POLICY ISSUE
(Notation Vote)

May 9, 2022 SECY-22-0043

FOR: The Commissioners

FROM: Daniel H. Dorman
Executive Director for Operations

SUBJECT: PETITION FOR RULEMAKING AND RULEMAKING PLAN ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (PRM-35-22; NRC-2020-0141)

PURPOSE:

The purpose of this paper is to request Commission approval to consider a petition for rulemaking (PRM) in the rulemaking process and to provide a rulemaking plan. The PRM asks the U.S. Nuclear Regulatory Commission (NRC) to amend its requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," to include certain nuclear medicine injection extravasations as reportable medical events. The rulemaking plan also addresses issues associated with extravasations that staff independently identified.

SUMMARY:

The NRC received a PRM under 10 CFR 2.802, "Petition for rulemaking—requirements for filing," submitted by Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC, dated May 18, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20157A266). The petition requests that the NRC amend 10 CFR Part 35 to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 Sieverts). In accordance with

CONTACTS: Pamela Noto, NMSS/REFS
301-415-6795

Sarah Lopas, NMSS/MSST
301-415-6360

Enclosure 5 transmitted herewith contains Official Use Only – Sensitive Internal Information. When separated from Enclosure 5, this transmittal document is decontrolled.

OFFICIAL USE ONLY
SENSITIVE INTERNAL INFORMATION
LIMITED TO THE NRC UNLESS THE
COMMISSION DETERMINES OTHERWISE

10 CFR 2.803, "Petition for rulemaking—NRC action," the staff docketed the petition as PRM-35-22 and reviewed the petition under 10 CFR 2.803(h)(1).

This paper summarizes the staff's review of the petitioner's requested rulemaking and the staff's independent evaluation of whether radiopharmaceutical extravasations should be reported as medical events. The staff considered information from the petitioner; input from the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), Agreement States, and external stakeholders; and available published literature on extravasations. The staff addresses the specific assertions in PRM-35-22 and summarizes and responds to public comments on the petition in the enclosed *Federal Register* notice (Enclosure 1). The staff recommends initiating a rulemaking to address the issues raised in PRM-35-22 and identified by the staff's independent evaluation. The rulemaking would amend NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury. This paper includes a rulemaking plan.

BACKGROUND:

Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation is not limited to the administration of radiopharmaceuticals, and published studies indicate extravasation rates for all drugs, including radiopharmaceuticals, range from 0.10 to 16 percent for all injections.[1] Common factors that contribute to the probability of extravasation include the anatomy, condition, and movement of the patient; the training, experience, and technique of the clinician administering the injection; and catheter size.[2]

In 1980, the Commission amended 10 CFR Part 35 to require quarterly reporting of diagnostic misadministrations and prompt reporting of therapeutic misadministrations (the term "misadministration" would later be replaced with "medical event").[3] In this final rule, the Commission excluded radiopharmaceutical extravasations from the reporting requirements, stating, in part, that, "[e]xtravasation frequently occurs in otherwise normal intravenous [IV] or intra-arterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration."

In 2008 and 2009, the NRC staff requested that the ACMUI evaluate whether extravasations should continue to be excluded from medical event reporting after a licensee reported (and later retracted) an extravasation involving a common diagnostic radiopharmaceutical. During ACMUI public meetings in December 2008 and May 2009, the ACMUI discussed diagnostic and therapeutic extravasations and recommended all extravasations should continue to be excluded from medical event reporting.[4]

---

1 See Refs. 1–5 in Enclosure 3.

2 See Ref. 6 in Enclosure 3.

3 "Misadministration Reporting Requirements" (45 FR 31701; May 14, 1980).

4 During the December 2008 meeting (ADAMS Accession No. ML090340745), ACMUI members observed that diagnostic extravasations are relatively common but rarely result in adverse clinical outcomes or the need for a repeat diagnostic procedure. During the May 2009 meeting (ADAMS Accession No. ML092090025), ACMUI members discussed reporting therapeutic extravasations based on obvious tissue damage instead of using a dose threshold criterion because extravasation dose calculations are not standardized. Ultimately, the ACMUI supported continuing to exclude therapeutic extravasations from medical event reporting because (1) patients would be well aware of tissue damage from a therapeutic extravasation and (2) the U.S. Food and Drug Administration Adverse Event Reporting System was an existing mechanism to track adverse reactions from radiopharmaceuticals.

At an April 2019 ACMUI public meeting, Lucerno Dynamics, LLC, presented information about the prevalence and consequences of diagnostic extravasations, along with the company's technology for detecting extravasations. Upon request from the staff, the ACMUI established an extravasation subcommittee to evaluate whether extravasations should be reported as medical events.[5] In September 2019, the ACMUI endorsed the extravasation subcommittee's recommendation that extravasations should be considered a type of "passive" patient intervention, and extravasations that lead to unintended permanent functional damage should be reported as medical events.[6]

In January 2020, the staff began an independent evaluation of whether extravasations should be reported as medical events. Additionally, in May 2020, the petitioner submitted PRM-35-22, stating that "ample evidence has been published demonstrating that nuclear medicine extravasations are, in fact, avoidable and are capable of causing considerable harm to the patients," and asking that the NRC "revisit the policy established in 1980 in light of the existing evidence and require the reporting as medical events of certain extravasations." In September 2020, the NRC published a notice of docketing and requested public comment on the petition.[7] In December 2020, the staff held a public meeting to discuss their planned evaluation of extravasations and medical event reporting and to obtain input on the issue from external stakeholders.[8] In April 2021, the staff gave a preliminary evaluation of extravasations and medical event reporting to the ACMUI extravasation subcommittee for review and recommendations; in September 2021, the ACMUI held a public meeting to discuss the staff's preliminary evaluation.[9] In October 2021, the staff sent a draft rulemaking plan to the Agreement States for review and comment, and the Agreement States provided their comments on the rulemaking plan in December 2021.

There has been congressional interest in reporting extravasations as medical events throughout the staff's independent evaluation and the review of the petition. Several Members of Congress have sent letters of support for the petition, citing concerns about patient safety and diagnostic imaging issues affecting health outcomes. Additional examples of congressional interest in this subject include the Fiscal Year (FY) 2020 Further Consolidated Appropriations Act requiring a report to Congress,[10] the FY2021 Omnibus and COVID Relief and Response Act requiring a briefing for appropriations committee staff,[11] and the FY2022 House and Senate Energy and Water Appropriation Committee Reports, stating that the committees encourage the NRC "to consider the inclusion of significant extravasations in medical event reporting to improve safety, quality, and transparency for patients, treating physicians, and the Commission itself."[12]

---

5 "Official Transcript of Proceedings, Meeting of the Advisory Committee on the Medical Uses of Isotopes," April 3, 2019 (ADAMS Accession No. ML19154A523).

6 See ACMUI Subcommittee on Extravasation, "Final Report," October 23, 2019 (ADAMS Accession No. ML19316E067). See also NRC, "Official Transcript of Proceedings, Meeting of the Advisory Committee on the Medical Uses of Isotopes," September 10, 2019 (ADAMS Accession No. ML19304B440).

7 "Reporting Nuclear Medicine Injection Extravasations as Medical Events" (85 FR 57148; September 15, 2020).

8 "Summary of December 8, 2020, U.S. Nuclear Regulatory Commission Public Meeting on Radiopharmaceutical Extravasations," March 16, 2021 (ADAMS Accession No. ML21005A436).

9 See ACMUI Subcommittee on Extravasation, "Subcommittee Review and Comments on NRC Staff Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting," July 30, 2021 (ADAMS Accession No. ML21223A085). See also ACMUI, "Meeting Summary," September 2, 2021 (ADAMS Accession No. ML21267A021).

10 See House Report 116-83 and Senate Report 116-102. See also NRC, "Updates to Injection Quality Monitoring, Classification, and Reporting Requirements for Extravasations," March 2020 (ADAMS Accession No. ML20050W303).

11 House Report 116-449.

12 House Report 117-98 and Senate Report 117-36.

DISCUSSION:

The staff's review of PRM-35-22 and independent evaluation focused on 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.[13]

The Radiation Safety Risk from Certain Extravasations May Merit Medical Event Reporting

The staff considered the radiation safety risks associated with extravasations—the radiological consequences and the likelihood of those consequences—to determine whether certain extravasations may merit medical event reporting. The staff looked at diagnostic and therapeutic intravenous (IV) radiopharmaceutical procedures: diagnostic procedures typically involve smaller amounts of radioactivity for medical imaging, and therapeutic procedures typically deliver larger amounts of radioactivity for treatment of cancer and other ailments. Diagnostic procedures comprise the large majority of the 18.5 million IV radiopharmaceutical administrations per year, and extravasation of diagnostic radiopharmaceuticals may be common (a study cited by the petitioner found a 15.2-percent average extravasation rate for positron emission tomography/computed tomography [PET/CT] radiotracers[14]). However, as indicated by published studies[15] and information gathered by the staff, most diagnostic extravasations are of low radiation-safety significance and would rarely be expected to result in adverse tissue effects. The staff does not support medical event reporting of low radiation-safety-significant extravasations.

Conversely, the likelihood of radiation injury is higher for therapeutic extravasations due to the higher radiation doses they deliver.[16] Even a relatively small-volume extravasation of a therapeutic radiopharmaceutical may result in tissue damage around the administration site unless mitigation measures are performed. With regard to tissue damage from extravasation, the ACMUI stated, "[w]hile exceedingly rare, there have been reports of patients who developed severe tissue damage following extravasation of radiopharmaceuticals (almost exclusively from therapeutic radiopharmaceuticals). When this occurs, the effort involved in assessing the event and determining a potential dose to affected tissue is warranted."[17] Because certain extravasations may result in tissue damage around the administration site, the staff believes that a risk-informed medical event reporting requirement may be warranted to capture these radiation-safety-significant extravasation events.

---

13 "Medical Use of Byproduct Material; Policy Statement, Revision" (65 FR 47654; August 3, 2000).

14 See Ref. 4 in Enclosure 3.

15 See Ref. 7 in Enclosure 3. One published study of PET/CT injections found an extravasation rate of 21 percent, but in 98 percent of these extravasations, less than 1 percent of the total administered dose was extravasated (see Ref. 8 in Enclosure 3).

16 A comprehensive study published in the *European Journal of Nuclear Medicine and Molecular Imaging* in 2017 reviewed 3,016 radiopharmaceutical extravasations: 3,006 involved diagnostic radiopharmaceuticals and 10 involved therapeutic radiopharmaceuticals. Just three diagnostic extravasations required follow up because of skin irritation and tissue swelling around the injection site, whereas 5 of the 10 therapeutic extravasations resulted in ulceration around the injection site (see Ref. 7 in Enclosure 3).

17 "Subcommittee Review and Comments on NRC Staff Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting, Final Report," September 16, 2021 (ADAMS Accession No. ML21288A125).

Extravasations Are Not Entirely Preventable

Input from the medical community and the ACMUI indicates that extravasations are not entirely preventable. Even the most skilled clinician may extravasate an injection. Patient anatomy, age, body habitus, hydration, and prior medical treatment are all factors outside the control of the clinician that may impact a successful IV administration. However, the staff expects that classifying radiation-safety-significant extravasations as medical events may increase licensee focus on injection factors within their control, such as adequate training, technical skill, correct tools, and extravasation mitigation measures, which could reduce the likelihood of extravasation and improve extravasation outcomes.

Reporting Radiation-Safety-Significant Extravasations Aligns with the U.S. Nuclear Regualtory Commission's Medical Event Reporting Objectives

The NRC regulates unintended exposures in medicine through its medical event reporting criteria. Licensee reporting and subsequent analysis of medical events by regulators helps the NRC to identify the causes of medical events and ensure that corrective actions are taken to prevent their recurrence. Medical event reporting also allows the NRC to follow up on events and determine whether other licensees might be experiencing the same or similar challenges. For example, the NRC assesses trends or patterns, identifies generic issues or concerns, and recognizes inadequate or unreliable equipment or procedures. If the NRC identifies similarities in reports from multiple facilities, the NRC issues generic communications[18] that may help prevent additional incidents.

Excluding extravasations from medical event reporting means that radiation-safety-significant extravasations—even those that are severe enough to meet the NRC's dose criterion for an abnormal occurrence[19]—are not required to be reported to the NRC. Even if the staff had knowledge of a severe extravasation, it could not be classified as an abnormal occurrence because it would not be a medical event. Excluding extravasations from medical event reporting limits the NRC's ability to obtain operating experience on radiation-safety-significant extravasations. Operating experience is an essential element of the NRC's regulatory process for ensuring that licensed activities are conducted safely, and medical event reporting is an important source of operating experience. By including radiation-safety-significant extravasations in medical event reporting, the staff could obtain operating experience and track and trend these events. This information could be shared with medical licensees with the goal of improving radiation safety for patients receiving IV-administered radiopharmaceuticals. Medical event reporting of radiation-safety-significant extravasations would align with the

---

[18] Examples of recent generic communications on medical events include information notices on yttrium-90 microsphere therapeutic administration, patient contamination with iodine-131 meta-iodobenzylguanidine, strontium-82/rubidium-82 generator elution issues, and methods to avoid medical events (see information notices 19-12, 19-06, 19-11, and 19-07 at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2019/index.html).

[19] The NRC is required by law to report abnormal occurrences to Congress and make certain information about abnormal occurrences publicly available. An "abnormal occurrence" is defined as an "unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety." Currently, the abnormal occurrence criteria for events involving medical uses are (1) it must be a medical event as defined in 10 CFR 35.3045 and (2) it must exceed by 10 gray (Gy) (1,000 rad) the expected dose to any other organ or tissue from the administration defined in the written directive. (NUREG-0090, Volume 43, "Report to Congress on Abnormal Occurrences – Fiscal Year 2020," June 2021. ADAMS Accession No. ML21152A287.)

objectives of medical event reporting and provide staff with data necessary to take regulatory actions if required.

Reporting Radiation-Safety-Significant Extravasations Aligns with the U.S. Nuclear Regulatory Commission's Medical Use Policy Statement

The NRC follows its Medical Use Policy Statement in developing and implementing its medical use regulations. The staff considered how medical event reporting of radiation-safety-significant extravasations would align with the four objectives of the Medical Use Policy Statement, as summarized below.

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.

When the Commission excluded extravasations from medical event reporting in 1980, the use of injectable radiopharmaceuticals was limited to diagnostic dosages of lower energy gamma-emitting radionuclides. Since then, nuclear medicine has evolved to include the use of higher energy positron-emitting diagnostic radiopharmaceuticals (for PET imaging), and therapeutic radiopharmaceuticals—which use higher doses of radioactivity to treat certain cancers and diseases by killing cells. Given the continuing evolution of nuclear medicine and the corresponding increase in the possibility of radiation injury from certain extravasations, a risk-informed reporting requirement for extravasations could be necessary to provide for the radiation safety of patients.

2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

As discussed above, in light of developments in radiopharmaceuticals since 1980, the staff has found there may be a need to require licensees to report certain extravasations as medical events to provide for the radiation safety of patients. However, the staff has also sought to develop a standard for reporting extravasations that would not intrude into medical judgements or place undue burden on licensees. Therefore, the staff expects that the proposed risk-informed reporting requirement for extravasations would be consistent with objective 2.

3. NRC will, when justified by the risk to the patient, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

The NRC's regulations require that for therapeutic administration of radiation or a radionuclide, licensees must develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the authorized user's directions. The staff understands that due to factors affecting an IV administration that are outside the control of the clinician, even an administration that follows an authorized user physician's directions for a prescribed dosage may result in an extravasation. However, a significant extravasation can interfere with the administration of a radiopharmaceutical in accordance with the physician's directions and result in radiation injury to the patient. Therefore a risk-informed reporting requirement for radiation-safety-significant extravasations could further objective 3.

4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

The staff's development of a regulatory approach for extravasations considered input from the medical community and the ACMUI on the risk of extravasation inherent to all IV administrations and issues related to dosimetry for extravasations. In consideration of this input, the staff is recommending a reporting requirement that would screen out extravasation events of low radiation-safety significance because the proposed reporting requirement is based on suspected radiation injury instead of a dose threshold. If the Commission approves a rulemaking for extravasations, the rulemaking effort would further consider industry and professional standards in the development of a specific medical event reporting requirement and associated regulatory guidance.

The Staff Considered Input from External Stakeholders

The staff considered comments received on the petition and from a December 8, 2020, public meeting[20] on the staff's independent evaluation. The *Federal Register* notice in Enclosure 1 summarizes and responds to comments received on the petition. Comments from the public meeting are summarized below.

The NRC heard from medical professionals strongly opposed to regulating extravasations who stated that (1) significant injury from extravasation is extremely rare, (2) there are no clinical data supporting the petitioner's claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue, and (3) there are well-established procedures to manage extravasation of therapeutic radiopharmaceuticals. Some representatives of the medical community commented that no technology can prevent extravasation: although monitoring for extravasation could allow clinicians to begin mitigation measures sooner, monitoring would not prevent extravasation. Multiple commenters stated that requiring extravasations to be reported as medical events would create significant regulatory burden on licensees with no added safety benefit, and it could even divert resources away from more important safety issues. One commenter stated that the NRC did not need to regulate extravasation. Many institutions already have initiatives for injection quality monitoring and improvement. Additionally, multiple mechanisms exist to evaluate and promote the safe medical use of radioactive materials, including regulation and monitoring by the U.S. Food and Drug Administration, the U.S. Centers for Medicare and Medicaid Services, and Joint Commission on Accreditation of Healthcare Organizations.

Some participants at the December 8, 2020, public meeting stated that extravasation is an important patient safety issue and supported monitoring and reporting requirements for extravasations. Proponents of PRM-35-22 stated that injection quality monitoring plus quality improvement processes would improve injection administration techniques, which would in turn enhance patient safety and health outcomes (through better diagnostic imaging quality). These commenters pointed out that because the medical community does not monitor for, or evaluate the effects of, extravasations, it does not know whether extravasations are harming patients. The commenters stated that extravasation of diagnostic radiopharmaceuticals can result in localized doses to tissue exceeding the 50-rem dose threshold, and these events should be reported like other medical events.

---

20 "Summary of December 8, 2020, U.S. Nuclear Regulatory Commission Public Meeting on Radiopharmaceutical Extravasations," March 16, 2021 (ADAMS Accession No. ML21005A436).

The Staff Coordinated with the Agreement States

The NRC held government-to-government meetings with the Agreement States in July 2020 and November 2021 to brief the Agreement States on the staff's independent evaluation of extravasations. The Organization of Agreement States (OAS) and two states submitted comments on PRM-35-22 in November 2020.[21] At this time, the OAS and one state urged the NRC to accept the petition for rulemaking and commented that the rationale for excluding extravasation from medical event reporting in 1980 was no longer appropriate given the evolution of nuclear medicine; the other state supported reporting extravasations as medical events under the existing regulations. In December 2021, the OAS and five Agreement States provided comments[22] on the options in the staff's draft rulemaking plan: the OAS and two states supported the staff's recommended rulemaking option; one state continued to support the petition; and two states did not support an extravasation rulemaking and suggested gathering more data on the radiation-safety significance of extravasations to determine whether a rulemaking would actually improve patient safety. One of the states opposed to rulemaking commented that the subjectiveness of the staff's recommended rulemaking would lead to inconsistent regulation of extravasations across the National Materials Program with minimal safety benefits.

The Staff Considered the Recommendations of the Advisory Committee on the Medical Uses of Isotopes

The ACMUI held a public meeting on September 2, 2021, to discuss the Subcommittee on Extravasation's review of the staff's independent evaluation and the subcommittee's draft recommendation report.[23] The ACMUI unanimously approved the subcommittee's report and recommendations, as summarized in the following four points:[24]

(1) The ACMUI supports the staff's recommended rulemaking with the following amendments: "If a patient requires medical attention for a suspected radiation injury due to extravasation which results in tissue damage at or near the administration site, and this radiation injury is confirmed by a physician authorized user of the licensee to be due to radiation from the extravasation, then this will require medical event reporting." The staff's recommended rulemaking would provide the NRC with information on radiation injuries caused by extravasation and the frequency of such injuries. It also would establish appropriate medical event criteria to capture those extravasation events that could result in patient harm so that they can be evaluated further for meeting the abnormal occurrence criteria and, if so, reported as abnormal occurrences.

(2) Monitoring for extravasation will not prevent extravasations from occurring. While there should be a quality assurance policy to monitor and improve the extravasation rate at an institution, as there exists for many medical procedures, this monitoring should be conducted as part of a medical quality improvement program and not be subject to NRC regulation.

---

21 Comments from the OAS, North Carolina Department of Health and Human Services, Arkansas Department of Health, and North Carolina Radiation Protection Commission on PRM-35-22 are available at ADAMS Accession Nos. ML21019A494, ML21019A495, ML20336A269, and ML21015A409, respectively.

22 Compiled OAS and Agreement State comments on the staff's draft rulemaking plan, dated December 21, 2021, are available at ADAMS Accession No. ML21348A764.

23 "Official Transcript of Proceedings: Meeting of the Advisory Committee on the Medical Uses of Isotopes," September 2, 2021 (ADAMS Accession No. ML21286A807).

24 See fn. 17, *supra*.

(3) Requiring extravasations that result in a localized tissue dose exceeding 50 rem to be reported as medical events would create significant licensee and regulatory burden with no additional benefit to patient safety.

(4) There is no clinical evidence that patients are being harmed, either from excess radiation dose or compromised diagnostic studies, because of radiopharmaceutical extravasation.

The Staff Considered How International Counterparts Address Extravasation

The International Commission on Radiological Protection has recommended that therapeutic administrations be monitored for extravasation, and if an extravasation occurs, mitigation measures should be implemented, the extravasation should be recorded, and the patient followed-up.[25] The International Atomic Energy Agency classifies extravasation as a type of misadministration that involves the wrong route of administration, and recommends that nuclear medicine services have procedures to prevent, monitor for, manage, and document all misadministrations.[26]

RULEMAKING PLAN:

In the staff requirements memorandum for SECY-15-0129, "Staff Requirements—SECY-15-0129—Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (ADAMS Accession No. ML16034A441), the Commission directed the staff to provide a streamlined rulemaking plan in the form of a SECY paper that would request Commission approval to initiate all rulemakings not already explicitly delegated to the staff. Accordingly, the NRC staff requests approval to initiate a 10 CFR Part 35 rulemaking to consider the issues raised in the petition.

Title

Reporting Nuclear Medicine Injection Extravasations as Medical Events.

Regulation

10 CFR Part 35.

Regulatory Issue

The NRC excludes radiopharmaceutical extravasations from its medical event reporting regulations. Therefore, extravasations that cause radiation injury, and even those that meet the public health and safety significance criteria for an abnormal occurrence, are not required to be reported to the NRC and cannot be considered in the NRC's evaluation of abnormal occurrence medical events. Given the expected increasing use of therapeutic radiopharmaceuticals, medical event reporting of certain extravasations should be considered in the NRC's rulemaking process. If radiation-safety-significant extravasations were reported to the NRC, the staff could track and trend these events and share information on their occurrence, detection, mitigation, and possible preventive strategies.

---

[25] See Ref. 9 in Enclosure 3.

[26] See the International Atomic Energy Agency's FAQs on misadministrations in diagnostic nuclear medicine at https://www.iaea.org/resources/rpop/health-professionals/nuclear-medicine/diagnostic-nuclear-medicine/misadministrations (accessed April 29, 2022). See also Ref. 10 in Enclosure 3.

Existing Regulatory Framework

The NRC's medical event reporting requirements appear in 10 CFR 35.3045, "Report and notification of a medical event."[27] Medical event reporting is mandatory, and the expectation is for prompt notification and follow up. After discovery of the event, the regulation requires the licensee to notify the NRC Operations Center by the next calendar day and submit a written report within 15 days. In addition to timely notification to the regulator, the licensee must notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery (unless, based on medical judgment, informing the individual would be harmful). If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible.

All reported medical events are captured in the Nuclear Material Events Database (NMED). NMED contains records of events involving nuclear material licensed under NRC regulations or compatible Agreement State regulations and reported to the NRC by NRC licensees, Agreement States, and nonlicensees. NMED is not accessible by the public. However, event notification reports are publicly available on the NRC's Web site, and the ACMUI conducts annual public meetings during which the staff and the ACMUI give presentations on the medical events from the past fiscal year.[28] If the NRC identifies similar problems reported from multiple facilities, the NRC may issue generic communications to help prevent additional incidents from occurring.

Administration of therapeutic radiopharmaceuticals are also subject to 10 CFR 35.40, "Written directives," and 10 CFR 35.41, "Procedures for administrations requiring a written directive." A written directive is an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject. Written directives must contain the information specified in 10 CFR 35.40, and 10 CFR 35.41 requires, in part, that licensees develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Explanation of Why Rulemaking Is the Preferred Solution

The staff evaluated the "no action" and several rulemaking options. Three options are discussed below, and Enclosure 4 documents additional options evaluated by the staff but not recommended for Commission consideration. All rulemaking options would require that certain extravasations be reported as medical events, which would allow reporting of extravasation events that meet the public health and safety significance criteria for abnormal occurrences.

For both rulemaking options, the staff would develop a dosimetry model for extravasations that licensees could use to estimate the dose to tissue from an extravasation. Even for a reporting regulation not based on dose, licensees may want to perform a dose assessment of an extravasation because knowing the estimated dose to tissue could help licensees assess

---

[27] In addition to 10 CFR 35.3045, medical licensees are required to report events in accordance with 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child"; 10 CFR 35.3067, "Report of a leaking source"; 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection against Radiation," Subpart M, "Reports"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; and 10 CFR 30.50, "Reporting requirements."

[28] Event notification reports are available at https://www.nrc.gov/reading-rm/doc-collections/event-status/event/index.html. The ACMUI and staff annual reports are available at https://www.nrc.gov/materials/miau/med-use-toolkit.html#events.

suspected radiation injury.[29] A standardized dosimetry model would be a useful tool for licensees to assess the severity of an extravasation and would help the National Materials Program collect more reliable information on the impact of extravasations.[30]

Option 1, "No action," would maintain the status quo, and extravasations would continue to be excluded from medical event reporting.

There are a number of reasons to consider continuing to exclude extravasations from medical event reporting: (1) Extravasations are rarely significant from a radiation safety risk perspective; (2) extravasations are not fully preventable so licensees should not have to report them as medical events and (3) unlike other medical events, the occurrence of an extravasation does not necessarily indicate a potential problem in a medical facility's use of radioactive materials nor does it mean the administration deviated from the written directive or the authorized user physician's intent. Continuing to exclude extravasations from medical event reporting aligns with the views of some in the medical community that extravasation is a generic medical issue that does not need to be regulated and is best addressed at the institutional level. Medical community stakeholders and some Agreement States have questioned whether regulating extravasations would appreciably reduce their occurrence. The NRC's existing medical use regulations are protective of public health and safety, and even without a regulation for reporting extravasations, significant extravasations would still be clinically addressed by physicians. Furthermore, recent congressional and regulatory attention on extravasation has prompted the nuclear medicine community to increase focus on injection quality. Instead of rulemaking, the staff could continue to spotlight the potential for extravasations by working with the ACMUI to issue a generic communication on the radiological risks of extravasation.

Published literature provides evidence that some extravasations can cause severe tissue damage, and the expected continued increase in the use of therapeutic radiopharmaceuticals may increase the occurrence of these radiation-safety-significant extravasations. Continuing to exclude extravasations from medical event reporting would not address the regulatory issues discussed above related to the NRC's ability to evaluate severe extravasations and collect and share operating experience.

Option 2, "50-rem dose threshold," would require medical event reporting for all extravasations that exceed a localized dose equivalent of 50 rem. Licensees would need to monitor every radiopharmaceutical IV administration for extravasation because minor extravasations resulting in tissue doses around 50 rem would likely otherwise go undetected. Monitoring for extravasation would require taking an image over the injection site soon after administration or using some type of radiation detector device to monitor the administration. If an extravasation were detected, the licensee would then need to calculate radiation dose to determine if the extravasation exceeded the 50-rem dose threshold for reporting. Under

---

29 The staff's recommended reporting requirement is based on "suspected" radiation injury. Reporting extravasations that require medical attention because the licensee suspects the extravasation may result in radiation injury is a lower reporting threshold than that of observed radiation injury. Reporting based on suspected radiation injury will allow licensees to report the event at the time a radiation-safety significant extravasation is detected, mitigated, and assessed. The staff's recommended reporting requirement also would capture extravasation events that require medical attention for observed radiation injury.

30 The benefits of the NRC sponsoring a standardized dosimetry model for extravasations would extend beyond improving medical event data for the National Materials Program. The staff is exploring the possibility of adding an extravasation module to VARSKIN+, which is a computer code that calculates dose for skin contamination. VARSKIN+ is already used by many international government agencies and adding an extravasation dosimetry model could improve international collaboration on addressing risks from extravasation.

Option 2, the NRC estimates there could be at least 28,000 reportable extravasation medical events per year[31] (currently, on average, 50 medical events are reported annually).

Option 2 would improve patient safety by allowing the NRC to collect and analyze operating experience on extravasations of varying levels of radiation-safety-significance. The reporting dose threshold of 50 rem may improve injection quality through increased licensee focus on clinician training, technique, and tools. Additionally, reporting extravasations at 50 rem would be consistent with the existing 50-rem dose threshold for reporting other types of medical events. Several patient advocacy groups, some medical community stakeholders, and two Agreement States support reporting extravasations at 50 rem.

However, the NRC's medical event reporting criteria are set at conservative levels that would rarely cause patient harm, and this low-dose threshold for reporting could result in tens of thousands of extravasation events of low radiation-safety significance reported annually with no corresponding benefit to patient safety. Requiring the reporting of events of low radiation-safety significance would not align with the objectives of medical event reporting nor the NRC's Medical Use Policy Statement. Option 2 would impose significant regulatory and financial burden on licensees to monitor all radiopharmaceutical administrations and perform dosimetry for each detected or suspected extravasation without safety benefit. The staff estimates that costs for licensees to comply with Option 2 could approach $140 million per year (see the "Description of Rulemaking: Estimate of Resources" section of this paper for details of this cost estimate); the staff considers this to be a low estimate.

To implement Option 2, the NRC and Agreement States would require significant resources to review tens of thousands of extravasation events of low radiation-safety significance annually to screen for significant events. The staff estimates that costs for the Agreement States to implement Option 2 could approach $4.8 million per year. The NRC implementation costs for Option 2 also could approach $4.8 million per year, which includes managing thousands of additional records in NMED. (Currently, NMED tracks a total of about 500 materials events per year.)

Option 3, "Extravasation events that require medical attention for suspected radiation injury," would be a non-dose-based option for reporting extravasations. If a patient requires medical attention for suspected radiation injury from an extravasation, then this extravasation would require medical event reporting. Reporting based on medical attention for suspected radiation injury means that licensees can report radiation-safety-significant extravasations at the time they are detected, instead of waiting for a radiation injury to manifest. In this situation, dose assessment may be useful to help licensees characterize the potential for radiation injury. Alternatively, if an extravasation is undetected at the time of administration, but the patient follows up with the licensee several days or weeks later for an adverse tissue reaction around the administration site, then this extravasation also would be reported. As part of this option, the staff would publish a request for information in the *Federal Register* to obtain early feedback from the medical community on qualitative criteria for determining radiation injury and defining medical attention—this feedback would inform the staff's regulatory basis for the rulemaking. Under Option 3, the staff estimates there could be approximately 80 reportable extravasation

---

31 The staff used information cited by the petitioner at https://lucerno.com/take-action/ (accessed January 23, 2022), for its extravasation event estimates. There could be about 28,000 reportable extravasation events per year, given 18.5 million nuclear medicine injections per year, a total extravasation rate of 15.2 percent, and estimating only 1.0 percent of extravasations could exceed a 50-rem localized dose to tissue.

events per year.[32] Option 3 is estimated to result in annual implementation costs of $153,000 for licensees, $55,000 for Agreement States, and $49,000 for the NRC (see the "Description of Rulemaking: Estimate of Resources" section for detailed cost estimates).

Option 3 would improve patient safety by screening out extravasations of low radiation-safety significance and allowing the NRC to collect and analyze operating experience on radiation-safety-significant extravasations. Because Option 3 would be based on suspected radiation injury, it would not require monitoring of all radiopharmaceutical administrations or dosimetry to determine whether an extravasation meets the criteria of a medical event. (However, the NRC would develop a dosimetry model to support licensees in characterizing the radiation-safety-significance of an extravasation.) Option 3 is supported by the ACMUI, the OAS Board, and two of the Agreement States that provided comments on the staff's preliminary extravasation evaluation. The staff believes that a risk-informed reporting requirement for radiation-safety-significant extravasations considers medical community input regarding the risk of extravasations and their unavoidability in some cases, and would align with the objectives of medical event reporting and the NRC's Medical Use Policy Statement.

Because Option 3 would not require monitoring of all extravasations, and would rely in part on patients self-reporting adverse tissue reactions to an authorized user physician, not all patients would seek follow up for adverse tissue reactions, which could result in under-reporting. Patient advocacy groups also have criticized this option as putting the responsibility of reporting on the patient instead of the physician. There also is concern about the subjectiveness of Option 3. Medical event reporting based on suspected radiation injury would be a change in paradigm from the existing dose-based medical event reporting criteria, and a regulation based on a physician authorized user's assessment of what constitutes "medical attention for suspected radiation injury" would be less clear than a dose threshold.[33]

The Staff Recommends Option 3, "Extravasation Events that Require Medical Attention for Suspected Radiation Injury"

The staff believes that Option 3 could strike the appropriate balance between capturing radiation-safety-significant extravasation events to improve patient safety while avoiding undue regulatory burden on licensees and the Agreement States. Option 2 could capture tens of thousands of diagnostic extravasations of low radiation-safety significance, which would likely result in only a marginal increase in safety compared to the staff's more risk-informed approach in Option 3, but with significant regulatory burden to licensees and Agreement States. (The staff discusses the costs and benefits of Option 2 and Option 3 in the "Description of Rulemaking: Estimate of Resources" section of this paper.)

---

32 The Option 3 radiation injury criterion would likely screen out all but the most severe diagnostic extravasations, so the staff assumed an estimated 177,500 therapeutic IV administrations per year, a 0.18 percent extravasation rate, and that 25 percent of these extravasations could result in suspected radiation injury. The staff assumed a 0.18 percent extravasation rate for therapeutic IV administrations (versus the 15.2 percent extravasation rate for all administrations) because this is the extravasation rate for chemotherapy, and the staff sees similarities between chemotherapy and radiopharmaceutical therapy administrations.

33 In the 1980 final rule for misadministrations (45 FR 31701; May 14, 1980), the Commission abandoned "clinically detectable adverse effect" as a reporting criterion for diagnostic misadministrations due to stakeholder feedback that this criterion was unclear. To address similar concerns about the Option 3 reporting criteria, the staff would obtain early stakeholder feedback to define "medical attention for suspected radiation injury" and would develop guidance for evaluating and reporting extravasation events. The staff also proposes to develop a dosimetry model to support licensees in characterizing the radiation-safety-significance of an extravasation.

Description of Rulemaking: Scope

Under the staff's recommended Option 3 rulemaking, the NRC would revise 10 CFR 35.2, "Definitions," 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045.

Description of Rulemaking: Preliminary Backfitting and Issue Finality Analysis

The Commission's backfitting provisions in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"; 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste"; and 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," and issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," do not apply to the reporting requirements in 10 CFR Part 35. However, in accordance with the NRC's Principles of Good Regulation, and as further discussed in the "Description of Rulemaking: Estimate of Resources" section of this paper, the staff would consider the costs and benefits of the rulemaking and develop a draft regulatory analysis for public comment to accompany any proposed rule.

Description of Rulemaking: Estimated Schedule for Option 3

The staff estimates the following schedule for Option 3:

- Publish a request for information in the *Federal Register*—approximately 3 months after Commission approval.
- Publish the regulatory basis for comment—approximately 16 months after Commission approval.[34]
- Submit the proposed rule and draft guidance document (with consideration of comments on the regulatory basis) to the Commission—16 months after the regulatory basis comment period closes.
- Submit the final rule and final guidance document (with consideration of comments on the proposed rule and draft guidance) to the Commission—16 months after the proposed rule comment period closes.

This schedule includes time to coordinate reviews with the Agreement States and the ACMUI. The Agreement States typically receive 30 to 90 days to review the regulatory basis and the proposed and final rule packages. The ACMUI receives a minimum of 60 days to review the regulatory basis and 90 days to review the proposed and final rule packages. Consistent with the plans for rulemaking innovation,[35] the staff will continue to look for opportunities to increase efficiency as the work proceeds.

---

34 The tracked action will be transmittal of the regulatory basis to the Commission for awareness; after 10 days, the staff would publish the regulatory basis for comment.

35 "Rulemaking Process Innovation at the U.S. Nuclear Regulatory Commission," July 2020 (ADAMS Accession No. ML20198M408).

Description of Rulemaking: Preliminary Recommendation on Priority

Based on the NRC's common prioritization of rulemaking methodology, updated in September 2018 (ADAMS Accession No. ML18263A070), the preliminary priority for the Option 3 rulemaking is medium (18 of 45 possible points). The priority for a rulemaking activity can change over time. Common reasons for a change in priority are new Commission or senior management direction or changes in the rulemaking scope. The staff evaluated the rulemaking's impacts as follows:

- Medium contributor toward the NRC's strategic plan goals by implementing two safety goal strategies: (1) maintain and enhance the NRC's medical uses regulatory program, using information gained from operating experience, lessons learned, and advances in nuclear medicine, and (2) further risk-inform the current medical regulatory framework in response to advances in nuclear medicine.

- Medium contributor toward the NRC's Principles of Good Regulation by implementing two principles: (1) enhancing the agency's independence as a regulator through ethical and professional performance that has been informed by objective, unbiased assessments of all information provided by stakeholders and (2) enhancing the agency's ability to uphold its safety mission in an open and transparent way through medical event reporting of radiation-safety-significant extravasations.

- Medium contributor toward the governmental priority by addressing congressional interest in reporting significant extravasations as medical events.

- Medium contributor toward the public priority because it would resolve a petition for rulemaking and would garner considerable interest from external stakeholders.

Description of Rulemaking: Estimate of Resources

Enclosure 5 of this report presents an estimate of the resources needed to implement the recommended rulemaking option (Option 3) presented in this paper.

Option 1 would result in no costs or benefits.

One-time rulemaking costs associated with both Option 2 and Option 3 include (1) completion of a medium complexity rulemaking, (2) development of a dosimetry assessment, model, and model software for extravasations and an associated regulatory guide, (3) adoption of the new regulations by the Agreement States, and (4) the staff's regulatory review of revised Agreement State regulations. The staff estimates these activities would cost the NRC approximately $2.7 million and Agreement States approximately $3.5 million.

Option 2 would require medical event reporting for all extravasations that exceed 50-rem localized dose to tissue. For licensees, implementation costs for Option 2 would be approximately $140 million per year because licensees would be required to—

- Monitor all 18.5 million radiopharmaceutical administrations to detect even minor extravasations.

- Conduct dosimetry for all 2.8 million suspected extravasations to determine whether the dose to tissue exceeded 50 rem.

- Report potentially 28,000 extravasations that exceed the threshold.

Most of these licensee costs would be related to monitoring and dosimetry.[36]

Annual costs to screen thousands of extravasation reports and follow up on radiation-safety-significant events would be approximately $770,000 for the NRC and $4.8 million for the Agreement States. The NRC also would be responsible for an additional $4 million per year associated with increased NMED costs to track more than 28,000 additional events each year. The staff estimates that due to the increased regulatory and institutional focus on extravasation, the number of reportable extravasations may decrease over time. However, most of the implementation costs for Option 2 involve monitoring all administrations and conducting dosimetry for all extravasations, so costs are not expected to decrease appreciably even if reportable extravasations decrease. Based on the staff's preliminary estimate, Option 2 would likely not be cost justified.

Costs associated with implementing Option 3 are significantly lower because Option 3 would not require monitoring of all injections and dosimetry for all extravasations (although the staff did assume licensees would perform dosimetry on the 80 reportable extravasation events). Option 3 implementation costs to the licensees would be approximately $153,000 per year[37] to assess and report extravasations that result in suspected radiation injury. The costs to the Agreement States would be $55,000 and to the NRC $49,000 per year to review and follow up on extravasation events. Most of the NRC costs would be for maintaining the events in NMED.

The staff estimates that Option 3 could provide the following qualitative benefits:

- *Protection of Public Health and Safety*: The rulemaking would result in improved safety for patients, in accordance with the NRC's Medical Use Policy Statement. Increased regulatory independence and openness through medical event reporting requirements for radiation-safety-significant extravasations would improve oversight of medical licensees across the National Materials Program. The staff would consider medical community input to define the meaning of radiation injury and risk-inform the new reporting requirements.

- *Increased Regulatory Effectiveness*: The rulemaking would remove an exception for reporting radiopharmaceutical extravasations that result in radiation injury or even meet the public health and safety significance criteria for abnormal occurrences.

- *Future Regulatory Benefit*: The staff would obtain operating experience and could track and trend radiation-safety-significant extravasation events. This information could be shared with medical licensees using generic communications to help licensees improve injection quality. Regulating extravasations may increase medical licensee focus on

---

36 Using the estimated extravasation assumptions outlined in fn. 31, the staff assumed that (1) monitoring all 18.5 million radiopharmaceutical IV administrations for extravasation would take, on average, an additional 90 seconds per administration, (2) performing dosimetry using the standardized dosimetry model that the NRC would provide would take an average of 15 minutes for each of the 2.8 million extravasations, and (3) reporting the 28,000 reportable extravasation events and following up with regulators as needed would take an average of 1 hour per event.

37 Using the estimated extravasation assumptions outlined in fn. 32, the staff assumed that (1) there would be no additional administration monitoring costs because reporting would be based on suspected radiation injury, (2) performing dosimetry using the standardized dosimetry model that the NRC would provide would take an average of 15 minutes for each of the 320 extravasations, and (3) reporting the 80 extravasation events and following up with regulators as needed would take an average of 4 hours per event.

quality improvement programs for IV administration of radiopharmaceuticals. Obtaining data on radiation-safety-significant extravasations could help prepare the National Materials Program for future expected increases in the use of therapeutic radiopharmaceuticals and radiotheranostics.

While Option 2 and Option 3 would both capture radiation-safety-significant extravasation events, Option 2 also would capture tens of thousands of extravasations of low radiation-safety significance. Option 2 may result in a marginal increase in patient safety versus Option 3, but that increase would be far outweighed by the significant increase in regulatory burden and costs for licensees to comply with Option 2 and Agreement States and the NRC to implement Option 2. Additionally, during the December 8, 2020, public meeting, the staff received comments that overregulation of extravasation could have a chilling effect on nuclear medicine, discouraging physicians from going into nuclear medicine (and especially pediatric nuclear medicine, where patient intervention is a concern and specialized pediatric venipuncture teams are needed to establish IV access in children).

The staff is recommending the Option 3 rulemaking. While Option 3 still would result in rulemaking and implementation costs for licensees, the NRC, and Agreement States, the expected increases in patient safety and transparency about radiation-safety-significant extravasation events would justify the costs. During the regulatory basis stage of rulemaking, the staff would develop a more detailed analysis of costs and benefits.

Cumulative Effects of Regulation

The staff's preliminary assessment of the cumulative effects of regulation concludes that implementing the proposed changes would not significantly impact any known activities or affected entities. To ensure the adequate identification of potential effects not currently foreseen, the staff plans to request input from external stakeholders, Agreement States, and the ACMUI on this issue during the regulatory basis and proposed rule phases of the rulemaking. The staff has identified one additional rulemaking for 10 CFR Part 35:

On January 13, 2022, the Commission approved the staff's recommended rulemaking in SECY-21-0013, "Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies" (ADAMS Accession No. ML22013A266).

The staff is coordinating these efforts related to 10 CFR Part 35. If the Commission approves more than one 10 CFR Part 35 rulemaking activity, the staff will evaluate areas of overlap and optimize application of staff resources and opportunities for stakeholder participation.

Agreement State Considerations

Agreement States would need to adopt compatible regulations for the revised subparts that this recommended rulemaking would affect. The staff has coordinated with the Agreement States in the review of PRM-35-22 and the development of this rulemaking plan. An Agreement State representative participated in the petition working group and the rulemaking plan working group, and a member of the OAS Board participated on the Petition Review Board. The staff gave the Agreement States 60 days to review and comment on the draft rulemaking plan, and the NRC has considered their comments in the final rulemaking plan. If the Commission approves the rulemaking plan, the staff will continue to work with the Agreement States throughout all stages

of rule development, in accordance with SA-801A, "Agreement State Participation in Rulemaking Working Groups," dated January 16, 2019 (ADAMS Accession No. ML18263A239).

Guidance

The staff expects that it would develop a new guidance document for reporting extravasations as medical events in parallel with the rulemaking.

Advisory Committee on Reactor Safeguards Review

This review is not required for medical rulemakings.

Committee to Review Generic Requirements Review

This review is not necessary because the backfit regulations do not apply, as described in the "Description of Rulemaking: Preliminary Backfitting and Issue Finality Analysis" section of this rulemaking plan.

Advisory Committee on the Medical Use of Isotopes Review

The staff will coordinate with the ACMUI on this rulemaking. The ACMUI will review and comment on the staff's regulatory basis, draft proposed rule, and draft final rule. The staff will hold a series of public meetings to discuss the ACMUI's comments and recommendations.

Analysis of Legal Matters

The Office of the General Counsel has reviewed this rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

COMMITMENT:

If the Commission approves initiation of the rulemaking, in accordance with SECY-16-0042, "Recommended Improvements for Rulemaking Tracking and Reporting," dated April 4, 2016 (ADAMS Accession No. ML16075A070), the staff will add the rulemaking to the agency's rulemaking tracking tool (i.e., the agency's list of funded rules at the next appropriate budget cycle).

RECOMMENDATION:

The NRC staff recommends that the Commission take the following actions:

(1) Approve closure of the docket for PRM-35-22 by considering the PRM in the rulemaking process.

(2) Approve the draft notice (Enclosure 1) for publication in the *Federal Register* and inform the petitioner (Enclosure 2).

(3) Approve the staff's recommended rulemaking option (Option 3).

RESOURCE:

Enclosure 5 includes an estimate of the NRC resources needed to complete this rulemaking.

COORDINATION:

The Office of the General Counsel has reviewed this package and has no legal objection. The Office of the Chief Financial Officer has reviewed this package and has no concerns with the estimated resources in Enclosure 5.

Daniel H. Dorman Digitally signed by Daniel H. Dorman
Date: 2022.05.09 08:31:12 -04'00'

Daniel H. Dorman
Executive Director
for Operations

Enclosures:
1. *Federal Register* notice
2. Letter to the Petitioner
3. Literature References
4. Other Options Considered
5. Estimated Rulemaking Resources (not publicly available)

SUBJECT: PETITION FOR RULEMAKING AND RULEMAKING PLAN ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS (PRM-35-22; NRC-2020-0141) DATED: MAY 09, 2022

ADAMS Accession Nos.: ML21268A005 (package); ML21268A006 (SECY paper)

OFFICE	MSST/MSEB:PM	REFS/RASB:PM	MSST/MSEB:TL	MSST/MSEB:BC
NAME	SLopas	PNoto	CValentin-Rodriguez	CEinberg
DATE	9/15/2021	9/15/2021	9/15/2021	1/28/2022
OFFICE	REFS/RASB:BC	REFS/MRPB:BC	NMSS/MSST:D	NMSS/REFS:D
NAME	CBladey	JShepherd	KWilliams	KCoyne
DATE	9/23/2021	9/23/2021	1/28/2022	10/14/2021
OFFICE	Region I/DNMS	Region III/DNMS	Region IV/DNMS	RES/DSA
NAME	BWelling	DPelton	MMuessle	KWebber
DATE	11/17/2021	11/15/2021	11/22/2021	11/15/2021
OFFICE	OCFO	OCIO	QTE	REFS/RASB
NAME	JJohnson	DCullison	KAzariah-Kribbs	CBladey
DATE	11/19/2021	11/17/2021	1/03/2022	2/17/2022
OFFICE	OGC – NLO	NMSS	EDO	
NAME	MSmith	JLubinski	DDorman	
DATE	3/18/2022	4/03/2022	5/ 09/2022	

OFFICIAL RECORD COPY