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Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2022-0218-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events

Document: NRC-2022-0218-DRAFT-0053
Comment on FR Doc # 2023-08238

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General Comment

See attached file(s)

Attachments

NRC-2022-2018 Kirk Comment Ltr dtd 2023-07-17

July 17, 2023

Brooke P. Clark
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Docket ID NRC-2022-0218

Dear Secretary Clark:

I am commenting on the referenced docket item as a concerned and involved citizen. All views expressed are my own.

Background

The matters discussed in the proposed rule "Reporting Nuclear Medicine Injection Extravasations as Medical Events" (the "Proposed Rule") raise important public health concerns, as well as concerns about the usage and proper regulation of irradiated materials for medical treatment. I thank the Nuclear Regulatory Commission (the "NRC") for creating the opportunity for public comment on the matters raised by the Proposed Rule and for the tailored questions to assist NRC in gathering relevant information for final rulemaking.

I strongly support the enactment of a rule. The Proposed Rule is an interesting start. Clearly, much work remains.

The NRC asks several questions; this comment letter intentionally does not address all of the questions raised.

I commented on the petition for rulemaking filed by Lucerno Dynamics LLC ("Lucerno"), Accession No. ML20157A266 (the "Petition"). My letter of November 25, 2020 is Exhibit A to this submission; it is incorporated by reference and for ease of noting prior comments made that are relevant to the NRC's current request.

Summary

This comment letter calls for:

- Structured training requirements for licensees;
- Structured procedural requirements for licensees;
- Structured notice requirements;
- Mandated data keeping requirements, to include particular data types, with the format and media also mandated;
- Mandated data reporting to NRC;
- Oversight of training, procedures and notices via mandated data submission, NRC review of such data and on site inspections of licensees.

I. Definitions

No comments are submitted related to Questions 1-3 pertaining to the proposed definitions.

II. Procedures

I noted generally in Exhibit A that procedural improvements would occur at treatment centers[1] subject to regulation. See, for example, the responses to Exhibit A, Section I, Questions 4 and 5 on page 4. See also the response to Exhibit A, Section II, Question 1 on page 5.

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?

Licensees generally will not take any meaningful steps voluntarily. They have not done so for decades. NRC should enact a rule requiring the following at the bare minimum:

1)NRC should institute required annual training, to include all new hires within one week of their hire date, covering at least these topics as applicable to each employee:

- Impact on patients resulting from extravasation, emphasizing the worst case scenarios, with illustrative photographs or other images;
- Proper storage and handling of radiopharmaceutical materials;
- Proper treatment room set up for radiopharmaceutical injections, to include necessary equipment and medical supplies for the radiopharmaceutical injection, as well as the equipment necessary to detect an extravasation after the injection.[2]
- Proper techniques for administering a radiopharmaceutical injection;
- Proper techniques to identify an extravasation including:
    - Use of real-time monitoring technology that has been listed with or cleared by the FDA to immediately detect the presence of excess radiotracer at an injection site or
    - A post administration image of the injection site before patients are permitted to depart.[3]

[1] The terms "treatment center" and "licensee" are used interchangeably for purposes of this letter.
[2] See also the response to Question 6.
[3] Many can or will dispute the need for real-time monitoring or imaging of the injection site. However, since a) radiopharmaceuticals are not easily detected without technology or images, b) early mitigation is important for protection of patients and c) assessment of severity is important these should be required. Observation periods are required after many other procedures; radiopharmaceutical injection should be no different.

2)NRC should require that licensees develop written procedures addressing the following issues:

- Required annual training and credentialing, required content for such training (to include annual updates reflecting scientific and technical advances), and required documentation of the administration of the training, to include the materials used to conduct such training;
- Proper preparation to administer a radiopharmaceutical treatment;
- Proper detection techniques for extravasations;
- Proper responses to extravasations;
- Proper notices to provide to patients and their primary care physicians;
- Proper administration of any other applicable rule or requirement imposed by NRC or any other applicable governmental authority.

The ultimate long term correct answer to this question is "By adhering to the new NRC regulations requiring specified training and detailed procedures of all licensees." However, that answer only can be correct if NRC, in fact, enacts detailed regulations AND institutes a reporting system, with an inspection process, to ensure compliance with such regulations.

Question 5 and 6:

5. What steps should the licensee take when an extravasation is suspected or discovered?

Treatment centers should focus quickly on patient treatment and safety. Question 6 itself suggests certain courses of action that seem completely appropriate: Use available technologies to verify suspicions and/or provide treatment.

Whatever else can be medically performed at that time to prevent worsening of the patient's condition should be discussed with the patient, including movement to another medical facility better suited to provide care if deemed medically necessary.

Once the patient has been examined, the extent of the injuries has been documented[4], the patient has been treated and deemed to be stable, the patient can be released.

When the above is completed, treatment centers should follow *at least* the administrative requirements regarding incident tracking and documentation proposed in this comment letter.

6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

[4] The requirements for such documentation should be mandated by rule to ensure that all patients are treated equally. Requiring the documentation type will inherently require certain medical treatments to be administered or procedures be used.

All of the examples are procedures that should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection. Importantly, all should be required by regulation and required to be part of written procedures used for radiopharmaceutical injection.

A potential counterargument to the proposed approach is cost. The incremental cost should not be an issue for licensees. Technology exists today that can identify extravasations at the time of the administration far more accurately than visual observation and patient feedback. It is borderline malpractice that technology is not being used today to ensure patients are not being extravasated. Furthermore, camera technology also can be used to perform post-treatment imaging after administration that can also identify extravasations. (Such techniques are not as timely as using technology during the administration process, which should be the standard.)

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?

No response is provided for Question 7.

8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?

At least 72 hours **PRIOR** to any scheduled radiopharmaceutical treatment, a patient should receive a one page document containing the following information, made available in all languages spoken within a fifty mile radius of the treatment center spoken by at least 10% of the population as last measured by the most recent federal census:

- A description of the procedure;
- Any preparation required by the patient for the procedure;
- The prospective dosages of radiologic material expected to be injected;
- Potential side effects of the treatment to include a description of an extravasation;
- Warning signs of problems post procedure.

Immediately following any radiopharmaceutical treatment, a patient must receive a one page document containing the following information, made available in all languages spoken within a fifty mile radius spoken by at least 10% of the population as last measured by the most recent federal census:

- The prospective dosages of radiologic material actually injected;
- The exact location of the injection (in non-medical terms);
- Potential side effects of the treatment to include a plain language description of an extravasation;
- Warning signs of problems post procedure;
- The addresses, phone numbers and email addresses of the treatment center and the nearest two additional radiological treatment centers;[5]

[5] The additional treatment center information will provide the patient with optionality to be treated for any problem at a center OTHER than the treatment center that caused the problem. Treatment centers will vigorously oppose this

- The importance of reporting side effects or issues to the original treatment center promptly.

NRC should carefully consider requiring licensees to provide patients with evidence (based on imaging) that the injection was performed correctly.

Importantly, these documents should be required by regulation to be provided in hard copy to the patients. Email, text or other delivery methods should be permitted only as additional delivery methods unless a patient knowingly waives the right to receive a hard copy of these specific notices via electronic signature.

The format need not be regulated; the content must be.

Other regulators successfully use this model. See, for example:

1)Federal Trade Commission: https://www.ftc.gov/business-guidance/privacy-security

2) Securities and Exchange Commission:
https://www.sec.gov/divisions/marketreg/tmcompliance/modelprivacyform-secg.htm

https://www.sec.gov/rules/final/34-42974.htm#P225_87089

Licensees are familiar with notice requirements because of HIPAA[6], as regulated by Health and Human Services:

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html.

The distinction, though, between HIPAA notices and the proposed extravasation notice is simple: the former is delivered upon request; the latter MUST be provided to patients.

9. When should a reportable extravasation be counted as "discovered" for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

A reportable extravasation be counted as "discovered" for the purposes of notification at the time an extravasation that exceeds the current medical event reporting dose to tissue threshold was identified OR if a licensee has not proactively identified an extravasation, then when ANY person identifies an injury from radiation, regardless of the stage of discovery or by whom.

For patient protection, early detection and assessment is important. Waiting until medical attention is administered is not the right point, unless treatment is provided moments after the extravasation occurs. In this scenario, cause and response nearly are simultaneous, blurring the line for "discovery". Allowing the discovery date to be set at a later time, when earlier detection was possible, provides the wrong incentive to licensees.

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concept, which frankly is better for patients. Treatment centers can avoid "losing business" by training their employees to prevent and avoid extravasations.

[6] Health Insurance Portability and Accountability Act of 1996

Example:

> If a person identifies an extravasation at the time of administration, 10:00 AM July 18, but the severity assessment of the extravasation happens at 1:30 PM on July 19, the discovery date should be recorded by the treatment center as July 18. [7]

Ultimately, this is a common sense decision that hopefully will not be skewed by treatment centers. Only through detailed recordkeeping requirements and regulatory oversight will treatment centers learn to keep and retain accurate records.

As I noted in Exhibit A, it would be useful for NRC to require licensees to use standardized incident tracking numbers. Perhaps that format could be:

License Number--Year (as a four digit number)--Incident Number (as a seven digit number to ensure that even the largest treatment center likely never would run out of incident numbers in any given year).

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?

If the discovery occurs in conjunction with the delivery of radiopharmaceutical treatment, the individual should be notified in person before such individual leaves the treatment center. Such notification should be acknowledged by the individual and the administering medical personnel in writing.

In all circumstances, licensees should notify the referring physician and the individual by telephone, text and in a formal writing (letter) within 24 hours of the discovery of the medical event.

Documentation of these events should be a mandated portion of NRC's future recordkeeping requirements.

11. Who (e.g., patient's primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a "suspected radiation injury"?

It is woefully late for a patient if an extravasation is NOT identified at the time of suspected radiation injury. Failing to detect extravasations at the time of the radiopharmaceutical injections is (or should be made regulatorily) unacceptable. However, if an extravasation has escaped detection for lack of proactive monitoring or imaging, any medically trained person at the licensee who is in contact with individuals receiving radiopharmaceutical treatment MUST be

[7] This is one of the scenarios envisioned by the question. It is the logical date of discovery. The need to codify this date by rule should seem obvious from the reams of data that show that many treatment centers do not track these events. However, recordkeeping also should reflect the date of the radiopharmaceutical injection.

able to identify an extravasation that could result in a "radiation injury". Identification of extravasations should be part of the required training.[8]

Such a regulation will require local licensees to provide training for all local medical personnel meeting this definition. However, one meaningful way to reduce the burden on local licensees is that such licensees could provide the training materials to any local medical care systems to provide the training themselves. Such local medical care systems also would need to retain applicable records for examination.[9],[10]

12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

No response is provided for Question 12.

III. Healthcare inequities

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?

NRC could require licensees to create forms using standardized NRC questions allowing patients to voluntarily submit demographic information as part of intake/patient admission. Given various (including recent) Supreme Court decisions, creating a requirement for patients to provide such data potentially could be overturned as overreaching, among other things. Admittedly, if a voluntary system is implemented, the resulting data collection will be weaker. However, in this circumstance, something is better than nothing. All such data collected should be submitted in a mandated format to NRC for assimilation and review.

Of course, if the suggestions provided elsewhere are implemented, it is very likely that the rate of extravasations is reduced. When that becomes the case, the need for such data should be ameliorated.

14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

Any approved medical tool, technology or technique that can reduce the potential for extravasations should be welcomed and used by the medical community with open arms.

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[8] See response to question 4.
[9] See response to question 4 for suggested training topics.
[10] There is no "one size fits all" solution to this problem. Ultimately, a treatment center in a suburban or rural area bears the burden of ensuring that referring physicians are trained.

III. General Commentary

Many agencies use similar proposed rulemaking requests to gather information before enacting rules. Doing so is laudable and potentially expedites regulatory action.

However, the questions posed accompanying the Proposed Rule do not address true regulation:

- Requirements to submit data to NRC for NRC to study and evaluate;
- Requirements for particular recordkeeping systems and required elements of such records that must be collected to ensure that sufficient information is available for substantive NRC review. Examples:
    - Requirements for scans to be retained for a particular period of time;
    - Requirements for treatment records to be retained for a particular period of time;
    - Requirement for extravasations of certain size or larger to be reported (by incident tracking number) to an NRC controlled database containing specified mandated fields).
    - Any other data or documentation that the NRC believed was not available (or available only in statistically insuffient quantities at the time of the Petition.
- Requirements for records to be maintained in specific formats, structures or media to allow NRC to compare licensees performance to the standard AND among licensees, as well as compiled for bigger picture analysis.

These are just a few examples of how other regulators ensure compliance with their rules. I strongly encourage the NRC to ensure that the proposed rule scheduled for 2024 contains these and other elements of consistent and diligent regulatory oversight.

IV. Conclusion

A. Paraphrasing from materials found at this URL:
https://www.nrc.gov/materials/miau/med-use.html

*NRC has [**been entrusted with]** regulatory authority over the possession and use of byproduct, source, or special nuclear material in medicine.* (Bracketed portion inserted and emphasized.)

NRC historically has chosen not to gather complete data on the extravasations described in the Petition. NRC should require detailed reporting and recordkeeping related to such extravasations to enable NRC to gather and review real data upon which to make further decisions.

B. The potential course(s) of action outlined above (such as notice requirements, incident tracking numbers, data submission requirements, and the creation of a searchable database) are well within the guidelines summarized by the NRC itself on the web page outlining this request for comment [related to the Petition]:

"*NRC's Medical Use Policy Statement (65 FR 47654) states, in part, that the NRC will not*

intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." [11]

Nothing outlined above intrudes upon or supersedes medical judgements. A properly designed database, combined with the other recommendations in this comment letter, would support and improve such medical judgements, giving practitioners important reference points to support and improve their practice. Rulemaking as requested by the Petition (and as outlined in the skeleton Proposed Rule) would provide for the radiation safety of workers and the general public.[12]

The preceding sentences in this Conclusion were copied (with slight revisions) from the Conclusion to my comment letter related to the Petition. These concepts have not changed in the subsequent period of nearly three years.

I appreciate the opportunity to comment on the Proposed Rule.

I look forward to seeing a significantly revised rule proposal incorporating the concepts introduced in this comment letter. As noted in this letter and in Exhibit A, the basic regulatory concepts are used by other federal agencies with regularity. NRC should do the same to ensure patient safety.

Sincerely,

/s/ Keith T. Kirk

[11] See the first sentence at Section V: https://www.regulations.gov/document?D=NRC-2020-0141-0004.
[12] Significant portions of the first five paragraphs of Section IV appeared in Section IV of Exhibit A. They are repeated here (although slightly rephrased) for emphasis and to facilitate NRC's review.

Exhibit A

November 25, 2020

Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Docket ID NRC-2020-0141

Dear Ms. Vietti-Cook:

I am commenting on the referenced docket item as a concerned and involved citizen.

Background

The matters raised in the petition for rulemaking filed by Lucerno Dynamics LLC ("Lucerno"), Accession No. ML20157A266 (the "Petition") raise important public health concerns, as well as concerns about the usage and proper regulation of irradiated materials for medical treatment. I thank the Nuclear Regulatory Commission (the "NRC") for creating the opportunity for public comment on the matters raised by the Petition.

For the reasons outlined below, I support Lucerno's Petition.

The NRC request for comment ("RFC") includes two main categories: 1) Injection Quality Monitoring and 2) Medical Event Classification and Reporting Criteria. My comment letter does not address all questions raised by the NRC. However, questions that are addressed will be answered in the order in which they were posed.

I. Injection Quality Monitoring

Question 1: How frequently does radiopharmaceutical extravasation occur?
Question 2: Do you know of any extravasations that have resulted in harm to patients? If so and without including information that could lead to the identification of the individual, describe the circumstances, type of effect harm, and the impacts.

Questions 1 and 2 will be answered together, as the issues raised are tightly linked.

A. Common sense: Question 1's request for input on the frequency of these events essentially is the reason the Petition was filed. By virtue of asking the question about the frequency of these events, NRC is conceding that it is not gathering sufficient data to assess questions 1 & 2 on its own. The request relies on persons (or their medical use licensee facilities, hereafter, "Facilities" or "Facility") that essentially are making mistakes (the extravasations) to self-report now during the comment process when previously no reporting or tracking of this kind was required by regulation.

There appears to be no regulation that requires such Facilities to create or maintain detailed records regarding these extravasations. Even if one were to concede that, in the past, there was not an easy means of measuring the severity of extravasations, there appears to be no requirement to maintain consistent detailed or organized records of the occurrence of extravasations.

Essentially, NRC has created a situation whereby it may not receive a sufficient number of examples (as requested in the RFC) during this comment period merely because NRC failed to create sufficient regulations to require record keeping or tracking mechanisms of such events.

Rhetorically: Will persons or Facilities that have extravasations to show actually provide comments with scans showing the scope of these events? I hope so. However, they are not compelled to do so. Many may not even be aware of the Petition and RFC. To the extent there are such responses, I presume that such responses will not be in sufficient number to provide any useful or actionable information to NRC. Any lack of data provided in response to these questions will not prove that regulation is unnecessary. The lack of data proves that regulation is necessary.

The solution: Require, by rule, that extravasation data be submitted to NRC in a standardized format on at least some periodic basis or within some reasonable timeframe after each occurrence.

B. Harm to patients: As will be further explained below under **Medical Event Classification and Reporting Criteria**, creation of a distinct reporting and tracking database/mechanism will facilitate discovery of harm to patients. One wonders if all patients currently (or historically) ever learn(ed) about certain extravasations. Proper rulemaking would require that notice be provided to the patient, and that appropriate data (to include a tracking number) be reported to that patient and NRC. Patients would be aware that they should be monitoring themselves for any complications. The data filed at the time of event would be ready and available for further reporting, tracking and treatment should any given patient ever require follow-up treatment. Aggregated data could be used to educate Facilities and medical practitioners.

C. Data gathering by other federal regulators[1]: Not all federal rule making is designed to prevent only the worst behavior or outcome. Some federal rule making is designed intentionally to gather necessary data. The following are examples from other regulatory agencies.

1. Federal Aviation Administration (the "FAA").

The FAA could take the approach that its only obligation is to track and assess the safety of aircraft. Clearly, based on the FAA's homepage, it believes that it has greater obligations. See, for example, the various data gathered and displayed at this location on the Internet: https://www.faa.gov/data_research/.

[1] While making this argument, I concede that all federal rulemaking must be enabled by some form of legislation. NRC faces no such obstacle in the areas raised by the Petition; it has sufficient authority to enact the proposed rules.

This webpage from the FAA website circa November 2020 shows that the FAA gathers data on unruly passengers and on time data, to name only two examples.

Unruly passengers and on time statistics do not rise to the level of terrorist attacks, hijackings, felony murders or other heinous crimes. FAA is gathering data on unruly passengers so that it can make air travel safe not simply from the perspective of "can the airplane get from point A to point B?", but also from the perspective of "what negative impact do unruly passengers have on the overall safety of air travel?".

Similarly, the FAA chooses to gather data about how well the airline industry sticks to schedules. While we all admire timeliness, the implication is clear: The FAA chooses to oversee timeliness because a lack of timeliness adversely affects air travel. A potential impact would be that a particular airline or airport could cause safety issues by hurrying to stick to a schedule or having too many aircraft operating in a small space in a narrow time window. Backlogs at certain airports can strain the overall aviation system, causing safety risk and operational risk.

2. Securities and Exchange Commission (the "SEC" or the "Commission" in this section only)

In 2015, the SEC proposed a rule related to data submission. The resultant rule created Form N-PORT, which in part ultimately required certain registrants to submit data to the SEC in a format that the SEC designed solely for its own purposes. See, for example, these two excerpts from the final rule release:

As the primary regulator of the asset management industry, the Commission relies on information that funds file with us, including their registration statements, shareholder reports, and various reporting forms such as Form N-CSR. ***The Commission and its staff use this information to understand trends in the fund industry and carry out regulatory responsibilities, including formulating policy and guidance,*** *reviewing fund registration statements, and assessing and examining a fund's regulatory compliance with the federal securities laws and Commission rules thereunder*.[2]

As a result, although we will collect certain information on Form N-PORT that may be similarly disclosed or reported elsewhere (e.g., portfolio investments would continue to be included as part of the schedules of investments contained in shareholder reports, and filed on a semi-annual basis with the Commission on Form N-CSR), ***we believe that it is appropriate to also collect this information in a structured format for analysis by our staff as well as investors and other potential users.***[3]

3. Consumer Product Safety Commission (the "CPSC")

At the URL immediately below, the CPSC recently published a report that it assembled from data that had been submitted to CPSC. The report covers deaths from engine driven tools over a ten-year period. There were a total of 820 deaths.

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[2] See, Investment Company Reporting Modernization, Investment Company Act Release No. 32314 (Oct. 13, 2016) [81 FR 81870 (Nov. 18, 2016)] ("Adopting Release") at pp. 17-18, emphasis added.
[3] See also, Adopting Release at p. 24, emphasis added.

https://www.cpsc.gov/s3fs-public/GeneratorsandOEDT_COPoisoningFatalitiesReport2020.pdf?oEcUAwBi4G0hObM8g9MLca9x_vxhssQz

The CPSC collects, assembles, analyzes and publishes data that relates to human safety as a means of analyzing trends or perhaps designing additional rules or regulations to save those lives.

Conclusion: NRC has an opportunity to perform similiar service to its constituents by enacting the rulemaking requested under the Petition, and by ensuring that the data collected is assembled in such a way as to be consumable by multiple stakeholders.

Question 3: No comments are submitted related to Question 3.

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

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

Questions 4 and 5 also will be answered together, as the issues raised are tightly linked.

The answer to the first question raised in each of questions 4 and 5 is: Absolutely.

Simple logic and human behavior dictate that answer. If Facilities using radiopharmaceutical techniques are required to report extravasations, they will train and monitor their personnel more carefully, if for no other reason than to avoid events triggering the reporting requirements. To the extent Facilities ultimately are required to report, they will redouble their training efforts. Why? They will not want their Facility to appear worse than others in statistical data. The positive effect of data reporting would be enhanced if data regarding these incidents and the overall Facility track records (sortable by geographical location of the centers-again with due considerations for the requirements of HIPAA- as defined below) were made publicly available. Such publicly available data would allow doctors to refer patients to better Facilities and empower patients to independently assess the use of radiopharmaceutical techniques.

The above paragraph describes the type of analytical work embraced by the three regulators cited above in I. C. 1, 2 and 3. The Petition presents the NRC with an opportunity to create that type of regulation and provide that type of analytical support to patients and the medical community.

II. Medical Event Classification and Reporting Criteria

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

Question 1 essentially invites comment on the required cost benefit analysis for federal rule making.

As a generality, a well-designed 21st century quality data input system would reduce costs for both licensees and the NRC. With proper development, the input system would feed a data depository that NRC staff could mine, allowing the NRC staff to structure data pulls and generate internal and external reporting as needed. Multiple federal agencies have designed such systems; there is little to no reason precluding NRC from doing so. (NRC's Nuclear Material Events Database (NMED) perhaps could be upgraded to this capability if NMED currently is not this powerful.)

Naturally, if certain recommendations made in this letter are adopted, data collected and displayed under the rule making would need to meet the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA); (Pub.L. 104–191, 110 Stat. 1936, enacted August 21, 1996) and any other applicable privacy laws or regulations.

One clear benefit of such a data input and tracking system is obvious: NRC would know, without having to ask, how many of these incidents occur and where they occur. Another benefit, mentioned in response to Questions 4 and 5 in Section I, would be the ability of doctors and patients to mine this database to find better (or the best) treatment centers for radiopharmaceutical procedures. Also mentioned supra is that training and procedural improvements very likely would be developed to avoid incidents that would meet the reporting requirements.

Human behavior dictates that people will respond to regulation by improving their behaviors.

Any burdens of this regulation should be considered in contrast to the long-term benefit of gathering this data, which otherwise is unavailable. The NRC is in the position of asking certain of the questions in the RFC precisely because it has not collected this data.

Questions 2 and 3: No comments are submitted related to Questions 2 and 3.

III. General Commentary

A. Examples from disasters: The Buffalo Creek Disaster[4] chronicles a series of lawsuits involving a flood in the 1970s in West Virginia. Millions of dollars in judgements were awarded.

More currently famous cases, such as the events memorialized and portrayed in the movies "Erin Brockovich" (2000) and "Dark Waters" (2019), have made it clear that companies can and will miss or ignore (intentionally or negligently) scientific facts that can cause health problems. (Collectively, these three incidents are the "Disasters".)

How are these three Disasters relevant to this request for comment?

[4] See Gerald M. Stern, The Buffalo Creek Disaster, Vintage, 2008.

Ignoring important scientific data or the refusal of proper authority to collect or act on scientific evidence were actions (or lack of actions) that clearly led and contributed to each of the Disasters.

The NRC has an opportunity to begin collecting and analyzing data that can determine conclusively how much harm all extravasations cause. Such studies would be independent of the very parties that cause extravasations with poor techniques, lack of controls, lack of training and certainly, at times, innocent well-meaning mistakes.

B. Form letter submissions: I note that a large number of comments submitted are form letters. Many of these form letters are weakened by the author omitting the name of their Facility, as NRC cannot discern easily whether these letters come from a single geographic area, were initiated by a single organization or sprung from a wide spread array of respondents. The multitude of identical letters suffer also from redundancy. Redundant form letters do not add to the NRC's study of the issues presented in the Petition and the RFC.

Given those facts, I am hopeful that the NRC also is mindful of the general "relevant matter presented" standard employed by many regulatory agencies when reviewing redundant comment letters. I also am hopeful that NRC will strongly consider the self-interest of these redundant commenters to avoid and attempt to prevent a requirement to report extravasations.

C. With all due respect to the experience of the commenters from the medical field, the form comment letters citing "my vast experience" do not address some key points. Those points are:

1. If patients have a problem at a medical facility (of any kind), they rarely go back to that same facility for any medical care. Therefore, it is likely that only a rare subset of the medical community currently has a consistent set of observations upon which to base their conclusions.
2. Like many scientific discoveries, it may take years to uncover the truth. NRC's failure to collect appropriate data may well be delaying an important discovery.

IV. Conclusion

A. Paraphrasing from materials found at this URL:
https://www.nrc.gov/materials/miau/med-use.html

*NRC has [**been entrusted with]** regulatory authority over the possession and use of byproduct, source, or special nuclear material in medicine.* (Bracketed portion inserted and emphasized.)

NRC historically has chosen not to gather complete data on the extravasations described in Lucerno's Petition. NRC should require detailed reporting and recordkeeping related to such extravasations to enable NRC to gather real data upon which to make further decisions.

B. The potential course(s) of action outlined above (such as notice requirements, incident tracking numbers, data submission requirements, and the creation of a searchable database) are well within the guidelines summarized by the NRC itself on the web page outlining this request

for comment:

"*NRC's Medical Use Policy Statement (65 FR 47654) states, in part, that the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public."* [5]

Nothing outlined above intrudes upon or supersedes medical judgements. A properly designed database, combined with the other recommendations in this comment letter, would support and improve such medical judgements, giving practitioners important reference points to support their practice. Rulemaking as requested by the Petition would provide for the radiation safety of workers and the general public.

I appreciate the opportunity to comment on the Petition.

Sincerely,

/s/ Keith T. Kirk

[5] See the first sentence at Section V: https://www.regulations.gov/document?D=NRC-2020-0141-0004.