## Sarah Lopas (She/Her)

**Subject:** FW: Medical Event Reporting of Extravasations

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**From:** randrewgarner@bellsouth.net <randrewgarner@bellsouth.net>
**Sent:** Wednesday, July 13, 2022 1:24 PM
**To:** Williams, Kevin <Kevin.Williams@nrc.gov>
**Cc:** lailagoharioon@ossof.senate.gov; michael.williams3@mail.house.gov; brandonhoneycutt@warnock.senate.gov; naomiplasky@warnock.senate.gov; Wright, David <David.Wright@nrc.gov>; Hanson, Christopher <Christopher.Hanson@nrc.gov>; Baran, Jeff <Jeff.Baran@nrc.gov>; Johnson, William <William.Johnson2@nrc.gov>; Spicher, Terri <Terri.Spicher@nrc.gov>; brandon.neath@mail.house.gov; safernuclearmedicine@gmail.com
**Subject:** [External_Sender] Medical Event Reporting of Extravasations

Dear Mr. Williams,

Thank you for your attached letter dated June 29, 2022 (attached). My takeaway from your correspondence is that the ACMUI has reviewed and considered the questions that I sent on July 11, 2021, and because they are not obligated to respond to my questions, I should not expect a reply. I also understand that the ACMUI reports to you. And thank you for offering to address any other questions or concerns that I have. I do have additional questions.

Last year I asked some very logical questions regarding the ACMUI views on extravasations. I summarized them in another email to Sarah Lopas on May 23, 2022 (see below). It would seem to me that these are questions that the NRC medical staff would also want answered to better understand the extravasation issue. If the ACMUI reports to you why wouldn't you ask the ACMUI to answer these questions so that your medical staff could make the most informed decision?

I also have some other questions. If I am extravasated as a nuclear medicine patient, what amount of radiation in my tissue should concern me? It is my understanding that the purpose of medical event reporting is to capture errors that result in high doses to the wrong parts of my body AND that were caused by human error, lack of training, or lack of quality checks. The goal of reporting these errors is so others can learn from them and not make the same mistake. An extravasation is a human error. So, what amount of radiation in my healthy tissue concerns the NRC? How would I know how much radiation has been accidentally injected into my tissue if the center is not aware that it happened or if they are aware and chose not to measure it? And how would the NRC know if a center is routinely extravasating their patients with high doses of radiation. What am I missing here? Isn't this exactly what your team should want to know?

Late last year, I read an Op-Ed in STAT by Dr. Dan Fass. He suggested that the NRC medical staff is deferring to the industry they regulate rather than putting patient protection first. Based on my recent interactions with the medical staff, I am reaching the same conclusion.

Last month, I reached out to the Patients for Safer Nuclear Medicine Coalition. As you may recall, many of them wrote to the NRC last summer and participated in the September 2, 2021 ACMUI meeting. I sent the coalition my email communications with the medical staff. They asked me to forward my correspondence to a Mr. William Johnson and Ms. Terry Spicer of the NRC. So, I am cc'ing them. I have also cc'd my members of Congress and their staffs.

As I have stated before, I know the members of the ACMUI are highly credentialed, but it seems to me that this group of taxpayer-supported advisers is no different from the 2008 and 2009 group that did not want to have to report what were obviously mis-administrations of radiation in patients. So, it would be very helpful if they could explain to the NRC and to patients their answers to the previously posed questions. If they cannot, then why would the NRC, and thus taxpaying patients, pay for their services?

Thank you for considering my request.

Sincerely,

Drew Garner

**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
**WASHINGTON, D.C. 20555-0001**

June 29, 2022

Drew Garner
4705 Village Green Drive
Roswell, GA 30075

Via email to randrewgarner@bellsouth.net

Dear Mr. Garner:

I am responding to the emails dated May 16, May 19, and May 23, 2022, with respect to medical event reporting of extravsastions and a request for the Advisory Committee on the Medical Use of Isotopes (ACMUI) to respond to comments from July 2021, submitted in advance of the ACMUI public meeting on extravasations in September 2021. In the July 2021 comments, a response was requested from the ACMUI related to the committee's past evaluations of reporting extravasations as medical events, and the radiological impacts of nuclear medicine extravasations. In the subsequent emails from May 2022, the staff was asked why the ACMUI did not respond to the comments or provide answers to the questions.

The ACMUI is a federal advisory committee that reports to me, the Director of the Division of Materials Safety, Security, State, and Tribal Programs in the Office of Nuclear Material Safety and Safeguards. The operations of the ACMUI are governed by the Federal Advisory Committee Act of 1972 (5 U.S.C. app). As a result, the NRC provides the public with an opportunity to submit written comments to the ACMUI for the committee members' consideration prior to the committee's public meeting on a given topic. As part of the ACMUI's review of extravasations, they did review your comments to inform their review. This is consistent with Federal Advisory Committee Act requirements. Additionally, at the discretion of the ACMUI chair or another committee member who leads the ACMUI public meeting, members of the public are given an opportunity to provide oral comments during the ACMUI public meetings. However, the NRC's bylaws and procedures do not require ACMUI members to respond to public comments.

As Ms. Lopas noted in her email dated May 17, 2022, your comments and questions were provided to the ACMUI for the members' review prior to the extravasation public meeting and were appended to the published meeting transcript (see page 79 of the transcript, which is available in ADAMS at Accession No. ML21286A807), and the meeting transcript was placed on the docket as supporting material related to the petition for rulemaking on reporting nuclear medicine injection extravasations as medical events (PRM-35-22).

The Commission recently received the staff's recommendations on reporting certain extravasations as medical events and for resolving the PRM-35-22. The Commission will consider all the information placed on the petition docket during its evaluation of the staff's recommendations. If you have any further questions or concerns, please feel free to contact me by email at Kevin.Williams@nrc.gov, or by phone at 301-415-3340.

Sincerely,

Signed by Williams, Kevin
on 06/29/22

Kevin Williams, Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

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|---|---|
| **From:** | randrewgarner@bellsouth.net |
| **To:** | Lopas, Sarah |
| **Cc:** | brandon.neath@mail.house.gov; brandon_honeycutt@warnock.senate.gov; laila_goharioon@ossof.senate.gov; gabriella_vesey@warnock.senate.gov; Wright, David; Baran, Jeff; Hanson, Christopher |
| **Subject:** | [External_Sender] Nuclear Medicine Extravasations - Patient Safety Should be a Priority |
| **Date:** | Monday, May 23, 2022 3:53:12 PM |

Hi Sarah,

Thanks so much for the continued correspondence. And thanks so much for adding me to the email distribution. I understand from your latest email that the medical staff recommendation cannot be shared with me.

It is also good to know that my comments that I sent in last July were read. However, I still have not heard back regarding my questions that I sent in last July.

I have gone back to my public comment and pulled the questions (see below) that I think can be answered by the ACMUI with NO conflict now that the Commissioners have the recommendation from the medical staff. I have slightly modified a few questions to make them clearer, now that I have had another year to research this topic.

- Did the subcommittee members or any of the ACMUI members read the actual transcripts of the 2008-2009 meetings that discussed the reporting exemption? If not, why not?
- What has happened since 2009 that has resulted in "passive patient intervention" to be the cause of extravasations rather than the causes ACMUI predecessors outlined several years ago?
- Why did the ACMUI members ignore the evidence that the exemption should be removed in 2008-2009?
- How could the current ACMUI (other than Ms. Weil) endorse this previous recommendation that traded patient safety for keeping clinician reporting to a minimum?
- What specific evidence did the Subcommittee on Extravasation members find that would support the 1979-1980 comment that extravasations are nearly impossible to avoid?
- Have the ACMUI members talked to vascular access experts about "passive patient intervention," and if so, what did the vascular access experts say?
- Does Mr. Sheetz think that extravasated radioactivity is somehow not irradiating tissue in the area near the injection site?
- Can Mr. Sheetz or someone else on ACMUI describe what happens when 10 mCi of 18F is extravasated during an FDG injection like the recent case from North Dakota that the NRC asked the center to retract?
- Isn't a positron essentially a positively charged electron?
- If the fluorine atoms can be imaged in an area of arm tissue near the injection site, wouldn't all of the positron energy that resulted in the creation of the image be deposited within in just a few millimeters of the fluorine atoms?
- If you know that you injected the entire dose into the tissue and you determine the amount of extravasated activity at time of imaging, Dr. Fisher says you can estimate biological clearance; in this case, would not the absorbed dose to 5-10 cm3 of arm tissue be far greater than 0.5 Gy?

- Isn't the 7 sieverts irradiation from F-18 the same as 7 sieverts from Lu-177 in the medical event of a leak from Vanderbilt that was accepted by the NRC and that resulted in patient tissue injury? If so, **other than the 1980 policy**, does it make any sense to ACMUI members that the North Dakota case is not a medical event? Shouldn't we follow this patient to see if tissue damage happens later?

- Didn't this North Dakota diagnostic radiopharmaceutical extravasation obviously exceed the reporting limit?

- How does the ACMUI actually know that tissue doses are not exceeding either the reporting threshold or adverse tissue reaction thresholds if hospitals are not performing dosimetry on extravasations?

I know that there are highly credentialed members on the ACMUI, so I am legitimately trying to understand how these members have reached the recommendation that they reached. What possible reason could there be for the ACMUI not sharing answers to these questions with a nuclear medicine patient. Frankly, I am confused by the lack of response.

Kind Regards,
Drew Garner

**From:** Lopas, Sarah
**To:** randrewgarner@bellsouth.net
**Cc:** Valentin-Rodriguez, Celimar; Clark, Brooke; McCloskey, Bridin; Einberg, Christian; Bavol, Rochelle
**Subject:** RE: RE: Following up on your emails regarding nuclear medicine extravasations
**Date:** Friday, May 20, 2022 10:59:00 AM
**Attachments:** image001.png

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Hi Mr. Garner,

Yes, that is correct, the Commission has the staff's recommendation paper now—they received the paper just about a week ago. Because this paper addresses a petition for rulemaking, it will not be made publicly available until after the Commission makes a decision on the petition and notifies the petitioner. Until that time, staff is unable to provide any details on our recommendation. I have added your email to our Medical List Server email distribution list.

Because the extravasation issue involves a petition, all correspondence has been put on the petition docket, available at www.regulations.gov under Docket ID NRC-2020-0141. The ACMUI and the NRC staff considered all comments received as part of their evaluations of radiopharmaceutical extravasations and medical event reporting. The Commission and the Commission's staff will also consider all comments received in their evaluation of the staff's recommendation paper. If the Commission directs the staff to conduct a rulemaking for extravasations, there will be additional opportunities for public comment during the rulemaking process. (We will use our Medical List Server and our Medical Use License Toolkit website to help inform the public of those public comment opportunities.)

Thank you again for sharing your concerns about extravasation and the petition. Unfortunately, I do not have a timeframe on when the Commission will make a decision, but we will notify the public via the Medical List Server email distribution as soon as we are allowed.

Thank you,
Sarah

**Sarah L. Lopas** (she/her)
Project Manager
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security,
State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Sarah.Lopas@nrc.gov | 301-415-6360
**HQ T-5D37 most Tuesdays and Thursdays**

**MSST Vision:**
Active partnership and trustworthy leadership for... safety and security, engaged people, reliable relationships, and smart regulatory solutions

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**From:** randrewgarner@bellsouth.net <randrewgarner@bellsouth.net>
**Sent:** Thursday, May 19, 2022 11:00 AM
**To:** Lopas, Sarah <Sarah.Lopas@nrc.gov>
**Cc:** Valentin-Rodriguez, Celimar <Celimar.Valentin-Rodriguez@nrc.gov>; Clark, Brooke <Brooke.Clark@nrc.gov>; McCloskey, Bridin <Bridin.McCloskey@nrc.gov>; Einberg, Christian <Christian.Einberg@nrc.gov>; Bavol, Rochelle <Rochelle.Bavol@nrc.gov>
**Subject:** [External_Sender] RE: Following up on your emails regarding nuclear medicine

extravasations

Sarah,
Thank you for getting back with me….I appreciate the quick response.

Yes, I would like to be added to the medical announcements email distribution.

It sounds like the Commissioners have a recommendation from Staff? Are you at liberty to disclose what the recommendation is?

Lastly, to my knowledge, neither the NRC or the ACMUI answered my questions. I believe the questions are legitimate ones. Why not answer them?

Kind Regards,
Drew Garner

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**From:** Lopas, Sarah <Sarah.Lopas@nrc.gov>
**Sent:** Tuesday, May 17, 2022 6:01 PM
**To:** randrewgarner@bellsouth.net
**Cc:** Valentin-Rodriguez, Celimar <Celimar.Valentin-Rodriguez@nrc.gov>; Clark, Brooke <Brooke.Clark@nrc.gov>; McCloskey, Bridin <Bridin.McCloskey@nrc.gov>; Einberg, Christian <Christian.Einberg@nrc.gov>; Bavol, Rochelle <Rochelle.Bavol@nrc.gov>
**Subject:** Following up on your emails regarding nuclear medicine extravasations

Good afternoon Mr. Garner,

My name is Sarah Lopas, I am a Medical Radiation Safety Project Manager at the U.S. Nuclear Regulatory Commission (NRC) and am the point-of-contact for the NRC staff's evaluation of reporting extravasations as medical events. Ms. Jamerson received your email dated July 11, 2021, in which you submitted a written statement for the consideration of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for their September 2, 2021, meeting on extravasations. The ACMUI reviewed your written statement, and it was appended to the September 2 ACMUI meeting transcript, which is available at https://www.nrc.gov/docs/ML2128/ML21286A807.pdf. A summary of the September 2 meeting is available at https://www.nrc.gov/docs/ML2126/ML21267A021.pdf and the ACMUI extravasation subcommittee's final report is available at https://www.nrc.gov/docs/ML2128/ML21288A125.pdf.

Thank you very much for taking the time to provide your perspective on extravasations as a nuclear cardiology patient—I also remember your participation in the staff's December 2020 public meeting. The NRC staff considered your July 11 written statement and December 8 public comment, along with other public comments, in its evaluation of whether extravasations should be reported as medical events. The Commission is now considering the staff's evaluation and recommendations. If you would like to be notified when the Commission makes a decision about regulating extravasations, please let me know and I will add your email to the NRC's medical announcements email distribution list, which provides timely notification of medical-related NRC regulatory actions.

If you have any questions or need additional information, please contact me.

Thank you again,
Sarah Lopas

**Sarah L. Lopas** (she/her)
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**From:** randrewgarner@bellsouth.net <randrewgarner@bellsouth.net>
**Sent:** Sunday, July 11, 2021 2:39 PM
**To:** 'Kellee.Jamerson@nrc.gov' <Kellee.Jamerson@nrc.gov>
**Cc:** 'David.Crowley@dhhs.nc.gov' <David.Crowley@dhhs.nc.gov>
**Subject:** Written statement for the July 15, NRC ACMUI meeting

Good afternoon, Ms. Jamerson.

My name is Drew Garner. I am a recently retired executive with a finance background. I understand the importance of processes in getting repeatable results. I understand the need for quality control, checks, and balances, and for transparency. During my 40+ year career I was the Chief Financial Officer at several large organizations. While the financial processes were very similar from one business to the next, I had to quickly learn about the markets, customers, and product technical details for each new business I joined. As a result, I am no stranger to new concepts. When I became a nuclear medicine cardiology patient, I wanted to learn all about these processes, too. As a result, I became aware of the extravasation issues several years ago. As you may recall, I participated in, and provided a comment during, the December 8, 2020, public comment meeting. Thank you for providing the opportunity then and this opportunity now. I am also providing these comments to my representatives in Congress, as I have done in the past.

I was pleased to see that the last two ACMUI patient advocates who completed their terms, Dr. Darrell Fisher through public comment and Ms. Lara Weil through a dissenting opinion as a member of the Subcommittee on Extravasations, both support the reporting of significant extravasations.

However, as I mentioned during the December 8th meeting, it is concerning to me that the patient voice is typically not reflected in many of the conversations regarding extravasations. To help ensure the patient perspective is heard, I have continued to research the extravasation topic, including the associated physics, and I have several comments to provide the NRC and the ACMUI. I also have specific questions for the ACMUI members and would appreciate hearing their responses during the meeting.

In 2019, the ACMUI Subcommittee on Extravasations recommendations referenced the 2008/2009 ACMUI decision to retain the exemption. A review of the actual transcripts of these meetings (not just the final recommendation) showed that the previous ACMUI members discussed that diagnostic extravasations were common, that doses could easily exceed reporting limits, and that they could be avoided if licensees used the more careful therapy administration technique for diagnostics administrations. Comments regarding the causes of extravasations focused on the experience level and training of the technologists performing the administrations, as well as their techniques and

injection tools that they used. Despite all the discussion of points that suggested the exemption should be removed, the transcripts provide insight into the reason the ACMUI supported the retention of the reporting exemption. ACMUI member Dr. Nag, discussing doses of 3-5 Sv that exceeded the reporting limit and would qualify as medical events without the exemption in place, said: "However the first thing before us is, should NRC consider it as a medical event. Now if we consider this as a medical event, if we go through all the procedures and identify whatever-3 or 4 or 5-- the patient will have to be informed; the physician will have to be informed, blah blah blah, and the - you have to go into all the reporting mechanisms. And therefore, I am thoroughly against this being reported as a medical event."

**Did the subcommittee members or any of the ACMUI members read the actual transcripts of these meetings? If not, why not? If so, what has happened since 2009 that has resulted in "passive patient intervention" to be the cause of extravasations rather than the causes your predecessors outlined several years ago? If so, why did they ignore the evidence that the exemption should be removed? And how could they endorse this previous recommendation that traded patient safety for keeping clinician reporting to a minimum?**

It is my understanding that the reason that the NRC initially exempted extravasations from being reported in 1980 is because the NRC was told that extravasations were nearly impossible to avoid. Since one of the reasons for misadministration or medical event reporting is to share learnings from these events to prevent them from occurring again, I am assuming the NRC concluded that if these events are impossible to avoid then they should not be reported. I read the Association for Vascular Access position statement. I also attended a recent webinar to hear what vascular access experts had to say about radiopharmaceutical administration techniques. All of these vascular access experts clearly state extravasations can be avoided. They also claim it is NOT the patient's fault. I also have read many examples in the literature that show definitive, immediate reduction in extravasation rates from hospitals that actively monitor their administrations. I also saw an interesting letter submitted on March 16, 2021, by Dr. Daniel Fass. Dr Fass and several other experts highlighted a statement by an SNMMI leader. This leader submitted a comment to NRC that "monitoring is not expected to improve administration techniques." However, this same leader co-authored a poster presented at an SNMMI meeting. In the poster, he clearly stated that active monitoring did in fact improve administrations and ongoing monitoring was important to ensure technologists did not return to their previous ineffective techniques.

**What specific evidence did the Subcommittee on Extravasation members find that would support the 1979-1980 comment that extravasations are nearly impossible to avoid? Have the members talked to vascular access experts about "passive patient intervention," and if so, what did the experts say?**

The subcommittee members also concluded that no diagnostic radiopharmaceutical extravasation could in fact, exceed the reporting limit of 0.5 Sieverts. I understand that diagnostic isotopes produce gamma rays that will not deposit significant energy in patient tissue, but in that same webinar, I heard Dr. Fisher explain that these isotopes also have other energy emissions. I also read Dr. Sheetz' comments in the March 16, 2021, transcripts regarding the "cystic" model of radioactivity in the tissue.

**Mr. Sheetz is a radiation safety officer. Can he explain his cystic comment that he made to Dr. van der Pol? Does he think that the extravasated radioactivity is somehow not irradiating tissue in the area near the injection site? Can he describe what happens when 10 mCi of 18F is extravasated during an FDG injection like the recent case from North Dakota that the NRC asked the center to retract? Isn't a positron essentially a positively charged electron? If the fluorine atoms can be imaged in an area of arm tissue near the injection site, wouldn't all of the positron energy be deposited within in just a few millimeters of the fluorine atoms? If you know that you injected the entire dose into the tissue and you determine the amount of extravasated activity at time of imaging, Dr. Fisher says you can estimate biological clearance; in this case, would not the absorbed dose to 5-10 $cm^3$ of arm tissue be far greater than 0.5 Gy?**

**I**n the recent NRC staff report on medical events, a patient received a dose of 7 sieverts when a Lu-177 therapeutic radiopharmaceutical leaked on their skin during a procedure. The patient confirmed that her tissue did experience radiation injury. My understanding is that the unit of measure, sieverts, takes into consideration the type of energy emission.

**So, isn't the 7 sieverts irradiation from F-18 the same as 7 sieverts from Lu-177 in the medical event accepted by the NRC? If so, other than the 1980 policy, does it make any sense that the North Dakota case is not a medical event? Shouldn't we follow this patient to see if tissue damage happens later?**

As I noted earlier, I attended a webinar in May where experts discussed radiopharmaceutical extravasations. Two vascular access experts showed an image of patient that had gone through the same cardiology study that I went through. Unfortunately, it appeared that much of the Tc99M radioactivity from both injections was extravasated. Dr. Fisher described that Tc99M is more than a gamma emitter. That ~12% of the energy emitted are conversion electrons, Auger electrons, and low energy gamma rays, while I am not sure what all this energy actually is, by the end of the week, the patient began experiencing very disturbing tissue reactions. This leads me to two questions.

**Didn't this diagnostic radiopharmaceutical extravasation obviously exceed the reporting limit? Since radiation injury can take weeks, months, or more likely years to show, how does a licensee, how do the societies, how does the ACMUI actually know that tissue doses are not exceeding either the reporting or adverse tissue reaction thresholds if hospitals do not perform dosimetry on these extravasations?**

I would like to make one final observation; this is directed for the NRC staff. There seems to be a belief that there is a conflict of interest regarding the petition. As a patient, here is what I have seen and heard. There have been comments that the company Lucerno Dynamics has a product to sell that can help solve this problem. If so, what is the problem? In the NRC request for public comments the NRC stated that they encourage authorized users to use the latest technology to help them deliver radioactive material safely. It seems to me that this company has developed technology that cannot only help clinicians know when they have an extravasation, but also help technologists improve their technique and to determine the biological clearance of a radiopharmaceutical. I think the device can provide the technologist insight right away if there may be a problem. From the patient perspective, I would be asking the NRC and providers why aren't you REQUIRING this process be monitored with that device? Again, from the patient perspective, if this company discovered that the 1980 exemption is incorrect, why do I care if they sell their products to hospitals to help them fix this issue. To me the really important question that has come from my researching this issue is the fact that the ACMUI has the true conflict of interest. Dr. Nag's specific comment is very disturbing. The ongoing ACMUI focus on blaming patients for extravasations makes me question the ACMUI's motives. And then I read the transcripts of the meeting between the subcommittee members and the NRC Commissioners. The changing stories, the evasion, and the misinformation shared with the Commissioners is not what I expect as a taxpayer paying these members to advise the NRC. My concerns were certainly reinforced by Dr. Schleipman's comments in the December 8 meeting. He mentioned his role in the ACMUI and then went on to describe a very large study. He implied to the NRC and to all who were listening that if extravasations were an issue, they would have been described in this million-patient study on adverse events. His comments made me take pause before I decided to speak at that meeting and certainly tempered the public statements I did eventually make at the end of that same meeting. Then, months later, I read the comment from Dr. Daniel Fass that pointed out that Dr. Schleipman had failed to mention that extravasations and any issues from extravasations had been specifically excluded from the million-patient study. I thought that was completely unacceptable and it frankly makes me question the credibility of the ACMUI. I would encourage the NRC and Congress to reevaluate the role that the ACMUI specifically plays and should play when it comes to discussing the merits of regulations intended to protect patients from inadvertent radiation doses.

Thank you again for providing me an opportunity to offer my opinions as a nuclear medicine patient.

Sincerely,

Drew Garner