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Comment On: NRC-2016-0122-0003

Program-Specific Guidance About Medical Use Licenses; Extension of Comment Period

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Submitter Information

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Organization: Health Physics Society

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General Comment

See attached file(s)

11

Attachments

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HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

March 29, 2017

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Docket ID No. NRC-2016-0122

Subject: NRC Request for comment on NUREG 1556 Vol 9 Rev 3 "Consolidated Guidance about Materials Licenses: Program-Specific About Medical Use Licenses".

The Health Physics Society¹ (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments in response to the published information request. The HPS provides comment to the Federal Register Notice in the attached document.

The HPS appreciates this opportunity to provide input into the regulatory process. If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

Eric W. Abelquist

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Nancy Kirner, CHP, HPS Past President
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¹ The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Background

The Nuclear Regulatory Commission (NRC) published in the Federal Register (Vol. 81, No. 234, 12/6/2016, NRC-2016-0122) a request for input from licensees, Agreement States and the public regarding the draft of NUREG 1556 Vol 9, Revision 3 "Program Specific Guidance About Medical Use Licenses". This document, in its various iterations, provides guidance to licensees when applying for medical use licenses and criteria for NRC in evaluating such licenses. For this reason, it is important that it be based on accurate science. Version 3 addresses additional issues that were not covered in Version 2 and expands the discussion of certain key areas related to medical use programs.

Summary Position

The document as a whole includes expanded sections regarding key areas of compliance and licensing and clarified language that enhances the understanding of NRCs intent and interpretation of the regulations pertaining to medical uses of radioactive material. Upon a review of the extensive document and comparison with the previous version and generally accepted radiation safety and compliance practices, the primary area of concern to the Health Physics Society (HPS) is the revised Appendix U – Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials.

Appendix U and the associated guidance are central to using radioactive materials in the practice of medicine. Every nuclear medicine patient seen in the United States, and many brachytherapy patients are potentially affected by changes in how the patient release rule is applied and how compliance is assessed. We recognize that the model procedure is not rulemaking and does not change the regulatory requirements overtly. However the regulated community also recognizes that such "guidance" by NRC's own admission sets the bar for how licenses and licensee procedures for compliance are reviewed and therefore has a direct effect on the standards of practice.

The historical precedents on which the methodology and guidance was originally based is well described in NUREG 1492, with the underlying dose estimation model being based on NCRP Report 37 (1970). However, there have been significant advances in knowledge, medical practice and credible published literature on dose assessment and release of patients since the underlying models and assumptions that persist in Appendix U were formulated. For example, NCRP Report 37 has been superseded and updated models and data are presented in NCRP Report 155 (2006). Better information is available on the use and assignment of occupancy factors, patient specific dose modeling, patient instructions, restriction times and dose assessments than was available at the time that the core of Appendix U (e.g. NUREG 1492 and the follow on guidance in Regulatory Guide 8.39 upon which Appendix U is based) was developed.

While NRC made some changes to the "model procedure" such as clarifying expectations with respect to internal dose assessment and transitioning to more appropriate dose conversion factors, we note that NRC should update the underlying methodology or references in several critical aspects. The NRC should revisit the dose to a sleeping partner, which is an important factor in release determination and

the development of adequate restriction times according to the NCRP and the American Thyroid Association.

HPS understands that the model procedure in Appendix U is non-binding and that licensees are free to establish acceptable procedures for ensuring compliance with the patient release rule. However, experience dictates that many licensees and many regulators will default to the model procedures for various reasons. Therefore, we believe it is critical that careful attention be given to any updates or revisions, especially since such procedures directly impact medical practice and may have trickle down effects on access to care, practice sustainability, overhead and compliance burdens for the medical community. We encourage NRC to carefully consider the enthusiastic but cogent analysis and references provided in the comments submitted on January 6, 2017 by Sigel, Stabin, Marcus and Sacks as part of any assessment in addition to our own comments. In particular, we would direct the attention of the Commission to discussion about the ability of licensees (qualifications and dedication of appropriate expertise and resources) to conduct adequate patient specific release determinations, and by inference, offer patients appropriate and specific counseling tailored to their situation. We do so while recognizing that NRC must straddle a line between ease of demonstrating compliance through use of conservative methodology (reducing licensee burden) and being overly conservative in applying restrictions to the net detriment of patients and the public at large.

For example, use of the extremely conservative NRC model and reference values for release of patients receiving diagnostic quantities of radioactive material provides a convenient "check off" for demonstrating compliance since these procedures then incur no additional tracking, paperwork, etc. for most cases. While we recognize that the projected doses to others using this method are notably much higher than the actual radiation doses (e.g. they are not realistic and should not be used for any purpose other than a compliance boundary condition check), we agree that the existing framework is more than adequate for public protection while minimizing any regulatory burden.

Application of the models, assumptions and attendant dose projections for therapeutic applications is much more problematic due to the need to devise adequate instructions and determine whether patients may be reasonably released from confinement, which is a complicated endeavor related to the practice of medicine. These assessments may affect ability to return to work, living conditions, family care issues, quality of life and many other aspects of a patient's life and medical care after therapy, including the perceived radiation risks to others from medical treatment with radioactive materials. It is in this category especially where a transition to a more realistic and risk informed methodology is of benefit to patients and the public at large and where improvements in guidance and suitable references will make the most positive impact.

Specific Comments of Note

1. Page U-1, Lines 10-13, "*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.*" This statement should be clarified to distinguish that the judgement to release or not release from control under 35.75 is separate from

the judgement to release based on medical considerations. In other words, that there is a regulatory basis under Part 35 for release that exists separate from the medical basis as determined by a physician.

2. Page U-1, Lines 21-22, *"Although the regulations are not explicit, licensees should consider implementing the 5 mSv as an annual limit for multiple administrations during a calendar year."* This statement is not consistent with interpretation of the current rule. In the Final Rule statements "The NRC is establishing a dose limit of 5 millisieverts (0.5 rem) total effective dose equivalent to an individual from exposure to the released patient for each patient release" (62 FR 4122, 1/29/97). This is why the NRC said in their RIS 2008-07 that they would have to pursue rulemaking to "incorporate the NRC's intent" to make the patient release criteria an annual dose limit. Until the current rule is changed, licensees should not be encouraged or expected to implement a 5 mSv annual limit for multiple administrations during a calendar year. In addition, it is inconsistent to suggest this solely for I-131 therapy and neglect all other contributory sources of radiation exposure to the population from administration of radioactive materials. However, it is well established that enforcement of an annual dose limit for patient release is both impractical and of dubious benefit to the public welfare.
3. Page U-1, Lines 25-32, *"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). For more information on this topic, see RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011."* There is no data or study to support the statement that release of a radioactive patient to a location other than a private residence will result in radiation exposures to members of the public in excess of that permitted by 10 CFR 35.75(a). An ACMUI subcommittee report¹ addressed the release of I-131 therapy patients to locations other than a private residence. "As part of the analysis, the subcommittee calculated the radiation dose to other individuals from release of an I-131 therapy patient to a hotel using overly conservative assumptions and parameters, to demonstrate that even highly unlikely dose projections do not exceed the release criteria". The ICRP² also suggested that a patient could "stay at a nonhospital living facility, such as a hotel, for several days" when the patient's home situation would put the patient in close contact with children due to physical or social constraints, because this "is less expensive than staying in a hospital". The guidance document should emphasize that the licensee assess the radioactive patient's planned living situation upon release, and provide the patient with any additional radiation safety precautions that may be appropriate for such locations.
4. Page U-2, Lines 33-36, *"For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term*

averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate. The application of such a high occupancy factor may result in overly conservative calculations and may not be appropriate in many cases. It can be shown that use of such high occupancy factors for patient specific calculations can cause unnecessary restrictions and patient burden and that more realistic values should be used based on the specific situation. However, insofar as it is used as a boundary condition input for certain classes of patients with the caveat that the estimated dose is for compliance demonstration only and not the actual dose, use of such factors can be acceptable. NRC should clarify that when such very conservative inputs are used for demonstrating compliance, the radiation dose to the public thereby generated is not realistic and is solely for the purposes of demonstrating that a realistic dose resultant from the activity is below the regulatory limits.

5. Page U-4, Lines 2-3, *"an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day."* Same comment as in number 4.
6. Page U-11, Instructions Regarding Radiopharmaceutical Administrations *"Drink one glass of water each hour."* This instruction on fluid intake should be based on the patient's medical condition and come from the physician Authorized User.
7. Page U-11, Lines 1-5, *"Licensees should consider not releasing patients administered I-131, whose living conditions may result in the contamination of infants and young children. The licensee should provide information on the potential consequences, if any, from failure to follow these instructions (e.g., could result in significant doses to the child's thyroid and potentially raise the risk of subsequent radiation-induced thyroid cancer)."* While we are unaware of any study to support the statement that patients administered I-131 present a significant exposure pathway and dose consequence to the thyroid of an infant or child from contamination in actual practice, we agree that the possibility should be considered by licensees on a case-by-case basis. Patients are given instructions on methods to reduce or control possible contamination post therapy. However, we recognize that licensees should consider patient specific situations and account for the possibility that there may be a situation that would necessitate special instructions or holding a patient who may otherwise be releasable.
8. Page U-15, Table U-5., starting with Tin-117m and the radionuclides below it, the half-lives and exposure rate constants are incorrect.
9. Page U-17, Lines 18-21, *"In Table U-1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day)."* Same comment as in number 4.

10. Page U-18 – General Comment RE: Occupancy Factors: Occupancy factors are a well-established and useful tool for dose estimation. However, in the guidance (as has been the case since it was first promulgated), the description of the occupancy factors gives restriction times. These restriction times may not be appropriate and use of them may lead to inadequate instructions that may result in a dose estimate exceeding the regulatory limit. One example is the dose to sleeping partner of a hyperthyroid treatment patient. Using the model in NCRP 155 with a typical activity and taking credit for biokinetic excretion and patient self-attenuation, it is clear that the 500 mrem dose limit may be exceeded if the patient sleeps alone for only the first night as implied by the information in the guidance. More detailed guidance and instruction on proper use of occupancy factors and patient specific instructions is needed in this document and/or the references to clarify that use of default restriction times listed may very well be inappropriate for demonstrating compliance.
11. Page U-18, Lines 6-7, "*E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.*" Same comment as in number 4.
12. Page U-20, Lines 6-12, "*However, simple exponential excretion models do not account for (i) the time for the I-131 to be absorbed from the stomach to the blood; and (ii) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of I-131.*" This assumption is overly conservative and is inconsistent with the published literature and understanding of iodine biokinetics after oral administration of NaI and may also be inappropriate for other radiopharmaceuticals.
13. Page U-23 B.3 Internal Dose, A fractional transfer of $1E-5$ is assumed for the internal dose to an individual from exposure to a released patient. The reference cited by NRC states that even under accident conditions, the fractional transfer of $1E-6$ is generally appropriate and sufficiently conservative. This has been borne out in the studies of iodine concentration in patient families post therapy. Therefore, we recommend use of a $1E-6$ fraction, with the caveat that a licensee may adopt other models for estimating the internal dose contribution from isotopes. For example, only a fraction of excreted activity is available for transfer to a receptor and it may therefore be overly conservative to apply the transfer fraction to the total activity administered to a patient.
14. The following radionuclides should be added to Tables U-1, U-2, U-3, and U-5, as appropriate: F-18, Ga-68, Ra-223, Lu-177, Cs-131 (sealed sources for implant).

15. Page 8-43 lines 19-20 regarding manual brachytherapy sources and Appendix Q Model Leak Test Program – visual inspection for damage should be included as part of the routine monitoring program.
16. General Comment: Much of the NUREG model procedure is focused on I-131 sodium iodide therapy for hyperthyroidism and thyroid cancer. While these therapies are currently the most prevalent, the document should provide generic guidance for all sealed and unsealed radionuclide patient therapy release. Consideration should be given to creating a separate section for the precautions that are specific to I-131 sodium iodide therapy.
17. General Comment: while some of the guidance on patient instructions is clarified and improved from previous versions, there remains precious little in terms of establishing restriction times. The methodology buries this information in the assignment of an occupancy factor – with the given values inappropriate for many scenarios. The guidance and the community at large would greatly benefit from a more appropriate treatment of restriction times and how they may be determined as this clearly varies substantially between licensees and therefore leads to confusion and concern in the patient population.
18. General Comment: NRC should take advantage of the indexing and hyperlinking functionality available with the PDF format of the document to make it more user friendly.

References:

1. U.S. Nuclear Regulatory Commission. Advisory Committee on the Medical Uses of Isotopes (ACMUI): Patient release report. 2010. Available at: <http://pbadupws.nrc.gov/docs/ML1034/ML103481099.pdf>. Accessed March 8, 2017.
2. ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004 – see paragraph (106), item (v).
3. NCRP (2006). National Council on Radiation Protection and Measurements. Management of Radionuclide Therapy Patients, NCRP Report No. 155 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).
4. NCRP (1995). National Council on Radiation Protection and Measurements. Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients – Commentary No. 11 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

5. Siegel JA, Marcus CS, and Stabin MG. Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with ¹³¹I. Health Phys 93:667-677, 2007.