopsies are very rarely done on these patients.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. The term authorized user was added to the end of the first paragraph of Section C.2.4.

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Carol S. Marcus	Recommendation	P.18 k: Children and pregnant women do not require different instructions than other adults at this low radiation dose.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. Children and pregnant women have been shown throughout literature to be more sensitive to radiation effects.
Carol S. Marcus	Specific	P.18 Paragraph 2: Licensees do not usually meet family members of patients to be treated, and only occasionally meet caregivers. Talking to family members and caregivers about the possible death of a patient does not make sense. Dying patients belong in the hospital and should not receive I-131 Nal.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. There have been cases in the past where a patient received radiation treatment and then subsequently passed away, and the cause of death was not the radiation treatment. This section will remain for licensees to consider this potential occurrence and to consider following the guidance provided. The NRC understands that the probability of a cremation contamination incident is low; however, this has occurred. See "Radiation Contamination Following Cremation of a Deceased Patient Treated with a Radiopharmaceutical." Journal of the American Medical Association (JAMA, 321:8, pg. 803). February 2019.
Carol S. Marcus	Recommendation	P.19 2.5: I am not aware of any long-lived contaminant in any therapeutic radiopharmaceutical that is present in high enough concentration to be an actual hazard. If NRC has no actual examples, this paragraph should be removed.	Section C.2.5 has been deleted. Long-lived contaminants are not an issue in regard to patient release.

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Carol S. Marcus	Recommendation	P.20 3.1: NRC states that the record should include the patient's identifier. At the end of section 3.1 NRC states that the records should not contain the patient's name or any other information that could identify the patient. These are mutually exclusive requirements. The patient's hospital number could be used to identify the patient. Just exactly what does the NRC want us to use? Please give specific examples. In addition, the word "RADAR" should be enough for a and c.	The patient's identifier should be prepared in a way that would ensure that confidential information is not traceable or attributable to a specific patient. For example: A licensee could use a computer-generated random number to identify patients and only a small number of authorized individuals would be able to match the patient's identity to that that number. Dosimetry analysis and potential inclusion of RADAR will be evaluated during phase 2 of the regulatory guide update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	P.20 3.2: Needed corrections to Table 3 were mentioned previously.	No change was made to the guidance in response to this comment. An evaluation of potential updates to Table 3 will be done during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	Appendix A, P.A-1: As noted previously, these radionuclides are very dated.	No change was made to the guidance in response to this comment. An evaluation of which radionuclides are to be potentially added or removed will be done during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Recommendation	Appendix B, P. B-1, B-1.1: As mentioned previously, it makes no sense to use an occupancy factor of 1.0 instead of 0.25 just because the radionuclide has a half-life under an hour. In addition, the continuation of this paragraph on the next page states that an occupancy factor of 0.25 may be used with the physical half-life. This is: fraudulent. An occupancy factor of 0.25 may be used with the effective half-life.	No change was made to the guidance in response to this comment. An evaluation of the occupancy factor will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

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Carol S. Marcus	Recommendation	Appendix B, P.B-2, B-1.2: This is concocted NRC garbage and an effort to thwart the use of the occupancy factor with irrelevant variables. It has no basis in science and has not been used for 22 years and should be rejected in its entirety. Remove this entire section, with the: fraudulent example as well. Scientifically correct examples are on RADAR.	No change was made to the guidance in response to this comment. An evaluation of the occupancy factor will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Recommendation	Appendix B, P.B-2 Paragraph 2: This is utter nonsense. The AU decides on the occupancy factor, not the NRC.	No change was made to the guidance in response to this comment. An evaluation of the occupancy factor will be performed during phase 2 of the regulatory guide update of 8.39. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	Appendix B, Page B-3 B-2: The equations for effective half-life are correct. However, the entire section following on p. B-4 is fraudulent. Absorption from the stomach is very rapid, and urinary hold-up is not an issue because patients start off well hydrated and drink copious amounts of water after dose administration and urinate very quickly and frequently. This has been pointed out to the NRC for 22 years, to no avail. The fake pharmacokinetic claim of the NRC continues to pollute this document, with NRC refusing to accept published pharmacokinetic data, such as found in ICRP No. 53 and its references. Example 2 is worthless and should be thrown out. More extensive scientifically correct examples, including answers, are in RADAR.	No change was made to the guidance in response to this comment. The dosimetry analysis and potential inclusion of RADAR will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Carol S. Marcus	Specific	Appendix B, Page B-5, Table B-1: The NRC calculates an effective half-life of 5.2 days for the thyroid fraction of a hyperthyroid patient with an 80% uptake. The NRC states that it used data from a paper by Stabin MG, et al. However, in looking at the data in that paper, the biological half-life of the thyroidal fraction in a patient with 80% thyroidal	No change was made to the guidance in response to this comment. The NRC understands the inconsistency of the examples in Appendix B and plans to confirm and update the examples in Appendix B during the Phase 2 revision. Phase 2 revision will be completed in 2023.

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		uptake did not average 15 days, as NRC states, but averaged 10 days, and the effective half-life is not 5.2 days, as NRC states, but 4.4 days. Example 3 is worthless and should be omitted.	
Carol S. Marcus	Specific	Appendix B, P.B-6, B-3: This section is fraudulent because the literature shows an assumed fractional intake of lxl0 exp-6 and NRC uses lx10 exp-5, 1000% too large.	No change was made to the guidance in response to this comment. Updates to the dosimetry used in the example will be evaluated during phase 2 revisions. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

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Clark Snelgrove	General	I am concerned that when nuclear regulations are presented to the public that the public gets the wrong impression about the meaning of these regulations. The science is clear what the risk are from exposure to ionizing radiation. The regulations should require not only the informing of the public that there is a risk but also an explanation of what these risks actually are in terms that anyone can understand. The application of the ALARA principle has been misunderstood by the public when it comes to safety and risk awareness. We give the public no sense of what reasonable means. Without an explanation of what is reasonable the public is left to guess and they almost always guess wrong about the risks of everything. They have been told for so long that radiation is dangerous without any qualifications that they believe that any level of exposure create a large risk even when the risks are actually small. Simple statements such as those given by The Health Physics Society should be presented and explained as needed. The Health Physics Society recommends against quantitative estimation of health risks below an individual dose of 5 rem in one year or a lifetime dose of 10 rem above that received from natural sources. There is substantial and convincing scientific evidence for health risks following high-dose exposures. However, below 510 rem (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are nonexistent. Health Physics Society Position Statement on Radiation Risk in Perspective. August 2004 Presenting a numerical explanation is very important. Patients should receive something like the following: The 5 mRem exposure limit set in the regulation presents an extremely low risk so that	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The NRC follows the linear no threshold model.

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		it is probably a reasonable risk in most situations. The LNT would suggest that a 5 mrem exposure over a 75 year lifetime would increase the risk of developing cancer by 0.21%. An increase in lifetime risk of 0.21% relative to a lifetime risk of 42% for cancer in general is a small increase in risk. In the case of a single exposure of 5 mrem the risk is therefore probably undetectable in light so many other risks. A risk that is undetectable is probably a reasonable risk. The public has been given the impression that somehow the risk of ionizing radiation can never be reasonable but this example illustrate that the risks are probably much lower than the risks associated with not having the medical procedure done. The risk to public health of inducing unnecessary fear about ionizing radiation into the public is exactly the as dangerous as the hyperbole associated with the risk of not being immunized for common diseases. The risk of not being immunized is in the noise yet since we don't help others to quantify risks, we allow those that would use fear to get attention to rule the public mind. We cannot allow government regulations to be misused to induce fear.	

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Thomas Morgan	Recommendation	Section 2.4, 1st paragraph states These constraints and radiation safety procedures to be applied in practice should be determined in close consultation with the RSO in which the therapy was administered. Comments: (1) This is an incomplete sentence recommend changing wording to ...the RSO of the facility which... (2) This is the ideal situation but will often be impractical if a patient is subsequently admitted to a different hospital or facility after release. In this case, the local RSO should be involved.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4, second paragraph, has been modified by adding a sentence to state: "If a patient is subsequently admitted to a different hospital or facility after release and then passes away, the local RSO should be involved."
Thomas Morgan	Recommendation	Section 2.4 discusses cremation some municipalities may limit or prohibit cremation of patients containing radioactive materials. A statement should be made that cremation may not be allowed based on local regulations.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4, sixth paragraph, has been modified by adding a sentence to state: "Cremation may not be allowed based on local regulations and the RSO should consult with local authorities prior to making cremation arrangements."
Thomas Morgan	Recommendation	Section 2.4 a statement about precautions to be taken to protect family members and general public during visitation prior to burial or internment should be included.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4, last paragraph, has been modified by adding bullet "c" stating: "Precautions should to be taken to protect family members and the general public during visitation prior to burial or internment."
Edwin M. Leidholdt	Recommendation	Tables 1, 2, and A-1 do not include the radionuclides F-18, Ga-68, Lu-177, and Ra-223. F-18 and Ga-68 are used frequently in PET imaging and Lu-177 and Ra-223 are used in radiopharmaceutical therapies. Table 3 of the document includes these radionuclides; we suggest that they be included in all the tables.	No change was made to the guidance in response to this comment. An evaluation of which radionuclides are to be added or removed will be done during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
Edwin M. Leidholdt	General	For some radiopharmaceuticals, there are typically multiple administrations to a patient in a year. The draft regulatory guide does not discuss this nor take this into account regarding the annual doses to members of the public. For example, Lu-177 dotatate is administered to patients up to four times in a year, which may suggest a release value for this radiopharmaceutical of 0.125 Sv per administration. We suggest this issue be discussed.	No change was made to the guidance in response to the comment. The NRC staff will consider emerging radiopharmaceuticals and their treatment protocols requiring multiple sequential administrations in the phase 2 revision of this regulatory guide.
James Grice	Recommendation	Section 2.4 (Death of a Patient Following Radiopharmaceutical Administration or Implants) doesn't address how to handle permanent or temporary seed implants. It could be useful if the regulatory guide addressed when seeds should be explanted versus left in the deceased patient, who should explant seeds (i.e. licensee trained staff versus individuals performing an autopsy and/or morgue/funeral home employees), and some guidance for crematory employees who may encounter seed implants post cremation (ALARA guidance for handling and guidance for disposal).	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The purpose of this RG is to provide guidance for patient release and not to provide guidance concerning deceased patients. The NRC is considering developing a separate guidance document on issues pertaining to death of a patient following radioactive treatment.
Peter Crane	Specific	I appreciate the opportunity to submit comments on Draft Regulatory Guide DG-8057, the proposed Revision 1 to Regulatory Guide 8.39, dealing with the release of patients after their treatment with radioactive pharmaceuticals. I wish I could commend it in the same way I can praise a related NRC document: a web page, "Information for Patients Administered Radioactive Iodine (I-131)," https://www.nrc.gov/materials/miau/patient-release.html, which was posted to the web about two years ago, I am told. That web page includes a link to a printable brochure for patients, the practical,	No change was made to the guidance in response to this comment. An evaluation of potential updates for other references for patient release will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
		understandable guidance that the thyroid cancer community has long been waiting for. When you compare the two documents, DG-8057 and "Information for Patients," the contrast is striking. To begin with, the list of references in DG-8057 includes, at p. 23, citations to two documents that are so flawed as to be valueless. These are NUREG-1492 (1994) and the NRC/ACMUI "Patient Release Report" (2010). The first was written before the Patient Release Rule was put in place, to justify its adoption, and the second much later, to justify keeping it unchanged. Both were advocacy pieces, lacking the factual accuracy and dispassionate analysis that were needed. At the same time, DG-8057 fails to cite two documents of considerable value: the NRC Regulatory Issue Summaries from 2008 and 2011 (RIS 2008-11 and 2011-1), in which the NRC staff tried to mitigate some of the harm that the Patient Release Rule had caused. Both were, on the other hand, referenced in the staff's "Information for Patients," which is yet a third document that DG-8057 unaccountably omits to mention.	
Peter Crane	Specific	Insurance companies, as millions of Americans have come to realize, have usurped much of the decision-making power that should be in the hands of patients and providers. In this case, they leaped on the fact that hospitalization for high-dose I-131 treatments was no longer an absolute requirement for every patient. Many insurers stopped covering the cost of inpatient treatment, regardless of whether the patient lived alone or with a houseful of small children in a residence with only one bathroom. Providers in turn	The NRC staff does not agree with the comment and no changes were made to the guidance in response to the comment. The NRC does not regulate insurance issues related to patient release; therefore, it is not discussed in the RG.

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		learned that if they prescribed the inpatient treatment that the individual living situation required, they might not be reimbursed.	
Peter Crane	General	The central, continuing problems with the NRC Patient Release Rule go unaddressed and untouched in this Draft Regulatory Guide. These problems include: (1) that patient release is based upon calculated external dose, on the assumption that internal dose is inconsequential; (2) that the NRC allows radiation doses to family members and the public that are five times what national and international standards call for; (3) that non-binding guidance has proved ineffective in correcting the inadequacies in current protection; (4) that the rule has been interpreted to allow newly treated patients to go to hotels, where they contaminate the rooms they stay in and the linens they sleep on; (5) that the NRC has outsourced the protection of the public from licensees, where it belongs, to the conscience of the individual patient, who may or may not be informed and altruistic; and (6) that in practice, the rule allows insurance companies, who look only at the bottom line, to dictate whether patients and their families receive adequate radiation protection. If the NRC is unwilling to initiate a corrective rulemaking on its own, which seems apparent, the only solution at this point is a petition for rulemaking from members of the thyroid cancer community, who can attest from personal experience to the harm that the current rule has inflicted, and continues to inflict, on them and their families. Persons with no connection to the treatment of thyroid cancer can also join the petition, to make the point that they want neither their children nor themselves to be exposed to	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The portion of the comment letter that is requesting a change to the rule may be submitted as a petition for a rulemaking pursuant to 10 CFR 2.802.

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		radiation while on public transportation or staying in hotels. Not only should such a petition not be necessary, there is no guarantee that the NRC would act on it expeditiously – it has a history of putting petitions that raise awkward issues into cold storage14 – but I see no other way.	
Geraldine McGinty	Specific	B. Discussion, Background: The ACR recommends updating all relevant references to National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," on page 5 and throughout the NRC's revised guidance document. The content of NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," has been updated and incorporated into NCRP Report No. 155.	No change was made to the guidance in response to this comment. An evaluation of potential updates for other references for patient release will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Geraldine McGinty	Specific	Harmonization with International Standards: The draft text on page 7 details harmonization with the International Atomic Energy Agency (IAEA) Safety Report Series No. 63 titled "Release of Patients after Radionuclide Therapy," which is predominantly informed by the European practice of radionuclide therapy and lacks the input of US standards. The ACR recommends incorporating the content on page 7 into a broader discussion of domestic standards, such as NCRP Report No. 155. Alternatively, the NRC should remove the two paragraphs on international harmonization from the draft guide to avoid potential confusion with domestic standards.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The NRC does not adopt international standards. The NRC does look at international documents for potential consistency globally.

Commenter	Comment Category	Specific Comments	NRC Resolution
Geraldine McGinty	Recommendation	Table 1: For simplification and clarification, the ACR recommends that NRC modify the specified tables to display radionuclides actively used in medicine. Tables 1, 2, and A-1 contain radionuclides that are no longer available or used for human use medicine, such as Ag-11, Cr-51, Sc-47, Se-75, and Sn-117m. There are also a number of currently used radionuclides that are not included (e.g., Lu-177, Ra-223, all the positron emitters such as F-18, O-15, Rb-82, Ga-68, etc.).	No change was made to the guidance in response to this comment and an evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Geraldine McGinty	Recommendation	Table 2: For simplification and clarification, the ACR recommends that NRC modify the specified tables to display radionuclides actively used in medicine. Tables 1, 2, and A-1 contain radionuclides that are no longer available or used for human use medicine, such as Ag-11, Cr-51, Sc-47, Se-75, and Sn-117m. There are also a number of currently used radionuclides that are not included (e.g., Lu-177, Ra-223, all the positron emitters such as F-18, O-15, Rb-82, Ga-68, etc.).	No change was made to the guidance in response to this comment and an evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Geraldine McGinty	Recommendation	Paragraph 2: The ACR recommends that NRC update the reference (Ref. 6) to more current resources. The 1995 reference (Ref. 6), "Internal Dosimetry in Pediatric Nuclear Medicine," is described as the primary external resource to use for calculating infant dose from radiopharmaceuticals not listed in Table 3. Our understanding is that the 1995 publication is outdated, and that there are more recently published resources with updated methodology by the same authors: · Michael G. Stabin, Radiation Dose Concerns for the Pregnant or Lactating Patient. Semin Nucl Med. 2014;44:479-488 · M. Stabin, Fundamentals of Nuclear Medicine Dosimetry. Springer; 2008	No change was made to the guidance in response to this comment and the dosimetry models and potential inclusion of RADAR will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
		· Michael Stabin and Jeffry A. Siegel, RADAR Dose Estimate Report: A Compendium Of Radiopharmaceutical Dose Estimates Based On OLINDA/EXM Version 2.0. J Nucl Med. 2018;59:154-160. · RADAR - the Radiation Dose Assessment Resource, http://doseinfo-radar.com/ Additionally, the ACR recommends that the guidance clarify that licensees are able to use other resources from relevant professional societies or relevant peer-reviewed literature if they maintain a record of the calculation as required by 10 CFR Part 35.2075(b). Newer or preferred methodologies may become available over time.	
Geraldine McGinty	Recommendation	Section 2.3.1 "Pretreatment Discussions on the Administration of Radiopharmaceuticals": The ACR recommends deletion of the second paragraph under this subsection, which appears to be an unintentional copy of the final two sentences of the first paragraph.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. In Section C.2.3.1 duplicate sentences were deleted.
Geraldine McGinty	Recommendation	Section 2.4, Paragraph 2: The ACR recommends the following sentence “A specified form of identifier (e.g., bracelet, badge body tag) should be used to attached with relevant information to identify the radioactive body.” to be revised to read as "A specified form of identifier (e.g., bracelet, body tag) should be attached with relevant information to the radioactive body."	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4 was modified to state: “A specified form of patient identifier (e.g., bracelet, body tag) should be attached with relevant information to the radioactive body.”
Geraldine McGinty	Recommendation	Section 2.5, Precautions for Long-Lived Contaminants: The ACR recommends elimination of Section 2.5. The issue in the reference (Ref. 11) addresses a disposal concern for Lu-177 syringes/vials that are not permitted to decay-in-storage because the long-lived contaminants are greater than 120 days. The information from that	Section C.2.5 has been deleted. Long-lived contaminants are not an issue in regard to patient release.

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		reference is being extrapolated without sufficient evidence as a hypothetical patient release concern.	
Geraldine McGinty	Recommendation	Paragraph 2: The ACR recommends the following sentence, "Autopsy and pathology staff should wear standard protective clothing (i.e., gloves, laboratory coats, and eye protection), and personnel monitoring should be considered." to be revised to read as "Autopsy and pathology staff should follow protective measures meeting standard infection control procedures (i.e., gloves, laboratory coats, and eye protection), and personnel monitoring should be considered, if significant activity of photon emitting radionuclides are involved."	The NRC staff does not agree with the recommendation that the guidance should be revised to say that licensee staff should follow protective measures meeting standard infection control procedures. However, the NRC staff agrees with the remainder of the comment. Changes were made to the guidance in response to the comment. Section C.2.4, paragraph 4, edits were made to include a statement that photon emitting radionuclides are for external exposure only and do not take into consideration potential internal inhalation exposure. The revised text states: “Autopsy and pathology staff should wear standard protective clothing (i.e., gloves, laboratory coats, and eye protection), and personnel monitoring should be considered, if significant activity of photon emitting radionuclides are involved.”
Geraldine McGinty	Recommendation	Paragraph 3: The ACR recommends the following sentence, "the RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment." to be revised to read as "When an RSO has been notified that a patient has died shortly after an administration of therapeutic quantities of radioactive material, the RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2,4, paragraph 5, includes suggested changes.

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		contamination during embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment."	
Geraldine McGinty	Recommendation	The ACR recommends that NRC emphasize at the beginning of Section 2.4 the exceedingly low radiation risk that recently deceased patients of radionuclide therapies generally pose to crematorium/funeral home workers. The concern of contamination of these workers and the general public from such releases is hypothetical, undocumented, and of such low risk that it is currently immeasurable. The overarching implication of Section 2.4 is that RSOs have a responsibility to provide precautionary information to crematoriums, morgues, and funeral homes. The ACR supports prudent and risk-based precautions when prior information is provided; however, the activities seem to be most feasible in scenarios in which a patient's death occurred at the treating facility and the RSO was onsite and readily available. The guide does not consider the additive roles in information exchange of treating AU physicians, care managers/referring physicians, family members/caregivers, health care administrators for the licensed facility, regulators, professional/trade associations, and others. The guide also does not consider potential scenarios such as: The RSO was not present in the facility at the time of death; The death occurred post-release from the licensee; The death occurred in a healthcare facility unaffiliated with the treating licensee; or, The RSO was provided insufficient or inaccurate information and was thus rendered unable to complete the described responsibilities (for example, the RSO was not explicitly informed of the funeral	The NRC staff does not agree with the comment and no changes were made to the guidance in response to the comment. The NRC understands that although the probability of a cremation contamination incident is low, this did occur in the past. See "Radiation Contamination Following Cremation of a Deceased Patient Treated with a Radiopharmaceutical." Journal of the American Medical Association (JAMA, 321:8, pg. 803). February 2019. The RG recommends that the licensee provide the patient and caregivers with instructions as to what to do should the patient unexpectantly pass away. This communication should occur prior to the treatment. Section C.2.3.2, instruction (b) states to have the individual contact the facility. Separately, the NRC is considering developing a guidance document on death of a patient following treatment with radioactive material.

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		home/crematorium the deceased was taken to). Many RSOs on NRC and Agreement State licenses are AU-physicians with patient care responsibilities, or are physicist-contractors providing RSO services to multiple healthcare facilities. NRC should consider the practical availability of such RSOs to perform the precautionary activities described in Section 2.4, and should clarify that these activities are aspirational out of an overabundance of caution and not universally practical or feasible. Additionally, the ACR recommends that NRC play a more proactive role in education of the crematorium and funeral home industries that could reduce or eliminate RSOs' administrative burden in Section 2.4. Two such examples of potential NRC outreach activities: · NRC could issue a general communication for crematorium and funeral home facilities. This general communication could educate these facilities about the low radiation risk and suggest that hospital morgues, funeral homes, and crematoriums voluntarily install simple, low cost radiation detectors. · NRC could also sponsor (or co-sponsor with public health agencies) the participation of national medical physics/health physics organizations in the conferences and workshops of trade associations that represent the crematorium and funeral home industries. Finally, the ACR believes it would be most useful for NRC to place emphasis on the available resources and guidance documents from the Centers for Disease Control and Prevention (CDC), U.S. Department of Energy (DOE), American Association of Physicists in Medicine (AAPM), and the National Funeral Directors Association (NFDA), among others: · Low risk of radioactive contamination from	

Commenter	Comment Category	Specific Comments	NRC Resolution
		cremation when proper safety procedures followed (AAPM): https://w3.aapm.org/media/releases/LowRiskRadioactiveContaminationFromCremation.php · Guidelines for Handling Decedents Contaminated with Radioactive Materials (CDC): https://emergency.cdc.gov/radiation/pdf/radiation-decedent-guidelines.pdf · Model Procedure for Medical Examiners/Coroners Handling body/remains potentially contaminated (USDOE): https://www.energy.gov/sites/prod/files/em/TEPP/2-b4MedicalExaminer-CoronerGuideforHandlingBody-HumanRemains.pdf · Radiation Protection Guidelines for Safe Handling of Decedents (National Funeral Director's Association): http://www.nfda.org/news/in-the-news/nfda-news/id/4153	
Geraldine McGinty	Recommendation	Section 3.1, Records of Release: The ACR recommends the following sentence, "Records should be kept in a manner that ensures the patient's confidentiality (i.e., the records should not contain the patient's name or any other information that could identify the patient." to be revised to "Records should be kept in a manner that ensures the patient's privacy/confidentiality." This specification provides unnecessary detail outside NRC's regulatory purview and indicates a patient privacy consideration addressed by other federal regulatory agencies.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.3.1 was modified to state: "Records should be kept in a manner that ensures the patient's privacy/confidentiality."

Commenter	Comment Category	Specific Comments	NRC Resolution
Geraldine McGinty	General	The ACR supports the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) recommendations for this draft guide, and we encourage NRC to include all advisory committee endorsed content. The ACR also encourages the NRC to consider the availability of information developed for the public by medical experts and freely provided by medical associations. For example, the Radiological Society of North America (RSNA) and the ACR co-sponsor RadiologyInfo.org, an online educational resource for patients and caregivers containing basic information on over 260 procedures, exams, and disease descriptions covering diagnostic and interventional radiology, nuclear medicine, and radiation therapy.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to the comment. The NRC has reviewed the suggested references. The NRC staff verified that the patient instructions incorporated in the guidance considers the information in the referenced documents.
Geraldine McGinty	Recommendation	Table A-1: For simplification and clarification, the ACR recommends that NRC modify the specified tables to display radionuclides actively used in medicine. Tables 1, 2, and A-1 contain radionuclides that are no longer available or used for human use medicine, such as Ag-11, Cr-51, Sc-47, Se-75, and Sn-117m. There are also a number of currently used radionuclides that are not included (e.g., Lu-177, Ra-223, all the positron emitters such as F-18, O-15, Rb-82, Ga-68, etc.).	No change was made to the guidance in response to this comment. An evaluation of which radionuclides are to be added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Geraldine McGinty	Recommendation	Appendix B: As with other relevant areas of the draft guide, Revision 1, the ACR recommends that NRC reassess and update Appendix B with respect to the current NCRP Report No. 155. Additionally, the ACR recommends that NRC include a reference in Appendix B to alternative acceptable procedures for calculating doses based on patient-specific factors that are provided by peer-reviewed literature.	No change was made to the guidance in response to this comment. The dosimetry analysis and potential inclusion of alternative methods will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
Craig Little	Point of Clarification	Page 16, Section 2.3.2 specifies that the licensee under certain circumstances may be required to hold a patient until they "can be released without having to follow any specific instructions". There is some concern whether a patient's insurance would pay for such an admission that may not be medically necessary, and the subsequent impact on ability of the patient to receive care. Does the licensee only need to show that the likely dose to the maximally exposed individual is < 1 mSv (100 mrem) as per 10 CFR 35.75 by use of a patient specific calculation and appropriate instructions that they may be capable of following for example?	The NRC staff does not agree with the comment and no changes were made to the guidance in response to the comment. Insurance issues for patient release is not an NRC regulatory issue; therefore, it is not discussed in the RG. 10 CFR 35.75(b) requires the licensee to provide the released individual or the individual's parent or guardian with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).
Craig Little	Specific	Page 20, 3.1 specifies that records of release should include patient identifiers but later states that the patients identifying information should not contain the patient "name or any other identifying information that could identify the patient". These statements appear contradictory.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.3.1was modified to state: "Records should be kept in a manner that ensures the patient's privacy and confidentiality (i.e., the records should not contain the patient's name or any other information that could identify the patient but instead a patient identification number, date, and treatment type.)"
Craig Little	Specific	Appendix A, Table A-1 - Exposure rate constants could be obtained from a single, more up-to date reference, such as the recent publication by Smith DS and Stabin MG. Health Phys 2010; 102(3):271-291.	No change was made to the guidance in response to this comment. An evaluation for updates to dosimetry analysis and exposure rate constants will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
Craig Little	Recommendation	Appendix A, Table A-1 Footnote e.: Consider changing "release activity is not based on beta emissions" to "radionuclide is a pure beta emitter (and there is no single exposure rate constant associated with the secondary bremsstrahlung radiation applicable for such radionuclides)."	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Footnote "e" in Appendix A was modified to state: "Radionuclide is a pure beta emitter (and there is no single exposure rate constant associated with the secondary bremsstrahlung radiation applicable for such radionuclides)."
Craig Little	Specific	Appendix B, Section B-2: "The behavior of I-131 can be modeled using two components" should be qualified as sodium iodide throughout Appendix B, as appropriate.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section B.2 was updated to state: "The behavior of disassociated I-131 can be modeled using two components:…"
Craig Little	Specific	Appendix B, Section B-3: "For some radionuclides, such as I-131, the concern is that the internal dose of an individual from exposure to a released patient could be significant." This is not necessarily true for bound I-131, e.g., I-131 MIBG or an I-131 radiolabeled antibody. In addition, when assessing internal dose it should be clarified that the appropriate chemical form should be used in the assessment.	The NRC understands the inconsistency of the examples in Appendix B and plans to confirm and update the examples in Appendix B during the Phase 2 revision. Phase 2 revision will be completed in 2023.
Craig Little	Specific	Page B-5. "In the example above, the thyroidal fraction, F2 = 0.05, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F2 has been measured for a specific patient, the measured value may be used" (along with F1 calculated as 1 - F2).	No change was made to the guidance in response to this comment. Potential updates to dosimetry analysis and thyroidal fractions will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Craig Little	Specific	Page B-6. "In the example above, the thyroidal fraction, F2 = 0.8, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F2 has been measured for a specific patient, the measured value may be used" (along with F1 calculated as 1 - F2).	No change was made to the guidance in response to this comment. Potential updates to dosimetry analysis and thyroidal fractions will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
Craig Little	General	Summary: There have been significant advances in understanding the likely radiation exposures to others from the release of radioactive patients and human subjects since the regulatory analysis in NUREG 1492 and the publication of NCRP 37. NRC should revise the methodologies in Regulatory Guide 8.39 to adopt more realistic models that include the determination of restriction times for various activities that are risk informed. Recent advances in therapy with radioactive materials have highlighted the issues surrounding radioactive decedents, with more sick patients undergoing treatment with products such as Y-90 microspheres, I-131 MIBG and Lu-177 Dotatate. A reasonable, consistent standard that allows for adequate protection of the public while permitting for compassionate disposition of remains should be established.	No change was made to the guidance in response to this comment. Updates to dosimetry analysis and models will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Terry Derstine	Specific	Page six contains a formatting error. There should be a space between the third and fourth bullets.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. A space was added between the bullets under "Background."
Terry Derstine	Specific	Table 1: The entries for Y-90 in Columns 1 and 2 refer to footnote "c," which states "Activity and dose rate limits do not apply because of minimal exposures to members of the public..." This contradicts the current "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" (February 12, 2016, Revision 9), found in the NRC's Medical Toolkit. On page ten of the guidance, it states licensees "...should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Y-90 is deleted from Table 1 and Table 2 for the guidance and will be re-evaluated during phase 2 of the RG update.

Commenter	Comment Category	Specific Comments	NRC Resolution
		subject permits his or her release in accordance with 10 CFR 35.75."	
Terry Derstine	Specific	Table 2: Similar comment to number three above. Y-90 value in table refers to footnote "b," which again states activity and dose rate limits are not applicable. This contradicts the commitment statement from the current Y-90 toolkit guidance. Either the medical toolkit guidance should be revised to align with the Regulatory Guide, or the Regulatory Guide should align with the Medical Toolkit.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Y-90 is deleted from Table 1 and Table 2 of the guidance and will be re-evaluated during phase 2 of the RG update.
Terry Derstine	Specific	The last two sentences of the first paragraph and the two sentences that comprise the second paragraph are the same.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Duplicate sentences in Section C.1.1 were deleted.
Terry Derstine	Specific	The Board recommends revising the wording on page 16 (10). Collect anything that is disposable and possibly contaminated in a strong plastic bag that won't easily leak or tear. Store these collected items for at least one month [or other time period specific to the radionuclide] before taking out to the curb or to the waste disposal facility in your town. This would include tissues, napkins, sanitary products such as incontinence pads, and scraps of food that came into contact with your saliva. The bag should be tightly closed and secured in a remote area of the garage, basement, etc. away from food, people and pets.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. In Section C.2.3.2, bullet (10) was revised to include the word "strong."

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Terry Derstine	Specific	Section 2.3.2: Because the waste facility usually does not know the cause of the alarm, these loads are rejected and typically sent back to their point of origin, which triggers additional action by the waste hauler, state personnel, and the point of origin. This is a drain on available resources, time and money for the involved parties. Agreement State staff spend hours completing faults to issue Department of Transportation exemptions and contacting other states to inform them that loads will be returning to their state or passing through their state. Because these alarms have also resulted in actual hazards unrelated to medical waste, Agreement State staff must treat all alarms as if they are a potential public health risk. To help reduce the number of responses to municipal waste alarms, the Board recommends that the guidance say that, while not required by regulation, licensees may want to provide instructions about holding waste to all patients.	The NRC staff does not agree with the comment and changes were not made to the guidance in response to this comment. The guidance includes a recommendation that licensees provide instructions to patients on holding their waste in order to prevent municipal trash issues.
Terry Derstine	Specific	Section 2.3.2: Also, the first sentence of the section states "The licensee should consider following precautions/measures for most patients..." It seems as though there should be the word "the" between "consider and "following," so that the sentence reads "The licensee should consider the following precautions/measures..."	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.3.2 was revised.

Commenter	Comment Category	Specific Comments	NRC Resolution
Terry Derstine	Recommendation	Section 2.3.3: The Board suggests more details in the instructions to patients. Here are a few examples that some states have added for 1-131. • Drink plenty of clear liquids (water, juice, tea, etc.) • Always sit when using the toilet. • Empty your bladder at least once every hour for the first 8 hours. • Get up at least once during the first night and empty your bladder. • Flush the toilet twice to remove any radioactivity from the toilet bowl. • Minimize your time with others and keep at least six feet away, especially from infants, children and pregnant women. • Shower 2 - 3 times a day for the first two days. • If whole fruits (e.g. apples, pears, etc.) are eaten it is recommended that sections be sliced off the core, rather than biting into the fruit whole. This prevents contamination of portions of the food that will be thrown away. In general, minimize the amount of uneaten food that has come into contact with your saliva. After five days of use, replace the toothbrush. The old one is to be placed with the trash being held for a month prior to disposal. • Wash linen, personal clothing, towels, etc. separately from those items used by family members. A second rinse cycle is recommended. • Avoid using disposable items, such as plastic utensils and cups, to minimize the amount of potentially contaminated waste generated. (Note that this conflicts with this draft which recommends using disposable utensils.) • Limit close personal contact; keep approximately six feet of distance between yourself and others.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section 2.3.3 was revised to include the additional instructions while avoiding duplication. However, the recommendation on disposable utensils was not accepted. These guidelines are generic in nature and the licensees should tailor their instruction to the specific treatment that will be administered to the patient.

Commenter	Comment Category	Specific Comments	NRC Resolution
Terry Derstine	Specific	The DG states that 10 CFR 35.75 permits the release of a patient that has been administered unsealed byproduct material or implants containing byproduct material if the TEDE to any individual from exposure to the released individual is not likely to exceed 5 mSv. The footnote explicitly says this is a per treatment limit not a yearly limit. Draft revision 3 of NUREG 1556 Volume 9 stated: Although the regulations are not explicit, licensees should consider implementing the 5 mSv 22 [0.5 rem] as an annual limit for multiple administrations during a calendar year. For more information on this topic see Regulatory Issue Summary (RIS) 2008-07, "Dose Limits for Patient 24 Release Under 10 CFR 35.75," March 27, 2008. However, this language is missing from final NUREG 1556 Volume 9, and now instructs readers to go to RG 8.39 for guidance. The OAS Board objects to changing the guidance from a yearly limit to a per treatment limit without any discussion or justification.	The NRC staff agrees with the comment in part and the footnote was removed from the document.
Terry Derstine	Specific	Do the values in Table 1 assume only one administration per year? If yes, this should be noted so that the licensee can adjust them accordingly if more than one treatment is expected or planned.	The values in Table 1 do not assume only one administration per year. The activity values in Table 1 were computed based on a 5 millisievert (mSv) (0.5 rem) total effective dose equivalent from a single administration.

Commenter	Comment Category	Specific Comments	NRC Resolution
Daniel Miron	Specific	I recommend that the data for I-123 NaI in table 3 Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child be reviewed and updated to reflect the current clinical use of I-123 NaI. Specifically the recommended duration of interruption of breastfeeding should be changed to Complete cessation due to the reasons listed below. The ACMUI report Nursing Mother Guidelines for the Medical Administration of Radioactive Materials, Final Report, January 31, 2019 (https://www.nrc.gov/docs/ML1903/ML19038A498.pdf) is making a big mistake in the administered activity for I-123 NaI. In tables 1, 3 and 4 they are using 0.4 mCi as the maximum administered activity, which is the usual maximum for just uptake studies. A lot of facilities are using up to 5 mCi clinically for whole body scans. Using 0.4 mCi is a major error in the calculations in the report. It should also be noted that the potential I-125 contaminate in the I-123 is not being accounted for in the calculations although the radiopharmaceutical package inserts for I-123 NaI state that I-125 may be present. How can you justify not accounting for this when the approved package inserts say it may be there? I know that one manufacturer will not commit to their I-123 being I-125 free. A couple package inserts are attached for your review. Item 4 on page 12 for the January 31, 2019 report discusses why the ACMUI is going with 3 days for cessation. I assume that this is based on the 0.4 mCi and low/no I-125 contaminate. The calculations need to be done for 5 mCi, not 0.4 mCi, to see how the recommendations change. The contribution from I-125 should also be	No changes were made to the guidance in response to this comment. Further analysis on Table 3 for the recommended duration of interruption of breastfeeding will be performed during phase 2 of the RG update. Phase 2 revision is going to be completed in 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
		included in these calculations. The Society of Nuclear Medicine Procedure Guideline for Scintigraphy for Differentiated Papillary and Follicular Thyroid Cancer (http://snmmi.files.cms-plus.com/docs/Scintigraphy%20for%20Differentiated% 20Thyroid%20Cancer%20V3%200%20(9-25-06).pdf) states that Oral 123I may be administered at a dosage typically between 0.45.0 mCi, which may avoid stunning. This clearly states that a maximum of 5 mCi may be administered clinically.In table 3 of the January 31, 2019 report the mean whole-body absorbed dose to newborn is 0.104 rad and the mean thyroid absorbed dose to newborn is 4.90 rad for 0.4 mCi (I assume without accounting for I-125). ~12 times (5.0 mCi /0.4 mCi) this is approximately 1.3 rad and 60 rad, respectively. Are doses at these levels still acceptable to the NRC and ACMUI for a breastfeeding infant or child?	
Cynthia McCollough	Specific	Table 1 Activities and Dose Rates for Authorizing Patient Release: We believe the NRC needs to update the tables in the draft guidance to reflect new therapeutic isotopes such as Lu-177, Cs-131, and an array of alpha emitters (e.g., Ra-223, At-221, At-211, Bi-213).	No changes were made to the guidance in response to this comment. An evaluation of which radionuclides may be added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Cynthia McCollough	Specific	1.3 Release of Patients Based on Patient-Specific Dose Calculations: Values calculated for Implanted isotopes assume permanent implants; eye plaques with I125, for example, would not have the same release criteria. This concept should be expanded upon in Section 1.3 as one of the explicit factors.	No change was made to the guidance in response to this comment. Updates to the dosimetry analysis will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
Cynthia McCollough	Specific	Table 2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release: We believe the NRC needs to update the tables in the draft guidance to reflect new therapeutic isotopes such as Lu-177, Cs-131, and an array of alpha emitters. The values calculated for implanted isotopes assume permanent implants. We believe this must be clarified and expanded upon. Eye plaques with I-125, for example, would not have the same release criteria.	No changes were made to the guidance in response to this comment. An evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Cynthia McCollough	Specific	Table 3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child: This table includes a lot of new radionuclides that are not included on Table 1 or Table 2. We believe additional consideration should be given to adding these new radionuclides to Tables 1 or 2.	No changes were made to the guidance in response to this comment. An evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Cynthia McCollough	Recommendation	2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals Recommendation (3). Most radiopharmaceuticals will see a voiding on the order of 50% of the administered activity within the first few hours. For therapeutic administrations of beta-emitting radiopharmaceutical treatments (RPTs), which usually have administered activities in the hundreds of millicuries (Sm-153, Lu-177, etc.), this represents a large amount of activity and almost invariably some contamination in the restroom where the patent first voids. We believe it would be reasonable to suggest or mandate that the patient stay in the treating facility and use a designated quarantined restroom, regardless of whether the activity or dose rate is below threshold. As stated, the calculations are based on gamma radiation, but concerns of contamination and potential ingestion	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.3.2 was modified to add bullet (c) that states: "In the case of a medical emergency, the patient, or a caregiver or family member, should inform the ambulance or the emergency care location of the recentness of the radioactive therapy treatment. "

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		should also be considered, consistent with patient guidelines given. We believe this section should also include the following question: What are the notification requirements if the patient requires emergency medical care? Both ambulances and emergency rooms potentially could be impacted.	
Cynthia McCollough	Recommendation	Paragraphs 1 and 2 (Page 14) contain duplicative language as follows: "Additionally, early engagement. . . release instructions." We recommend deleting one of those sentences.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Duplicative language was deleted in Section C.2.3.1 stating: "Additionally, early engagement with the patient allows the patient to ask the licensee questions that will help him or her comply with the release instructions. It also helps the licensee to determine whether the patient will be able to follow the release instructions."
Cynthia McCollough	Recommendation	We recommend changing the awkward wording of the burial/cremation question. We suggest using one of these alternatives: • What are the potential restrictions on burial or cremation if the patient should pass away within a certain period of time following treatment? • What are the potential restrictions on burial or cremation if the patient were to pass away within a certain period of time following treatment?	This regulatory guide is for the release of patients. The NRC is considering a separate guidance document specifically for death of a patient following radioactive administration.

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Cynthia McCollough	Recommendation	2.3.3 Patient Instructions: We recommend considering having separate instructions or at least a different emphasis for patients regarding the nature of the radiation concern between beta- and alpha-emitters. While alpha- emitters used in therapy typically have low administered activities, such that gamma radiation is not a concern, the danger from contamination and ingestion is much greater.	The NRC staff does not agree with the comment and changes were not made to the guidance in response to this comment. Section C.2.3.3 was written to be generic in nature so that the instructions could be applied to alpha, beta, and gamma emitters. The section states that patient instructions should be tailored to the specific type of material that is administered. For these reasons, the NRC did not draft instructions specific to alpha, beta, and gamma emitters.
Cynthia McCollough	Recommendation	2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants: We believe the first sentence is awkwardly worded. We recommend changing this language to: If the licensee learns that a patient has died shortly after a therapeutic quantity of radioactive material was administered, then the treating medical practitioner and the radiation safety officer (RSO) should be notified immediately. The RSO or designee should perform an assessment of the type and amount of retained activity, based on the patient records. We added “or designee” above because many RSOs are physicians at small hospitals, and they rely on others to perform dose calculations for them. Often these would be consulting physicists, so they may not be technically a part of the radiation safety office or committee. We recommend that the language, “The RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment.” be changed to: When an RSO has been notified that a	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4, first paragraph, was revised to include the words "or authorized user" based on this comment and another comment. The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section 2.4, paragraph 6, has be revised to state: "When an RSO has been notified that a patient has died shortly after a therapeutic quantity of administration of radioactive material, the RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material …...” Also, the NRC staff agrees that there is no standard mechanism to inform the licensee/RSO of a death of a patient, especially if the location is not the patient's primary care location. The licensee can make note of this while going over the instructions with the patient and or caregiver prior to the treatment. In addition, the NRC does not license funeral homes. The purpose of this RG is for patient release and not for specific guidance concerning deceased patients. The NRC is considering developing a separate guidance

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		patient has died shortly after a therapeutic quantity of administration of radioactive material, the RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial or cremation. These include the use of gloves and protective clothing and proper cleaning of equipment. We note that we are not aware of any standard mechanism for informing RSOs about the death of a patient, specifically if patients have been treated and are living further away. We note, as well, that Section 2.4 places much emphasis on the RSO providing precaution information, however, there are times when the RSO is not immediately informed that a patient has died shortly after a therapeutic quantity of administration of radioactive material (e.g, when a patient is released from hospital care and expires at home or in another town/county/state). Therefore, it would be more appropriate for Section 2.4 to place emphasis on available guidance already in place for funeral directors: Low risk of radioactive contamination from cremation when proper safety procedures followed (AAPM): https://w3.aapm.org/media/releases/LowRiskRadioactiveContaminationFromCremation.php Guidelines for Handling Decedents Contaminated with Radioactive Materials (CDC): https://emergency.cdc.gov/radiation/pdf/radiation-decedent-guidelines.pdf Model Procedure for Medical Examiners/Coroners	document specifically for issues pertaining to death of a patient following radioactive treatment.

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		Handling body/remains potentially contaminated (USDOE): https://www.energy.gov/sites/prod/files/em/TEPP/2-b4MedicalExaminer-CoronerGuideforHandlingBody-HumanRemains.pdf Radiation Protection Guidelines for Safe Handling of Decedents (National Funeral Directors Association): http://www.nfda.org/news/in-the-news/nfda-news/id/4153 While the draft talks about cremating a body, it says nothing about release limits to the air of the volatile radionuclide from cremation. We believe a table of these limits should be included in this guidance.	
Cynthia McCollough	Specific	Appendix B Procedures for Calculating Doses Based on Patient- Specific Factors: We suggest that the NRC give consideration to eliminating repetitive information from page 5 "Discussion." We believe that Appendix B should include a reference to alternative acceptable procedures for calculating doses based on patient-specific factors that are provided in NCRP Report No. 155. We believe that Appendix B should include a specific example on temporary implant exposure rate criteria, which differ from exposure rate criteria for permanent implants. Values calculated for Implanted isotopes assume permanent implants; eye plaques with I-125, for example, would not have the same release criteria.	No change was made to the guidance in response to this comment. Updates to the dosimetry used in the examples will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

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David Reindl		The footnote on page 1 says that the 500 mrem patient release limit is a "per treatment" release, not an annual release. This contradicts the NRC's position described in Regulatory Issue Summary 2008-07 which states "if multiple administrations or applications in a single year are planned, anticipated, or potentially may be required for an individual, the decision about releasing that individual following each of the administrations should, in NRC's view, be based on the cumulative TEDE from all administrations or applications in a given year not exceeding 5 mSv (0.5 rem) for the maximally exposed other individual." What is the radiation safety basis for relaxing the patient release criteria?	The NRC staff agrees with the comment in part and the footnote was removed from the document.
Josh Mailman	Specific	We note that both Tables 1 and 2 of DG-8057 do not include Lu-177 as a listed isotope and perhaps some treatment centers are defaulting to the language of 2.3.2 without the isotope being listed. With the approval of Lu-177 dotatate and the use of Lu-177 PSMA in clinical trials, the commission may consider adding Lu-177 to both tables with the dose that would trigger instructions being given. It is our understanding that the activity and the dose rate for Lu-177 dotatate are currently below the current instruction requirement. We continue to have members of our community who are being told to follow the instructions outlined in 2.3.2 adding additional hardships and stress for those undergoing cancer therapy.	No changes were made to the guidance in response to this comment. An evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Caitlin Kubler	Specific	Page 6, bullet 7: For radionuclides with a half-life that is less than or equal to one day, it is easier to justify an occupancy factor of 0.25 as the patient is in the nuclear medicine clinic and their contacts can be controlled.	No change was made to the guidance in response to this comment. An evaluation of the potential updates for the occupancy factor will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

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Caitlin Kubler	Specific	Page 8, section 1.1: The requested calculations are often obtained by using the RADAR interactive dose calculator; keeping a record of the actual calculations may be difficult for some labs.	No change was made to the guidance in response to this comment. Potential inclusion of RADAR will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Caitlin Kubler	Specific	Page 11, table 2: Please consider adding F-18, N-13, O-15, Ga-68, Lu-177, I-124 and Ra-223 to the table as these are more commonly used. Ag-111, Au-198, I-125, Re-186, Re-188, Sc-47, Se75, Sn-117m, or Yb-169 are not commonly used in practice.	No change was made to the guidance in response to this comment. An evaluation of which radionuclides are to be potentially added or removed will be performed during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.
Caitlin Kubler	Specific	Page 12, paragraph 1: The guidance is confusing as the regulatory limit is 500 mrem, not 100 mrem.	The NRC staff disagrees with the comment and no changes were made to the guidance in response to this comment. The regulatory threshold for a patient to receive instructions about breast feeding is 100 mrem and not 500 mrem.
Caitlin Kubler	Specific	Page 12 and 13, table 3: Some of the breastfeeding interruption limits should be revisited. For example, I-123 MIBG should not be 24 hours. It should be "no interruption". The guidance document could also notate the pharmaceutical attached to Ga-68 and Zr-89. It appears there may be confusion regarding Lu-177, a beta-emitting radionuclide which is used as a therapeutic agent. Please include the 500 mrem calculations.	No changes were made to the guidance in response to this comment. Further analysis on Table 3 for the recommended duration of interruption of breastfeeding will be performed during phase 2 of the RG update. Phase 2 revision is going to be completed in 2023.
Caitlin Kubler	Specific	Page 13, Footnote b, at the end, the NRC states, "For Tc-99m radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single 24-hour interruption period is recommended. Although this time interval may be longer than necessary for some Tc-99m labeled radiopharmaceuticals, it is compliant with the 0.1-rad dose limit and simplifies the guidance, thereby avoiding confusion and reducing the likelihood of error." This is confusing as the limit is 0.5 rad, not	No changes were made to the guidance in response to this comment. Further analysis on Table 3 for the recommended duration of interruption of breastfeeding will be performed during phase 2 of the RG update. Phase 2 revision is going to be completed in 2023.

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		0.1 rad. While it may be easier for people to remember, providing a table to facilitate informed discussion in more detail may be useful for patients who want to resume breastfeeding sooner if possible.	
Caitlin Kubler	Specific	Page 16 (1): Children and pregnant women may receive up to 500 mrem just like other adults, and in almost all cases may remain at home. If the child is very young and requires a great deal of care, then another caregiver needs to be present, however, they can be in the same household.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.3.2(a) was modified to state: "Or can another individual come and take care of the children and any pregnant household member in their home?"
Caitlin Kubler	Specific	Page 16 (2): It might not be practical to try to stop the patient from cooking for others. If the patient is making food for others, discontinuing cooking would be preferred, however if the patients wash their hands well or use disposable gloves, that could mitigate exposure to others who might eat the food.	The NRC staff does not agree with the comment and no changes were made to the guidance in response to this comment. The patient precautions listed in Section C.2.3.2, "Patient Precautions," are topics that should be considered by the licensee. The license should use judgement with the instructions needed for the patient on a case by case basis based on the treatment.
Caitlin Kubler	Specific	P.18 2.4: The Authorized User (AU) Physician should be handling this, rather than the RSO (who is often another physician). Autopsies are very rarely done on these patients.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.2.4, end of the first paragraph, was revised to include the term "authorized user."
Caitlin Kubler	Specific	P.19 2.5: We are not aware of any long-lived contaminant in any therapeutic radiopharmaceutical that is present in high enough concentration to be an actual hazard. If NRC has no actual examples, this paragraph should be removed.	Section C.2.5 has been deleted. Long-lived contaminants are not an issue in regard to patient release.

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Caitlin Kubler	Specific	P.20 3.1: Please clarify the following: NRC states that the record should include the patient's identifier. However, at the end of section 3.1 NRC states that the records should not contain the patient's name or any other information that could identify the patient.	The NRC staff agrees with the comment and changes were made to the guidance in response to this comment. Section C.3.1 was revised to state: "Records should be kept in a manner that ensures the patient's confidentiality (i.e., the records should not contain the patient's name but instead a patient identification number, date, and treatment type.)"
Caitlin Kubler	Specific	Appendix B, Page B-5, Table B-1: The NRC calculates an effective half-life of 5.2 days for the thyroid fraction of a hyperthyroid patient with 80% uptake. The NRC states that it used data from a paper by Stabin MG, et al. However, in looking at the data in that paper, the biological half-life of the thyroidal fraction in a patient with 80% thyroidal uptake did not average 15 days, as NRC states, but averaged 10 days, and the effective half-life is not 5.2 days, as NRC states, but 4.4 days.	No change was made to the guidance in response to this comment. The NRC understands the inconsistency of the examples in Appendix B and plans to confirm and update the examples in Appendix B during phase 2 of the RG update. Phase 2 revision is going to be completed in 2023.
Aria Razmaria	General	We are submitting comments on Draft Regulatory Guide DG-8057. It is with much concern that we reviewed the recent draft revision of the regulatory guide on release of patients after administration of radiopharmaceuticals. The reiteration of the antiquated 33 mCi rule, whereas the 500 mrem calculated dose limit has been established as a more scientifically sound dose limit, and the interchangeable use of a 100 mrem and 500 mrem dose limit is alarming. Also, many of the patient instruction recommendations are poorly medically informed. It is a surprise to us that this draft guide lacks reference to the relevant existing body of scientific literature pertaining to this topic. A short list of these peer-reviewed publications is included at the end of this comment letter. The overly conservative draft guidance is particularly counter-	No change was made to the guidance in response to this comment. Updates to dosimetry analysis and models will be evaluated during phase 2 of the RG update. Phase 2 will update the dosimetric equations and analysis and will be completed by 2023.

Commenter	Comment Category	Specific Comments	NRC Resolution
		productive for out-patients, provoking needless anxieties, pointless inconvenience, or even delay of their radiotherapies. Along with other already provided in-depth comments to the Draft Regulatory Guide DG-8057, we strongly advocate for a complete revision of this document with inclusion of outside input form experts in internal and external dosimetry, incorporation of complete list of relevant scientific literature, and comprehensive consultation with nuclear medicine medical community.	

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Christine Pepper	Specific	Among other proposed changes, the draft guide, Revision 1, includes a new Section 2.4 entitled "Death of a Patient Following Radiopharmaceutical or Implants Administration." Section 2.4 is a good initial step in recognizing that funeral directors and crematory operators need to be informed (1) when the remains of a decedent in their care contains 'therapeutic quantities of radioactive materials' and (2) of appropriate precautions to minimize radioactive exposures and radioactive contamination for embalming, burial and cremation. However, NFDA considers it critically important for its members to receive this information promptly in order to protect themselves in treating the remains and to ensure that family members, particularly those who may have compromised immune systems, are pregnant or breast feeding, etc. are not exposed to radiation when viewing or touching the remains. There are no suggested times frames referenced in the guide for communication of this information. The guide suggests that it is for the Radiation Safety Office at the treating institution to provide such information to the funeral director and the crematory operator and to determine on a case by case basis what information to provide. However, this approach does not ensure that funeral directors and crematory operators receive the needed information before or immediately upon receipt of the remains. Also, the guide does not specify the kind and quantum of information to be provided. In some situations, the Radiation Safety Office may not be informed of the patient's death. In that case, the funeral director or crematory operator will be dependent upon the family or caregiver to disclose that the decedent had radioactive treatment. Funeral	The NRC staff does not agree with the comment and changes were not made to the guidance in response to this comment. Section C.2.3.2 states that the patient or caregiver should contact the licensee in case of an emergency or if the patient passes away. It is incumbent on the licensee to communicate this information to the patient and the caregiver.

Commenter	Comment Category	Specific Comments	NRC Resolution
		directors and crematory operators do not routinely receive reliable and sufficiently detailed information from family members of the deceased, the treating medical practitioner, the radiation safety officer at the treating institution or others that the remains contains radioactive material, what kind of material, its half-life, and the risks of exposure from that material. This means that a funeral director or crematory will not necessarily know whether precautions should be taken to minimize radiation exposure and radioactive contamination when embalming, burial, and/or cremation are conducted. For that reason, NFDA also suggests that the Patient Precautions discussion in Section 2.3.2(b} (p.16) include both a written description of the treatment that the patient has received and a statement that, in the event of death, the family member or caregiver immediately advise the funeral home or crematory operator of the nature of the treatment and also that the funeral director or crematory operator contact the Radiation Safety Office immediately for further instructions. This approach would close some of the communication gaps in the process and go further to ensure that the funeral director or crematory operator will receive adequate information about treatment and needed precautions.	