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Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses

Comment On: NRC-2016-0122-0002
Program-Specific Guidance About Medical Use Licenses; Request for Comments

Document: NRC-2016-0122-DRAFT-0003
Comment on FR Doc # 2016-29214

Submitter Information

Name: Jeffry Siegel

General Comment

To whom it may concern:

Attached please find comments respectfully submitted by Michael Stabin, Carol Marcus, Bill Sacks and me regarding Docket ID NRC-2016-0122.

Sincerely,

(3)

12/6/2016
81FR89978

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Attachments

NUREG Comments (Siegel et al. Docket ID NRC-2016-0122)

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Add= K. Tapp (KNS1)

January 6, 2017

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H8
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Docket ID NRC-2016-0122, Draft Program-Specific Guidance About Medical Use Licenses

Dear Ms. Bladey:

We wish to comment on the above-named draft guidance announced in the Federal Register on December 6, 2016 (81 FR 87978).

The revised NUREG-1556, Vol. 9 is a 405-page guidance document that contains a number of appendices. We reserve the right to comment on the entire document, but of particular concern to us is Appendix U on pages 315-341, dealing with the release of patients administered radioactive materials. We do not understand why this revision, essentially a reproduction of the previous version, was even necessary. We have published more than 20 articles (see reference list below) dealing with patient release and commented directly to the NRC on numerous occasions about the deficiencies of the previous version of this appendix and are dismayed that our work and that of other experts has been either ignored or dismissed.

In addition to our peer-reviewed publications, the NRC approved a guidance document for diagnostic nuclear medicine that was written by Jeffry A. Siegel, Ph.D., in 2001[1] and published by the Society of Nuclear Medicine (now the Society of Nuclear Medicine and Molecular Imaging). It was posted on the NRC web site and determined to be an acceptable alternative to the NUREG at the time for nuclear medicine licensee compliance with the regulations. The book was updated in 2004[2] to include radiopharmaceutical therapy and while the NRC never made a decision about accepting the therapeutic portion, they never rejected it, either. Patient release methodologies in this book and in our 2007 publication in Health Physics,[3] as well as some of our other publications listed below, were used in the Radiation Absorbed Dose Assessment Resource (RADAR) website, which, in addition, provides a calculational tool enabling estimation of more realistic doses. The radiation absorbed dose calculating function on this website is in wide national and international use for estimating radiation absorbed dose to others from patients who have been administered radioactive materials.

According to 10 CFR 35.75, the previous NUREG-1556, Vol.9 "describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv," and the stated purpose of revised Appendix U is to provide "acceptable procedures for the release of patients...." However, this entire third revision of the appendix (preceded by Regulatory Guide 8.39 in 1997 and two versions of the NUREG), sets back the practice of radiation protection science at least 15 years, with material that is scientifically baseless, disregarding the large body of published literature demonstrating the proper methodology. "Acceptable" procedures should at least involve somewhat accurate dose

estimates, especially since valid data exist to "calibrate" parameter values and improve the accuracy of dose estimation. But, this appendix does not use such data and instead all the dose estimates are highly inflated and therefore of limited value.

In 1997, the NRC amended its regulations pursuant to 10 CFR 35.75 concerning the criteria for the release of patients administered radioactive material. The new criteria authorized patient release according to a dose-based limit – the likely dose to other individuals exposed to the patient cannot exceed 500 mrem – instead of using the previous activity- or dose-rate-based limits (<30 mCi or <5 mrem/h at 1 m) for all radiopharmaceuticals. According to Appendix U licensees may demonstrate compliance with this dose limit by either: (a) using the provided default table for activity (e.g., <33 mCi for ^{131}I) or dose rate at 1 meter (e.g., <7 mrem/h for ^{131}I), or (b) performing a patient-specific dose calculation. Patients can be released with much higher activity or dose rate at 1 meter than the default values, if a patient-specific dose calculation is performed.

The entire first part of the appendix bases patient release on the discredited "point source in air physical decay only" algorithm which uses parameter values that have been scientifically demonstrated to be incorrect. The "default" patient release values for administered activity and dose rate (provided in Table U-1) inflate actual values by assuming fictitiously that the source of radiation emanating from the patient can be represented as a point source, one that is unshielded, and that the decreasing activity within the patient is only due to physical decay of the radionuclide involved with no account taken of biological excretion. For Na^{131}I all three assumptions have been known to be fallacious for many years, and to a much greater degree for patients with thyroid cancer than with hyperthyroidism. These assumptions have also been applied to a variety of radionuclides without any justification; activity release limits range from 2 mCi for ^{75}Se to 790 mCi for ^{188}Re (at least NRC has recognized that since each radionuclide is characterized by a different physical half-life and spectrum of emissions, the universal 30-mCi release limit is not applicable). Therefore, use of this overly simplistic model will significantly overestimate actual dose to others from Na^{131}I (and many of the other radionuclides) and also significantly underestimate the administered activity required to deliver that dose. It is worth noting that the "30 mCi" rule, dropped in 1997 and replaced by the dose-based rule in the revised 10 CFR 35.75, is essentially resurrected in guidance for Na^{131}I patient release (acceptable activity release limit is 33 mCi) and considered to be an acceptable methodology. This is quite regressive, since as we have written, there is not credible origin or scientific basis for this rule,[4] and there still is none. Using erroneous assumptions and parameter values, the "calculated" dose is fictitious, making it impossible to properly instruct patients. Since this is neither an "acceptable" procedure for patient release nor a risk-informed, performance-based approach, it should be eliminated from guidance.

The NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), published its "Patient Release Report" on December 13, 2010, indicating that NRC guidance overestimates doses, as it uses unrealistically conservative (putatively protective) assumptions. The ACMUI made a host of recommendations, including that the guidance and assumptions be updated with assistance from experts and should include information on actual radiopharmaceutical biokinetics and measured patient dose rates. Interestingly, NRC staff apparently disagreed with the ACMUI and all our publications, asserting that over-conservatism is appropriate and that any

criticism of this practice "reflects a misunderstanding of the guidance." Pursuant to SECY-12-0011, "Data Collection Regarding Patient Release," dated January 25, 2012, "The patient release rule is dose-based, and only requires licensees to show that they are releasing patients in a manner that complies with the rule. Licensees may use any method of calculation they wish in showing compliance, using any parameters and assumptions they deem appropriate..." Further, while the patient release rule has no built-in conservatism, the SECY document goes on "The calculations performed by NRC and described in the NUREG, and the tables that are based on these calculations, are intended to serve as screening tools for the convenience of licensees who may not wish to do their own calculations, or *who do not have the technical expertise* to do them [emphasis added]." Thus, NRC, through its guidance, apparently finds it "acceptable" to massively overestimate doses to others in order to allow licensees, who either don't wish to do calculations or who may lack the requisite expertise to even do them, to treat and release radionuclide therapy patients. We, of course, strongly disagree.

Radiation protection science and the evidence-based literature demand that patient release be determined at the very least with realistic patient-specific dose calculations to provide a more complete and appropriate estimation of dose to others so that valid patient release instructions can be given. No licensee should opt to use the significantly flawed and scientifically baseless "default" values for activity and dose rate in order to unjustifiably "simplify" their procedure for patient release. Patient-specific calculations are both feasible and easily derived, and, contrary to the belief of NRC staff, licensees *should* be required to "have the technical expertise to do them." If licensees are unable to perform these simple calculations, this would suggest that the mandated training and experience to attain Authorized User or Radiation Safety Officer status is inadequate and should be strengthened.

It is no surprise, however, that based on the draft revised guidance many licensees might be unable to perform patient-specific calculations, because the appendix deals almost exclusively with $Na^{131}I$ – and does so incorrectly (equation B-5 on page U-20). Further, the calculational methodologies provided are unjustifiably overly conservative (putatively protective of potentially exposed persons); the two biggest contributors to the conservatism are: 1) use of an unshielded point source value for the exposure rate constant, a value requiring correction for radionuclide distribution and patient attenuation and 2) use of a nonexistent 8-hour non-void period and an associated unjustified increased value of 0.75 for the occupancy factor during this time period, resulting in a highly inflated imaginary 45% contribution to the total estimated dose an exposed individual is likely to receive, in the case of exposure to a released thyroid cancer patient. Our cited work listed below addresses these overestimates and recommends a more accurate dose estimation schema with parameter values that result in dose predictions, unlike those recommended in guidance, that have been validated by actual empirical measurements. Direct measurements are the best way to obtain the dose any exposed individual is likely to receive based on the reality of daily life. Dosimeter measurements obtained in 65 household members of 30 patients who received outpatient ^{131}I therapy for thyroid carcinoma indicated that the measured dose was on average a factor of 10 lower that that predicted based on the guidance-recommended equation for patient-specific dose estimation (equation B-5).[5]

To better illustrate the difference between the "default" (using Equation U-2) and "patient-specific" (using Equation B-5) approaches in determining the administered activity required to

expose another individual to a dose of 5 mSv, consider a thyroid cancer patient being treated with $Na^{131}I$. Based on the guidance-acceptable parameter values, the releasable administered activities would be 33 mCi and 221 mCi for the default and patient-specific approaches, respectively. The 6.7 times greater activity using the patient-specific approach is more realistic, but because it employs a fictitious nonvoid period and does not account for patient attenuation, the estimated dose per unit activity is still too high and, concomitantly, the activity value per unit dose is still too low, as we have reported.[3]

The recommended NUREG method for calculation of internal dose (equation B-6) uses an assumed fractional intake of 10^{-5} that is also a factor of 10 too high in order "to add a degree of conservatism to the calculations," presumably intended to mean erring on the side of caution. But such erring generally entails possible unintended consequences that the NRC does not choose to consider. As we have written,[3] "When data are not available, use of conservative calculations may be reasonable, as they can identify or rule out a potential problem and may be used to add a margin of safety to procedures that do not have well-defined outcomes. However, when data are available, as they are in the case of patients treated with $Na^{131}I$ for thyroid cancer and hyperthyroidism, the overuse of conservatism does not serve the goal of radiation protection practice." Massive conservatism places an undue burden on those enforcing dose limits and on those subject to the limitations. Exaggeration of putative risk places a further burden on the public and the medical community by reinforcing the unwarranted but widespread fear of radiation.

Using these overly conservative methods, example 4 on page U-24 contradictorily indicates, presumably unrecognized by the NRC, that the calculation violates patient release pursuant to 10 CFR 35.75 because the 5 mSv dose limit is exceeded (5 mSv external dose estimated + 0.17 mSv internal dose estimated = 5.17 mSv total dose). Also on page U-24, a regulatory burden not codified in the regulations appears. NRC asserts, "Internal doses may be ignored in calculations of total dose, if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose." But based on guidance-recommended patient-specific calculation of external dose and the separate calculation of internal dose, the internal dose component will always be estimated as 6% and 23% of the external dose component for hyperthyroid and thyroid cancer patients, respectively, irrespective of the administered activity, as we have previously reported.[3] Thus, while internal dose would never have to be taken into account for hyperthyroid patients, it would, were the recommendation to be followed, always have to be accounted for in the case of thyroid cancer patient release.

Furthermore, in example 5, NRC notes that for the treatment of thyroid remnants and metastases, the internal dose is about 24% of the external gamma dose so "the internal and external doses must be summed to determine the total dose." There is no recognition in the guidance document that this will be true, not for just this one example, but for all thyroid cancer patients, *if the guidance methods were to be followed.* Interestingly, however, there is no scientific basis or evidence that internal contamination is more likely for thyroid cancer patients than for hyperthyroid patients. If a more realistic intake factor of 10^{-6} had been used in equation B-6, the internal dose component would always be less than 10% of the external dose component for both hyperthyroid and thyroid cancer patients. Further, the 10% "threshold" for inclusion/exclusion of

the internal dose component is irrelevant, as the calculations in example 4 indicate – even though the internal dose component is only 3% of the external dose in this example, when added to the external dose of 5 mSv (the fictional dose predicted for a 33-mCi administered ^{131}I activity per "default" Table U-1), the total dose exceeds the 5 mSv dose limit thus placing the licensee in violation of 10 CFR 35.75.

Taking all this unfounded and self-contradictory conservatism into consideration, guidance asserts, on page U-5, that "the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis." However, on page U-13, it is stated that "a calculation may be case-specific for a class of patients who all have the same patient-specific factors." Thus, patient-specific calculations are not even required, only class-specific calculations need to be done, and only once for all thyroid cancer patients released and again for all hyperthyroid patients. Therefore, the patient-specific calculation referred to in the appendix is not patient-specific at all; rather it is class-specific and therefore intended to be applicable to all patients (under the unproven and apparently "acceptable" assumption they all have the same patient-specific factors). So the dose estimation and required patient instructions will likely be incorrect for almost all patients, yet this is inconsistently considered to be "acceptable." Licensees are of course free to do their own calculations with more realistic case-specific parameter values (in fact, if more realistic values than those recommended in the appendix are selected, a class-specific calculation may indeed prove to be a reasonable approach) and to provide personalized instructional guidance to patients to assure compliance with the applicable release criteria. Unfortunately, not many licensees are likely to do so, even though much has been published and is available for use (see our reference list). As indicated on page U-14 "Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this Appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75." Since licensees likely have little idea what may or may not be considered "an acceptable alternative method," and many lack the requisite expertise to even propose an alternative or select a more appropriate method from the scientific literature, they are apt to willingly follow guidance methods, even if they know they are flawed.

The revised Appendix U unfortunately retains essentially all of the discredited science from the previous version, and the proposed methodologies remain terribly flawed. In addition, regulatory burden is added, something outside the usual content of a guidance document but which should be taken into account. Blind adoption of the recommendations in this flawed appendix will result in significant negative impacts in daily practice for medical licensees administering radionuclide therapy treatments. Several examples of added regulatory burden appear on page U-1 but are not codified in the regulations. These burdens should be removed. They include the following:

1. NRC states, "However, a patient who meets the release criteria in 10 CFR 35.75 is not required to be released immediately following administration of radioactive materials. Inpatient treatment is always an option and may be the appropriate choice, given the patient's specific situation."

If a patient meets the release criteria in 10 CFR 35.75 there is no radiation safety reason for hospitalization, period. If the patient is releasable but hospitalized for other reasons, he/she

can be placed in a regular hospital room with no NRC-mandated procedures or precautions necessary – guidance is silent on this issue.

2. NRC says, "Although the regulations are not explicit, licensees should consider implementing the 5 mSv [0.5 rem] as an annual limit for multiple administrations during a calendar year."

This issue has already been discussed at length. Making 5 mSv a yearly limit imposes significant paperwork on licensees: if patients are treated in other institutions, this may produce HIPAA issues and may result in inappropriate delays in patient treatment. This language creates a *de facto* regulation that does not exist and was purposely avoided in the original rulemaking.

3. "Although 10 CFR 35.75 does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the U.S. Nuclear Regulatory Commission (NRC) strongly discourages this practice, because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses that are not as low as is reasonably achievable (ALARA)."

The licensee can no more assess compliance with 10 CFR 35.75 in a residence than in a hotel, and the NRC states that the licensee cannot be responsible for what actually takes place after the patient leaves the medical institution or medical practice. On page U-6 guidance asserts that licensees may "develop their own instructions" and on page U-7 it is noted that "The NRC does not intend to enforce patient compliance with the instructions, nor is it the licensee's responsibility to do so." We therefore agree with ACMUI's statement in its 2010 "Patient Release Report" that "Once an I-131 therapy patient is released, NRC's regulatory control, and thus the licensee's responsibilities, ends."

More importantly, the NRC has no valid scientific data showing that there is any danger in releasing a patient to a hotel. While public fear of low-dose radiation exposure, reinforced in no small part by some of the policies of the NRC, can create uncomfortable issues, it is lack of public education in valid radiation science, and long-existing misinformation, that are the primary causes of this radiophobia. Rather than issue this recommendation the NRC should endeavor to educate the public with valid low-dose effect information so as not to provide further false information that only reinforces the public's existing fear, originating in, and continuing due to, decades of misinformation.

The continued poor quality of the revised Appendix U 20 years after the codification of the dose-based rule pursuant to 10 CFR 35.75 is inexcusable given all the available literature demonstrating the scientific invalidity of methodologies still retained. The entire revised appendix should be withdrawn until such time as it can be accurately rewritten. The first part of Appendix U should be mostly deleted and the second part regarding patient-specific dose calculation needs to be entirely rewritten. This is because the first part is scientifically baseless, ignoring a plethora of published literature, and the second part would not, even if the basis were valid, offer meaningful guidance on how to either appropriately perform a patient-specific calculation or properly instruct a released patient to maintain doses to others ALARA. Appropriate instructions cannot be supplied to patients since the recommended dose calculations are massively overconservative, thereby placing undue and unjustifiable burdens on licensees, patients, and their associated families and friends, and not patient-specific at all. The result will therefore be inaccurately predicted doses resulting in inaccurate patient instructions for almost all treated patients. We disagree with NRC's reasoning and stated belief that massive

overconservatism is "acceptable" for guidance as it provides licensees incorrect information that obviates their meaningful compliance with 10 CFR 35.75.

We would be happy to lend our expertise to NRC in order to appropriately revise the draft Appendix U for the benefit of patients, their families, and licensees.

Thank you for the opportunity to comment on this NRC work product.

Respectfully submitted,

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