Colonial Heights
Hopewell
Petersburg
Richmond
Virginia (counties):
Charles City
Chesterfield
Dinwiddie
Goochland
Hanover
Henrico
New Kent
Powhatan
Prince George

Area of Application. Survey area plus:

Virginia (cities):
Charlottesville
Emporia
Virginia (counties):
Albemarle (Does not include the Shenandoah National Park portion)
Amelia
Brunswick
Buckingham
Caroline
Charlotte
Cumberland
Essex
Fluvanna
Greene (Does not include the Shenandoah National Park portion)
Greensville
King and Queen
King William
Lancaster
Louisa
Lunenberg
Mecklenburg
Middlesex
Nelson
Northumberland
Nottoway
Orange
Prince Edward
Richmond
Sussex
Westmoreland

Roanoke

Survey Area

Virginia (cities):
Radford
Roanoke
Salem
Virginia (counties):
Botetourt
Craig
Montgomery
Roanoke

Area of Application. Survey area plus:

Virginia (cities):
Bedford
Buena Vista
Clifton Forge
Covington
Danville
Galax
Lexington
Lynchburg
Martinsville
South Boston
Staunton
Waynesboro
Virginia (counties):
Alleghany
Amherst
Appomattox
Augusta (Does not include the Shenandoah National Park portion)
Bath
Bedford
Bland
Campbell
Carroll
Floyd
Franklin
Giles
Halifax
Henry
Patrick
Pittsburgh
Pulaski
Rockbridge
Wythe

* * * * *

[FR Doc. 2022–28318 Filed 12–29–22; 8:45 am]

BILLING CODE 6325–39–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM–35–22; NRC–2020–0141]

Reporting Nuclear Medicine Injection Extravasations as Medical Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; consideration in the rulemaking process.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will consider in its rulemaking process issues raised in a petition for rulemaking (PRM), PRM–35–22, submitted by Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC. The petitioner requested that the NRC amend its regulations to require reporting of certain nuclear medicine injection extravasations as medical events.

DATES: The docket for the petition for rulemaking, PRM–35–22, is closed on December 30, 2022.

ADDRESSES: Please refer to Docket ID NRC–2020–0141 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0141. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; or email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andrew Carrera, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1078, email: *Andrew.Carrera@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. The Petition

The NRC received and docketed a PRM (ADAMS Accession No. ML20157A266) dated May 18, 2020, filed by Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC. On September 15, 2020, the NRC published a notice of docketing and request for public comment on the petition (85 FR 57148). The petitioner requested that the NRC amend its regulations in part 35 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Medical Use of Byproduct Material,'' to require reporting of certain nuclear medicine injection extravasations as medical events. Extravasation is the infiltration of

injected fluid into the tissue surrounding a vein or artery. Extravasation is not limited to the administration of radiopharmaceuticals.

A. Background

In 1980, the Commission amended the medical use regulations in 10 CFR part 35 to require the reporting of medical misadministrations (later renamed medical events) (45 FR 31701; May 14, 1980). Misadministration reporting allowed the NRC to investigate misadministrations for possible violations, evaluate licensee corrective actions, inform other licensees of potential problems, and take generic corrective actions. In this 1980 rulemaking, the Commission stated in a comment response that it did not consider extravasation to be a misadministration because extravasation frequently occurs in otherwise normal intravenous or intraarterial injections and that extravasations are virtually impossible to avoid.

The misadministration reporting requirements were updated in 1991 (56 FR 34104; July 25, 1991) with dose criteria based on the National Council on Radiation Protection and Measurements dose levels. These dose criteria were added to clarify the definition of misadministration and to exclude events involving diagnostic procedures, which the Commission considered low-risk. The next major update of 10 CFR part 35 was completed in 2002 (67 FR 20250; April 24, 2002). The term ''misadministration'' was replaced with ''medical event,'' the existing dose reporting criteria for patient exposures from medical events was retained, and a dose threshold of 0.5 Sv (50 rem) shallow dose equivalent to the skin was added. The extravasation exemption was not addressed.

B. Issues Raised in the Petition

The NRC identified two issues in the petition as follows:

Issue 1: The exemption of radiopharmaceutical extravasations from medical event reporting is based on the incorrect assertion that radiopharmaceutical extravasations are virtually impossible to avoid and therefore does not protect the public from unsafe irradiation. The petitioner requested that the NRC amend § 35.2, ''Definitions,'' 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.''

Issue 2: Exemption of extravasations from medical event reporting requirements results in a lack of transparency to patients, the public, and the NRC. The petitioner also requested that the NRC amend § 35.3045(a)(1), ''Report and Notification of a Medical Event,'' by adding a new paragraph (iv) as follows: ''(iv) An extravasation that leads to an irradiation resulting in a localized dose equivalent exceeding 0.5 Sieverts (Sv) (50 rem).''

II. Public Comments on the Petition

A. Overview of Public Comments

On September 15, 2020, the NRC requested comments from the public on the petition and posed eight specific questions to gain information on the scope of and basis for the issues raised by the petitioner. The comment period closed on November 30, 2020. The NRC received 488 public comment submissions, including late-filed submissions. All the comment submissions received on this petition are available on *https://www.regulations.gov* under Docket ID NRC–2020–0141. A *comment submission* is a communication or document submitted to the NRC by an individual or entity, with one or more individual comments addressing a subject or issue. Eighty-eight submissions (from the Association for Vascular Access, Organization of Agreement States, congressional representatives, and private citizens) generally supported the petition, 396 submissions (from 11 medical communities and private citizens) generally opposed the petition, and two submissions were duplicates. The NRC reviewed and considered all comments in its evaluation of the petition.

B. Comments Received in Response to Specific Questions in the Docketing Request for Comment

The following is a summary of the feedback that the NRC received from the public on the eight specific questions posed in the notice of docketing and request for public comment on the petition.

Question 1: How frequently does radiopharmaceutical extravasation occur?

Comments Received: Twenty-five comments provided at least one of the following replies to the frequency of radiopharmaceutical extravasations: (1) there is clinical evidence that extravasation rates are greater than 1 percent of all administrations; (2) the frequency rate is unknown because extravasations are not reported; or (3) some groups are understating the frequency and potential harm to patients.

Four comments stated that the extravasation frequencies cited in the petition—average of 15 percent and a range of 2 to 23 percent of all administrations—are misleading and biased. Twenty-one additional comments stated that the frequency of either therapeutic or diagnostic extravasations is very rare, typically less than 1 percent of injections. Some of the 21 comments stated that this information is based on their own clinical observations, which these comments further stated is consistent with the results from peer-reviewed manuscripts.

Question 2: Do you know of any extravasations that have resulted in harm to patients? If so, what were the circumstances, the type of effect or harm, and the impacts.

Comments Received: Thirty-nine comments provided at least one of the following responses related to patient harm due to extravasations: (1) it is difficult to know if extravasations have resulted in patient harm because they are not tracked and rarely studied; (2) it can take months or years for the effects to become evident; (3) there are over 50 peer-reviewed papers that list the following adverse biological effects of extravasations—local pain, erythema, swelling, lesions, wet and dry desquamation, severe tissue damage, and radiation necrosis; (4) even diagnostic extravasations can lead to high radiation doses to injection site tissue; and (5) extravasations can hinder the ability to deliver therapeutic applications of nuclear medicine.

Forty-nine comments provided at least one of the following responses related to patient harm due to extravasations: (1) despite millions of nuclear medicine injections, there have been no serious cases of patient harm; (2) no instances of patient harm have been observed during decades on the job; and (3) there is a lack of clinical and research studies demonstrating instances of harm.

Question 3: For medical use licensees, does your facility currently monitor for radiopharmaceutical extravasations? If so, why and how do you monitor? If not, why not?

Comments Received: Sixteen comments stated that they are currently monitoring for extravasations through scans or other methods. Ten comments stated they have capabilities to monitor for and minimize extravasations but some clinics are doing a better job of monitoring than others. The same ten comments stated that requiring monitoring of extravasations would

hold all clinics to a higher bar and increase injection quality and patient health. Four comments agreed that not all institutions monitor extravasations probably because they do not need to report extravasations.

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

Comments Received: Thirty-six comments stated that monitoring extravasations would improve injection quality. The same comments stated that tracking would lead to a better understanding of how often extravasations occur, which would lead to better training to reduce the frequency of occurrence. In addition, the same comments noted that there is plenty of evidence in clinical observations and peer-reviewed literature that the frequency of extravasations can be reduced.

Twelve comments stated that monitoring and reviewing extravasations would not improve injection quality because highly trained professionals are already doing their best to prevent extravasations from occurring, so monitoring would only cause unnecessary burdens. Three comments stated that monitoring extravasations would not improve injection quality because extravasations occur largely as a result of patients having poor vascular structure. In addition, the same comments noted that, in particular, pediatric, geriatric, and chemotherapy patients often have compromised vascularity.

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

Comments Received: Fourteen comments stated that they had concerns about the health of patients for both therapeutic and diagnostic extravasations. The same comments stated that reporting of extravasations would lead to a better understanding of their frequency and severity, which could reduce how often they occur and lead to better patient health. One comment supported the petition because extravasations then could be tracked and their frequencies reduced to the benefit of patients.

Four comments stated that there would not be improvements to patient health due to monitoring and reporting of extravasations because they are not preventable. Seven comments stated that there would be no health benefits but there would be additional burdens to medical licensees. Two comments stated that monitoring for extravasations would negatively impact patient health because any manipulation of the injection site or addition of sensors could decrease blood flow, resulting in radioactive material remaining in the injection site for a longer period of time.

Question 6: 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?

Comments Received: Forty-two comments stated that there would be considerable burdens to monitoring and reporting extravasations without much, if any, benefit. One commenter provided the example that 14 million diagnostic procedures are performed annually and if there is a 1 percent extravasation rate, then the result would be 140,000 medical events annually. The commenters stated that the main burdens they are concerned about are (1) reporting with minimal or no benefit, (2) considerable increase in paperwork, (3) considerable financial costs for practitioners and the entire medical field—possibly hundreds of millions of dollars, (4) the total time for extra monitoring and the frequency of nuclear medicine injections would allow for fewer patients to be seen, and (5) it may create false radiation safety concerns in patients and increase public fear concerning nuclear medicine.

Eight comments listed the following benefits to monitoring and reporting extravasations: (1) patients will know when an extravasation occurs, (2) it will lead to better diagnostics, (3) it will lead to better data for tracking, and (4) it will reduce medical workload and costs. Ten comments stated that those in opposition are overstating the burdens to the medical community. The comments also stated that the new detection methods are more cost effective for detecting extravasations than traditional computed tomography (CT) scans. Lastly, the comments noted that while there could be additional costs, it would increase the incentive to provide quality injections.

Question 7: If the NRC were to require that licensees report certain extravasations as medical events, what reporting criteria should be used to provide the NRC data that can be used to identify problems, monitor trends, and ensure that all licensees take corrective action(s)?

Comments Received: Nine comments were in favor of the petitioner's proposed 0.5 Sv (50 rem) reporting level because it is consistent with the level used for nuclear medicine both domestically and internationally. In addition, the same comments stated that the petitioner's proposed reporting level will lead to better monitoring and reduce the frequency of extravasations.

Eight comments stated the following concerns with the petitioner's proposed reporting level of 0.5 Sv (50 rem): (1) the criterion is arbitrary and does not harm the skin or tissue; (2) it takes more than 2 Gray (Gy) (200 rad) to cause impacts to skin in fluoroscopy procedures, which is much higher than the proposed criterion; and (3) if an extravasation does occur, the nuclear agents end up in the intended part of the body similar to a non-extravasated injection (*i.e.,* extravasations migrate from the lymphatic system and end up in the venous system). Nine comments did not support the petitioner's proposed criteria of 0.5 Sv (50 rem) because there is not a good or technically sound way to evaluate the dose to the tissue. Two comments stated that there should not be any criteria because there should be no reporting of extravasation.

Question 8: 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?

Comments Received: Eighteen comments stated that there should not be a distinction between diagnostics and therapeutics for classification of medical events because (1) if you exceed 0.5 Sv (50 rem), you could be causing harm regardless of the method, (2) diagnostic extravasations can cause harm or compromise scans, and (3) few facilities monitor diagnostic injections, but monitoring tools now exist that could lead to a better understanding of the frequency and help reduce the occurrence of extravasations. One comment supported the classification of therapeutic injection extravasations as medical events; explaining, however, that some diagnostic doses are used as ''test doses'' to determine injection quality; and stated that classifying these ''test doses'' as extravasations would be contradictory since they are meant to improve patient safety.

Twenty-five comments expressed concerns regarding classification of diagnostic extravasations as medical events because they are of such low dose that they do not cause harm or compromise scans. The same comments also noted that while therapeutic extravasations can cause tissue damage, they are extremely rare events that are dealt with under existing regulations. Lastly, most of these 25 comments do

not support the classification of diagnostic or therapeutic extravasations as medical events, with an especially strong position against the classification of diagnostic extravasations as medical events.

C. NRC Response to Additional Public Comments

The NRC received thirty-three additional comments related to the petition that did not provide a direct response to the specific questions in the notice of docketing and request for public comment on the petition. In addition, the NRC received three comments that were out of scope. The NRC has binned these additional comments related to the petition into two categories. The following discussion provides a summary of each category and the NRC's response to the grouped comments, including—if appropriate—a summary of the basis for the response.

1. Comments Supporting the Petition

Comment: The NRC received nine comments supporting the proposed criteria of 0.5 Sv (50 rem) because the dose to the skin from extravasation can be estimated and this limit is 500 times higher than the dose from an ''ideal injection.''

NRC Response: The NRC disagrees with this comment. The NRC's medical event reporting dose threshold criteria (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) are conservative dose levels that would not be expected to cause patient harm. The criteria were implemented in part to screen out medical events involving diagnostic procedures because, as stated by the Commission, the NRC agrees that routine doses from diagnostic procedures represent a small amount of risk to the patient. On the dose levels, the Commission further commented that these levels correspond to a threshold well below the onset of acute, clinically detectable adverse effects that may be caused by exposure to ionizing radiation. Reporting extravasations at 0.5 Sv (50 rem) would result in many extravasation events of low radiation safety significance being reported. However, the NRC agrees that the topic of extravasation is important and therefore is considering the issues raised in the petition and assessing a more risk-informed reporting requirement in the rulemaking process.

Comment: The NRC received a comment stating that reporting extravasations is within the purview of the NRC. While administration of radiopharmaceuticals is a practice of medicine, misadministration of radiopharmaceuticals should be reported and this will not intrude on the practice of medicine.

NRC Response: The NRC agrees with this comment. Requiring medical event reporting of radiation-safety-significant extravasations is within the purview of the NRC's regulatory authority and supports the NRC's public health and safety mission.

Comment: The NRC received one comment concerning the lack of rationale explaining why extravasation of diagnostic injections should be exempted from medical event reporting.

NRC Response: The NRC agrees with this comment. The NRC questions whether excluding diagnostic administrations from an extravasation reporting requirement is supportable. Due to the smaller amounts of radioactivity used in diagnostic procedures, extravasation of diagnostic radiopharmaceuticals would rarely be expected to result in adverse tissue effects. However, while rare, significant extravasations of diagnostic radiopharmaceuticals with longer half-lives (such as thallium-201) could result in adverse tissue effects (Van der Pol et al., 2017) and would be considered a safety-significant medical event.

2. Comments Opposing the Petition

Comment: The NRC received four comments stating that extravasation is a generic medical issue outside the NRC's regulatory authority and is best managed at the institutional level.

NRC Response: The NRC disagrees with this comment. The radiation safety impact of some extravasations can be severe enough to warrant regulatory action, and reporting and tracking these incidents is of interest to the NRC.

Comment: The NRC received three comments concerning diagnostic extravasations. The comments state that minor diagnostic extravasations occur frequently but can be detected by scans and do not reduce scan quality or affect patient health. The comments further state that concerns regarding diagnostic extravasations are overstated and extravasation should be managed at the institutional level.

NRC Response: The NRC partially disagrees with this comment. While diagnostic extravasations of safety significance are rare, significant extravasations of certain diagnostic radiopharmaceuticals can cause adverse tissue effects, such as prolonged erythema and even skin necrosis (Van der Pol et al., 2017). The NRC is interested in medical event reporting of radiation-safety-significant extravasations, regardless of whether they involve diagnostic or therapeutic radiopharmaceuticals.

Comment: The NRC received 11 comments stating that the NRC's extravasation exemption is outdated.

Response: The NRC agrees with this comment. In 1980 the use of injectable radiopharmaceuticals involved diagnostic dosages of lower energy gamma emitting radionuclides. Since then, nuclear medicine has evolved to include use of higher energy positron-emitting diagnostic radiopharmaceuticals (for positron emission tomography imaging) and therapeutic radiopharmaceuticals, which use higher doses of radioactivity to treat certain cancers and diseases. The NRC is revisiting the exclusion of extravasation from medical event reporting in light of intervening changes in radiopharmaceuticals in the rulemaking process.

III. Reasons for Consideration

Although the petitioner requested that the NRC require the reporting of radiopharmaceutical extravasations exceeding 0.5 Sv (50 rem) localized dose equivalent, the NRC considered the issue more broadly and evaluated whether to require reporting of certain radiopharmaceutical extravasations of radiation safety significance as medical events. The NRC evaluated whether (1) the radiation safety risk from extravasations merits medical event reporting, (2) extravasations are preventable, (3) including extravasations in medical event reporting would align with the objectives of the NRC's medical event reporting regulations, and (4) regulating extravasations would align with the NRC's Medical Use Policy Statement (65 FR 47654; August 3, 2000). The staff recommends further evaluating, within the NRC's rulemaking process, medical event reporting of extravasations that require medical attention for a suspected radiation injury. The remaining paragraphs of Section III summarize the NRC's evaluation of the two issues identified in the petition.

Evaluation of Petition Issues

Issue 1: The exemption of radiopharmaceutical extravasations from medical event reporting is based on the incorrect assertion that radiopharmaceutical extravasations are virtually impossible to avoid and therefore does not protect the public from unsafe irradiation.

The petitioner stated that recent evidence demonstrates that extravasations are avoidable, invalidating the NRC's 1980

determination and subsequent exemption of extravasations from medical event reporting requirements. The petitioner asserted that reporting extravasations as medical events would reduce the amount of extravasations and protect patients from harmful injections. In addition, the petitioner asserted that diagnostic and therapeutic extravasations can result in significant radiation doses to injection site tissue, potentially causing adverse tissue reactions and cancer. The petitioner stated that diagnostic extravasations can also affect the accuracy of imaging study results, affect the patient's care, and may lead to unnecessary radiation dose due to repeat imaging studies. Lastly, the petitioner asserted that, per the NRC's Medical Use Policy Statement, the NRC has the obligation to regulate extravasations as necessary to provide for the radiation safety of workers and the general public.

NRC Evaluation: The NRC believes that the Commission's 1980 decision to exclude extravasations from medical event reporting should be reconsidered in the rulemaking process given the evolution of nuclear medicine since then. However, the NRC does not agree with the petitioner that the 1980 decision is invalidated because extravasations are avoidable. Although there have been many advancements in nuclear medicine since 1980, there is still no technology or technique that can fully prevent an extravasation. While monitoring technology could help identify extravasations earlier and improvements in training, skill, and tools could help reduce the prevalence of extravasations, there is no way to fully prevent extravasations from occurring. Even the most skilled clinician may infiltrate an injection due to many factors outside of the control of the clinician. Patient anatomy, age, body habitus, hydration, and prior medical treatment are all factors that may impact an intravenous administration.

The NRC agrees with the petitioner that medical event reporting of extravasations may focus some medical licensees on reducing their extravasation rate through implementation of quality improvement programs for intravenous administration of radiopharmaceuticals, and reducing the extravasation rate would improve radiation safety for patients.

The NRC agrees that certain extravasations can result in radiation-safety-significant doses to the tissue around the administration site, which could result in adverse tissue effects. However, published studies (Van der Pol et al., 2017; Hall et al., 2006) and input from the medical community and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) indicate that due to the smaller amounts of radioactivity used in diagnostic procedures, extravasations of diagnostic radiopharmaceuticals are typically of low radiation safety significance and would rarely be expected to result in adverse tissue effects. The NRC agrees that extravasations of therapeutic radiopharmaceuticals, which deliver larger amounts of radioactivity to treat cancer and other ailments by killing cells, may cause tissue damage around the administration site (Van der Pol et al., 2017; Bonta et al., 2011; Tylski et al., 2018; Benjegerdes et al., 2017).

The NRC's Medical Use Policy Statement says, in part, that the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the safety of workers and the general public. The policy also states that the NRC will regulate radiation safety, when justified by the risk to the patient, primarily to assure the use of radionuclides is in accordance with the physician's directions. The NRC agrees that medical event reporting of certain extravasations would support these patient safety objectives of the Medical Use Policy Statement by potentially reducing the occurrence of radiation-safety-significant extravasations. Therefore, the NRC is considering the issues raised by the petitioner in a rulemaking process that will assess risk-informed reporting requirements for extravasations.

Issue 2: Exemption of extravasations from medical event reporting requirements results in a lack of transparency to patients, the public, and the NRC.

The petitioner asserted that the exemption of extravasations from medical event reporting requirements results in a lack of transparency to the patients, the public, and the NRC as the extravasation events are not documented in the NRC's Nuclear Material Events Database (NMED), which contains records of events involving nuclear material reported to the NRC. The petitioner asserted that this may result in patients and clinicians being unaware that the diagnostic image or intended therapy may have been compromised, and the NRC remains unaware when licensees misadminister radiopharmaceuticals resulting in doses that exceed medical event reporting limits.

NRC Evaluation: Under the NRC's current practice of excluding extravasations from medical event reporting, extravasations that result in suspected radiation injury, or even those that meet the NRC's public health and safety significance criteria for an abnormal occurrence, are not required to be reported to the NRC. The NRC agrees that reporting radiation-safety-significant extravasations would increase transparency between patients, physicians, and the NRC. If certain extravasations were required to be reported under § 35.3045, this would enhance transparency through medical event reporting requirements for notifying the patient, referring physician, and the NRC within 24 hours of discovering the event and through event notification reports published by the NRC. These event notifications would be publicly available on the NRC website. These extravasation events would be shared with and evaluated by the ACMUI on an annual basis. Additionally, the reporting and analysis of safety-significant extravasation events would allow the NRC to identify similarities in reports from multiple facilities and issue generic communications to share information that may help licensees to reduce the occurrence of radiation-safety-significant extravasations and mitigate their consequences.

IV. Availability of Documents

The documents identified in the following table are listed in the order in which they are cited in this notice and are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/ **Federal Register** citation
Petition for Rulemaking (PRM–35–22)—Lucerno Dynamics, LLC, Petition to Amend 10 CFR 35.3045, May 18, 2020.	ML20157A266.
Notice of Docketing and Request for Comment on Petition for Rulemaking, Reporting Nuclear Medicine Injection Extravasations as Medical Events, September 15, 2020.	85 FR 57148.
Final Rule, Medical Use of Byproduct Material, April 24, 2002	67 FR 20250.
Final Rule, Quality Management Program and Misadministrations, July 25, 1991	56 FR 34104.

Document	ADAMS accession No./web link/ **Federal Register** citation
Final Rule, Misadministration Reporting Requirements, May 14, 1980	45 FR 31701.
Medical Use of Byproduct Material; Policy Statement, Revision, August 3, 2000	65 FR 47654.
Van der Pol, J., S. Voo S, J. Bucerius, and F.M. Mottaghy, ''Consequences of Radiopharmaceutical Extravasation and Therapeutic Interventions: A Systematic Review.'' *European Journal of Nuclear Medicine and Molecular Imaging,* Vol. 44, No. 7, July 2017.	*https://pubmed.ncbi.nlm.nih.gov/28303300.*
Hall, N., J. Zhang, R. Reid, D. Hurley, and M. Knopp, ''Impact of FDG Extravasation on SUV Measurements in Clinical PET/CT. Should we routinely scan the injection site?'' *The Journal of Nuclear Medicine,* Vol. 41, Supplement 1, Pg. 115, May 2006.	*https://jnm.snmjournals.org/content/47/suppl_1/115P.2.*
Bonta, D.V., R.K. Halkar, and N. Alazraki, ''Extravasation of a Therapeutic Dose of 131I-Metaiodobenzylguanidine: Prevention, Dosimetry, and Mitigation.'' *The Journal of Nuclear Medicine,* Vol. 52, No. 9, September 2011.	*https://pubmed.ncbi.nlm.nih.gov/21795365.*
Tylski, P., A. Vuillod, C. Goutain-Majorel, and P. Jalade, ''Dose Estimation for an Extravasation in a Patient Treated with ^{177} Lu-DOTATATE.'' *Journal of Medical Physics,* Vol. 56, Supplement 1, December 2018.	*https://doi.org/10.1016/j.ejmp.2018.09.071.*
Benjegerdes KE, Brown SC, Housewright CD, ''Focal Cutaneous Squamous Cell Carcinoma Following Radium-223 Extravasation.'' *Baylor University Medical Center Proceedings,* Vol. 30, No. 1, January 2017.	*https://pubmed.ncbi.nlm.nih.gov/28127143.*

V. Conclusion

For the reasons cited in this document, the NRC will consider the issues raised in the petition in the rulemaking process. The NRC will evaluate the current requirements and guidance for reporting of certain nuclear medicine injection extravasations as medical events. The NRC tracks the status of all rules and PRMs on its website at *https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html.* The public can monitor further NRC action on the rulemaking titled, ''Reporting Nuclear Medicine Injection Extravasations as Medical Events,'' that will address the issues in this petition by searching for Docket ID NRC–2022–0218 on the Federal rulemaking website, *https://www.regulations.gov.* In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2022–0218); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link. Publication of this document in the **Federal Register** closes Docket ID NRC–2020–0141 for PRM–35–22.

Dated December 22, 2022.

For the Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

[FR Doc. 2022–28356 Filed 12–29–22; 8:45 am]

BILLING CODE 7590–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701 and 714

[NCUA–2022–0185]

RIN 3133–AF49, 3133–AE96

Financial Innovation: Loan Participations, Eligible Obligations, and Notes of Liquidating Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is seeking comment on a proposed rule that would amend the NCUA's rules regarding the purchase of loan participations and the purchase, sale, and pledge of eligible obligations and other loans (including notes of liquidating credit unions). The proposed rule is intended to clarify the NCUA's current regulations and provide additional flexibility for federally insured credit unions (FICUs) to make use of advanced technologies and opportunities offered by the financial technology (fintech) sector. The proposal would also make conforming amendments to the NCUA's rule regarding loans to members and lines of credit to members by adding new provisions about indirect lending arrangements and indirect leasing arrangements. Finally, the proposal would make other conforming changes and technical amendments in other sections of the NCUA's regulations. The Board does not view these conforming and technical changes as substantive.

DATES: Comments must be received by February 28, 2023.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: https://www.regulations.gov.* The docket number for this notice of proposed rulemaking is NCUA–2022–0185. Follow the instructions for submitting comments.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public inspection: All public comments are available on the Federal eRulemaking Portal at: *https://www.regulations.gov* as submitted, except when impossible for technical reasons. Public comments will not be edited to remove any identifying or contact information.

If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: *For policy questions:* Laura Smith, Senior Credit Specialist, or Naghi Khaled, Director of Credit Markets, Office of Examination and Insurance, at (703) 518–6360; *for legal questions:* Frank Kressman, General Counsel, the Office of General Counsel, at (703) 518–6540; or by mail at National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Summary of the Proposed Rule

A. Background

The Board is proposing to amend §§ 701.21, 701.22, 701.23, and part 714 of the NCUA's regulations regarding the purchase of loan participations and the purchase, sale, and pledge of eligible obligations and other loans (including