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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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MONDAY,

JUNE 17, 2024

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The meeting was convened via Teleconference, at 2:00 p.m. EDT, Hossein Jadvar, ACMUI Chairman, presiding.

MEMBERS PRESENT:

HOSSEIN JADVAR, M.D., Ph.D., Chairman

RICHARD L. GREEN, Vice Chairman

REBECCA ALLEN, Member

ANDREW EINSTEIN, M.D., Member

MICHAEL R. FOLKERT, M.D., Ph.D., Member

JOANNA R. FAIR, M.D., Ph.D., Member

RICHARD HARVEY, Dr.Ph., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member HARVEY B. WOLKOV, M.D., Member

John Angle, M.D. Committee Consultant

NRC STAFF PRESENT:

CHRISTIAN EINBERG, DFO

LILLIAN ARMSTEAD, ACMUI Coordinator

DANIEL DIMARCO, NMSS/MSST/MSEB

SARAH LOPAS, NMSS/REFS

KATHERINE TAPP, NMSS/MSST/MSEB

ALSO PRESENT:

DAVID BUSHNELL, M.D.

KYLE UNDERWOOD

PAUL WALLNER, M.D., ACR

AGENDA

P R O C E E D I N G S

2:01 p.m.

MR. EINBERG: Okay, if everybody else is ready, I'm going to go ahead deal with the opening remarks, and then turn it over to Dr. Jadvar.

So good afternoon. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Chris Einberg, I'm the Chief of the Medical Safety and Events Assessment Branch, and I've been designated as the Federal Officer for this advisory committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. This meeting is being transcribed by the NRC, and it may also be transcribed or recorded by others.

The meeting was announced in the June 4, 2024, edition of the Federal Register, Volume 89, page 48001.

The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee

provides counsel for the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values their opinions.

I request that whenever possible, we try to reach a consensus on the various issues that we will discuss today, but also recognize there may also be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I would like to perform a roll call of the ACMUI members participating today.

Dr. Hossein Jadvar, nuclear medicine physician and chair of the committee?

CHAIRMAN JADVAR: Present.

MR. EINBERG: Mr. Richard Green, vice chair, nuclear pharmacist?

VICE CHAIRMAN GREEN: Present.

MR. EINBERG: Michael Folkert, radiation oncologist?

DR. FOLKERT: Present.

MR. EINBERG: Mr. Josh Mailman, patients' rights advocate?

MR. MAILMAN: Present.

MR. EINBERG: Ms. Melissa Martin, nuclear

medicine physicist? Melissa, I'm not sure if you had your mic on or off, but Melissa is present.

MS. MARTIN: I am present. As far as I know, everything's on. Melissa is present.

MR. EINBERG: Very good, thank you.

Dr. Michael O'Hara, FDA representative?

I didn't see him on earlier.

Okay, Mr. Zoubir Ouhib, radiation therapy physicist?

MR. OUHIB: Present.

MR. EINBERG: Ms. Megan Shober, state government representative?

MS. SHOBER: Present.

MR. EINBERG: Dr. Harvey Wolkov, radiation oncologist?

DR. HARVEY: Present.

MR. EINBERG: Dr. Richard Harvey, radiation safety officer?

DR. EINSTEIN: Present.

MR. EINBERG: Dr. Andrew Einstein, nuclear cardiologist?

DR. EINSTEIN: Present.

MR. EINBERG: Dr. Joanna Fair, diagnostic radiologist? Okay, I didn't see her on earlier.

And Ms. Rebecca Allen --

DR. FAIR: Present.

MR. EINBERG: Healthcare administrator?

MS. ALLEN: Present.

MR. EINBERG: We have a quorum, so we can proceed.

So Dr. Joanna Fair recently was selected as a diagnostic radiologist representative. And she's pending for a security clearance and will not have voting rights for any of the actions requiring a vote, but may participate in the discussions during today's meeting, if she joins us.

DR. FAIR: I am here. This is Joanna Fair, I am here.

MR. EINBERG: Oh, okay, well thank you.

DR. FAIR: I'm not sure that you heard me when I said present.

MR. EINBERG: I did not, yeah, thank you for confirming that, I appreciate that.

Dr. John Engle, interventional radiologist, consultant to the ACMUI, may participate in today's discussion, but does not have voting rights for any of the actions requiring a vote.

All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes

that they may have a conflict of interest as they -- that term if broadly used within 5 CFR Part 2635 with regard to the agenda item to be addressed by the ACMUI, this member should divulge it to the chair and the DFO as soon as possible before the ACMUI discusses it as an agenda item.

ACMUI members must recuse themselves for participating in any agenda item for which they may have a conflict of interest unless they receive a waive or prior authorization from the appropriate NRC official.

I would like to add that we are also using Microsoft Teams so that members of the public and other individuals can watch online or join via phone. The phone number for the meeting is 301-576-2978. The phone conference ID is 558-124-30#.

The handouts and agenda for this meeting are available on the NRC's ACMUI public website.

We have several NRC staff members on the call today. Among them are Lillian Armstead, who is our ACMUI coordinator; Dr. Katy Tapp; Daniel DiMarco; and Sarah Lopas.

Members of the public who notified Ms. Armstead that they would be participating via Microsoft Teams will be captured as participants in

the transcript.

Those of you who did not provide prior notification, please contact Ms. Armstead by email at LXA5@nrc.gov. Once again, that's LXA5@NRC.gov at the conclusion of this meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for the audio of today's meeting and to view presentation material in real time. The meeting material and agenda for this meeting can be accessed from the NRC's public meeting schedule.

For the purpose of this meeting, the chat feature in Microsoft Teams has been disabled. Dr. Jadvar, at his discretion, may entertain comments or questions from members of the public who are participating today.

Individuals who would like to ask a question or make a comment regarding the specific topic the committee has discussed and are in the room can come up to the, well, can raise their hand and indicate to the Ms. Lopas that they'd like to make a comment.

For those individuals on Microsoft Teams, please raise your hand. And Ms. Armstead, if you wish to speak, if you have called into Microsoft Teams

using the phone, please ensure that you have unmuted your phone.

When you begin your comment, please clearly state your first and last name for the record. Comments and questions are typically addressed by the committee near the end of the presentation, after the committee has fully discussed the topic.

We will announce when we are ready for the public comment period portion of the meeting. And Ms. Armstead now will assist in the facilitating of the public comments.

For those who submitted comments prior to the meeting, those comments will be included with the meeting transcript.

At this time, I ask that everyone who is not speaking to please mute your Teams microphones or phone. And for those in the room, please mute your phones.

And so I'm going to turn this on over to Dr. Jadvar. Dr. Jadvar?

CHAIRMAN JADVAR: Thank you very much, Mr. Einberg. Good morning, or good afternoon as the case may be, to all. And I hope you all had a great day yesterday at Father's Day.

Today in this ACMUI public meeting, we are

going to hear the ACMUI subcommittee's report on the NRC's staff draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events.

With that, I will turn this now to Ms. Melissa Martin, who served as the chair of the subcommittee. Ms. Martin?

MS. MARTIN: Thank you, Dr. Jadvar.

It was my privilege to serve as chair of this committee. This is the report of our subcommittee on extravasations. Next slide, please.

Our subcommittee members included Dr. Andrew Einstein, Mr. Richard Green, Dr. Richard Harvey, myself, and Ms. Megan Shober. And Daniel DiMarco served as our NRC staff resource. Thank you very much. Next slide.

We received this -- our subcommittee received this expanded charge from the U.S. Nuclear Regulatory Commission staff that the -- we received the charge to review the NRC Commission staff's draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events and provide feedback and recommendations. That was our official expanded charge. Next. Next slide, please.

This report incorporates several years of prior discussions on this topic. In 2019, the ACMUI revisited the NRC decision to exclude extravasations from medical event reporting. Was recommended that extravasations be considered a type of passive patient intervention.

In 2020, the ACMUI reiterated that extravasations be considered a time of passive patient intervention, and that an extravasation that leads to unintended permanent functional damage be reported as a medical event under 10 CFR 35.3045(b).

In 2021, the ACMUI supported the reporting as medical events of extravasations that require medical attention due to a suspected radiation injury as determined by an authorized user physician of the licensee. Next slide.

As background for this report, the NRC staff has drafted a proposed rule and draft implementation guidance in response to the Commission's direction on the staff's proposal to codify requirements of certain nuclear medicine injection extravasations as medical events. Again, this has been prepared at the request of the Commission.

The Commission directed staff to codify

requirements for the medical event reporting of extravasations that require medical attention for a suspected radiation injury.

The Commission tasked the staff to explore approaches that would reduce the reliance on patient reporting. Next slide, please.

The Commission directed the staff to evaluate whether the NRC should require licensees to develop, implement, and maintain written procedures to provide high confidence that radiation-significant extravasations will be detected and reported, and to create guidance to comprehensively explain and illustrate the medical event reporting criteria for evaluating and reporting all medical events, not only extravasation events. Next slide.

So in this preliminary proposed rule package, the documents include, one, a draft proposed rule as published in the Federal Register; the draft implementation guidance, which includes a draft regulatory guide for the evaluating and reporting of medical events including extravasation medical events. Third, it includes a draft model procedures for detecting and report extravasation medical events. Next slide, please.

The ACMUI Subcommittee on Extravasations

has a couple of general comments. Number one, the subcommittee supports the publication of this draft regulation and the draft regulatory guide. They are well-written, and the draft regulatory guide contains useful information for licensees. So in general, the subcommittee is very much in support of publishing these documents. Next slide, please.

For the topics of extravasation and patient education, the background to this is that the U.S. Nuclear Regulatory Commission has drafted a model procedure for management of patients that may have an extravasation of a radiopharmaceutical.

The current document that covers this is the draft model procedures for evaluating and reporting extravasation medical events. It is recognized that extravasations of radiopharmaceuticals may occur, but occurrences that may result in a radioactive medical event are infrequent. Next slide.

Identification of events involving radiopharmaceutical extravasations are included in this document, with indications of radiopharmaceutical extravasations. There is discussion of management of events involving radiopharmaceutical extravasations, including discontinuation and resumption of administration, appropriate notifications, mitigation

strategies, and dose assessments. Next slide, please.

There is document -- there is recommendations for event documentation and follow-up care, including documentation in the patient's records, follow-up care for ongoing care and referrals to other specialties as needed.

There's recommendations for patient education, consisting of policies and procedures consistent with available information from professional societies. There is patient information and discharge instructions. Next slide, please.

For specific comments on the proposed rule. The definition of extravasation: as proposed in this rule, the NRC defines extravasation to mean the unintentional presence of a radiopharmaceutical in the tissues surrounding the blood vessel following an injection.

The subcommittee believes that this is overly specific and excludes other possible injection errors that may occur, such as during intra-arterial injections, intrathecal injections, as well as injections intended for a specific body cavity or space. So the subcommittee's recommendation is to broaden the definition of extravasation. Next slide, please.

Our specific comments on the proposed rule. If you are reading it or if you read it in the future, page 1, we would say this proposed rule would affect all medical licensees that administer radiopharmaceuticals for diagnostic and therapeutic purposes.

On page 5 and page 10, we would like to expand the definition of extravasation to include spinal or body cavity into which it was intended following an injection. On page 11, again, this proposed rule would affect all NRC and agreement state medical licensees who administer radiopharmaceuticals for diagnostic and therapeutic purposes. Next slide, please.

On page 13, we would like to remove "IV" from before the work "injection." This imposing a dose-based criterion would require monitoring millions of administrations per year, which would result in significant regulatory burden for medical licensees for only a marginal increase in radiation safety.

The subcommittee agrees with the comment that in light of the above information on the potential risk posed by extravasations of radiopharmaceuticals, the NRC believes such a dose-based requirement would be inappropriate. Next slide,

please.

On page 14, we would insert the word "may" in the phrase "normal biological processes may transport the dose to the intended target."

On page 17, we would suggest the following sentence be removed: "Both radiopharmaceuticals mentioned are not currently commercially available in the United States, for example, extravasations from I-131 iodocholesterol, resulting in erythematous plaque and Thallium-201." That's the sentence we would like to have removed because those items are not used in the U.S. Next page please -- I mean next slide, please.

On page 20, upon consideration of this feedback in this proposed rule, the NRC defines the term "extravasation" in Section 35.2 as the unintentional presence of a radiopharmaceutical in the tissue around a blood vessel, spinal cord, or body cavity into which it was intended following an injection. Next slide, please.

On page 26, we -- the subcommittee agrees with the comment "The conclusion from the analysis is that this proposed rule and associated guidance would result in a cost to the industry, meaning NRC and agreement state medical licensees that administer

radiopharmaceuticals for both diagnostic and therapeutic purposes."

On page 30, we have the -- we agree with the question "Who will be required or asked to respond," and this is answered by "NRC and Agreement State licensees who administer radiopharmaceuticals for diagnostic and therapeutic purposes." Next slide, please.

So we are reiterating extravasation means the unintentional presence of a radiopharmaceutical in the tissue surrounding a blood vessel, spinal cord, or body cavity into which it was intended following an injection. Next slide, please.

The next document we were asked to comment on is the draft regulatory guide. And in Section 1.1.1, the subcommittee recommends that a statement about whether it is reportable if an unintended dosage was administered and the licensee did not fill out a written directive when they should have. In other words, there was no prescribed dosage to be added.

This would address situations where the administered dose was greater than 20% different from the intended dose that the physician failed to complete the written directive. So it our recommendation that we add a statement about that

possibility. Next slide, please.

In Section 4, instead of referencing the best practices via -- available through the medical library number, we recommend that listing the best practices explicitly in the regulatory guide as there are only five short best practices.

Appendix B, add an example of a microsphere medical event. Next slide, please.

In Appendix B right now, two of the examples use Lutathera. The subcommittee recommends limiting that to one example per radiopharmaceutical, or describing the radiopharmaceuticals generically, such as a beta-emitting radiopharmaceutical. We don't want to imply that all accidents happen -- that happened use Lutathera. Next slide, please.

The other document we were asked to comment on is the draft model procedures. Page 1, informed consent should not be required for either diagnostic or therapeutic nuclear medicine procedures. That is the subcommittee's recommendation.

Patient education, whether done verbally and/or in printed format, is the appropriate method of communication between the patient and physician or healthcare professional. Next slide, please.

Guidelines for observation of unexpected

sensations by the patient or other developments observed by the medical staff or the patient should be developed by each facility in accordance with recommendations from the professional medical societies, such as the Society of Nuclear Medicine and Molecular Imaging, the American College of Radiology, the American Society for Radiation Oncology, and the American Association of Physicist in Medicine. Next slide.

Thank you for your attention, and now we have time for questions, first from the ACMUI subcommittee members. I'll turn this over to Dr. Jadvar, who will handle the questions.

CHAIRMAN JADVAR: Thank you very much, Melissa, for that report.

So as Melissa mentioned, this is now open to the subcommittee members for any comments or questions regarding this report. I hear none --

MR. OUHIB: This is Zoubir Ouhib.

CHAIRMAN JADVAR: Okay, go ahead.

MR. OUHIB: This is Zoubir Ouhib. I have a --

CHAIRMAN JADVAR: Are you one of the subcommittee members?

MR. OUHIB: Yes, this is Zoubir Ouhib.

CHAIRMAN JADVAR: Okay, very good. Go ahead.

MR. OUHIB: I have questions, suggestions, et cetera, for the subcommittee. On page 6, the third sentence, it says, "In that extravasations are virtually impossible to avoid." I was wondering if perhaps we could say "In that extravasation are not always predictable and virtually impossible to avoid," which is in my opinion is the fact. I mean, we can't really predict these.

The last sentence on page 6, it says "Under Section A, none of these update address extravasation." I'm wondering if we can provide a short explanation for that justification. Why was that not addressed at all? Perhaps there's a reason for, you know, the reader to understand that.

On page 8 under Section 4, the second paragraph, it says "The Commission directed the staff to explore approaches to reduced reliance on patient reporting, etc., etc."

I am not really sure if that's a good idea in my opinion. Because for the majority of the time, when there are issues on or with any procedures, including extravasations, it's the patient that actually report the unusual item that they're

experiencing.

You know, we see that in radiation oncology, whether it's brachytherapy or radiation beam or whatnot. And when there is a mishap, usually the patient is the first one that actually detect that. So I would -- I'm sure if that's a good idea to reduce the reliance on patient reporting.

On page 10, the first bullet point, it says "Revising the definition for extravasation to mean the unintentional presence of radiopharmaceutical, et cetera, et cetera" And I was wondering if it's just we say the unintentional resulting presence. Because that basically this is something that happens afterwards. It's not already present there.

On page 19, the last sentence under Section G, it says "All healthcare professional--" oh, my apologies. I would say to add perhaps, because the key item there is to really focus on the providing physician there, whether it's a nuclear medicine physician or rad onc, whatnot.

But I think we should add something is that all healthcare professionals however involved in patient care are encouraged to communicate with their staff physician should they identify any unexpected

observation or findings related to extravasation or anything else, for that matter. So in other words, not to exclude the rest of the staff completely, because what I understood, they're really not sort of per se qualifying and leave it to the providing physician.

Page 22, I would -- well, let me skip that since I've got a few. Page 23, the use of the term "high confidence." I'm not sure if it's needed as it might lead the reader believe that the rest of the recommendation are sublevel of confidence.

The slide No. 13, I would suggest changing patient information to patient education. I'm not sure what was meant about patient information.

The consent form. I feel very strong about this, as the informed consent is one of the nine core principles of the American Medical Association's Code of Medical Ethics.

And if you look at the -- for instance, just as an example, the APEx, which is the accreditation, you know, for a radiation oncology department, the consent form is required. And it's a document that the institution is to provide, basically. If it's not available, then that's a strike.

So I think that's really very, very critical, because in that, in the consent form, there is a discussion regarding the diagnosis. The proposed treatment plan, the risk and benefit of the plan, which is there can be discussed at something like this can happen or this can happen, etc.

But also provide alternative options in the consent form. In other words, the patient doesn't necessarily have to go through that procedure, and they can perhaps look into other things.

And then finally of course it's what happen if you do nothing. And all that is included in the informed consent form. And that's usually signed by the radiation oncologist.

I can tell you in our practice, we used to have not only the rad onc, but also the patient, because you could always have a patient saying nobody discussed anything with me, I don't know what you're talking about, should there be a problem. But then if you have a signature, you have a documentation that these discussion actually took place.

MR. EINBERG: Mr. Ouhib, this is Chris Einberg from the NRC.

MR. OUHIB: Yeah.

MR. EINBERG: I'm just going to suggest to

you and Dr. Jadvar and to yourself that you've provided a lot of comments all at once. And I'm not sure that the subcommittee can, you know, remember all the comments.

MR. OUHIB: Sure.

MR. EINBERG: Maybe it'd be better to address them one by one. And so I'll leave that to Dr. Jadvar to decide how to proceed.

MR. OUHIB: Yeah.

CHAIRMAN JADVAR: Sure. Well, I want to thank Zoubir for all the comments. And I'm sure this is being transcribed, so hopefully this will be taken into account by the subcommittee. And again, thank you.

Now, I see Dr. Michael Folkert's hand is up. Dr. Folkert?

DR. FOLKERT: Hi, Mike Folkert, ACMUI member. I wanted to echo what Mr. Ouhib had said, in particular about the informed consent.

I definitely think that an informed consent should be absolutely required, especially for the high-dose therapeutic procedures. And so, and it should just be a required part of the procedure. We've been discussing in the medical events committee how important it is to include a timeout.

And one key part of the timeout is, you know, making sure that everyone knows what the procedure is that you're doing and that they're understand why they're doing it. And I think this is a critical way to improve patient safety and to reduce the risks of a misadministration or other medical event. So I do think that informed consent should be required.

The patient education is critical to us being able to deliver treatment safely. I mean, we, once patients have been administered a radiopharmaceutical, they have to understand the patient safety concerns in order to keep their friends and family safe when they return home.

So I mean, this is all part and parcel for the whole part of the procedure. Informed consent should be required. Patient involvement, patient education is required and is key to the safe delivery of radiopharmaceutical therapy.

CHAIRMAN JADVAR: Thank you, Dr. Folkert. I see that Mr. Richard Green has his hand up too.

VICE CHAIRMAN GREEN: Thank you, Dr. Jadvar.

Mr. Ouhib, he had lots of good comments. I want to -- I can't remember them all, as Chris

Einberg mentioned, there was quite a few. I just want to address a few that came to mind.

I believe in the context of the charge from the commissioners, there was a direct quote from the historical record that Melissa Martin described, the various years where the NRC has approached the ACMUI for comments. And that's where the direct quote was, that extravasations are almost impossible to avoid.

And that's not a current comment or a current thought, that's an historical record. And that should be in there. Same with the, I'm not sure if it was the commissioners or it was the NRC staff that said with high level of precision, you know. So again, that should be a direct quote.

One, I'll let others embellish upon this. I think there are many professional societies and accreditation organizations that require a written -- require an informed consent, signed informed consent. And I think they will still continue to do so, and I think that's appropriate.

I think what the subcommittee was stressing, not that the NRC be a requirer of written, of informed consent, but highly recommend that the licensees conduct patient education with materials to

alert the patients so that they without a great deal of technical background, should know if something went awry and be able to inform their caregivers if they suspect something is amiss.

So informed consent plays a role but we don't think as a subcommittee that it was a required as part of the NRC regulation. And hopefully others, I know Dr. Einstein was also very well spoken on this point.

Thank you.

CHAIRMAN JADVAR: Thank you, Richard. I see Melissa has her hand up. Melissa?

MS. MARTIN: Yes, I was wondering if Dr. Folkert would differentiate the requirement for informed consent versus patient education based on whether the administration was going to be diagnostic or therapeutic.

Are you saying that you want -- your recommendation is to require the informed consent for all 12 million injections that happen per year? Or do you -- are you comfortable with requiring it for the therapeutic administrations?

DR. FOLKERT: Yeah, this is Mike Folkert. I said specifically for the therapeutic administrations.

MS. MARTIN: Thank you. I did not hear that, thank you very much.

CHAIRMAN JADVAR: Okay, moving on, I have Dr. Richard Harvey.

DR. HARVEY: Thank you, Dr. Jadvar. It's Dr. Richard Harvey, the radiation safety officer Representative.

So I think the items that Dr. Folkert had mentioned, those things are already, already being done. It's not like they're not being done. We don't need informed consent to do all the things that he mentioned. They're all already being done. And doing informed consent for every injection is just really superfluous. It's just not necessary.

It's not going to improve radiation safety, it's not going to improve the quality of what's being done. There are already -- there's already education, there's already discharge instructions.

Patients sign off on those discharge instructions. Patients have consults prior to the procedure where everything is discussed. There are alternatives. Everything that they, you know, could do or don't have to do or might be able to do.

So the addition of informed consent really

offers no additional benefit. And everything that you mentioned is already being done. So I think that's important to recognize with this. Thank you.

CHAIRMAN JADVAR: Thank you, Dr. Harvey. Mr. Green, do you still have a question? I see your hand still up. Is that from before or new?

VICE CHAIRMAN GREEN: My apologies, I failed to lower my hand.

CHAIRMAN JADVAR: All right, very good. So we go to Dr. Einstein.

DR. EINSTEIN: Yeah, I would second what, the points which Dr. Harvey and Green have mentioned. This came up and it was the subject of numerous discussions among the extravasations subcommittee.

Certainly for diagnostic radiopharmaceutical administration, it would cripple the system for 15 million patients and maybe 20 million injections per year in the United States to require written informed consent.

But the thought of the subcommittee was even for therapeutic administrations of radiopharmaceuticals, to add specifically in the context of extravasations a requirement for formal written informed consent as distinguished from patient education, which is really what's central. We want to

inform patients.

We don't necessarily want to institute onerous requirements of more paperwork that are not going to improve the quality of patient care and patient outcomes here. And that's why the subcommittee after numerous discussions came to this conclusion.

CHAIRMAN JADVAR: Thank you, Dr. Einstein. Any other comments by the ACMUI members?

I have one minor comment on slide No. 14. The sentence regarding surrounding the blood vessel. I mean, this was really focused initially, as you mentioned, on intravenous injections in the vein. But as you know, arteries also are blood vessels.

So I would kind of spell it out, intravenous, intra-arterial. And then as you added also intrathecal and any body cavity or space, which I agree with. Because they're both vessels.

Any comments from the ACMUI members? Okay, thank you.

Now with that--

MR. MAILMAN: So I do actually. This is Josh, I do have my hand up.

CHAIRMAN JADVAR: Yes.

MR. MAILMAN: So there are a couple

things, you know, sorry about that. I'm traveling in the car and I apologize for some of our connectivity issues I have here.

But I will want to add a few things here. So first of all, adding this to informed consent becomes challenging when we don't have what we're informing the patient on.

If we say that extravasations happen but don't have the frequency to which medical event happens, we're, you know, to some of the earlier comments, we're adding information but not giving them a likelihood of what it is that they're consenting to, right.

They're -- we need to say it happens in two percent of the times in this procedure. And I think, or whatever that number is. And I think that's one of the challenges that I have here as a patient, is that we want to do patient education, which is like their team, and yet -- and maybe informed consent or adding it to whatever standard checklist that we're talking about in addition to what we already go through with patients.

But we need to be able to give the numbers that matter to a patient. Just saying here is the risk, we don't really know what the risk is

actually inappropriate. And we need to actually quantify the risk if we're going to talk about the risk. We can talk about how to tell, you know, what it is informationally so that they can report it.

But if they're consenting to something, it's nearly impossible to consent to an unknown. And that's what -- certainly these are -- these are drugs and things that are not in trials, where we might have an unknown. These are things that we should have a known about.

Can you turn it back to slide 13 by chance? Yeah, thank you. And slide 13 talks about, you know, medical societies giving patient education if I -- remembering talks about patient education. And I do think that we need to make it part of a standard checklist of what we talk to the patients, whether it's the discharge information or however it is, and that's part of the guidelines.

But I also think that we need to use standard language across the medical societies, and that we should -- we really do need to have specific information again. Giving patient education on an unknown is really challenging for patients to absorb.

So, and I know there was some comment about the initial charge that the subcommittee had

about lessening the reliance on patient-reported information.

I will say it doesn't preclude the reporting of patients in that it means to me that we're not solely relying on patients and that everyone's in the game of all -- everyone should be looking at that checklist. And everyone is a partner in this and we're not just solely relying.

So I don't mind if the language took the onus off the patient. You're absolutely right, Zoubir, that patients will notice these things a lot. And (audio interference) in many conditions, but that doesn't take the onus off everyone else in the chain to make sure that part of the reporting structure and part of the observation structure.

So I think the charge to the subcommittee was correct in saying you just can't fall on the patient because that's I think inappropriate. But we have to give patients good information of which they can help, work and be a partner in their healthcare.

With that I'll turn it back and try to lower my hand on my phone.

CHAIRMAN JADVAR: Thank you, Josh.

So I have two hands up again. Dr. Folkert?

DR. FOLKERT: I apologize, we have power failures. I'm reconnecting my phone.

You know, my concern particularly for that consent comment, so I apologize, I'm going back to that, is that on that page 24, it says "Informed consent should not be required of the procedures."

It doesn't say anything about any -- about extravasations, it doesn't say anything like that. It says "should not be required." And that is really not in keeping with what we've been thinking about in other discussions for medical events.

I'm not saying that it needs to happen at the time of the therapeutic procedure, but it is an important part of it, of the overall treatment plan for a patient. And for the NRC to make a statement that informed consent should not be required, I think that's overstepping. I think that's overreach.

CHAIRMAN JADVAR: Good point. Dr. Richard Harvey. Dr. Harvey, did you have your hand up?

DR. HARVEY: Apologize, I hit mute and didn't come off of mute and I started talking, and I apologize. So again, it's Dr. Richard Harvey, radiation safety officer representative.

So much to comment on there. Let me start with Dr. Folkert's because it's the most recent. I

kind of agree, we don't want to -- we're not -- the intent is not to say that you can't have informed consent. Anybody could implement informed consent at their own organization. I think the intent there is that it's not required.

Thinking about some of Mr. Mailman's comments, which are important, very important as well, is this is certainly a team-based approach for the procedures in nuclear medicine. So when the IVs are placed or the injections are done, whoever's doing it, the nuclear medicine technologist, a nurse, someone else, they're going to be monitoring, they're going to be looking for, they're going to identify extravasations.

You're going to talk to your patient. Do you feel any unusual sensations, do you feel any burning? They're going to be looking for swelling. They're going to be looking for anything out of the ordinary.

And you know, you're going to see this on, you know, possibly when you're doing imaging. You might see some of the dose at the site of extravasation. There's definitely a team-based approach to make sure that, you know, this burden is not all on the patient. That I don't think was

anyone's intent. Everyone here is for the patient, making sure the patient gets the best possible care that they can.

And you know, anyone in nuclear medicine wants to put out high quality studies to benefit their patients. So I think that's really important to recognize that, you know, this is a team-based approach and it always has been.

With regards to extravasations, they do occur. They're relatively uncommon. That can be argued a bit. But I've been doing this for 33 years, and I've never seen an extravasation cause a radiation injury. And I think it's very important to segregate or distinguish between the fact that you can have a small amount of the radiopharmaceutical extravasating and it's going to have no impact on the patient.

I am aware of one extravasation in my career that happened somewhere else, and yes, I've seen pictures and they do happen. But we don't want to, at least in my opinion, make a mountain out of a molehill when we don't have very many extravasations causing radiation injuries.

So I think we really have to recognize that. And our thoughts are if you identify an extravasation, you provide the patient with education

and what to do going forward, and you work with them.

If you up front tell everyone that, you know, there can be an extravasation, it might cause this, it might cause that, you're probably unnecessarily causing fear and anxiety in patients, you know, for no, really no helpful reason.

You know, if an extravasation occurs, it's most likely going to be identified by the team, including the patient. And then it can be addressed and it can be dealt with going forward.

So that's sort of at least where I'm coming from on this, and I'm just going to stop there and give somebody else a change. Thanks.

CHAIRMAN JADVAR: Thank you, Richard. Let's see -

MR. MAILMAN: I'd like to --

CHAIRMAN JADVAR: Josh, yeah.

MR. MAILMAN: Re-comment on that really quick. When we have words like, you know, "very rare" or you know, "infrequent," these are what needs to be quantified. And I'm, you know, unfortunately I haven't been doing this for 30 years, and I've been poking my head around for several and with this topic, for at least the last year. And unfortunately, I have seen these things, not to myself.

And I do agree that they happen relatively rarely. And we can discuss what that is, whether it's one in 700, one in 1000, one in whatever that number is. But we have a set of, you know, we certainly get a set of comments that say this happens one in every 17 or one in every 30. And the other journal articles will say it happens one in every, you know, 30,000.

So I think we need to figure out how we get to a definitive number so that we can give people the relative risk. I completely agree with you that it is, you know, giving the information about what may happen so you can identify it and saying it happens very infrequently and here's what we know is much better than saying, you know, here it is, we think it doesn't happen very much but that doesn't -- that doesn't happen 'til we can quantify it.

And I'll turn off my mic now.

CHAIRMAN JADVAR: Okay, thank you, Josh. Dr. Harvey again.

DR. HARVEY: Yes, thank you very much, Dr. Jadvar. Dr. Richard Harvey again, the Radiation Safety Officer Representative.

I think what, please correct me somebody if I'm wrong, but I think what the NRC is proposing is that if we have an extravasation that causes a

radiation injury, it is reported as medical event. And I think then we get -- and we quantify those numbers, and those are useful for Mr. Mailman, for patients to understand.

But to try to quantify every extravasation that occurs that doesn't cause radiation injury, at least in my opinion, it doesn't have any value. So you can have --

MR. MAILMAN: Don't disagree.

DR. HARVEY: A little bit -- that's fine. And we can agree to disagree. And again --

MR. MAILMAN: No, I actually said I don't disagree with you at all. I mean, that's a challenge, is that if we study this enough or if we actually ran a trial that we could look at this so that we could really quantify it, it would be good.

And I'm -- I believe I'm closer to where you are in the occurrences, but I think we need to get that data, right. And just -- and that's what I'm -- that's not what I'm harping on, but what I believe is important.

But I don't disagree in your -- in what you're saying at all. We're not actually disagreeing at all.

It's more of I think we have the ability

with the number of phase III trials that are happening in therapy to really actually quantify these in a clinical study, in a clinical trial study that can help inform patients and clinicians in a relatively short time.

And that that would be a very useful exercise so that we're, you know, not waiting for years and years of collected data but we have something where we already have things that are ongoing where people are doing, where people -- where centers are doing, you know, three hours post-therapeutic scans. And we can really quantify and see, one, what's happening, and two, at what level do they cause injury so that we can -- we can really put some numbers behind it.

And that's all I'm saying, is that I think we have the means to do better, but I actually think that ultimately what you're seeing is that it is a relatively rare, and we can define what rare is, but that's it. We need to define what that is, because rare to me and rare to you was different until we put numbers on what that means.

DR. HARVEY: Thank you, Mr. Mailman. I serious, sincerely respect your comments and your opinions. I'll just reiterate I feel that

extravasations that result in radiation injury should be quantified and that others do not need to be.

And you know, maybe we'll just differ on that. And that's certainly okay. And thank you very much, and I certainly respect everything that you have said and you bring to the committee. Thanks.

CHAIRMAN JADVAR: I'll just add that talking about data, you see, you may have noticed that, you know, relatively recently you see some reports in some reports of extravasations of radiopharmaceutical agents. The most recent one I want to draw your attention to is a case report from the Netherlands Cancer Institute that was published in clinical nuclear medicine just this past month.

And in that, this patient was undergoing a peptide receptor radionuclide therapy, PRRT, with a lutetium-177 dotatate, and a third of dose was extravasated in that case. They had an image of that in the case report, and they did the usual thing with the lifting the arm above the level of the heart and warm pads and the usual interventions.

And in this particular case, actually after treating the patient at 24 hours, there was really very little left at the site of extravasation, of injection of the agent. And the agent slowly

cleared to the target -- to the targets, the somatostatin receptor expression tumors.

And they followed this patient for 11 months, and there was no radiation injury whatsoever. Although as I said, a third of the dose of therapeutic dose was extravasated.

So things of this sort are being published, and it would be good to keep track of these publications as they come out.

I see Melissa has her hand up. Melissa?

MS. MARTIN: Actually what I want to do is have Dr. Einstein speak, because he was very active in this subcommittee and has lots of information as a practicing nuclear medicine physician. I think his input would be very valuable.

CHAIRMAN JADVAR: Dr. Einstein, you're muted. Please unmute yourself.

MS. MARTIN: Take yourself off of mute, Dr. Einstein. No.

CHAIRMAN JADVAR: We still cannot hear you.

DR. EINSTEIN: Can you hear me now?

MS. MARTIN: Yes.

DR. EINSTEIN: Okay, fantastic. Yeah, you know, so I mean, I'm a practicing nuclear

cardiologist, not a general nuclear medicine physician, so the doses of the radiopharmaceuticals which I administer to patients are lower and the consequences of an extravasations lower as well.

But you know, I've researched this subject and spoken to nuclear medicine and interventional radiology colleagues as part of being on this committee just to understand things better.

And you know, my impression, having served on this committee, you know, based on what my colleagues think, it is really to share the opinion, again, that patient education, shared decision-making is important. But formal written informed consent goes beyond what would be required, given the statistically very rare occurrence. So I share the perspective taken by the subcommittee.

CHAIRMAN JADVAR: Thank you, Dr. Einstein. Any other comments by the ACMUI members? We had a very robust discussion, that's wonderful. Thank you.

Any other comments?

MR. OUHIB: Yes, this is Zoubir Ouhib.

CHAIRMAN JADVAR: Okay, just go ahead.

MR. OUHIB: I'd just like to go back to the consent form item. First of all, I don't think NRC should be involved or make any statement saying

that the informed consent form is not needed. That's not the role of NRC. That's medical practice, in my opinion.

And then there seemed to confusion between an informed consent form and patient education, patient instruction, and so on and so forth. The informed consent form is a legal document, especially for therapeutic dose, basically. And that's a requirement.

As far as patient instruction and patient education, that's -- that's part of the chart patient that it was provided that do this, don't do this, do this, do this, call us and so on and so forth.

So I want to clarify that. Thank you.

CHAIRMAN JADVAR: Thank you, Zoubir. Any other comments by the ACMUI members? All right --

MS. ALLEN: Hi, it's --

CHAIRMAN JADVAR: Okay, yeah, Ms. Allen, please.

MS. ALLEN: Yes, it's Rebecca Allen, healthcare administrator. You know, we talk about the informed consent and the NRC's role. However, just keep in mind is that the -- most informed consents in the hospital are dictated more from a joint commission regulatory guidelines, not about the radiation piece.

So regardless of NRC, if anyone recommends informed consent or not, this is by hospital about the requirements of who will need an informed consent or who does not. Thank you.

CHAIRMAN JADVAR: Thank you, Ms. Allen. I can just tell you that we do use informed consents for all the therapeutics injections.

Any other comments by the ACMUI members?

MR. DIMARCO: Hi, Dr. Jadvar?

CHAIRMAN JADVAR: Yes.

MR. DIMARCO: Hi, this is Daniel DiMarco from the NRC. I just wanted to come in and make a quick clarification about this entire discussion that we've been having.

In the proposed model procedures bit of the package that you all reviewed, there's a bit in there about patient information. And we've heard Dr. Harvey and Richard as well talk about the patient intervention part on that.

I want to be very clear about this. I very specifically did not say anything about a formal informed consent procedure. I agree with the other members of the ACMUI, but that it's not something that the NRC is -- that's not in the NRC's jurisdiction, it's likely not. It's likely very much a part of

medical practice.

The intention with that was never to be in a -- whether a recommendation on informed consent, merely just a recommendation that patient education could help in being part of the team response to a potential extravasation. Yes, so that was -- that was all the intention there. It was never to be a specific informed consent bit there.

I very specifically did not use the term "informed consent" for that reason. So yes, just to -- just to clarify for everyone that that was the intention there.

CHAIRMAN JADVAR: Thank you very much, Mr. DiMarco.

Now that you are -- any other comments by the NRC staff? Oh, I see Dr. Andrew Einstein again. Please, go ahead.

DR. EINSTEIN: Yeah, thank you. Daniel, I think the concern which the subcommittee had is that there was some verbiage originally proposed which used the word "informed" in there, and it's difficult to -- for readers to tease out about informed versus informed consent.

So once the original verbiage was going down that road, maybe not completely but leaning in

that direction, it was felt that there was a need to opine and weigh in there.

CHAIRMAN JADVAR: Okay. Any other comments by the NRC staff?

DR. TAPP: Yes. This is Katy Tapp with the NRC staff. One of the things is I asked Sarah to pull up the comment from the subcommittee's report. Because you guys had a lot of good discussion on this. And I just want to make sure that these is just a discussion right now, and that we're not recommending changes here to either of these recommendations.

I didn't hear anything, but I want to make sure I'm capturing your thoughts correctly. So I asked her to pull up the comment specifically on informed consent and making sure we're -- there wasn't any changes that we're missing here.

CHAIRMAN JADVAR: Melissa?

MS. MARTIN: I would agree with that. That's why we labeled them "specific comments." But this is not -- these were not specific motions to make changes at this time. They were items we thought should be considered.

CHAIRMAN JADVAR: Dr. Folkert.

DR. FOLKERT: Okay, it's me, Folkert. Yeah, I mean, this is, this particular comment,

though, this is the concern. As a policymaking body, the statement is being made that informed consent should not be required for either diagnostic or therapeutic. And that -- I mean, to say that informed consent should not be required, I do not think that that's an appropriate statement to be made.

CHAIRMAN JADVAR: Okay. Any other comments? I have Mr. Green.

VICE CHAIRMAN GREEN: Yes, this is Richard Green, the nuclear pharmacist representative. Dr. Folkert, I think we could take that item 17, page 1, and take that further where informed consent should not be required by the U.S. NRC or licensing agency. So it's this agency is not requiring it as part of this regulation.

If other agencies, other CMS and accreditation organizations, that's their prerogative. And that more likely is the case, that's a fact of life today. We just wanted to make sure that folks who read this guidance document didn't see, you know, inform your patient is basically what it said. I go, well, that's confusing. That's -- it's ambiguous.

So yes, patients should be informed, they should be educated, they should be on the lookout. But we're not saying they have to have written

informed consent. So I think if we modify that to informed consent should not be required by regulators of the U.S. NRC, we can modify that. But that's what we were striving toward.

Thank you.

DR. FOLKERT: And that makes more -- that makes sense. And so it's just this statement is just far too global.

CHAIRMAN JADVAR: Okay, thank you. Dr. Wolkov, I think you had your hand up. Are you planning to speak?

DR. WOLKOV: I did have my hand up, but I think that was reasonable compromise language by Mr. Green. And I had an alternative language, but I actually prefer his to mine.

CHAIRMAN JADVAR: Okay. Dr. Harvey?

DR. HARVEY: I would second Mr. Green's motion. And I think we should vote on that. NRC staff can correct me if that's wrong, but I think I would second his motion. Thank you.

CHAIRMAN JADVAR: Very good. Let me see, I think we were going to wait a vote on the subcommittee's report at the end of the public comments, if that's okay.

But any other comments by the NRC staff

before we move on?

MR. OUHIB: Yeah, this is Zoubir Ouhib.

CHAIRMAN JADVAR: Okay.

MR. OUHIB: I'm just curious whether there is a need to have that first sentence at all. Why do -- why shouldn't -- what is the purpose of having that sentence "Informed consent should not be required for either diagnostic or therapeutic nuclear medicine procedure." What is the purpose of that?

Why don't we just strike and just simply put patient education, whether done verbally, et cetera, et cetera, et cetera?

CHAIRMAN JADVAR: Okay, Dr. Harvey.

DR. HARVEY: The only intent of that section -- that sentence, was to clarify. Because when some people read the document, they thought that it might be asking for written informed consent. So the point of that sentence was to clarify that the NRC and Agreement States, regulatory bodies are not asking for informed consent.

CHAIRMAN JADVAR: Very good. Okay, any other comments from NRC staff or other --

MR. MAILMAN: Would that be a separate informed consent? Because I think to, Dr. Jadvar, your comment as well, you require an informed consent

at USC, which is fine. It's just, we're not recommending a separate informed consent on board the subcommittee, which I think would be more appropriate than just throwing it out there.

CHAIRMAN JADVAR: Well, let's ask folks on this call that do you require informed consent for therapeutic injections at least?

DR. FOLKERT: Definitely. Mike Folkert, definitely. Required by JAYCO, required in --

CHAIRMAN JADVAR: Yeah.

DR. FOLKERT: By our professional societies across the board.

MR. OUHIB: Absolutely, it's a must.

CHAIRMAN JADVAR: Yeah, yeah.

MS. MARTIN: But I think to clarify, it wasn't a separate consent. I think that's the question. It's the one that you're required to have for joint commission and all the other accrediting bodies.

CHAIRMAN JADVAR: Yeah.

MR. OUHIB: But also required by, you know, ASTRO, by ACR, by there's a whole document --

MS. MARTIN: Right, which are accrediting bodies, right.

MR. OUHIB: There's a whole document

written by ACR ASTRO regarding that.

DR. FOLKERT: Yeah. Now, I'm not saying anything about a separate consent. I'm very concerned that there's a statement here saying "informed consent should not be required." It doesn't say anything about an additional consent, it doesn't say anything about a form.

It is a policymaking body, the NRC is stating that informed consent should not be required. And I don't think we should be saying that.

MS. MARTIN: Yeah. I like the modification that was made to the statement earlier, required by the NRC. With the idea that I think we could develop that statement further. It's developed, the informed consent should be developed in accordance with the professional societies.

CHAIRMAN JADVAR: Okay. All right, I think I'm going to turn this over to Ms. Sarah Lopas to navigate us through the hearing public comments on this subcommittee's report.

Sarah?

MS. LOPAS: First I wanted to just double check that we didn't need to go through any of Zoubir's earlier comments when he first started and he had kind of a list of comments. I just wanted to

double check that we didn't need to go back through the report, now that I'm sharing the report.

MS. MARTIN: I think we've covered most of them.

MS. LOPAS: Okay. All right, well, with that, I am going to -- we are going to open it up to the public to make comments. So I want to make a couple notes before we get started.

So those of you that have submitted comments ahead of time, written comments, those will be upended directly to this transcript. So those'll be publicly available, attached directly to this transcript. So that's one note.

I also want to note that we're looking for your comments today on what the ACMUI just discussed, on their recommendation report, which is available on the ACMUI website. If you have general comments on the extravasation proposed rulemaking, you know, generally, at some point in the future this rule may get published as a proposed rule and there will be a public comment period.

You know, there's several steps to get to that point. We have to finalize this document, we have to submit it to the Commission for their consideration and review. If they were to approve it

for publication, there's a couple more administrative processes.

And then it would finally get published and we would have -- we'd give everybody ample notice of when that proposed rule comment period is coming, and we would have probably several public meetings to help clarify the package for everybody.

So I just wanted to just let everybody know this isn't -- this isn't a one-and-done deal, right. This is one step of many in a public meeting process.

So with that, we're going to use the raise-hand function for those of you that are in the Teams app. For those of you on your cellphones, I believe you press star-5 to raise your hand. So that will let me know.

So we can kind of get right into it. And we do have to leave about 15 minutes at the end to allow the ACMUI to just finalize their thoughts based on what they've heard from the public and take their vote. So we will be kind of folding up comments at 3:45, just to give everybody a warning.

Okay, and I see David, I know you've had your hand raised for a long time, so go ahead, you can go ahead and unmute yourself. And please begin by

introducing yourself and stating your affiliation if you have one. That's helpful for the transcript as well and to give us all some context.

So thank you, go ahead, David Bushnell.

DR. BUSHNELL: Sure, thank you very much. David Bushnell, the National Program Director Nuclear Medicine in the Veteran's Health Administration.

A very interesting discussion, a very interesting process that's been going on here for a while. I thought I saw, and maybe I misread it, I thought I saw in one of the slides that NRC was potentially going to propose mitigation procedures.

And maybe I'm misunderstanding, but perhaps you could clarify whether they mean medical mitigation procedures. If that's the case, that would -- that would certainly not, I think we'd all agree, that would certainly not be appropriate.

MS. LOPAS: Dr. Harvey, do you have your hand raised?

DR. HARVEY: I do, thank you.

MS. LOPAS: Yeah.

DR. HARVEY: I think, so what I would recommend and what we talked about is individual licensees should have their own policy and procedures for identification, management, mitigation, patient

education.

Those things should all be handled with -- at the -- by the licensee. And I don't think there's any push from the subcommittee anyway to say that there should be specific procedures written by the NRC that licensees would have to follow.

Thank you.

DR. BUSHNELL: Thanks very much. Perhaps I misunderstood, and thank you for clarifying that. And I thought the -- by the way, the discussion on the informed consent was very good.

Obviously we all agree that there has to be informed -- from a medical standpoint. And certainly even though rare, we would include the potential radiation complications from extravasation for therapeutic procedures within the informed consent.

I mean, there's a lot of risks, right, there's a lot of risks that we deal with for radiopharmaceutical or radio-likened therapies. And this would be one, although rare that we would include as well. Thank you.

MS. LOPAS: All right thank you. Okay, and I see Dr. Wallner. Dr. Wallner, you can go -- oh, unless is somebody else going to jump in? I thought

I heard somebody. No?

Okay, Dr. Wallner, go ahead. You can introduce yourself and state your affiliation.

DR. WALLNER: Thank you very much. Dr. Paul Wallner representing the American College of Radiology. I'm a radiation oncologist.

We think there should be some clarification of some of the language regarding medical radiation injury. We think that the language should be clarified that it should be radiation injury requiring medical intervention.

I don't think we are interested in any potential radiation injury, just something that requires intervention. And I think that was the intent of the commissioners.

Secondly, again, regarding radiation injury, there is very speculative verbiage suggesting that it can be attributed to radiation. We would suggest that that be changed to "has been attributed to radiation" or "is most likely attributable to radiation." "Can be attributed to radiation" is highly speculative and could be judged by many people incorrectly.

The other issue regarding medical events reporting, we would recommend deleting, and this is in

quotes "or has the potential to result in radiation injury." Again, that's highly speculative.

There was some comment, and I will provide these comments in writing to Ms. Armstead so they can be added to the record. There was also some comment about clinical trials and the reporting of adverse events.

Any clinical trial in the United States certainly that is approved by an IRB, and that's effectively all clinical trials, requires adverse event reporting, regardless of the intervention or regardless of the adverse event. So that's readily available in those reports, and I wouldn't suggest any additional reporting mechanism in that regard.

Thank you very much.

MS. LOPAS: Okay, thank you, Dr. Wallner.

Okay, so a reminder that raise your hand, that's the little raise-hand icon. You can just tap that once on Teams. If you're on the phone, you press star-5. And we will give everybody a couple of minutes before we send it back to the ACMUI.

And just as a reminder, we're taking the public comments on the subcommittee's recommendations here today as they presented them today and in their report. And you can find that, their report and what

they reviewed for us on the ACMUI website.

I just pulled it up, right in time for this meeting. I pulled up, I Googled "ACMUI" and "recommendations and extravasations," and it came right up for me. So, very easy to find online if you do need to review that.

I think, Dr. Jadvar, seeing as I'm not seeing other, any other hands raised, I think I'm going to send it back to you all. And I don't know if Chris jumps in as well to help kind of close you out and maybe Dr. Tapp as well, so.

CHAIRMAN JADVAR: Okay, thank you, Sarah, for your help.

So let's go back to, we need to vote on the subcommittee's report. But before we do that, I want to make sure that if there is any alterations or other additions or changes that you want to make to the report based on all the discussions that the subcommittee heard.

MS. MARTIN: Hello, this is Melissa. I do think we need to take the comments that Richard Harvey made. I just remember Richard making them, I'm not sure who made them initially, but there was a couple of things that we agreed on to make it as -- modifications to this report.

CHAIRMAN JADVAR: Okay. Would you please repeat those items one more time for clarity?

VICE CHAIRMAN GREEN: This is Richard Green. I believe it was Item 17. We want to specify it's the informed consent is not required by the U.S. NRC.

MS. MARTIN: Correct.

VICE CHAIRMAN GREEN: I do know that's a very open statement that it's not required. So that should be modified. So I'm suggesting that informed consent should not be required by the U.S. NRC for either diagnostic or therapeutic nuclear medicine procedures. Just a small inclusion.

CHAIRMAN JADVAR: Anything else?

DR. HARVEY: I would second that. Richard Harvey.

CHAIRMAN JADVAR: Okay, thank you. Any other items? All right, so with that, do I have a motion for approval of the subcommittee's report with that stipulation that was recited?

DR. WOLKOV: So moved, Harvey Wolkov.

CHAIRMAN JADVAR: Any seconds?

DR. HARVEY: Second.

DR. FOLKERT: Second.

CHAIRMAN JADVAR: All in favor, say aye.

(Chorus of aye.)

CHAIRMAN JADVAR: Any opposed? None, none heard. Any abstentions?

DR. EINSTEIN: Aye.

MS. ALLEN: Aye. This is Rebecca Allen.

MR. MAILMAN: I don't know if you can hear me or not.

MR. OUHIB: This is Zoubir Ouhib.

CHAIRMAN JADVAR: Okay, I was talking about any abstentions.

MR. MAILMAN: Well, I don't know if --

DR. FOLKERT: Is the audio not going through? Sorry.

MS. MARTIN: No, we can hear you, Dr. Folkert, go ahead.

DR. FOLKERT: Yeah. No, so I mean, you had asked if there were other -- if there were other questions about the report?

CHAIRMAN JADVAR: Oh, yes, okay.

DR. FOLKERT: So that, you know, so I mean, so we mentioned this one. I mean, the other thing which I do think Dr. Wallner's point actually was quite good about removing "or has the potential." And so yeah. So that was --

MS. MARTIN: What line was that, do you

know which line?

DR. FOLKERT: Yeah, so let's see. If we go, let's see, it's in the -- so in the reporting nuclear medicine --

CHAIRMAN JADVAR: Page 10.

DR. FOLKERT: Page 10 and 11.

CHAIRMAN JADVAR: Yup.

DR. FOLKERT: And so like let's see, so on page 10, second paragraph from the bottom, "or has the potential to result in radiation injury."

MS. MARTIN: Yes.

DR. FOLKERT: And then also page 11, where it also says "or has the potential to--" Where was the? I was trying to do a search for that specific phrase, but there are, I know that there was more than location where it was said.

MR. OUHIB: You are correct, it was on 11 also.

DR. FOLKERT: Yeah. And then also, I mean, in the index also on point F, why does the report of threshold require reporting for extravasation of results or has the potential to result in a radiation injury from an extravasation.

So, I mean, I agree that removing "or has the potential" because I mean that's incredibly vague

and speculative. So removing that "or has the potential for causing injury" I think would make sense to remove.

MS. MARTIN: I agree.

MR. OUHIB: Yes.

DR. FOLKERT: I have those items on my list.

CHAIRMAN JADVAR: Okay, so we have to vote again. Any other items?

So I heard three stipulations or changes, alterations. Is that correct?

MS. MARTIN: Correct.

CHAIRMAN JADVAR: All right, so with that --

DR. TAPP: This is Dr. Tapp with the NRC. Can I?

CHAIRMAN JADVAR: Sure.

DR. TAPP: Just make sure that I'm following here. This is actually not on the report itself, but this is actually an additional recommendation to the proposed rulemaking, am capturing this correctly. So this is actually on the rulemaking text.

And we're talking about an extravasation that results or has the potential result in radiation

injury. So I just wanted to capture that that was to the text.

And just to give a little bit of history on staff's, so everyone's aware here that the thought on this text language was for when there is an extravasation that is maybe on a therapeutic, that is a large dose. And that you have a physician who believes and determines that it has a potential to result in radiation injury. So, a large does that has that potential.

And you know up front you want to do this quick reporting so we can have maybe something that is something that could reoccur in other locations, getting this quick reporting to the NRC, that was the purpose of adding this "or has the potential."

So, just want to make sure that background was given to the ACMUI for this.

MR. EINBERG: And this is Chris Einberg. Yeah, sorry to interject. This is a huge shift in fundamentally what our approach would be if we removed this language. And so if you make that recommendation, please make it fully informed that you know, this is a big shift in our approach.

CHAIRMAN JADVAR: Okay, thank you for that explanation.

Dr. Harvey?

DR. HARVEY: Rather than say "has the potential," can we say "expects"? I think the idea here is if the authorized user or the physician expects it to resolve in a radiation injury, that we report it, and take out the vagueness of "has the potential." It's just a thought.

PARTICIPANT: Results could be expected to result -- yeah, I like that phrasing, "that results or could be expected" or "would be expected to result."

MS. MARTIN: Could be expected results or would be expected to result.

CHAIRMAN JADVAR: Is then "would be expected," isn't that a little firmer than "has the potential"?

MS. MARTIN: Yes. It's harder.

CHAIRMAN JADVAR: It's harder. Is that -- is that what you want? You know, in other words you already have surmised that this is expected, it's going to happen. But "has the potential" is still is, I think is less firm. You know, you think it may happen, it may not happen.

DR. FOLKERT: Yeah, because when you're looking at doses --

CHAIRMAN JADVAR: So I think the "has the

potential" is -- I think "has the potential" is, I'm okay with that, but you know, I leave it up to you.

DR. EINSTEIN: How about "is likely to" as an intermediate language? "Has the potential to" could have a very tiny probability of it occurring.

DR. FOLKERT: I like that better.

DR. EINSTEIN: "Is expected to" has an extremely high probability.

DR. FOLKERT: Yup.

CHAIRMAN JADVAR: Okay, well.

DR. FOLKERT: "Likely" seems like a reasonable compromise.

PARTICIPANT: That's reasonable.

CHAIRMAN JADVAR: so Chris, going back to what you mentioned, Mr. Einberg. If this "has the potential" wording is changed to something else, is that a -- is that an issue, major issue? What -- is that okay?

MS. MARTIN: If it's changed to "is likely to," I think that's been the suggested changing -- changed wording.

MR. EINBERG: So I will ask members of the medical team to opine, either Dr. Tapp or Daniel DiMarco, to weigh in on this. Because I know that they extensive discussions in the working group when

they were developing this language, and I think Daniel is ready to discuss that.

MR. DIMARCO: Hi, Chris, hi, members of the ACMUI. Daniel DiMarco here for the NRC. The major change here with the addition or I guess the deletion of this wording, like Dr. Tapp said before, was that this specifically went to the timing of the extravasation, where we know that radiation effects typically have some sort of lag time or delay time.

And so the wording of this, like Dr. Tapp said before, as well as the wording that, from what I'm hearing, you guys are thinking about changing it to with "expected" or "is likely to," it was -- the wording was in there specifically to capture these events before any symptoms appear.

Where there's, you know, some amount of potential based on, well, where we have it as determined by a physician determination, there's some sort of potential for radiation injury, and therefore it could be reported before any symptoms appear so we can get the information quickly and help the patient as soon as we can.

So, from what I was hearing with some of the potential changes you were having with the wording here, if you're changing it from "has the potential

to" to maybe something like "is expected to" or "is likely to," then that wouldn't be a major change in the reporting requirements that we've set out.

But if you did away with the language altogether, that would be a major change to the reporting requirements as we've set them out. I hope that clarifies things.

CHAIRMAN JADVAR: Yeah, very much. Thank you.

MR. OUHIB: This is Zoubir, if I may.

CHAIRMAN JADVAR: Please.

MR. OUHIB: This is for DiMarco. What do you think if we say, you know, like, and notification of a medical event that result or based on certain indications, clinical indication, or whatever that is, has the potential to result in a radiation injury?

We just add something that's convincing that the potential is not vague, there's some -- there's something behind the justification for that matter.

MS. MARTIN: Well, I think that's what kind of we covered -- oh, go ahead -- by the "is likely to."

MR. DIMARCO: Oh, no, I think you were, well, that's, for the NRC, when I put that in there or

when we put that in there, the "as determined by a physician" bit at the very end of that, that was the key factor there, where the NRC is not interested in getting into these determinations of whether or not something like this has the potential for radiation injury.

We recognize that the physicians as well as their teams have the -- have the required experience and expertise as well as the tools necessary to make that determination themselves. And so we didn't want to step into the clinic, as it were, to make these determinations themselves.

And so we were putting the determination in the hands of those who have the best experience and the best tools to make that determination themselves, the physicians and their teams.

MR. OUHIB: Thank you.

CHAIRMAN JADVAR: Thank you. Yeah, I just give my opinion. I don't see any specific problem with this as it is. It says at the end is determined by a physician. Yes, there may be a potential based on judgment, clinical judgment, that it could be something like that. And you follow it, if that's what the physician decides.

I'm not sure, when you put "likelihood" or

"expected," you know, you're adding one level of certainty to it, and I don't know if that's necessary. "Potential" is open, you know, it could be may happen, may not happen. Anyway.

DR. FOLKERT: Well, I think the concern would be if just say "potential," that could be 1%, 2%, 3%, whereas if you say "likely," then that's at least probably more that 50% chance that there's a possibility.

CHAIRMAN JADVAR: Anywhere from say 20-80% would be the intermediate DQs (phonetic)-- yes.

DR. FOLKERT: But I mean, we're talking about therapeutics. I mean, even like half of a cc could have the potential of causing some issues. So it's like, yeah, just saying "potential" is, I agree, it just seems to be too vague, with the public comment.

So I would say at least go with "likely" or "expected."

CHAIRMAN JADVAR: Okay. Okay, so is everybody agreeing? And I think Dr. Einstein suggested "likely." Is that acceptable?

MS. MARTIN: I agree. I think, well this is Melissa. I think the "is likely to" is the best one.

CHAIRMAN JADVAR: Okay, "as determined by a physician," which is at the end of the sentence.

MS. MARTIN: Mm-hmm.

CHAIRMAN JADVAR: Okay. And I think that would be a-- that would not be a major change as described by Mr. DiMarco, right?

MS. MARTIN: Correct.

MR. EINBERG: Yeah, we agree. I see Dr. Tapp came on. If she could have a moment.

DR. TAPP: Yeah, and I know you guys, if I may, you do like specific language to provide in your recommendation. However, terms like "potential," "likely," and "expected" all do have a slightly different meaning when we go into regulations. And sometimes are, there are rulemaking trigger words that we don't like to add.

So if you prefer and you're still debating between "likely" or "expected," you could add both to your report if they're both okay to you, if you like them better than "potential." And then we can work through that back here with our administrative staff. Because I'm not sure, "likely" sometimes does have some concerns with our regulatory administrative staff that does look at this.

So if both are okay, maybe add, you could

add "likely or expected" to your recommendation.

CHAIRMAN JADVAR: Yeah.

MS. MARTIN: That's okay then.

CHAIRMAN JADVAR: Is that okay?

MS. MARTIN: That gives you guys a little bit of leeway.

CHAIRMAN JADVAR: Okay.

DR. TAPP: Thank you.

CHAIRMAN JADVAR: Okay, thank you, Kate. All right, sounds good.

So any other things before we vote again?

MR. UNDERWOOD: So I did have one question. And this may be obvious to me but I may have missed something. But "as determined by a physician" is a very wide statement. Is it -- I mean, is that meant to be "authorized user"? Or, so any physician with any medical degree can determine if the radiation injury is likely to occur and it's a reportable event?

MS. LOPAS: And just to clarify, this is Kyle Underwood. This is somebody, this is external. I'm just clarifying for the transcript, Kyle Underwood.

MR. UNDERWOOD: Sorry, thank you, I should have said that.

MS. LOPAS: No worries.

MS. MARTIN: In the past, we've gotten lots of comments from the public that it's too restrictive to restrict it to authorized users. So that's why it was left purposely at this point just by a physician.

CHAIRMAN JADVAR: Right. And I remember that what Daniel showed at the end of this reports, it says that the patient, when the patient received the dose and all that. So any physicians in medical degree should be able to determine that this may have been caused by radiation.

Anyway, so are we good, or additional comments before we do the vote?

So, let's have a motion again for this subcommittee report, with the stipulations that were recorded.

Do we have a vote -- do I have a motion? Anyone?

DR. EINSTEIN: So moved.

CHAIRMAN JADVAR: Okay, any seconds?

DR. FOLKERT: Second.

MR. EINBERG: Can you please -- can you please identify who made the motion and who seconded for the court reporter, please?

CHAIRMAN JADVAR: Oh yes.

DR. EINSTEIN: Andrew Einstein, so moved.

DR. WOLKOV: Harvey Wolkov, second.

CHAIRMAN JADVAR: Harvey Wolkov, second. All in favor, say aye.

(Chorus of aye.)

CHAIRMAN JADVAR: Any opposed?

MR. OUHIB: Aye.

CHAIRMAN JADVAR: Any opposed? Any abstention?

MS. ALLEN: Aye, Rebecca Allen.

CHAIRMAN JADVAR: Okay, thank you. So the subcommittee report is passed with the stipulations as recorded.

And I think that's the end of our business today. So I want to turn it back to Mr. Einberg.

MR. EINBERG: Okay, yeah, thank you, Dr. Jadvar. Thank you, subcommittee members who worked diligently with NRC staff for the support on this. Thank you for the ACMUI members as well. Thank you to the insightful comments that we received from the members of the public. This all helps us inform our rulemaking process.

As Sarah Lopas pointed out, as we move forward in finalizing our rulemaking and guidance

development, we will be providing this to the NRC commission. After such, if they agree to publish this, then there will be other opportunities for members of the public to comment on this.

So this is a, you know, a process where, you know, we value public input. And the members of the public will have additional opportunities to comment. As Sarah also pointed out, the comments that we have received will be appended to the transcript. And so that will be made part of the record as well.

And so with that, I thank you all on behalf of the NRC, and we can adjourn the meeting.

CHAIRMAN JADVAR: Meeting is adjourned. Thank you, everyone.

(Whereupon, the above-entitled matter went off the record at 3:40 p.m.)

To Whom It May Concern:

Thank you for considering this public statement regarding the June 17th meeting to discuss the ACMUI's subcommittee report on the NRC staff's proposed changes to NRC's requirements for medical use of byproduct material to address reporting of nuclear medicine injection extravasations as medical events.

I am Daniel G. Guerra Jr., founder and CEO of Altus, a technology services company that focuses on radiation technologists who work in clinics and hospitals to keep patients safe during medical imaging such as CT scans and radiation therapy. Altus offers a range of products including continuing education courses for radiation technologists, tools for clinics to organize their credentialing requirements, and webinars for scientific device manufacturers.

I have followed with great interest the actions of NRC, ACMUI, and Congress regarding medical event reporting of nuclear medicine extravasations. A couple of years ago, Altus hosted a panel discussion focusing on how radiopharmaceutical extravasation affects the quality and quantification of nuclear medicine imaging studies, and a series of interviews with subject matter experts on the topic.

From lobbying disclosure records and a recent critical report by NRC's Office of the Inspector General, I have become aware that professional societies that represent nuclear medicine physicians, whose members populate ACMUI, are engaged in lobbying against medical event reporting of large extravasations. This policy position is counter to the views of prominent individual physicians and subject matter experts, and counter to the view of a large coalition made up of dozens of patient advocacy organizations.

I think all parties involved would agree this is an important issue for patient safety and transparency. I also believe it is critical that policymakers and regulators benefit from honest, unbiased, and unconflicted advice as they decide this policy issue. NRC, Congress, and the public must hear an open exchange of views on this matter, in which statements not borne out by scientific and clinical evidence can be challenged and debunked. Policy must be based on the best scientific evidence for the benefit of patients, not predetermined by well-placed insiders.

That is why I offer the services of Altus to host an online forum featuring proponents and opponents of medical event reporting of large extravasations can make their arguments and challenge statements that they believe to be false. I believe this would be illuminating and helpful for policymakers, regulators, and the public. I hope NRC and ACMUI consider this good-faith proposal and accept it in the spirit of supporting the best science for the benefit of patients.

I look forward to hearing from NRC and ACMUI about this possibility.

Daniel G. Guerra Jr., CEO

Altus | PO Box 910 | Madison, WI 53701
Direct: 608-212-2391 | Email: dguerrajr@altusinc.co
Website: https://altusinc.co | https://thenhti.org

I am writing to express my concerns regarding the NRC rulemaking process and the proposed rule.

The public is being asked to provide comments and questions regarding the recently announced ACMUI subcommittee report on NRC's proposed rulemaking for the reporting of extravasations. I have no insight into the what the report says and was given an extremely short turnaround time to submit a comment. Additionally, the published Special Investigation report from the OIG would lead me to believe that the two individuals accused of violating federal ethics rule should recuse themselves from discussing this issue with NRC medical staff.

As such, I believe the proposed rule reflects the improper influence of conflicted members of the ACMUI. The recommendation to use qualitative reporting criteria for patient injuries related to extravasation of radiopharmaceuticals is alarming. It disregards the longstanding reasons for dismissing such criteria, which were clearly outlined in the 1980 Federal Register.

The proposed rule by the NRC exacerbates the problem for patients. Most patients are unaware they are being injected with radiation during nuclear medicine scans. Many patients believe they are being injected with some kind of contrast or dye. Additionally, it is a well-known fact that patients are not given information about the symptoms of ionizing radiation damage. Without monitoring for extravasations and without crucial information of symptoms that may arise weeks, months, or even years later, patients will not know they are experiencing effects from an extravasation.

Additionally, I have come to understand that nuclear medicine physicians typically do not take patient appointments. Even if they did, the question arises: who would bear the cost of these extra office visits? This is another added burden that patients should not have to shoulder.

My concerns extend to the broader issue of healthcare inequities and systemic racism in healthcare facilities. Qualitative patient-reported injury criteria disproportionately impact minorities. Since your committee lacks diversity, ACMUI may not fully grasp how unlikely it is for patients of color to report, much less convince a physician, that an injury is related to radiation exposure when there is no documentation of extravasation and potentially no visible skin damage. This creates a significant barrier for patients of color, further deepening the disparities in healthcare.

My stake in this issue is deeply personal. I started the New Day Foundation for Families in 2007 with my husband Michael. We both lost our first spouses to cancer, giving us an intimate understanding of the emotional and financial toll cancer takes. Both my sons receive yearly nuclear medicine scans due to their high risk of developing cancer. Without the monitoring of extravasations, I am not confident that the scans are 100 percent accurate.

Unfortunately, I cannot attend the June 17meeting due to previous commitments for my advocacy organization. I have two questions that I hope ACMUI will address during the meeting.

1. Have any of your members (on the subcommittee or the whole ACMUI) had any conversations with members of the professional societies regarding the subcommittee report before the June 17 meeting? If so, when did these conversations happen and what was communicated?

2. Will the NRC and ACMUI reconsider the implementation of qualitative reporting criteria for patient injuries related to radiopharmaceutical extravasation? It is imperative that we maintain objective, transparent, and accurate reporting standards to ensure patient safety and equity in healthcare. Large extravasations that exceed the existing NRC dose thresholds for a reasonable volume of healthy tissue indicate a potential problem in the handling of radioactive isotopes. These should be reported no differently than any other medical event. Not reporting these will continue to allow nuclear medicine centers to avoid improving their processes.

In summary, as a patient advocate, I do not feel that patients are being adequately represented in this process. I reiterate my concerns regarding the proposed rulemaking. Existing objective medical event criteria should be followed.

Thank you for your attention to this critical matter.

Gina Kell Spehn
New Day Foundation for Families
FoundationForFamilies.org

May 31, 2024

U.S. Nuclear Regulatory Commission,
Washington, DC 20555–0001
ATTN: Rulemakings and Adjudications Staff

Public Comment for Docket ID NRC–2022–0218

During the most recent ACMUI and NRC Commissioner meeting, Spring 2024 April 8-9, 2024, statements were made by members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) that provided the Commissioners with potentially misleading information regarding extravasations and considerations for Medical Event reporting. It is noted in the transcript that the Office of Inspector General (OIG) investigated a conflict of interest allegation and noted two ACMUI members had failed to notify the NRC of a potential conflict and the NRC policies on conflicts need to be revised. Though the integrity of the ACMUI group tasked in evaluating a change to reporting extravasations was reassured publicly, the decision-making needs feedback from unconflicted experts with knowledge of the human use of radiopharmaceuticals.

In light of the recent release of the "IAEA Human Health Series: Basics of Quality Management for Nuclear Medicine Practices" by the International Atomic Energy Agency (IAEA), a globally recognized authority in radiation protection, I believe it's important to consider this document in the NRC's request for public comments. The IAEA adopts a proactive approach to managing extravasations, treating them as incidents requiring active management, similar to other quality issues in nuclear medicine. The insights from this series should be integral to the NRC's discussion on the preliminary proposed rule language, ensuring that regulatory frameworks align with international standards and enhance the safety and quality of nuclear medicine procedures.

Definitions

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?

The term "extravasation" should be adopted by the NRC to describe the leakage of radiopharmaceuticals into surrounding tissue. This terminology is aligned with IAEA usage and specifically describes such incidents in nuclear medicine, highlighting its relevance and specificity. Historically, the nuclear medicine community, as noted by the SNMMI, has used the terms "infiltration" and "extravasation" interchangeably. However, "infiltration" generally refers to the non-specific occurrence of any substance entering surrounding tissues, which may not necessarily involve radiopharmaceuticals or radiation. Using "infiltration" could therefore lead to ambiguity in medical protocols and regulatory language, potentially complicating clinical and reporting practices in nuclear medicine. Moreover, standardizing on "extravasation" rather than "infiltration" avoids underestimating the associated risks. Although SNMMI highlights that the likelihood of damage is minimal in the diagnostic realm of PET, such a viewpoint might downplay the urgency required in responding to extravasation events. Adopting "extravasation" ensures consistency with international standards and enhances clarity and precision in medical and regulatory contexts.

2. What criteria should the NRC use to define “suspected radiation injury”?

NRC should not use the terms “suspected radiation injury.” As highlighted in "Basics of Quality Management for Nuclear Medicine Practices," "In a large number of countries, it is mandatory to report to the regulatory authorities any incidental situation that may have involved a radiation exposure above

a predefined threshold, both when staff members and when patients are involved[1]." Similarly, NRC should use existing radiation dose thresholds that prompt mandatory reporting.

3. What techniques or methods should be included in the definition of "medical attention"?

Medical attention, traditionally reactive and subjective, involves qualitative processes that vary based on the clinician's perspective and generally occur after a patient has suffered harm. This approach overlooks preventive measures that could mitigate or avoid such harm. In contrast, IAEA emphasizes the importance of objective criteria and adopting a preventive approach[2]. It suggests that all risks associated with patient preparation and administration should be carefully considered in a prospective risk analysis to prevent incidents before they occur[3].

In redefining "medical attention," it is crucial to expand beyond reactive strategies and include proactive measures that enhance patient safety and care quality.

Procedures

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

To minimize the chance of radiopharmaceutical extravasation, the licensee can implement a series of steps as outlined in "Basics of Quality Management for Nuclear Medicine Practices":

Risk Management[4]

- Identifying Potential Failures: "Using appropriate science based tools to identify in advance what could go wrong during care (i.e. failure to plan or execute a sequence of actions that results in the desired goal not being reached) and understanding the factors that influence this."
- Learning from Adverse Events: "Learning lessons from any adverse events (i.e. unexpected events related to the care process and result in unintentional and undesirable harm to the patient), whether preventable or not. An adverse event attributable to an error is 'a preventable adverse event,' and this includes 'near misses' (an error that has the potential to cause an adverse event but, either because it was intercepted or because it had no adverse consequences for the patient, did not occur)"
- Improving from Errors: "Learning from errors that do occur is a key factor in reducing the risk of repeating mistakes, or at least in decreasing the severity of their consequences, and in maintaining and improving the quality of health care."

Rigorous procedural adherence and staff training and awareness

- Preventing Accidental Exposures: "Minimizing the risk of accidental exposures: To minimize the likelihood of accidental medical exposures, including mis- and mal-administrations and unnecessary multiple medical exposures, detailed procedures should be defined and implemented in the NMS, with emphasis on the prevention of such exposures and unnecessary multiple exposures. These procedures should include aspects related to correct patient identification, staff training on technical tasks (e.g. training on correct radiopharmaceutical administrations to avoid extravasations), encouraging staff to work with awareness and

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[1] IAEA Human Series. No. 43. Basics of Quality Management for Nuclear Medicine Practices. 7.5.3. Incident reporting, p. 54.

[2] Same document. 7. RISK ASSESSMENT, pp. 43-45.

[3] Same document. 7.5.1. Incident prevention, p. 48.

[4] Same document. 2. RISK MANAGEMENT, p. 3.

alertness, availability of updated and detailed SOPs for all steps of the clinical processes involved, etc.[5]"

Preventive and Corrective Actions

- Continuous Improvement Practices: Engage in continuous improvement practices, where incidents are reviewed, and lessons learned are integrated into daily practices. "Links to the procedure for corrective or preventive actions and, when applicable, to the procedure for incident reporting, should be included in SOPs."

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

The document "Basics of Quality Management for Nuclear Medicine Practices" presents a detailed example of administering ^{223}Ra dichloride therapy, outlining specific steps taken upon the suspicion of extravasation[6]:

1. Immediate Suspension: Promptly stopping the injection to prevent further leakage of the radiopharmaceutical.
2. Resuming the Procedure if Appropriate: Continuing the administration only after ensuring the situation is stable and satisfactory.
3. Conducting Diagnostic Imaging: Performing imaging to "confirm biodistribution" and assess the extent of the extravasation.
4. Establishing a Working Group: Forming a team to thoroughly evaluate the incident and develop preventive actions.
5. Reviewing and Improving Practices: Analyzing current practices and materials used to identify and address potential improvements.
6. Updating Protocols and Equipment: Modifying protocols and equipment based on the findings and recommendations of the working group.
7. Final Reporting and Incident Closure: Formally documenting the resolution of the incident and the steps taken to prevent future occurrences.

Based on this example, we can identify essential steps that should be considered in similar situations, including the use of dosimetry to effectively assess the impact of extravasation. IAEA further emphasizes that "Management of incidents involves their identification, reporting, reviewing, monitoring and evaluation, including the timely rectification and effective actions to restore a safe environment for patients, staff, contractors, volunteers, and visitors[7]." This structured approach not only addresses immediate concerns but also facilitates long-term improvements in managing such incidents.

Documenting an extravasation in the patient's electronic medical record is critically important. Patients who have been extravasated -might be more likely to be extravasated again during future nuclear medicine procedures. Knowing that a patient has been previously extravasated will alert the medical team to pay extra attention to radiation protection during future administrations.

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?

To effectively identify an extravasation, a combination of techniques, technologies, and procedures is critical:

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[5] Same document. 8.9. SOPS FOR RADIATION PROTECTION OF PATIENTS, p. 75.

[6] Same document. 9.3.2. Examples of root cause analysis. 9.3.2.2. Example 2: Preventive action, pp. 94-95.

[7] Same document. 7.5.2. Incident management

Real-Time Monitoring Technologies: Given the limitations of visual observation and patient feedback, employing advanced technologies that can help determine possible extravasations during the delivery of radiopharmaceuticals is essential. These technologies can detect even minor deviations in the flow or distribution at the injection site, providing an immediate and reliable method for identifying extravasations as they occur.
Visual Observation and Patient Feedback: Although the small volumes involved in nuclear medicine injections and the absence of immediate visible or sensory changes at the injection site can make these methods unreliable, they are still encouraged by IAEA and SNMMI. Radiopharmaceuticals often do not cause visible changes or a burning sensation, which reduces the likelihood that patients will notice an extravasation. However, careful observation and listening to patient feedback remain important.
Post-Procedure Imaging: While post-procedure imaging is recommended by IAEA and SNMMI, it is often too late to mitigate the immediate effects of an extravasation. Still, it is crucial for confirming the distribution of the radiopharmaceutical, identifying any areas of unintended retention, and along with the patient's specific biological clearance an image helps determine the most accurate dosimetry.
7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?
Prompt identification and characterization of extravasation are critical to implement appropriate measures effectively. Once detected, characterization involves:

1. Recording Residual Radioactivity (In a case involving ^{223}Ra dichloride therapy, gamma camera images were used to monitor residual activity at the injection sites).
2. Calculating Effective Half-life.
3. Determining Initial Activity.
4. Calculating Absorbed Dose.

Contrary to the views of some medical societies that downplay the importance of detailed extravasation characterization, the IAEA recommends such characterization to fully understand its impact on procedures.

Additionally, ultrasound technology is being developed now that can assess damage to a patient's vasculature. Patients who have been extravasated should be monitored with this technology.

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?
Licensees should provide detailed information to patients to ensure they are well-informed and prepared to recognize and respond to potential effects from extravasations. It is crucial to educate patients on how to identify signs of extravasation, such as unusual pain, swelling, or redness at the injection site. Additionally, patients should be made aware that symptoms of radiopharmaceutical extravasation might not always be apparent, and the absence of immediate symptoms does not necessarily indicate that an extravasation has not occurred. They should be told that the energy emissions of concern from a potential extravasation may not travel far enough to result in visible damage to the skin, but rather be contained in the underlying tissue. They should be told that a high dose of radiation below the surface of the skin may damage their microvasculature and they should be aware that this can cause pain weeks, months, or years later. They should also know the importance of telling their physicians immediately if they suspect a radiation injury, so this can be documented in their medical record.
"In order for the NMS to offer the highest quality of care, it is important for it to work in partnership with all stakeholders, such as patients, referrers, and caretakers. This will assist them in gaining a better

understanding of the priorities and concerns of those who use the NMS[8]." By adopting this collaborative approach, licensees ensure that patients are proactive participants in their treatment, enhancing the effectiveness of care and aiding in the management of both apparent and potential adverse events.

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)?

Immediate detection of extravasation during the administration of radiopharmaceuticals allows for prompt mitigation steps, significantly reducing the detrimental impact on the patient's health. Delays in detecting and addressing extravasations can have serious consequences for the patient's well-being and may affect the results of imaging procedures ("nuclear medicine procedures are often quantitative, and a suboptimal injection can potentially hinder the quantitative aspects of the procedure[9]"). There is no reason to unnecessarily delay notifying the patient, the reading physician, and the medical team. Consideration should include potential exposure to the lymphatic system and axillary lymph nodes as some imaging have shown lymphatic uptake of the radiopharmaceutical. As a mechanism for removing the extravasated material, the lymph system has different flow dynamics than that of the venous system which could prolong radiation exposure to the lymphatic drainage in the affected limb. Additionally, particulate radiation, alpha and beta, would greatly increase the absorbed dose.

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 after assessing the absorbed dose to the patient's tissue, the licensee finds the dose exceeds medical event reporting criteria, they should follow the same timeline as other medical events. The referring physician and the patient should be notified of the extravasation medical event at a minimum within 24 hours of its discovery.

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"?

The identification and initial response to an extravasation that exceeds existing medical event reporting criteria, not suspected radiation injury, should primarily fall under the responsibilities of the nuclear medicine team performing the administration.

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

NRC should consider incorporating the following topics into its guidance:

Objective Identification Criteria: The guidance must emphasize the use of objective, dose-based criteria for identifying extravasation events. This includes quantifiable thresholds that prompt an evaluation for potential extravasation and necessitate immediate response measures.

Extravasation Management Protocols: It is important to establish protocols for immediate action in case of suspected extravasation. The example provided by IAEA of managing extravasation during ^{223}Ra dichloride therapy administration shows that quick response, followed by confirmation through imaging, can be the very first steps for extravasation management.

Reporting and Follow-up Mechanisms: There should be clear guidelines for reporting extravasation events. These guidelines must detail how to document the incident, analyze the root causes, and undertake corrective actions.

Healthcare Inequities

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[8] Same document. 2.3. EXPERIENCE AND INVOLVEMENT OF PATIENTS, REFERRERS AND CARERS, p. 4.

[9] Same document. 10.8.2.1. Example 1: Acquisition of syringes, needles, cannulas, butterfly lines, etc., p. 107.

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

To ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported, regulatory actions could focus on the following strategies:

Mandatory Training on Extravasation Management: Implement mandatory training programs that focus specifically on the identification and management of extravasations. These programs should emphasize the importance of equitable care, addressing potential disparities in patient treatment.

Objective, Dose-Based Identification Criteria: Regulators should mandate the use of objective, dose-based criteria for detecting extravasations. This reduces the subjective judgment that might inadvertently contribute to disparities in how extravasations are detected in different patient groups.

Reporting System: Develop and enforce enhanced reporting system. The system should prompt healthcare professionals to report all suspected extravasation events immediately.

By focusing on these areas, regulatory actions can help ensure that all patients, regardless of their background or the presence of healthcare inequities, have equal access to high-quality care.

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

The adoption of ultrasound-guided vein finders and other advanced vascular access tools is a proven approach to reduce the risks of extravasation and improve the overall quality of care for all patients, particularly addressing the unique needs of patients of color. Vascular access experts and societies recognize that the latest vein finding tools and proper vascular access training and ongoing credentialing are required to reduce the rate of extravasations. Using ultrasound and other vein-finding technologies enhances the precision of vascular access procedures by providing real-time, high-resolution images of veins. This is crucial for patients where traditional palpation techniques are less effective, such as those with darker skin tones where veins may not be as visibly distinct.

Additionally, IAEA emphasizes the importance of using high-quality equipment in the administration of radiopharmaceuticals. As stated in their guidelines on the "Acquisition of syringes, needles, cannulas, butterfly lines, etc.," “These supplies are fundamental for proper administration of radiopharmaceuticals and should be of sufficient quality to avoid risk of spillage, reduce the risk of extravasation, etc., given that these aspects are of particular relevance when the pharmaceuticals in use are radioactive[10].”

In particular, the Spring ACMUI meeting addressed reported Medical Events in 2023 and a Review of Prescription Error Reduction Methods. There was emphasis on the Five Rights for Medication Administration:

- The Right Patient
- The Right Drug
- The Right Dose
- The Right Route
- The Right Time

As the nuclear medicine community is aware, the proper administration of radiopharmaceuticals through an IV is, almost always, necessary for the proper results of the nuclear medicine study to be achieved. Extravasation of the radiopharmaceutical ensures that the dose is not being delivered through the proper route. Therefore, it is important to proactively know the radiopharmaceutical was administered correctly into the vein without extravasation. Possibly learning about an improper administration of a radiopharmaceutical from a patient reporting radiation injury weeks to months later is entirely inconsistent with the Five Rights for Medication Administration and IAEA guidelines. As a

[10] Same document. 10.8.2.1. Example 1: Acquisition of syringes, needles, cannulas, butterfly lines, etc., p. 107.

corporate member of the Patients for Safer Nuclear Medicine Coalition, my organization cannot support the proposed rulemaking and strongly urges the NRC to treat extravasations no differently than any other medical event.

John Witkowski
President
United Pharmacy Partners
5400 Laurel Springs Parkway
Suite 405
Suwanee, GA. 30024
Office: 770-205-2651

Paul E. Wallner, DO, a radiation oncologist, representing the American College of Radiology. Please include my name as participating in the subcommittee Teams call today, and as I indicated in my oral comments, these are the remarks that I would request be appended to the meeting transcript:

For your report of recommendations, the ACR asks ACMUI to consider making these 3 additional recommendations to NRC staff…

1. Recommend that a "radiation injury" require **medical intervention**, such as surgery, to be reported as this proposed Medical Event type. The Commissioners' decision explicitly directed NRC staff to focus on radiation injuries **requiring medical attention**, which indicates a higher level of safety concern than is evident in the draft proposed rule. Importantly, this rulemaking is about what patient data is collected in a federal database without a patient's consent—it should be of radiation safety significance and of actionable concern to NRC. In this regard, if a CTCAE grade is to be included in the recommendations, the minimum reporting grade should be grade 3.

2. Also, for the "radiation injury" regulatory definition, recommend changing the speculative verbiage "**can be** attributed to radiation" to the more explicit "**has been** attributed to radiation" or "**is most likely to be** attributed to radiation." Radiation attribution is key. This ensures data is correctly scoped to NRC's authority over byproduct material, and that NRC is not collecting common reactions to sterilization, needle puncture, non-radioactive substances, adhesive, or bandaging.

3. In the regulatory language for the new Medical Event type, recommend deleting "**or has the potential to result in**" (a radiation injury). This is speculative and likely to result in downstream compliance burden and confusion by investigators or licensees.

Thank you.

Paul E. Wallner, DO

I am providing this written comment and question in response to a notification I received regarding the Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting scheduled for June 17, 2024.

The notice suggested that persons wishing to provide a written statement should provide their comment by close of business on June 11 (today) and ensure their comment is related to the agenda topic. The topic for the June 17 meeting is the ACMUI subcommittee report on the NRC staff's draft proposed rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events.

Unfortunately, the subcommittee report was not available on the website. So, as you can imagine, it is difficult for me to ensure my comment is addressing legitimate concerns with the subcommittee report when the public doesn't have access to this report.

So instead, my comment will be focused on the proposed rule and the fact that the NRC and ACMUI are making it extremely difficult for unconflicted members of the public to effectively weigh in on the report and associated draft implementation guidance (since I don't think we have access to that info). But this approach appears to be consistent with the past processes used by the NRC to draft the proposed rule.

In January 2022, Ms. Mary Ajango and I wrote the NRC regarding the fact that the ACMUI appeared to be conflicted when it came to providing advice to the NRC medical staff regarding the radiopharmaceutical extravasation petition for rulemaking. While we have yet to hear back from the NRC on this issue, we were approached by the NRC Office of Inspector General because someone within the NRC had a similar concern. We provided the special agents our opinion and provided them with others to approach. While we are pleased that the OIG report confirmed that members of the ACMUI were conflicted and violated federal ethics rules, we are extremely disappointed that the NRC has not addressed these conflicts over the past two years. For those of you who have not seen the March 2024 U.S. NRC Office of the Inspector General (OIG) report you can see it here at this link: https://bit.ly/NRCOIG.

The OIG findings that two members of the subcommittee should have recused themselves from any discussion on the issue is the tip of the iceberg. Most ACMUI members who have commented on extravasations are also influential figures within medical societies that are actively battling against the effort to raise awareness about extravasations. It is completely unacceptable that these members are providing any guidance whatsoever to the NRC on this topic. From my research of ACMUI members associated with this topic, nearly every member except for the FDA representative and Ms. Laura Weil, the former patient advocate, should have recused themselves. The others held positions or past positions in their respective professional societies that likely influenced the drafting of society activities meant to influence the NRC to continue to exempt extravasation reporting.

The lack of proactive steps by the NRC to address these conflicts reveals that NRC has little interest in taking the patient's side on the issue of extravasation. And unfortunately, the OIG

report does not obligate the NRC to take action. While one would hope this OIG report would be enough to convince NRC and the ACMUI to ensure conflicts of interest do not arise in the future, and to take concrete steps to better position itself as a guardian of the patient's well-being. Unfortunately, we remain thoroughly disappointed in the NRC and ACMUI response. In an earlier NRC ACMUI meeting this Spring, Mr. Kevin Williams discounted the report and praised the ethics and performance of the ACMUI. It is obvious to patients that the only thing being guarded is the interests of the medical societies. Interests that are clearly at odds with the interests of patients.

Which takes me to my comments on the proposed rule. The proposed rule is inappropriate in so many ways. It is the only medical event or nuclear power safety event that relies on a qualitative reporting criterion. Even worse, NRC is suggesting patients, who have little to zero knowledge of radiation in general and the effects of ionizing radiation on tissue, report a medical event. This flies in the face of radiation protection tenets. It is a clear example of a failure of NRC staff to protect patients.

Patients will not stand for this. In October 2023, the Patients for Safer Nuclear Medicine (PSNM) Coalition filed a separate complaint with OIG. We provided OIG five specific, evidence-backed examples of how NRC has failed to appropriately protect patient safety by disregarding crucial clinical data, propagating factual errors in NRC documents, and more. We are actively working to ensure that the NRC OIG investigates these allegations with vigor. We have also shared these legitimate allegations with members of Congress.

Examples of bias and conflicts of interest clearly exist among those advising NRC. It is abundantly clear to anyone who reads the transcripts of the December 2008 and May 2009 NRC ACMUI meetings on extravasations, that the NRC has mismanaged its policy on nuclear medicine extravasations. NRC heard evidence that extravasations were not "virtually impossible to avoid." They heard that patients were receiving high doses that greatly exceeded reporting thresholds. And they heard Dr. Nag say even if patients got a high dose from these preventable medical events, he did not want to be bothered with having to tell the patient, their physician and then have to do all the blah, blah, blah, associated with reporting. When patients see these past meeting transcripts, when we see the subsequent NRC/ACMUI efforts to keep the reporting exemption in place despite knowing the exemption was incorrect, when we see meeting notification shenanigans intended to squelch the patient voice, we know that NRC has failed us. We know we must work with the Inspector General and Congress to hold the NRC accountable.

My final input on this meeting is for you all to realize that patients do not trust that you have their best interests in mind when making your decisions. You need to re-earn our trust. My advice is for you to study the evidence. The evidence is clear. If the nuclear medicine community addressed these accidental exposures, like they would if their wife, or child, or father was being extravasated during their important nuclear medicine procedure then they can start improving. Injections are a process like any other—if monitored and if focused on, the process can get better.

Thank you in anticipation of you making the right decisions today.

Best wishes

Simon Davies

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Simon Davies
Executive Director
Teen Cancer America
Tel: 310 208 0400
11845 Olympic Blvd. #775W
Los Angeles, CA 90064
simon@teencanceramerica.org
www.teencanceramerica.org

My name is Stephen Harris and I am a vascular access nurse and the Director of Research and Development for Vascular Wellness. Vascular Wellness is a multi-state vascular access company with a very high understanding of vascular access and the tools, training, and skills required to properly place and maintain vascular access. I have also previously been a clinical educator for Bard Access, a medical device company specializing in vascular access. Furthermore, I am also a co-author of a joint Vascular Access and Nuclear Medicine Technologist Expert peer-reviewed paper (**https://www.frontiersin.org/articles/10.3389/fnume.2023.1244660/full**) on the current nuclear medicine vascular access practices. I also presented these findings, before our manuscript was published, at the Annual SNMMI meeting a year ago in Chicago. I believe many members of the NRC medical staff may have been present. If you need to see my credentials, please reach out to me on our company website

Since, my position involves an extensive amount of traveling to help hospitals across the Southeast gain access in the most difficult venous access patients, I appreciate the chance to provide a written comment regarding the ACMUI subcommittee report on the proposed NRC rule and guidance for the reporting of large extravasations. In fact, I am drafting this comment now from a hospital based in southern Virginia and I will be traveling on June 17.

I also appreciate the opportunity to comment for another important reason. I have reviewed the credentials of the incredibly august membership of the ACMUI but did not find any member who is an expert in vascular access. I have worked in this field for over 20 years and have extensive experience working with nuclear medicine technologists trying to gain access in nuclear medicine patients. As a result, I feel that I am uniquely qualified to provide a vascular access perspective on the extravasation discussion that I have not seen covered by the NRC medical staff, the ACMUI, nor from my review in any of the history of this issue. In fact, the only vascular access connection I have found is a public comment from one of the leading vascular access societies, the Association for Vascular Access (AVA). AVA made several important statements(emphasis added)that should be reconsidered here:

> Many adverse outcomes related to vascular access are immediately recognized while others, like **extravasation of radiopharmaceuticals, may go unrecognized for a prolonged period of time (sometimes years) and may be associated with negative outcomes including missed diagnosis or suboptimal treatment of nuclear therapy used to treat malignancies.**
>
> **Clinician education is essential to avoid negative complications associated with venous access. Consistent, evidence-based education is lacking among clinicians who are expected to perform the procedure.**
>
> **Monitoring a vascular access device for complications like extravasation is a critical responsibility of the healthcare provider. Prevention and reduction of device complications may be achieved through clinician education, evidence-based education, and avoiding blind-stick insertions.** Finally, healthcare consumers must be educated about the risks associated with vascular access and enable them to become advocates for safe vascular access in all care settings.

I make these points because I do not have access to the ACMUI subcommittee report on the NRC proposed rule (for some reason I cannot find the report that NRC is asking for comments). Without having access to the report, I can only comment on the proposed rule as I know it. And my

comments on the proposed rule are in agreement with the AVA – monitoring for a complication like extravasations is a critical responsibility of the healthcare provider. Our Best Practices manuscript clearly shows that nuclear medicine technologists are not using anything close to the current best practices in vascular access. Conversations with nuclear medicine technologists online also show they have not been taught best practices. These knowledge and training gaps indicate that the onus is on the provider to close them**. It is not in any way the responsibility of patients.** As a vascular access expert, I want to be perfectly clear in my comments.

> Putting any responsibility on patients to monitor for or identify when they have been extravasated is entirely inappropriate. It is the responsibility of the nuclear medicine team to monitor for and identify extravasations when they happen. And then take the necessary steps to mitigate patient harm. Waiting to see if extravasated patients report injury has no place in vascular access management and especially when the purpose of vascular access is for the administration of radioactive drugs.

I would also like to make one other observation for the ACMUI and NRC to consider. Recently, a paper was published from the south of India. Nuclear medicine physicians found that without the use of vein finding technology, their teams were extravasating patients with darker skin more frequently than those with lighter skin. Based on my experience, this does not surprise me. And since nuclear medicine technologists rarely use vein finding technology in the United States, it is highly likely that patients of color are being extravasated at a higher rate than those with lighter color skin. A proposed rulemaking that puts the reporting requirements on patients will lead to an increase in health inequity. It is well known that patients of color are far less likely to report errors in their care than Caucasian patients.

My view as a vascular access expert is simple. NRC should scrap any idea of having patients play a role in monitoring and reporting poor quality administrations. If the NRC wants to protect patients, I suggest they treat extravasations like any other medical event. Centers that routinely have extravasations will then be forced to take the steps appropriate for their center to resolve their high rates of extravasation. While this recommendation is not in my best financial interest, since I benefit from helping nuclear medicine technologists gain access in difficult patients, it is absolutely the right recommendation for patients and healthcare.

I welcome any questions from any member of the NRC or ACMUI, and thank you for the opportunity to provide comment. You have my email address.

Stephen Harris CRNI, VA-BC
Director, Research and Development
Vascular Wellness
919-623-0675