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Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

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Submitter Information

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General Comment

Please find, attached, SNMMI's and ACNM's joint comment letter.

Attachments

NRC Extravasation Comment Letter Final_signed 11-25-20

November 25, 2020

Ms. Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
ATTN: NRC-2020-0141
Mail Stop O-16 B33
Washington, DC 20555-0001

Re: *[NRC-2020-0141] Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment*

Dear Secretary Vietti-Cook:

We are writing in response to the U.S. Regulatory Commission (NRC)'s request for comment on Reporting Nuclear Medicine Injection Extravasations as Medical Events. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 16,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice. The American College of Nuclear Medicine (ACNM) is a professional organization that directly represents the interests of nuclear medicine physicians before legislative and regulatory bodies, other medical organizations, the media and general public.

Our goal is to assure a legislative, legal, regulatory, and economic framework that encourages and makes practicable the safe, appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients. We appreciate the opportunity to provide comments to assist the NRC in clarifying **that the reporting of a nuclear medicine extravasation, which is an uncommon event, is a practice of medicine issue and not a regulatory issue.** Thus**, no further amendments to 10 C.F.R. §35 are warranted**. Our comments address the NRC's questions and refute certain remarks made by the Petitioner:

A. Injection Quality Monitoring

1. How frequently does radiopharmaceutical extravasation occur?

By definition, an extravasation is the deposition of some or all of a radiopharmaceutical, intended for intravenous or intraarterial injection, into the tissue surrounding the vessel. Thus, whenever such an injection is attempted, there is a potential for extravasation.

The question of frequency, however, is perhaps not the most relevant question for purposes of providing comment. **The more relevant question is: How often are patients harmed by nuclear medicine extravasations?** There are approximately 20 million doses of radiopharmaceuticals administered intravenously each year in the United States.[1] In a recent meta-analysis, van der Pol, *et al.* summarized 37 previously published reports of the consequences of radiopharmaceutical extravasation.[2] Of a total of 3016 diagnostic radiopharmaceutical extravasations, only three (< 0.1%) were associated with adverse reactions. In each case the adverse reaction was limited to the skin adjacent to the injection site and all were associated with relatively infrequently used radiopharmaceuticals. It must be emphasized that no adverse reactions were reported for the more than 3000 cases of extravasation of the commonly used ^{99m}Tc-, ^{123}I-, ^{18}F-, and ^{68}Ga-labelled radiopharmaceuticals. In summary, there are no clinical data that support the Petitioner's claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue.

The reporting of medical events according to the NRC's own policy language is intended to be risk-based.[3] In August, 2000, the NRC issued a revised Medical Use Policy Statement to focus its regulatory emphasis on those medical procedures that pose the highest, potentially significant, risks.[4] Specifically, the Medical Use Policy Statement states:

> [The] NRC **will not intrude into the medical judgements affecting patients**, except as necessary to provide for the radiation safety of workers and the general public. [The] NRC will, **when justified by the risk to patients, regulate the radiation safety of patients** primarily to assure the use of radionuclides is in accordance with the physician's direction. [The] NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety. (65 Fed. Reg. 47654 (2000))

[1] National Research Council (US) and Institute of Medicine (US) Committee on State of the Science of Nuclear Medicine. Advancing Nuclear Medicine Through Innovation. Washington (DC): National Academies Press (US) (2007) 2, Nuclear Medicine. Available from: https://www.ncbi.nlm.nih.gov/books/NBK11471/; *see* Delbeke, D., & Segall, G.M. (2011). Status of and Trends in Nuclear Medicine in the United States. *J Nucl Med.* 52, 24S–28S; *see also* Mettler, F. A., Faulkner, K., Gilley, D. B., *et al.* (2009). Radiologic and Nuclear Medicine Studies in the United States and Worldwide: Frequency, Radiation Dose, and Comparison with Other Radiation Sources—1950 – 2007." *Radiology*. *253*(2), 520-531.

[2] van der Pol J., Vöö S, Bucerius J., & Mottaghy F.M. Consequences of radiopharmaceutical extravasation and therapeutic interventions: a systematic review. (2017). *Eur J Nucl Med Mol Imaging. 44*(7), 1234-1243. doi: 10.1007/s00259-017-3675-7. Epub 2017 Mar 16. PMID: 28303300; PMCID: PMC5434120.

[3] 65 Fed. Reg. 47654 (2000).

[4] *Id.*

- The NRC will continue to regulate the medical use of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
- NRC **will not intrude into the medical judgements affecting patients**, except as necessary to provide for the radiation safety of workers and the general public.
- NRC will, **when justified by the risk to patients, regulate the radiation safety of patients** primarily to assure the use of radionuclides is in accordance with the physician's direction.
- NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

As reported by van der Pol *et al.*, less than 0.1% of diagnostic extravasations resulted in adverse reactions.[5] Similarly, the Australian Radiation Incident Register estimated that there are approximately 6 maladministrations (which include extravasations) per 100,000 procedures and believes that the risk of harm is low.[6] Thus, there is essentially no harm to patients. Furthermore, in the event a patient did experience harm, it would be considered an institutional practice of medicine quality control issue and not fall under NRC regulation (unless already indicated so in 10 CFR §35).

2. *Do you know of any extravasations that have resulted in harm to patients? If so and without including information that could lead to the identification of the individual, describe the circumstances, type of effect harm, and the impacts.*

As noted above, the recent review by van der Pol. *et al.*, reported **only three instances** where patients reported symptoms out of 3016 instances of diagnostic radiopharmaceutical extravasation (0.1%)

The SNMMI task force, charged with responding to this request for comment, consists of the clinicians listed below. Their combined experience in clinical nuclear medicine totals 165 years and the total number of studies performed per year is approximately 43,000 (a total of more than 7,000,000 studies). In all of these studies, none of the members listed below has ever encountered a case in which a patient experienced significant harm as the result of the extravasation of a diagnostic radiopharmaceutical.

Name: Jean-Luc Urbain, MD
Institution: Wake Forest University
Number of years practicing nuclear medicine: 34 years
Number of studies performed per year: 7500
Number of cases where you have seen significant harm come to patients: 0

Name: Tina Buehner, PhD, CNMT
Institution: Rush University Medical Center (previously at Northwestern Memorial Hospital and Loyola University Medical Center)
Number of years practicing nuclear medicine technology: 20
Number of studies performed per year: 1800
Number of cases where you have seen significant harm come to patients: 0

[5] Eight publications reported 10 cases of therapeutic tracer extravasation. The most severe symptom was ulceration. van der Pol, J., *et al.* at 1234.
[6] Larcos, G.S., Collins, L.T., Georgiou, A. & Westbrook, J.I. (2014). Maladministrations in nuclear medicine: revelations from the Australian Radiation Incident Register. *Med J Aust*. *200*(1), 37-40.

Name: Christopher J. Palestro, MD
Institution: Northwell Health
Number of years practicing nuclear medicine: 38
Number of studies performed per year: 10,000
Number of cases where you have seen significant harm come to patients: 0

Name: Richard L. Wahl, MD
Institution: Washington University School of Medicine, Mallinckrodt Institute of Radiology. Previously chief of nuclear medicine at Johns Hopkins University School of Medicine, Baltimore, MD. Previously director of nuclear medicine imaging University of Michigan.
Number of years practicing nuclear medicine: 37
Number of studies performed per year: 10,000
Number of cases where you have seen significant harm come to patients: 0

Name: Munir Ghesani, MD
Institution: Mount Sinai Health
Number of years practicing nuclear medicine: 24
Number of studies performed per year: 10,000
Number of cases where you have seen significant harm come to patients: 0

Name: Erin Grady, MD
Institution: Emory University School of Medicine
Previously at the Christiana Care Health System in Newark, DE and Loyola University Medical Center in Maywood, IL.
Number of years practicing nuclear medicine: 12
Number of studies performed per year: 7,000-10,000
Number of cases where you have seen significant harm come to patients: 0

3. *For medical use licensees, does your facility currently monitor for radiopharmaceutical extravasation? If so, why and how do you monitor? If not, why not?*

Below, please find our task force members' institutional monitoring/quality improvement policies:

Name: Jean-Luc Urban, MD
Institution: Wake Forest University
Extravasation Monitoring/Quality Improvement Policy: Monitoring is done through procedure protocol during the injection and imaging of the sites of intravenous injection. We do have regular technologist in-service education about nuclear medicine protocols and safety procedures.

Name: Tina Buehner, PhD, CNMT
Institution: Rush University Medical Center
Extravasation Monitoring/Quality Improvement Policy: All patients have an intravenous (IV) catheter placed for all radiology procedures requiring an IV injection. Nuclear medicine technologists are trained to identify infiltrations, which are extremely rare in the placement of IV catheters.

Name: Christopher J. Palestro, MD
Institution: Northwell Health
Extravasation Monitoring/Quality Improvement Policy: We conduct in-service education about nuclear medicine protocols and safety procedures. All intravenous radiopharmaceutical administrations are performed through a catheter that is checked for venous patency by the nuclear medicine technologist prior to radiopharmaceutical injection. For those studies in which there is a delay between injection and imaging (bone scans, MIBG, etc.), when the injection is performed in Nuclear Medicine, an image of the injection site is obtained before releasing the patient. All extravasations, for which a repeat injection is deemed necessary for satisfactory image quality, are reported to institutional quality management.

Name: Richard L. Wahl, MD
Institution: Washington University School of Medicine, Mallinckrodt Institute of Radiology.
Extravasation Monitoring/Quality Improvement Policy: All patients have an intravenous (IV) catheter placed for all radiology procedures requiring an IV injection. Nuclear medicine technologists are trained to identify infiltrations, which are extremely rare after the placement of IV catheter. Physicians routinely examine scans of the injection site for infiltrations and use such information to provide continued feedback to the technical staff for quality improvement.

Name: Munir Ghesani, MD
Institution: Mount Sinai
Extravasation Monitoring/Quality Improvement Policy: For exams such as a whole body bone scan, indium WBC scan and gallium scan, the physician interpreting the exam monitors the injection site as part of the quality control of the images prior to making interpretation and generating the report. If the physician finds any extravasation she/he communicates it to the technologist/nurse and the supervisor to emphasize proper technique of IV access and radioisotope administration.

Name: Erin Grady, MD
Institution: Emory University School of Medicine
Extravasation Monitoring/Quality Improvement Policy: We have instituted a policy of injecting only through a patent IV catheter which has reduced our extravasation rate to near zero. Technologists routinely evaluate the site of injection and both technologists and physicians

evaluate the images. No clinically significant diagnostic infiltrations have been recorded. There has only been one historically significant dose infiltration of a therapeutic radiopharmaceutical at our institution which occurred prior to my arrival.[7]

In summary, effective procedures are already in place as part of established nuclear medicine practice to prevent and detect extravasations of radiopharmaceuticals.

4. *Do you expect that monitoring for extravasation and reviewing the results would improve radiopharmaceutical administration techniques at medical use licensee facilities? If so, how? If not, why not?*

Monitoring is not expected to improve administration techniques. Rather, as in other areas of nuclear medicine practice and as documented in our response to Question 3, regular in-service education of those individuals who administer radiopharmaceuticals in adult, geriatric, and pediatric populations will improve administration techniques. Yearly, age-specific, competency is essential to working with special populations, particularly pediatric and geriatric populations, in whom venous access can be more difficult to achieve.

5. *Do you believe an NRC regulatory action requiring monitoring and review of extravasation would improve patient radiological health and safety? If so, how? If not, why not?*

NRC regulatory action requiring monitoring and review of extravasation will **not** improve patient radiological health and safety. Nuclear medicine extravasations are clearly within the scope of medical practice and quality improvement. Good nuclear medicine practices already include imaging injection sites in certain cases using gamma cameras. In the event an extravasation or partial extravasation is suspected, imaging of the injection site should be performed using a gamma camera. The authorized user should be notified to determine the appropriate course of action for the individual patient and their study.

It must be emphasized that virtually all patients injected with diagnostic radiopharmaceuticals are, of course, routinely imaged and thus any significant extravasations are already sensitively and unambiguously identified. Regulatory monitoring of extravasations is not only unnecessary but would further burden practitioners without any benefit whatsoever to patients.

Finally, it is important to reiterate that there is no evidence suggesting that patient radiological health and safety is at risk under existing NRC regulations. Therefore, further NRC regulatory action will not improve patient radiological health and safety.

[7] Bonta, D.V., Halkar, R.K., Alazraki, N., Extravasation of a therapeutic dose of ^{131}I-metaiodobenzylguanidine: prevention, dosimetry, and mitigation. (2011) *J Nucl Med*. *52*(9):1418-22. doi: 10.2967/jnumed.110.083725. Epub 2011 Jul 27. PMID: 21795365.

B. Medical Event Classification and Reporting Criteria

1. *Are there any benefits, not related to medical techniques, to monitoring and reporting certain extravasations as medical events? What would be the burden associated with monitoring for and reporting certain extravasations as medical events?*

We reiterate our position that there is no problem to be solved and, therefore, no additional rulemaking is needed. In fact, additional rulemaking as requested by the Petitioner would cause considerably more harm to the field of nuclear medicine and to patients than the extravasations themselves. Characterization of infrequent and clinically inconsequential extravasations as "medical events" will create a chilling effect on referring physicians and their patients by conveying a false sense of hazard, reinforcing "radiation paranoia", and resulting in some physicians and patients avoiding clinically important, beneficial and potentially life-saving nuclear medicine procedures.

In addition, a heightened NRC monitoring and reporting requirement will have devastating financial repercussions on nuclear medicine practices. Over the first months of the COVID-19 pandemic, data from 228 hospitals showed that that had lost an estimated $1.3 billion in revenue compared to 2019, the equivalent of $60 billion per month in lost revenue for hospitals nationwide.[8] As the healthcare system recovers from the COVID-19 pandemic, these unnecessary and excessive reporting requirements, which will be equally burdensome for nuclear medicine physicians and referring physicians, will cause medical practices to experience additional financial hardships due to inadequate reimbursement for the increased labor costs, required to comply with the new reporting requirements. Medical practices operating at slim margins will likely be unable to sustain their business and may be forced to close. A serious consequence of these closures, which cannot be overemphasized, is the adverse effect of such closures on patient access to life-saving nuclear medicine procedures, especially in those communities, which already are medically underserved.

2. *If the NRC were to require that licensees report certain extravasations as medical events (recorded in NMED), what reporting criteria should be used to provide the NRC data that can be used to identify problems, monitor trends, and ensure that the licensee takes corrective action(s)?*

As stated in our answer to question #B1, SNMMI, ACNM, and other professional organizations oppose the NRC requiring licensees to report certain extravasations as medical events beyond those listed in 10 CFR §35. Such a requirement would be harmful to patients because it would exacerbate "radiation paranoia," potentially causing a patient to avoid clinically important

[8] National Patient and Procedure Volume Tracker. "Analysis of 2 Million Patient Encounters Reveals U.S. Hospitals are Losing $60 Billion per Month; Uninsured Patients Up 114% During COVID-19 Pandemic." Version 5.11.2020. https://www.stratadecision.com/wp-content/uploads/2020/05/National-Patient-and-Procedure-Volume-Tracker-and-Report_May2020.pdf

radiopharmaceutical diagnostic and therapeutic studies. The COVID-19 pandemic has clearly demonstrated how fear of illness discourages patients from returning or seeking care even when proper precautions are in place. A study the SNMMI conducted among its membership revealed that nuclear medicine and radiology practices were forced to significantly reduce, and even cease, performing important services.[9] Almost 93% of respondents saw a decrease in the number of diagnostic nuclear medicine imaging studies performed as a result of COVID-19.[10] For conventional nuclear medicine procedures (other than PET), about 80% experienced a decrease of 50% or more in study volumes (~37% saw a 50% decrease; ~42% saw a 75% decrease).[11] Survey respondents also reported almost a 40% decrease in important radionuclide therapy volumes, with 15% halting all of these potentially life-saving procedures.[12] If patients are informed that extravasations, as inconsequential as they are, are a "medical event," the impact will be detrimental to nuclear medicine and, most importantly, to patients – with no corresponding benefit.

3. *If the NRC requires reporting of extravasations that meet medical event reporting criteria, should a distinction be made between reporting extravasations of diagnostic and therapeutic radiopharmaceuticals? If so, why? If not, why not?*

The Petitioner's proposed amendments do not differentiate between diagnostic and therapeutic extravasations. We do not believe such a differentiation is needed since the management and reporting of extravasations is a practice medicine issue and no additional NRC rulemaking is necessary. Furthermore, we take issue with the Petitioner's proposed amendments.

The Petitioner seeks to amend 10 C.F.R § 35.2 and 10 C.F.R. § 35.3045 to require the reporting of extravasations that exceed the 0.5 Sv dose equivalent to tissue as medical events. Specifically, the Petitioner states:

> 10 C.F.R. § 35.2 should be amended to include a definition of "extravasation" as follows: Extravasation means the inadvertent injection or infusion of some or all of a radiopharmaceutical dosage into the tissue surrounding a vein or artery. . . 10 C.F.R. § 35.3045(a)(1) should be amended by adding the following item iv.: (iv) An extravasation that leads to an irradiation resulting in a **localized** dose equivalent exceeding 0.5 Sv (50 rem). The effect of these modifications would be to require reporting of extravasations resulting in a localized dose equivalent exceeding 0.5 Sv (50 rem). (Incoming Petition for Rulemaking (PRM-22-35), p. 11)

[9] DaCosta, M.C., Hafez, A., Ghesani, M., *et al*. (2020). SNMMI COVID-19 Task Force Surveys. *J Nucl Med. 61*(9), 1N-4N.
[10] *Id.* at 1N.
[11] *Id.*
[12] *Id.*

Currently, the dose criteria for a reportable medical events include "A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following. . ."[13] An extravasated radiopharmaceutical administration would never deliver 0.5 Sv (50 rem) to any whole organ or tissue, including the skin – that is, if one averaged the absorbed dose or dose equivalent from an extravasated radiophamaceutical to any organ or tissue, that average value would be **far lower** than 0.5 Sv (50 rem).

We also take issue with the Petitioner's inclusion of the term "localized". Since the term is not defined, it is unclear what the Petitioner means when using this term. Does the Petitioner mean to refer to the injection site/injected volume itself? "Localized" is a very nebulous/ill-defined term, and the NRC should find that alone problematic. Ultimately any extravasated radiopharmaceutical is absorbed through the lymphatic system of the body and reaches the intravenous circulation. The inclusion of the term "localized" makes the proposed amendments ambiguous and unenforceable.

C. Rebutting the Petitioner's Remarks

1. *"Unlike patient interventions which are ostensibly outside of the control of a physician or other practitioner, extravasations are avoidable. . . and are capable of causing considerable harm to the patients." (Incoming Petition for Rulemaking (PRM-22-35), p. 2)*

Extravasations, as remarkably infrequent and clinically inconsequential as they are, may be further reduced through establishing best practices. They are, however, often related to patient-specific anatomy and not completely avoidable.[14] In 2019, the ACMUI Subcommittee on Extravasation reviewed the 1980 NRC decision to exclude extravasations from being considered a misadministration (medical event).[15] The Subcommittee agreed with the 1980 assessment that extravasations frequently occur in otherwise normal intravenous or intra-arterial injections and are virtually impossible to avoid. They concluded that extravasations are a practice of medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight. The Subcommittee reconfirmed that the exclusion of extravasation from medical-event reporting was appropriate for both diagnostic and therapeutic procedures.

The final report of the Subcommittee on Patient Intervention, which was presented and approved by the ACMUI at the April 2020 meeting also addressed this issue. The Subcommittee noted that "…the purpose of the Medical Event reporting rule is to evaluate if there was an error or problem in the licensee's program for ensuring that byproduct material or radiation from

[13] 10 CFR §35.3045(a)(1)(ii)
[14] Charkabarti, K. Extravasation Events: Imaging Drugs and Radiopharmaceuticals. FDA-NRC Workshop: Enhancing Development of Novel Technologies: Radiopharmaceuticals and Radiologic Devices, Virtual Workshop, October 14, 2020
[15] ACMUI, Subcommittee on Extravasation, Final Report, October 23, 2019

byproduct material was administered as directed by the [authorized user] AU, or if there was a generic issue that should be reported to other licensees, thereby reducing the likelihood of other Medical Events."[16] Medical Events that take place during the course of a properly performed clinical procedure, which are due to actions by the patient that could not have been reasonably prevented by the licensee, …" or from an anatomical or physiological condition of the patient which falls into the realm of the practice of medicine, should not need to be reported." The reporting of unavoidable patient-specific events will not reduce the likelihood of such events occurring in the future and doing so would potentially infringe on the practice of medicine.

2. *"While medical events are generally reportable to the NRC, medical events that qualify as patient interventions need not be reported. Patient interventions are defined in 10 C.F.R. § 35.3045 as "actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration." (Incoming Petition for Rulemaking (PRM-22-35), p. 10)*

In addition to the NRC's consideration of the question of radiopharmaceutical extravasations in 1980, the Commission has revisited this issue several times since. As stated previously, in August, 2000, the NRC issued a revised Medical Use Policy Statement to focus its regulatory emphasis on those medical procedures that pose the highest, potentially significant, risks.[17] In April, 2002, 10 CFR §35 was revised to be more risk-informed and performance-based, consistent with the revised Medical Use Policy Statement. Specifically, the term, "Misadministration," was changed to "Medical Event," and the reporting criteria were revised to include different types of deviations from the radiopharmaceutical administration that was prescribed (i.e., wrong activity, wrong radioactive drug, wrong route of administration, wrong patient, wrong mode of treatment, wrong treatment site, or implantation of leaking sealed source).

The definition of a Medical Event also includes dose-threshold criteria: an effective dose equivalent exceeding 0.05 Sv (5 rem), an organ or tissue dose equivalent exceeding 0.5 Sv (50 rem), or a shallow (skin) dose equivalent exceeding 0.5 Sv (50 rem).[18] There was an exclusion from the Medical Event reporting requirement for an event that results from "patient intervention."[19] However, a licensee must report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an

[16] Advisory Committee on the Medical Uses of Isotopes, Subcommittee on Patient Intervention, Final Report, April 6, 2020
[17] Federal Register, 47654, August 3, 2000, Volume 65 Nuclear Regulatory Commission,
Medical Use of Byproduct Material, Policy Statement; Revision
[18] 10 CFR §35.3045(a)
[19] "Patient intervention" is defined as: "actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration" (10 CFR §35.2)

organ or a physiological system, as determined by a physician.[20] Further, as in the case of stasis preventing administration of the complete activity prescribed for radioembolic therapy of liver tumors, patient-specific anatomic considerations are a form of "'passive' patient intervention."

3. *"Reporting Extravasations as Medical Events Will Increase the Likelihood that Radionuclides are Used in Accordance with Physicians' Direction." (Incoming Petition for Rulemaking (PRM-22-35), pp. 13-14)*

Radiopharmaceuticals are already used in accordance with the physician's direction and redefining extravasations as "medical events" will have no positive effect on administration of radiopharmaceuticals in accordance with the physician's direction. As already noted, the Petitioner's suggested amendment will discourage referring physicians from ordering nuclear medicine imaging studies in the future due to the increased reporting burden and the chilling effect of mischaracterizing occurrences with no clinical sequelae as "medical events."

In 2017, the ACMUI Patient Intervention Subcommittee examined unintentional treatment outcomes with ^{90}Y microsphere therapy and introduced the concept of "passive" rather than "active" patient intervention.[21] The subcommittee's report stated, "Unintentional treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met. Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated."[22]

As we conclude our comments, we want to emphasize that the Petitioner's request for additional rulemaking is not supported by any group that works in the field of nuclear medicine. In fact, on October 16, 2020, the North Carolina Radiation Protection Commission in their Special Called Meeting voted not to support the Petitioner's position. While the Organization of Agreement States (OAS) believes further rulemaking is warranted, this decision was apparently made in the absence of input from physicians or medical physicists since there are no physicians or medical physicists on its board. In contrast, the following organizations, all of which are engaged in day-to-day interactions with patients and/or clinical radiation safety support the SNMMI/ACNM position: The American Society of Nuclear Cardiology (ASNC), Health Physics Society (HPS), the American Society for Radiology Oncology (ASTRO), the American College of Radiology (ACR), the American Society of Physicists in Medicine (AAPM), the European Association of

[20] 10 CFR §35.3045(b)
[21] "Passive" patient intervention type was intended to address situations where there was a stasis of arterial flow or shunting of microspheres through aberrant vessels, resulting in a medical event for the Y-90 microsphere therapy. ACMUI, Subcommittee on Patient Intervention, Draft Report, Part II, April 27, 2017.
[22] *Id.*

Nuclear Medicine (EANM), the and Australian and New Zealand Society of Nuclear Medicine (ANZSNM).

In summary, the reporting of nuclear medicine extravasations is a practice of medicine issue and not a patient safety issue. Therefore, they are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation. Furthermore, the SNMMI recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies, and is actively addressing this as the quality-control issue that it is, rather than a patient safety issue.

Respectfully Submitted,

Alan B. Packard, PhD
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