PUBLIC SUBMISSION

As of: 6/23/17 9:55 AM
Received: June 21, 2017
Status: Pending_Post
Tracking No. 1k1-8x32-z2r2
Comments Due: June 27, 2017
Submission Type: Web

Docket: NRC-2017-0094
Patient Release Program

Comment On: NRC-2017-0094-0004
Patient Release Program; Extension of Comment Period

Document: NRC-2017-0094-DRAFT-0039
Comment on FR Doc # 2017-11027

82 FR 17465
4/11/2017
(53)

Submitter Information

Name: Michael Guastella
Address:
500 North Capitol Street, NW
Suite 210
Washington, DC, 20001-7407
Email: michael.guastella@corar.org

General Comment

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) request of input on patient release programs as prescribed in Federal Register, Vol. 82, No. 68, published on April 11, 2017 for Docket ID NRC-2017-0094.

CORAR's position is that the current requirements prescribed in 10 CFR 35.75 are adequate to maintain doses to patients, general public (including family and minors), and caregivers "as low as reasonably achievable" (ALARA) while maximizing the health benefits of medical procedures involving the use of radioactive materials. CORAR's position is based on published scientific data, industry best practices and performance, expert review of radiation protection criteria and NRC past reviews and rulemaking.

CORAR full comments are attached.

Thank you,

Michael Guastella (Executive Director)

Attachments

CORAR comments to NRC-2017-0094 (6-21-17)

CORAR

The Council on Radionuclides and Radiopharmaceuticals, Inc.

500 North Capitol Street, NW
Suite 210
Washington, DC 20001-7407
(202) 547-6582
Fax: (202) 547-4658
michael.guastella@corar.org

Michael J. Guastella, MS, MBA
Executive Director

June 21, 2017

Cindy Bladey
Office of Administration
Mail Stop OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: DOCKET ID NRC-2017-0094, PATIENT RELEASE PROGRAM; FEDERAL REGISTER VOL. 82, NO. 68; APRIL 11, 2017

Dear Ms. Bladey:

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) request of input on patient release programs as prescribed in *Federal Register,* Vol. 82, No. 68, published on April 11, 2017 for Docket ID NRC-2017-0094. CORAR is an industry association of firms that manufacture diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine and research, and also includes firms that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities.

CORAR's comments are enclosed for your review and consideration. Prior to providing comments to NRC-2017-0094, CORAR provides a background summary of previous petitions for rulemaking and NRC actions relevant to patient release programs as prescribed in Title 10 of the Code of Federal Regulations, Part 35, Section 75 (10 CFR 35.75).

CORAR's position is that the current requirements prescribed in 10 CFR 35.75 are adequate to maintain doses to patients, general public (including family and minors), and caregivers "as low as reasonably achievable" (ALARA) while maximizing the health benefits of medical procedures involving the use of radioactive materials. CORAR's position is based on published scientific data, industry best practices and performance, expert review of radiation protection criteria and NRC past reviews and rulemaking.

Please do not hesitate to contact me at (202) 547-6582 if you have questions or need additional information regarding our comments.

Sincerely,

Michael J. Guastella

Michael J. Guastella
Executive Director

MJG:mdl
Enclosure

Council on Radionuclides and Radiopharmaceuticals, Inc.

COMMENTS ON PATIENT RELEASE PROGRAMS AS REQUESTED ON DOCKET ID NRC-2017-0094 PUBLISHED ON FEDERAL REGISTER VOL. 82, NO. 68

On September 2, 2005, the U.S. Nuclear Regulatory Commission (NRC) received a petition for rulemaking (PRM-35-18) in response to 1997 NRC's revision (RIN 3150-AE41) to Title 10 of the Code of Federal Regulations, Part 35, Section 75 (10 CFR 35.75). NRC's revision included the following:

- Revised the patient release based on a dose-, risk-based approach rather than activity-based approach.
- Removed the need for record keeping of total effective dose equivalent to the exposed individual (family, caregivers, general public) when the dose is not likely to exceed 0.5 mSv (0.05 rem) per procedure to account for multiple radionuclide administrations in the same calendar year.
- Instituted requirements for providing safety guidance to patients.

After a request for comment and consideration, on April 23, 2008, NRC denied the petition for rulemaking.

In December 2010, at the request of NRC, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) reviewed the technical basis for patient release programs and published their findings in the *Patient Release Report*[1]. The comprehensive report reviewed current patient release criteria and provided additional technical basis for its adoption. The report included national and international recommendations for: dose control of released patients and other individuals (caregivers, family, and minors); patient isolation; risk-informed dose limits; and a review of the activity-based release criteria of "30-mCi" rule prior to the 1997 revision.

Requested Information and Comments

The following section provides the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) comments on NRC's request of input on patient release programs as published in the *Federal Register,* Vol. 82, No. 68, on April 11, 2017 for Docket ID NRC-2017-0094.

A. Should the NRC develop an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met?

It is CORAR's position that the current risk- and dose-based patient release criteria prescribed in 10 CFR 35.75 are technically sound and adequate to maintain patients and other individuals (public, family and caregivers) doses "as low as reasonably achievable" (ALARA) while taking into account socio-economic factors and the patient wishes[2]. The patient release guidance provided in NUREG-1556, Volume 9, Revision 2 and Regulatory Guide 8.39 supplement the dose estimates to the patients, family members, and caregivers to ensure compliance with 10 CFR 35.75.

NRC tasked ACMUI with reviewing the activity-based ("30-mCi" rule) patient release criteria approach used prior to the 1997 revision to Part 35.75 and re-evaluating the technical basis for a dose-based approach. In the 2010, ACMUI stated[1]:

[1] ACMUI 2010. Advisory Committee on the Medical Uses of Isotopes. *Patient Release Report.* ADAMS no. ML103481099

[2] 62 FR 4120: "Criteria for the Release of Individuals Administered Radioactive Material-Final Rule", NRC Docket No. RIN 3150-AE41, January 29, 1997

The Council on Radionuclides and Radiopharmaceuticals, Inc. • 500 North Capitol Street, NW • Suite 210 • Washington, DC 20001-7407
(202) 547-6582 • Fax: (202) 547-4658 • michael.guastella@corar.org

The Subcommittee finds no scientific merit in returning to such activity-based release criteria, which have no identifiable scientific basis.

ACMUI reports concentrated on the patient release from sodium iodide I-131 (I-131) administration as example. However, Part 35.75 applies to all radiopharmaceuticals administrated for therapy or diagnostic procedures – not just sodium iodide I-131 – regardless of the modality. The activity-based ("30-mCi") release criterion was based on an Atomic Energy Commission (AEC) decision under the premise that below 30-mCi the dose to other individuals would remain below 10 CFR 20.1301 dose requirements for general public (1 mSv/year or 0.1 rem/year)[3].

However, the activity-based rule lacked the scientific merit to make patient release decisions based on risk while taking into account the radiological and biological characteristics of the administrated radiopharmaceutical. For example, radiopharmaceuticals whose primary emissions are gamma rays would pose a greater risk for external exposure to others than those whose primary emissions are via beta particles. This is mainly due to the body acting as a shield. Additionally, as the biological excretion rate will differ between radiopharmaceuticals, higher biological excretion rates may yield to lower internal doses[4].

On NUREG-1556, Volume 9, Revision 2, Appendix U, Table U.1, NRC presents a guidance for releasing patients on a risk- and dose-based approach. The guidance provided in NUREG-1556 is conservative and consistent with the recommendations provided by the National Council on Radiation Protection and Measurements (NCRP) Report 11; NCRP Report 37 (and subsequently maintained on NCRP Report 155); International Council on Radiation Protection (ICRP) Publication 94; and International Atomic Energy Agency (IAEA) Safety Report Series No. 63.

Establishing an activity-based release criteria will increase the hospitalization/isolation of patients when the potential dose to members of the public, family and/or caregivers do not increase the biological risk. In such cases, the societal factors, to the patient and family, out-weigh the potential radiological dose risks[1] and increases direct and indirect costs[2,5]. Additionally, extended hospitalization/isolation practices may factor in the patient's decision to postpone or decline critical medical care if the family environment may be affected for a prolonged period of time (e.g., child care). Finally, prolonged hospital/isolation requirements will significantly increase treatment costs to hospital/isolation facilities when hospitalization/isolation is not necessary[6].

Adopting the "30-mCi rule" for patient release may negatively affect the access to and effectiveness of medical treatments as some practitioners may elect to fractionate therapy doses to comply with the release dose criteria. ACMUI concluded that "the 30-mCi rule is a special case of the 1997 release criteria" for sodium iodine I-131 meeting specific assumptions that includes, but is not limited to, ignoring the biological elimination of iodine by the body[1]. Moreover, ACMUI concluded that:

Change from the 30-mCi rule to the current 10 CFR 35.75 patient release criteria in no way weakened the NRC rules.

---

[3] Siegel Jeffry A. and Silberstein Edward B. Thyroid. November 2014, 24(11): 1625-1635

[4] ICRP 106. Radiation Dose to Patients from Radiopharmaceuticals. International Commission on Radiation Protection (ICRP). Report 106. 2008.

[5] NRC SECY 96-100: "Final Amendments to 10 CFR Parts 20 and 35 on Criteria for the Release of Individuals Administered Radioactive Material", Nuclear Regulatory Commission, May 8, 1996.

[6] NRC NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Materials, Final Report", by Stewart Schneider and Stephen A. McGuire, Nuclear Regulatory Commission, April 1996.

B. Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing individuals? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider?

It is CORAR's position that the time frame for the current dose limit in 10 CFR 35.75(a) does not need to be amended as it meets the intent of NRC final rulemaking[2].

NRC stated on its final rulemaking conclusions for the 1997 revision of 10 CFR 35.75, that the dose limits are on a per-release basis. NRC stated:

> *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.*

In its 2010 report, ACMUI provided an extensive review of the precursors to the release timeframe confusion and subsequent NRC rulemaking decision[1]. The release timeframe confusion arose from a discrepancy on NRC statements on the proposed rulemaking and the final rulemaking. In relation to the dose limit timeframe, NRC state in the final rulemaking that:

> *Upon reconsideration, based on public comments and consultation with the ACMUI, an NRC medical consultant, and the NRC Visiting Medical Fellow, the NRC has decided to delete this requirement. A review of medical treatment practices revealed no common practice that would result in doses exceeding the 5 millisievert (0.5 rem) limit because of multiple administrations in the same year to the same patient. Without the need to account for the dose from multiple administrations, maintaining records for the many tens of thousands of patients released when their dose to an individual is likely to exceed 1 millisievert (0.1 rem) becomes an unnecessary burden. The requirement to retain these records has therefore been deleted. Each patient release is to be treated as a separate event, and licensee knowledge of previous administrations is unnecessary.*

C. Should NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant woman, caregivers, hotel workers, and other members of the public when considering the release of patients?

CORAR's position is that the current 5 mSv (0.5 rem) dose criteria prescribed in 10 CFR 35.75 are adequate and should continue to be used for the release of patients undergoing medical procedures with radioactive materials.

The 10 CFR 35.75 dose criteria for patient release is consistent with the recommendations provided by the National Council on Radiation Protection and Measurements (NCRP) Report 11; NCRP Report 37 (and subsequently maintained on NCRP Report 155); International Council on Radiation Protection (ICRP) Publication 94; and International Atomic Energy Agency (IAEA) Safety Report Series No. 63.

A dose study[7] on family members of released patients treated with sodium iodide I-131 showed that the direct dose measurements ranged between 0.1 to 3.54 mSv (0.01 to 0.354 rem). Dose estimates conducted by ACMUI indicate that, even with the use of over conservative NRC guidance dose algorithms, the dose to other individuals are expected to remain below the 10 CFR 35.75 dose

[7] Rutar, F.J., S.C. Augustine, D. Colcher, J.A. Seigel, D.A. Jacobson, M.A. Tempero, V.J. Dukat, M.A. Hohenstein, L.S. Gobar and J.M. Vose. "Outpatient Treatment with 131I-Anti-B1 Antibody: Radiation Exposure to Family Members". *J Nucl Med.* 2001;42:907-915

criteria[1]. Other peer-reviewed publications validate the dose criteria for members of the public, family and caregivers[8,9,10].

In its most recent (March 2012) position statement, the Health Physics Society indicate that[11]:

The HPS considers the NRC patient release dose criteria to be consistent with the HPS position statement "Ionizing-Radiation Standards for the General Public," which calls for a general public limit of 1 mSv or, in special (infrequent) circumstances, a limit of 5 mSv in any one year (HPS 2009). The HPS discourages establishment of an annual dose limit for patient release criterion due to the potential for unnecessarily limiting a patient's access to treatment with therapeutic quantities of radiopharmaceuticals and sealed sources.

The Health Physics Society maintains that release of patients in accordance with 10 CFR 35.75 poses no discernible risk to the public, thus providing ample public health safety measures, and provides significant benefits to patients, their families, and society.

D. Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?

CORAR's position is that the current 5 mSv (0.5 rem) dose criteria prescribed in 10 CFR 35.75(a) paired with instructions for maintaining doses ALARA if the doses to others are likely to exceed 1 mSv (0.1 rem), including children and pregnant women, are adequate and should continue to be used for the release of patients undergoing medical procedures with radioactive materials.

The Health Physics Society position regarding radiation risk states that[12]:

Substantial and convincing scientific data show evidence of health effects following high-dose exposures (many multiples of natural background). However, below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero.

The health effects from low-dose radiation exposures (below 100 mSv) has been a point of contention in the last two decades as recent debates emerged about the use of the linear no-threshold (LNT) hypothesis by the NRC for establishing radiation protection requirements and standards. The LNT hypothesis assumes that any radiation exposure results in detrimental health effects. According to the Health Physics Society:

"...because of statistical uncertainties in biological response at or near background levels, the LNT hypothesis cannot provide reliable projections of future cancer incidence from low-level radiation exposures (NCRP 2001)."[13]

---

[8] Grigsby PW, Siegel BA, Baker S, Eichling JO. Radiation exposure from outpatient radioactive iodine (^{131}I) therapy for thyroid carcinoma. JAMA 283(17):2272-2274; 2000

[9] Pant GS, Sharma SK, Bal CS, Kumar R, Rath GK. Radiation dose to family members of hyperthyroidism and thyroid cancer patients treated with ^{131}I. Radiat Prot Dosimetry 118(1):22-27; 2006

[10] Siegel JA, Marcus CS, Stabin MG. Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with ^{131}I. Health Phys 93:667-677; 2007

[11] Health Physics Society. "Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources". Position Statement No. PS-027-0. Adopted on March 2012

[12] Health Physics Society. "Radiation Risk in Perspective". Position Statement No. PS-010-3. Revised on May 2016

[13] National Council on Radiation Protection and Measurements (NCRP). Evaluation of the linear-nonthreshold dose-response model for ionizing radiation. Report No. 136. 2001

IAEA position statement regarding Safety Report Series No. 63[14] indicates that the patient circumstances, medical condition and presence of young children should be considered when releasing patients that undergo medical procedures with radioactive materials. Additionally, IAEA warns about the use of "over-cautious" approaches for radiation safety precautions. Any advice or recommendation should aim to maintain doses to other individuals (family, public, children) less than 1 mSv (0.1 rem) whenever possible.

CORAR strongly believes that the physicians are better equipped to evaluate, and take into consideration, the patient home circumstance to maintain a balance between the potential radiation dose and the physiological and socio-economic impact to the patient and family to maintain doses ALARA and within the prescribed dose criteria in 10 CFR 35.75. Establishing a prescriptive dose of 1 mSv (0.1 rem) for young children and pregnant women may unnecessarily increase the need for patient isolation, treatment costs, and may place additional psychological burden of the patient and family members. Given that the potential dose is near background levels[6] and below 100 mSv, the statistical uncertainty of biological responses cannot provide reliable projections of adverse effects[11,12].

E. Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?

CORAR agrees that physicians should hold adequate discussions with patients prior to undergoing medical procedures that use radioactive materials; particularly when isolation may be necessary. CORAR, however, disagrees with establishing a prescriptive timeframe for holding discussions related to isolation.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) provided comments to NRC request for information concerning patient release practices (NRC-2015-0020)[15]. Their comments, stated:

> *It is of upmost importance that the treating physician has a good understanding of the patient's disease status and also be well informed on their current socioeconomic status, living arrangements, and ability to comply with the recommendations. This includes detailed communication between the practitioner and the patient, regardless of language barriers. Appropriate medical translators should be available, in person or via other approved electronic translation services. Occasionally, a family member or friend of the patient may also be a method to increase compliance and improve retention of the recommended precautions and risks.*
>
> *A discussion concerning the patient's release must take place in order to alert the patient of necessary precautions after radioiodine treatment. The suitability for release must be determined by the treating physician, who should consider the patient's understanding and willingness to comply with the precautions.*

On a policy statement, NRC stated that[16]:

> *The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.*

---

[14] IAEA Position Statement, "Release of Patients after Radionuclide Therapy", International Atomic Energy Agency, February 23, 2010

[15] Available at http://snmmi.files.cms-plus.com/docs/hpra/Patient_release_NRC_%20February2016_FINAL.pdf

[16] 65 FR 47654, "Medical Use of Byproduct Material; Policy Statement, Revision", Nuclear Regulatory Commission, August 3, 2000

CORAR strongly believes that clear discussion between the physicians and the patients are key for a successful treatment and adherence to care practices. However, it is CORAR's opinion that the physicians are better equipped to evaluate, and take into consideration, the patient home circumstance to maintain a balance between the potential radiation dose and the physiological and socio-economic impact to the patient and family to maintain doses ALARA and within the prescribed dose criteria in 10 CFR 35.75. Establishing prescriptive timeframes for holding isolation discussions may result in unnecessary license and regulatory burden for licensees.

F. Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., instructions should be given prior to the procedure)?

Similar to item E, CORAR agrees that physicians should provide clear instructions to the patient prior to undergoing medical procedures that use radioactive materials to ensure understanding of radiation safety practices and restrictions. CORAR, however, disagrees with establishing a prescriptive timeframe for providing these instructions.

As with any medical procedure, medical personnel provide instructions to patients in preparation for a procedure and for care after procedure completion. The content and patient understanding of post-procedure instructions have been a topic of concern for NRC in recent years. NRC and SNMMI partnered to provide instruction guidance to licensees, particularly for treatment procedures involving sodium iodine I-131[14].

CORAR strongly believes that a minimum standard for instruction content as well as patient understanding is necessary. However, it is CORAR's opinion that the physicians are better equipped to deliver clear instructions to patients regarding the procedures and radiation safety precautions within a sufficient timeframe to ensure understanding and compliance. Establishing prescriptive timeframes for providing instructions may result in unnecessary license and regulatory burden for licensees.