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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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

Document: NRC-2020-0141-DRAFT-0425
Comment on FR Doc # 2020-19903

Submitter Information

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General Comment

See attached file(s)

Attachments

NRC-2020-0141 RFC Comment Letter_final_11252020

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?

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[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.