Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Public Meeting on the Information Request Federal Register Notice (FRN) Related to the Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events

Docket Number: N/A

Location: Videoconference

Date: 05-24-2023

Work Order No.: NRC-2378 Pages 1-101

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1716 14th Street, N.W.
Washington, D.C. 20009
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC MEETING ON THE INFORMATION REQUEST FEDERAL REGISTER NOTICE (FRN) RELATED TO THE RULEMAKING ON REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS

+ + + + +

WEDNESDAY

MAY 24, 2023

+ + + + +

The Public Meeting convened via Videoconference, at 1:00 p.m. EDT, Dan Frumkin, Facilitator, presiding.

PRESENT

DAN FRUMKIN, Facilitator

DANIEL DIMARCO, NMSS/MSST/MSEB

KEVIN WILLIAMS, NMSS/MSST

IRENE WU, NMSS/REFS/MRPB

ALSO PRESENT

MARY AJANGO, Young Survivors Coalition

XANDER ARENA

GEORGE CHACKO

CATHY CUTLER, Brookhaven National Laboratory

SIMON DAVIES, Team Cancer America

MICHELE EDWARDS

DANIEL GOMEZ-CARDONA, Gundersen Health System

RICHARD HARVEY, Roswell Park Comprehensive Cancer Center

WILLIAM HINCHCLIFFE, Yale New Haven Hospital

RAMSEY KILANI, Global Security Innovative Strategies

TRACY KING, Medical Physics Consultants

BRYAN LEMIEUX

RALPH LIETO

HELEN NADEL, Lucile Packard Children's Hospital Stanford

CARMINE PLOTT, Forsyth Medical Center

JIM SLINEY JR., Patients Rising

GINA KELL SPEHN, New Day Foundation for Families

PAT ZANZONICO, Memorial Sloan Kettering Cancer Center

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

1:00 p.m.

MR. FRUMKIN: Good afternoon, everyone, and welcome. My name is Dan Frumkin. I'm going to be your facilitator for today's meeting. Good afternoon for those on the East Coast, Central Time. And Mountain, I guess it's still morning, maybe.

As facilitator, I want to welcome you all to this meeting regarding the information request in the Federal Register notice that was published on April 19, 2023 on the rulemaking on reporting nuclear medicine injection extravasations as medical events.

During this meeting, we intend to provide clarifications to the information in the April 19 FRN and also explain the process of providing feedback to the NRC.

This meeting is not intended to collect comments. And although it will be transcribed, statements made during this meeting are not automatically included in the rulemaking docket. The purpose is to encourage attendees and stakeholders to provide feedback using the means discussed in the FRN. That's feedback on the rulemaking.

We have allocated time during this meeting at several points in the staff presentations and also

at the end of the meeting to allow stakeholders and public to ask questions.

The slides for today's meetings are in our ADAMS document library under Accession No. ML23132A116. I'll drop that link in the chat.

My role is to help ensure the meeting is informative, productive, on topic, and on time. Of those four tasks, the most important is keeping the meeting on topic. We have a lot to do and a short time to do it. If you plan on speaking on something other than the topic of the public meeting, please hold those comments for a more appropriate venue.

If you are listening through a telephone line, you will be muted, and you will press *5 to raise your hand and *6 to unmute your mic. Phone attendees should email Irene Wu at Irene.Wu@nrc.gov if you would like your attendance recorded in the meeting summary.

Teams has a chat function. We would like to reserve the chat for technical questions about the Teams platform and for clarifications about the meeting features.

Please provide feedback orally through Teams after unmuting or via phone. The meeting is being transcribed. Therefore, we ask that your

feedback be provided during the audio portion of the meeting.

When speaking today, be sure to speak slowly, clearly, and directly into your microphone. And please start with your name and affiliation even if you have spoken before. So if you raise your hand and then you raise your hand again, please provide your name and affiliation a second time. And as much as possible, please minimize any background noises such as pets while you are speaking.

We want everyone who speaks to get the chance, so we would like to limit the comment time for comment to no more than two to three minutes. Let's stay on topic. And please, one speaker at a time.

Finally, our opinions may differ but we are all colleagues here. So let's maintain the quorum in our forum.

There may be opportunities where you raise your hand and you ask for some clarifications. We might cut you off to let other people have a chance. And you can just raise your hand again and get back into the queue. This has worked successfully in other forums.

Lastly, if there are any questions about the process for managing this meeting at this time,

let me know. If so, you will see there's a Raise Hand feature at the top of your screen or in the middle of your screen where you can raise your hand. I just activated it for myself and deactivated it.

When we get to points of questions, you can raise your hands. Then we will introduce you by name and you can unmute yourself to speak.

If you raise your hand as a caller, we'll recognize you by number. You press *5 to raise your hand and *6 to unmute. And with that, I will lower my hand.

We will start with Kevin Williams, who will give opening remarks. Kevin is the Director of the Division of Materials Safety, Security, State, and Tribal Programs in the NRC's Office of Nuclear Material Safety and Safeguards.

With that, Kevin?

MR. WILLIAMS: Thanks, Dan.

Good afternoon and good morning to all. Welcome to the public meeting on the information request FRN for the rulemaking on extravasations. We recognize there is a lot of energy and interest on this topic, so we appreciate everyone taking the time to attend this meeting.

Next slide, please.

As previously stated, the purpose of this public meeting is to provide information to stakeholders to help prepare their comments on this information request.

By way of background, on December 12th of 2022, the Commission approved the staff's recommendation to amend 10 CFR 35 to include certain nuclear medicine extravasations as medical events.

The staff developed an information request, which made available the preliminary proposed rule language, and included a number of questions for stakeholders to provide input on to help inform the staff's development of the proposed rule.

The NRC, as Dan had talked about, is not seeking comments at this meeting. Any comments should be formally submitted using the instructions we provide later in our presentation.

Although the NRC is not seeking comments at this meeting, as part of the feedback you give to us today at this meeting and any comments you submit in response to this information request, we welcome your thoughts on any questions that we may have missed or any new information that we should consider that wasn't part of the information request.

The comments we receive in response to

this information request will be considered in our development of the proposed rule.

Next slide.

Irene Wu will take us through the background on the topic of today, of the meeting. Daniel DiMarco will go over the information request and preliminary proposed rule language. We will provide information on how to submit comments and our next steps. And we will have some time for public feedback and questions.

I'd like to thank everyone again for attending this meeting. We look forward to your feedback.

I now turn the meting over to Irene Wu.

MS. WU: Hi. Thanks so much, Kevin.

I'm Irene Wu. I'm the Project Manager for this rulemaking. I'm in the Division of --

MR. WILLIAMS: Irene, you're on mute. We can't hear you.

MR. FRUMKIN: We can hear you, Irene. I don't know why Kevin can't hear you.

MS. WU: Can you hear me now, Kevin?

MR. WILLIAMS: I still can't hear you.

MR. FRUMKIN: Can you hear me?

MR. WILLIAMS: Dan, can you hear?

MR. FRUMKIN: Yes. I'll put it in the chat.

Go ahead, Irene.

MS. WU: Okay. I'll keep going. Let me know if you can't hear me.

Again, I'm in the Division of Rulemaking, Environmental, and Financial Support in the Office of Nuclear Material Safety and Safeguards here at the NRC.

For this next section of our presentation, as Kevin said, I'll give you some background on this rulemaking and the steps leading up to the information request that we published last month in the Federal Register.

I do want to add that we have several NRC staff in attendance at this public meeting, including quite a few members of the working group, myself and Daniel, who you will hear from shortly.

We also have Maxwell Smith, Ian Irvin, and Jen Scro from our Office of the General Counsel. We also have quite a few members from our NRC Medical Radiation Safety Team, as well as the Rulemaking Center of Expertise here at the NRC, who are supporting this meeting and may pop on camera if need be to help answer some questions.

Next slide, please.

I'll start off with the 1980 final rule. So back in 1980, the Commission amended part 35, which is our regulation on the medical use of byproduct material, to require quarterly reporting of diagnostic administrations and prompt reporting of therapeutic misadministrations.

And in that 1980 final rule, the Commission excluded radiopharmaceutical extravasations from the reporting requirements, stating in part that extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections and it is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration.

So just to remind folks what we mean by an extravasation, an extravasation is an unintentional leakage of injected material into the tissue surrounding a vein or artery.

And as included in our rulemaking plan, which I'll talk about in a little bit, studies indicate that overall radiopharmaceutical extravasation rates range from, I think, about three to 23 percent of injections.

And the probability of an extravasation

can be affected by several things: patient anatomy, condition, movement of the patient. There's also taking into consideration the training, experience, and technique of the clinician or medical personnel who is administering the injection. And then also the catheter size plays a role.

Next slide, please.

Since then, the NRC staff over the years has requested the Advisory Committee on the Medical Uses of Isotopes to evaluate whether extravasations should continue to be excluded from medical event reporting.

Most recently, in January of 2020, staff took a look at this and began an independent evaluation of whether extravasations should be reported as medical events. As part of that independent evaluation, we wanted to hear from the medical community and other stakeholders.

So in December of 2020, we held a public meeting to provide information on the staff's evaluation. And the ADAMS Accession number for the public meeting summary is ML21005A436.

Staff then provided its preliminary evaluation of reporting extravasations as medical events to the Advisory Committee on the Medical Uses

of Isotopes. And at a high level that evaluation contained six options, which were a mix of rulemaking and non-rulemaking options, and then there was the no-action option.

The recommendation was that extravasations events that require medical attention be reported as medical events. All of the non-rulemaking options were dismissed since staff determined that extravasations don't fit into the current medical event reporting criteria.

And then ACMUI after their review agreed with the staff's recommendation during their September 2021 public meeting. The Adams Accession number for that public meeting by ACMUI is ML21267A021.

Next slide, please.

Okay. So while the NRC staff evaluation was progressing in the 2020 time frame, we received a petition for rulemaking from Lucerno Dynamics in May of 2020, requesting that NRC revise its regulations to require medical event reporting of extravasations that result in a localized dose equivalent exceeding 50 rem.

So in September of 2020, we published a Federal Register notice announcing the docketing of that petition. And we had a 75-day public comment

period, which resulted in us receiving more than 480 comment submissions during that comment period.

Then in May of 2022, staff provided a rulemaking plan -- that being SECY-22-0043 -- to the Commission that presented options for amending part 35. And in that rulemaking plan, staff recommended including as reportable medical events nuclear medicine injection extravasations that require medical attention for suspected radiation injury.

Staff also committed in that rulemaking plan to develop regulatory guidance for the reporting of extravasations, including developing a dosimetry model that the medical community could use to characterize extravasations and assess expected radiation injury.

In December of 2022, the Commission issued its Staff Requirements Memorandum, SRM-SECY-22-0043, which directed staff to begin a rulemaking amending NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury.

In that SRM, the Commission also directed staff to explore approaches to reduce reliance on patient reporting, develop regulatory guidance for all medical events, and also look for opportunities to

accelerate the rulemaking schedule without shortening the public comment periods.

So that brings us to present day and the information request that we recently published. I'll turn it over to Daniel DiMarco to go through that and the preliminary proposed rule language.

MR. DIMARCO: Hi, everyone.

Thanks, Irene.

I'm Daniel DiMarco. I'm a health physicist here on the medical team for the NRC. I'm going to bring you all through explaining some of the things that were asking for in our information request, as well as an overview of some of our preliminary proposed rule language.

Next slide, please.

So this information request that we're talking about right now was published in the Federal Register on April 19, 2023. You can see the Federal Register number is there.

The deadline for comments on it is July 18, 2023. So please be sure to go in and get your comments in through the ways we'll show you later on in the presentation.

This notice made the preliminary proposed rule language for the rulemaking available, as well as

posing a few questions for us to obtain input from stakeholders.

Next slide, please.

I just want to say beforehand the preliminary proposed rule language here does not represent a final NRC staff position, nor has it been reviewed by the Commission. Therefore, this proposed rule language may undergo revision and almost certainly will undergo revision during this rulemaking process.

Specifically, this preliminary proposed rule language includes updates to two sections, 10 CFR 35.2 and 35.3045, as well as the addition of two sections, 10 CFR 35.42 and 35.2042.

Next slide, please.

And that's all in 10 CFR 35. Just to get into it, this is our preliminary proposed rule language, the addition into the 35.2 Definitions section of 10 CFR 35. First, we would like to add these three definitions in there:

Extravasation, which means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue;

Medical attention, which means any techniques used to reduce the chance, severity, or

symptoms of a suspected radiation injury;

And suspected radiation injury, which means a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

Next slide, please.

And so for this information request, we decided to group these questions into three separate topics: one on definitions, one on procedures, and another on healthcare inequalities.

For the next several slides I'll show you our preliminary proposed rule language, as well as any of the questions related to that. And so for this, we have our information request questions related to the definitions. Specifically, we've got these questions here.

Which term should the NRC use -- for example, extravasation or infiltration -- when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?

First of all, I would like to thank the ACMUI. They were here. We presented these questions to them last week at their public meeting, and they gave us a lot of good feedback on we should have used vein instead of blood vessel or artery. That was a

little bit redundant there.

But I do want to say for this question, we wanted to start out basically as simple as we could with this because, at least when I was doing my research for this, extravasation in a medical sense typically involves vesicants, of which there are no radiopharmaceutical vesicants that I know of.

And so when we wanted to ask these questions, we wanted to start with the very baseline of -- we use all of these words very frequently. And so we want to all know exactly what we're talking about regulatorily, but especially for these public meetings and things like that. We all need to know exactly what we're talking about to really have any sort of consensus on what we're getting at.

And so after that we've got, what criteria should the NRC use to define suspected radiation injury? This is kind of the crux of the issue here. How do we make these extravasations reportable? What level should we make them at?

And then afterwards we've got, what techniques or methods should be included in the definition of medical attention? This is very broad intentionally because there are a lot of different techniques that can be used to help mitigate the

chance of severity of these extravasations. And there are ways that these medical techniques interact that we definitely need more input from the stakeholders on.

Next slide, please.

Now that we've gone through the definition questions, I just want to open this up to take questions from the public on this. I want to say specifically we're asking for clarifying questions on these questions.

If there's anything in these questions you don't understand or you want me to clarify a bit more just to help get your comments in more accurately, process your views more accurately, then that's what this time is for.

And I believe, Dan, you've got some process stuff.

MR. FRUMKIN: Yes. Please raise your hand using the hand-raising system. You have the ability to unmute yourself so when we call on you, you will need to unmute yourself.

Please provide your name, affiliation, and your question for the staff regarding the information regarding the April 19th FRN. And at this point, we just want questions for the staff regarding the

definitions.

We have Pat -- I'm sorry -- Zanzonico?

DR. ZANZONICO: That's okay. Yes. This is Pat Zanzonico, Memorial Sloan Kettering Cancer Center in New York City.

It strikes me that the use of the term leakage, which implies basically a passive process, is entirely inconsistent with the use or characterization of an extravasation as a medical event.

Leakage is not something that's caused by a user, meaning the person performing the injection. It's a passive process whereby material within blood vessels is finding its way out of the blood vessels.

It really has nothing to do with what one normally understands to be a medical event. So to my way of thinking, it undermines the entire premise of characterizing extravasations as medical events.

MR. FRUMKIN: Pat, is there a question in there?

DR. ZANZONICO: No, other than that if this is the language that's ultimately used, it's inconsistent with the whole concept of a medical event.

So I don't know if you want to qualify this more specifically to match, I think, the

intention of this change in rulemaking. I think simply the use of the word leakage is incompatible with this rulemaking in general.

MR. FRUMKIN: Okay. Daniel, do you have any comments or clarifications to provide?

MR. DIMARCO: I will say that once we get into the next section, we'll go into some of the actual proposed rule language for where these reportable events will come from.

Just as a quick preview on that, we are not looking for all extravasations to be reportable events, just certain extravasations. But thank you for that comment.

Like we've said before, please put that into the Regulations.gov or a formal comment period to be heard on the rulemaking because these are the good perspectives that we're looking for on this. So thank you.

MR. FRUMKIN: Thank you.

Now we move to Ralph Lieto. Please state your name -- hopefully, I got it right -- affiliation and your question for the staff regarding clarification on the information from the April 19th FRN in the definitions portion.

MR. LIETO: Thank you. My name is Ralph

Lieto. I'm a medical physicist from Michigan.

Regarding the definitions, you may not have the answer to this right now, but it would be helpful to understand the source of these definitions that you're applying to these terms. Did this come out of some national standard from, say, nursing administrations or something from an oncology in terms of chemotherapy administration procedures?

It would have maybe some understanding of -- I think it goes a little bit to the question that Dr. Zanzonico had before, but also maybe trying to understand where you're trying to define in these terms because they seem to have a lot of questions in terms of their clarity.

MR. DIMARCO: Yes. Thank you for that. That was one of the troubles that we've had, especially when determining some of these information request questions. The preliminary proposed rule language in particular was -- we don't want to step on any toes of already-established medical terminology.

But of course, there's always issues with that when we're trying to be as specific as we are with the medical event reporting criteria that we've got. So yes, we will definitely take that into account going forward.

MR. FRUMKIN: The next question is from Daniel Gomez-Cardona. Please unmute yourself, state your affiliation and your question regarding the April 19th FRN, the definition section.

DR. GOMEZ-CARDONA: Thank you. I am a diagnostic physicist, Gundersen Health System in Wisconsin.

My question comes more about what encompasses extravasation and infiltration, which is by basic definition a fluid, and how that would encompass a scenario such as radioembolizations with microspheres, for example. Those are very high doses as well.

Would those be included in this type of proposal as potential issues that would affect the patient? I don't know if you're thinking about considering that.

MR. DIMARCO: That was a topic that was actually brought up by ACMUI recently where the nuclear pharmacist ended up including a bunch of different radiopharmaceuticals that are not administered through a vein or an artery.

And so that's something that we're also thinking about now going forward as to how to encompass the definition for all of those

radiopharmaceuticals that we would like these events to be reported as. So thank you.

MR. FRUMKIN: Thank you for your question.

It looks like we're getting close to the end of the questions here. There's going to be plenty of time to ask questions on the additional topics, procedures, and so forth. If questions do come up on this topic of definitions, those are welcome later in the meeting as well.

So with that, Simon Davies, you can unmute yourself. State your affiliation and clarifying question about the April 19th FRN, definitions.

MR. DAVIES: Yes. My name is Simon Davies. I'm the Executive Director of Team Cancer America, which works to develop programs and services for adolescents and young adults with cancer throughout America. I'm also part of a coalition or federation of efficacy organizations for Patients for Safer Nuclear Medicine.

I just wanted to talk about the use of the term suspected radiation injury and the work that you're going to do on defining that. I think one of the challenges in this is that the late effects of this can be considerably down the line.

And so our advocacy would be for all

incidents to be reported because it can be not clear at the point of the leakage or whatever term ends up being used for that. Injury is inevitable, but there are often cases of people who have radiation late effects, toxic effects some months afterwards.

And so we would advocate for a total reporting of all incidents regardless of a suspected radiation injury for the safety of patients. Thank you.

MR. FRUMKIN: Thank you for your comment. Okay.

Richard Harvey, you can unmute yourself. Please state your affiliation and your questions about clarifications on the definitions.

DR. HARVEY: Hi. Richard Harvey from Roswell Park Comprehensive Cancer Center in Buffalo, New York. I'm also the RSO on the ACMUI.

I'm in a dissenting view on this, but my concern is the last speaker. Reporting every extravasation would be extremely cumbersome and probably would not provide a lot of bang for the buck, so to speak.

Every time we penetrate a vein with an IV injection, you're essentially having some potential leakage of radioactive material. I think that the

NRC's proposed rulemaking where we're looking at those extravasations that could cause injury or potential injury makes more sense, to take a more middle-of-the-road approach.

The actual number of extravasations that you're going to have based on the number of procedures performed would be astronomical or at least very significant. I think suspected radiation injury, like others say, has to be defined clearly.

My understanding is unless we reach 50 rem, we don't have to report that. Is that correct?

MR. DIMARCO: I am not at liberty to discuss any of the specifics right now of what we're looking at for suspected radiation injury. We'll get into that in a little bit more in the next section.

As I said before, this is an information request notice. So nothing is set in stone yet. We're still getting comments from the stakeholders. That's all I can say right now on that.

MR. FRUMKIN: Thank you for your feedback.

We do want to remind folks that -- there was a question there -- we are looking for questions about what was in the FRN. So we can provide some clarity on the FRN.

We don't want to lose this input. That

would be something that we're trying to get as part of the Regulations.gov submittal of comments by the July date.

So these are very important, as Daniel said. And we do want to get that information, but this is a venue now to ask questions of the NRC staff on what was the intent of the language in this FRN.

William Hinchcliffe, you can unmute yourself and ask your question.

MR. HINCHCLIFFE: Hi. William Hinchcliffe. I'm the Radiation Safety Officer for Yale New Haven Hospital.

I'm looking for a little bit of clarity in the definition for medical attention and that it includes any techniques used to reduce the chance of a suspected radiation injury.

Really the question being that anytime you have any suspected extravasation with a radiopharmaceutical, it would be likely you have procedures in line with other pharmaceutical administrations in order to deal with the extravasation. So even if you are not seeing a potential or suspected radiation injury, you would still go through techniques to reduce the impact of that extravasation.

And I don't see how the definition as it exists now wouldn't end up requiring the reporting of all extravasations as long as you did any technique after the extravasation occurred, which you likely would.

MR. DIMARCO: Yes. So that is something that -- we left the medical attention definition intentionally broad to encompass all of those different techniques, either before or immediately after the extravasation for this.

Just to clarify as I probably should have put it in beforehand, in the next section we'll go into the specific reporting requirements themselves that we're looking at, the intention for these reporting requirements. Specifically, that it's not the application of any of these techniques that would be a reportable threshold there.

The reportable threshold itself would have to be determined either by the physician, if they were able to identify that an extravasation had occurred and had a good idea of the characterization of that extravasation, or in a worst case scenario where a patient would have to come back for the treatment of a radiation injury due to an extravasation.

So the level is not specifically at

medical attention. It is not specifically at an injury itself being observed. It would be a level of an extravasation occurring where a radiation injury could in all likelihood occur.

So that's obviously a very ephemeral idea. But that's why we included this information request, so we could nail down that reporting level as best as we could based on stakeholder input.

MR. FRUMKIN: Thank you for that question.

We have two more hands raised. After these two hands, we're going to try to push forward with the procedures section.

Ramsey Kilani, you can unmute yourself and ask your question. State your affiliation as well, please.

DR. KILANI: Hi. Dr. Ramsey Kilani, board-certified radiologist, Chief Medical Officer at Global Security Innovative Strategies in DC.

My question regarding number two is suspected radiation injury by whom? There's been discussion of the medical professionals identifying the possibility of an extravasation and a possible injury, and there's a dose threshold there that's implicit in that.

But I also heard and read in some of the

past commentary that there was a suggestion that a patient should somehow be able to know whether they should suspect a radiation injury. I think that needs to be clear.

MR. DIMARCO: Yes.

DR. KILANI: The latter seems kind of ridiculous.

MR. DIMARCO: Yes. That's part of our procedures section afterwards, but the intention for that is that the actual suspected radiation injury will only be able to be identified by some sort of professional who has the schooling, training, and experience to identify a radiation injury, whether that be an AU or a medical professional.

I've seen in different studies that sometimes dermatologists are called in to deal with these specific radiation injuries. But determining whether or not an injury is induced by radiation is not something that the patient would need to do.

The patient would just need to realize that an injury has occurred. Of course, this is in the worst case scenario that a medical professional or a medical team was completely unaware that an extravasation has occurred.

DR. KILANI: Sure. The point of this is

this is exactly why there's a 50 rem threshold in the rest of the NRC's reporting criteria. As we all know, radiation is insidious.

Often times, the acute effects of extravasation are just based on fluid volume and other things. And the likelihood of a true radiation-induced injury is going to be obscured to even professionals. We don't 100 percent know.

That's why the NRC's job has always been to create thresholds with safety factors built in, so that there's a mechanism to keep people as safe as possible. With that, I'll hold the rest of my comments for later.

MR. DIMARCO: Thank you for that comment. Please do send a comment through the Regulations.gov or other channels because we need to hear that commentary. Thank you.

MR. FRUMKIN: Thanks for your comment and your question.

Before we move on to the procedures section and that rulemaking language, Kathleen Hintenlang, please unmute yourself, ask your question, and state your affiliation.

DR. HINTENLANG: Thank you. I'm Kate Hintenlang. I'm a medical physicist querying on

behalf of the ACR.

And we'd like to know, are there any plans to use existing federal standards for this such as the National Cancer Institute's Common Terminology for Clinical Adverse Events, commonly referred to as CTCAE, which grades adverse event severity based on deterministic effects, if it required medical intervention levels? Thank you.

MR. DIMARCO: In short terms, yes. We have been looking into different medical communities as well as international guidelines on radiation effects to help, I guess, guide our thoughts on these classifications.

MR. FRUMKIN: Thanks for that question.

I'm going to pull back everyone to the same slide. We can move to the next section if that's okay with you, Daniel.

MR. DIMARCO: That's fine by me. Thanks, Dan.

MR. FRUMKIN: All right.

MR. DIMARCO: Okay. So this next section, starting off with some of the preliminary proposed rule language in 35.42. This is an entirely new section of 10 CFR 35, but it's very similar to 35.41, procedures for evaluating and reporting medical

events.

So for this, you can see here that for any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with 35.3045.

These written procedures required by paragraph (a) must address how the licensee determines that an extravasation meets the criteria for a medical event. And the licensee must retain a copy of the procedures written under paragraph (a) in accordance with 35.2042.

My next slide is 35.2042, which is basically completely in line with the 35.2041, where a licensee must retain a copy of the procedures required by 35.42 for the duration of the license. And so this is just to be in line with the rest of our regulations.

Next slide, please.

So here's, I guess, the meat and potatoes of it, the reporting and notification of a medical event where we're adding just one under 35.3045(a)(3),

the administration of byproduct material that results in an extravasation that requires medical attention for a suspected radiation injury. That's where these medical events will be reported under.

Next slide, please.

Going on to some of the questions for that, we've got a couple of slides for questions on this. I will go through all of the questions for these procedures ones, and then at the end open it up again for questions on these questions. Dan will open up these slides so you can move back and forth between them to refresh yourself for a question.

Question 4, what steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring? This is something that was not specifically asked by the Commission in the SRM, but something that we wanted to get more input on from the stakeholders.

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

What techniques, technologies, or procedures -- for example, post-treatment imaging, visual observation of the patient, or getting more patient feedback during the injection -- should be used to help identify an extravasation during or

immediately after a radiopharmaceutical injection?

Next slide, please.

Question 7, which techniques, technologies, or procedures -- post-treatment imaging or survey measurement, for example -- should be used to better characterize an extravasation immediately after radiopharmaceutical treatment?

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?

This is something that could be done before or during the treatment to help prime the patient for if there is any feelings that are going wrong during the treatment to help identify these extravasations as soon as possible.

The next question, when should a reportable extravasation be counted as discovered for the purposes of notification; for example, when medical attention is administered, when the physician identifies that the injury is from radiation?

In our regs we have very strict guidelines on identification of medical events and specifically when those notifications need to come out. So we would like more information on that specifically for

extravasations.

Next slide, please.

Like in this question where the NRC requires that the licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after the discovery of said medical event.

So when should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual who had been extravasated?

This next question harkens back to a previous question. Who -- for example, the patient's primary care physician, any authorized user, a nuclear medicine technician -- which, as a side note, thank you again to the ACMUI for correcting us on this. That should be nuclear medicine technologist, not technician. Who should be able to identify an extravasation that could result in a suspected radiation injury?

And then finally, what topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report these extravasation events in a timely manner?

Guidance is something that we are

currently writing for this. And so with this proposed rule, there will be guidance on how to report all of these extravasations depending on where we come down on that reporting criteria.

And so I believe this is the last question in the procedures section of it. I'll send it back over to Dan to field questions from the public.

MR. FRUMKIN: Yes. Please raise your hand and we can call on you. The slides are free. If you have a question about a specific question, let us know. We can bring people who are following me back to that slide.

With that, Pat?

DR. ZANZONICO: Yes. Pat Zanzonico, Memorial Sloan Kettering Cancer Center in New York City.

My perception about most of these questions, but in particular 4 through 6, is that they're well beyond the scope of regulatory oversight. This really is intruding, in my opinion, into medical practice, into how patients are managed and so forth, which obviously is an issue between the patient and the patient care team.

This is more of a question than a comment, but perhaps it could help in recasting these

questions. They just seem to delve far more into medical practice than regulatory issues typically do. I will just leave it at that.

MR. DIMARCO: Thank you for that comment. The answers to these questions specifically in this section of the FRN will likely be used to beef up any of the guidance, as well as any suggestions for procedural parts of that for specifically the guidance section of that.

A lot of these will not be going into rulemaking language themselves, but thank you again for your comment. Yes, thank you.

MR. FRUMKIN: Please use the Raise Hand feature on your screen. If you're unable to raise your hand, you can use the chat.

Jim from Patients Rising, you can unmute yourself -- I believe that's your affiliation; you can correct me -- and ask your question for the staff regarding clarifications of information on the FRN on the procedures section.

MR. SLINEY: Thank you very much. I see some language here that's encouraging as far as keeping the burden of identifying the problem and reporting the problem on providers and clinicians.

I think it really needs to be clear -- I

noticed in item 8 and item 10, there seems to be a little bit more burden put on the patient to make these identifications. I feel like the rulemaking, which was based on the petition for rulemaking and rulemaking plan on reporting nuclear medicine, was not -- it's somewhat flawed and incomplete, perhaps biased.

I think that any decisions that put an inappropriate burden on patients to identify that they have a problem or what to do about it if they think they may have a problem, which any of us who have been a patient before -- they're likely not to do anything about.

Oh, I have a bruise on my arm. No big deal, but that could be a big deal. How is the patient supposed to know that? So I think that the burden needs to put more on the professionals who know the difference. I think that the NRC should really think about that.

It's unacceptable to place that burden on patients. What is an extravasation and what do I do about it? That's my point. Thank you.

MR. DIMARCO: Thank you for that.

MR. FRUMKIN: I guess if I don't hear a question I'll just assume it's a comment. And please,

we are looking for all of these things as part of our outreach. We're going to talk about that at the end of the presentation, how to provide the input.

Daniel, if there's a question there that I missed, please cut me off.

Ramsey Kilani, please state your affiliation and your question about the clarification about the FRN.

DR. KILANI: Yes. Dr. Ramsey Kilani, GSIS in DC. I have a dissenting opinion from my esteemed colleague from New York regarding the validity of these questions.

With respect to radiopharmaceuticals and frankly, radiation that the public encounters in general, it is the job of the NRC to get involved. And so I don't think saying that this is the NRC regulating medical practice really holds a lot of water when you're talking about radiopharmaceuticals.

That's a special case. And there's a reason there's a separate regulatory body. So that's my only comment on that.

MR. FRUMKIN: Thank you for your comment.

With no hands raised, folks, please raise your hand or you can unmute yourself. There are some comments coming through the chat from Ron Parsons and

Xander Arena.

Please, we would like you to go on audio and ask those comments. If you can't, I can read them, but please ask me to read them in the chat so that we know that's what your intent is. Otherwise they won't be in the record.

Dr. Helen Nadel, you can unmute yourself and ask your question about the FRN's section on procedures. And state your affiliation, please.

DR. NADEL: Yes. Dr. Helen Nadel, Lucile Packard Children's Hospital at Stanford. You just asked us to unmute to ask a question.

My question is about -- I'd like to see the first slide. And I may have a question after that. It's the Information Request Questions. My question is -- actually, could I see 1 to 3, please? Okay.

For question 2, what criteria should the NRC use to define suspected radiation injury, will there be a numerical value put to that? There were some numerical values in the past rules that were there. And I just wonder if that could be clarified, please.

MR. DIMARCO: As of right now, we are not putting a numerical value on that. That may change

depending on the comments received from stakeholders.

So if you have an opinion one way or another whether or not there should be a numerical value on that, please comment on this information request. That would be very helpful.

DR. NADEL: Thank you. We will. Thank you.

MR. FRUMKIN: This is a question from the chat from Xander Arena. Using an Endoline catheter with positive blood return and multiple successful flushes is typically adequate. Suspected infiltrations should be imaged to determine the extent of extravasation.

That appears to be a comment, but now it's on the record.

MR. DIMARCO: Thank you for that. I'll take that as that's an example of a technology or technique that we would like to know about. That would answer some of these questions. So thank you.

MR. FRUMKIN: Attendees, please raise your hand and unmute yourself. If you have a comment in the chat you want us to read, let us know that as well. We have a few more sections, but I believe this is intended to be the largest section of the meeting. If I get a head nod from Daniel on that, that would

be -- okay, good.

Richard Harvey, please unmute yourself. And please share your question about the FRN.

DR. HARVEY: Yes, just a comment to go along with the previous comment. Dr. Richard Harvey, Roswell Park Comprehensive Cancer Center.

We image all of our patients after they have treatments with Pluvicto or Lutathera. So I think if you miss an extravasation upon administration, that's a useful way of maybe detecting that extravasation or infiltration of the radiation dose.

So just a comment to build on a comment from before. Thanks.

MR. FRUMKIN: I'm not seeing additional comments. Why don't we just go to the next session?

One question here. Has there been data gathered about injection techniques in relation to extravasation? In my career, I have noticed many facilities still do straight needle sticks. This is from Ebony M. Bush.

MR. DIMARCO: Yes. There certainly are studies out there, whether or not they're specific to radiopharmaceuticals. There are more on the chemotherapy and contrast CT side of things. As for

just injection quality in general, I'm not particularly well versed in the studies on that.

MR. FRUMKIN: If there are studies that you're aware of, please provide them as part of the comment period.

Next question, Simon Davies. Please state your affiliation and your question on the April 19th FRN procedures section. You can unmute yourself at any time.

MR. DAVIES: Simon Davies, Team Cancer America and also the Patients for Nuclear Safety. On that last point really, and I'm not sure whether it's covered because we can't see all the questions at once.

I think that actually a question from the NRC about what training and technology should be used -- training the staff in preparation for injecting radioactive fluid and also technology that's used because there is some technology, I understand, that can make the procedure safer, vein finding technology, et cetera.

So I wonder whether that should be one of your questions, if it's not already embraced in one of the questions you already asked.

MR. DIMARCO: I believe it is.

Dan, if you want to go back one slide, I believe that would -- I guess another slide back.

That would be encompassed in question 6, techniques, technologies, and procedures to help identify extravasations.

MR. DAVIES: Thank you for that. I just wasn't sure. Thank you.

MR. DIMARCO: Yes. Thank you.

MR. FRUMKIN: Before we get to William, Jim from Patients Rising, did we get your full name? If you can unmute and let us know.

MR. SLINEY: Sure. My full name is Jim Sliney, Jr., Executive Director of Patients Rising.

MR. FRUMKIN: Thank you.

William Janes, please state your affiliation and your question about the FRN after you unmute yourself.

DR. CHACKO: I'm sitting here at -- William Janes actually is my colleague and I'm sitting by him. My name is George Chacko. I'm an MD board-certified in nuclear medicine. I practiced nuclear medicine in Oklahoma for many decades. I've been administering radioisotopes to patients.

The thing is that if you have a pure beta-emitting isotope, how would you image it is my

question if there's an extravasation. You can't image it with conventional imaging devices. So I think I just wanted to bring that to the attention of the NRC.

That's a question of -- you would have to just look at what happens post-extravasation. Is there sloughing of the skin, some damage there? You really can't image it if it's a pure beta-emitting isotope that's been used. That's my comment.

MR. DIMARCO: Thank you for that. I may take some time on that. That's part of the reason why we're trying to be more agnostic on some of these questions, especially because we've seen a lot of public interest in pure alpha emitters for radiopharmaceutical therapy.

Like you said, pure beta emitters, things that don't have any gammas, as well as the increase in theranostics. There are a wide variety of radiopharmaceuticals out there on the market and more are coming every day.

So we would like to have as wide a range of technologies to deal with these extravasations because it's obvious that there's not a one-size-fits-all Band-Aid for this. That's why we're trying to cast as wide a net as we can, to see all of the different technologies that should be available to

help deal with these extravasations.

So thank you. And if you have any more comments on that and any technologies that could help with that, please put it in a response for this information request FRN.

MR. FRUMKIN: You can raise your hand, unmute yourself, or ask for a comment in the chat to be read. If we don't get something, we can move on to the next section. Maybe that will encourage new ideas. We can take questions from any of the three parts after that section as well.

Daniel, if you're ready, we will advance to the third section.

Ralph, hand up or hand down? You'll have an opportunity to ask questions at the end of this section. So thank you.

MR. DIMARCO: Yes. Okay. So on to the last two questions for our information request questions.

Just a little bit of background on why we're asking about these healthcare inequities. We've heard from patient safety groups some concerns about inequities in the healthcare community, and so we would like to ask for input from everybody on how this rulemaking specifically can help effectively address

these concerns.

So our 13th question, which regulatory actions could help ensure that the extravasations in patients affected by healthcare inequities are accurately assessed and reported?

And are vascular access tools and other technologies, such as ultrasound-guided vein finders, likely to reduce the potential for an extravasation in all patients, however particularly patients of color?

This is an import topic. We believe that the NRC could get some good information to help address these in this rulemaking. So we would like to take the opportunity to get more information from stakeholders on these questions.

I believe that's all I've got. I'll kick it back over to Dan to take questions.

MR. FRUMKIN: There's a citation from Jim of Patients Rising for Sensing Technologies for Extravasation Detection: A Review, which was published March 13, 2023. So that's also now on the docket.

And Josh Knowland is asking, what pharmaceuticals are pure beta emitters? I think that gets into the question of the tools.

MR. DIMARCO: Yes. None that I know of, but I don't have a comprehensive list of all

radiopharmaceuticals that are being used or produced.

Like I said, there are more coming online every day. There are constant new radiopharmaceuticals being produced and used. So we want to be a little bit more forward-thinking with our regulations here.

I see a few hands up. I'll send it back to you.

MR. FRUMKIN: Dr. Helen Nadel, please state your affiliation and your question regarding any part of this FRN.

DR. NADEL: Hello. Dr. Helen Nadel, Lucile Packard Children's Hospital at Stanford.

I'm not sure that it was in any of what you presented today, but can you define suspected radiation injury for me? What is suspected radiation injury? I'm asking a question about one of your questions.

MR. DIMARCO: If you could go back, Dan, to the proposed rule language?

MR. FRUMKIN: This one?

MR. DIMARCO: Yes. So suspected radiation injury, at least in this preliminary proposed rule language -- like I said before, this may change depending on public comment and has not gone up to the

Commission for any sort of review. Currently, suspected radiation injury is defined as a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

DR. NADEL: Daniel, I'm sorry I don't know your last name. It only comes up as Daniel D. In your first comment, as you started to speak you mentioned that by definition no radiopharmaceutical was a vesicant.

Assuming that this would be a deterministic health effect, would you say that this would be a deterministic health effect that you would be looking for as a sign of radiation injury?

MR. DIMARCO: I'm sorry. I don't think I understood the question.

DR. NADEL: It says you want a deterministic health effect.

MR. DIMARCO: Yes.

DR. NADEL: So my question to you would be, what is a deterministic health effect that would be from a suspected radiation injury? And you had already mentioned just as you began your discussion back in the beginning that radiopharmaceuticals are -- I believe it was you that said radiopharmaceuticals

are not vesicants.

MR. DIMARCO: So I'll go from the first question to the last one on that. My intention with the comment that radiopharmaceuticals are not vesicants -- if I'm misinformed, I apologize.

It was my understanding that vesicants typically operate under a chemical reaction for those types of injuries. Things such as chemotherapy drugs are typically more vesicants than radiopharmaceuticals where the method of injury is different there.

And so for your second question, or I suppose your first question on the deterministic health effect, one of the lower levels of deterministic health effect that we're looking at as a possible limit for this reportable event would be erythema of the skin specifically due to radiation.

There's obviously complications there where -- before I've said vesicants and other physical processes can result in erythema of the skin, but whether or not that would be radiation induced is where we're thinking that the limit for this reporting would be.

Did that answer your questions?

DR. NADEL: I think you answered your own question to say that erythema of the skin is likely

not a deterministic effect that could be attributed to specifically radiation from a radiopharmaceutical injection, as just any intravenous cannula insertion without anything injected could cause erythema of the skin.

MR. DIMARCO: Yes. Thank you. That is where the complications from this arise and that is why we're asking for more information from stakeholders on this. So thank you.

MR. FRUMKIN: All right. Let me jump back to the section we're in. We are getting some comments here.

Let me read this one from the chat from Josh Knowland. Based on emitted energies, skin injury may not be likely even though significantly higher dose affects the underlying tissue. I think that gets to the previous comment.

MR. DIMARCO: Yes. And that's why we didn't say specifically to the skin in any of our definitions. It was just the area around the injection site.

MR. FRUMKIN: Richard Harvey, you may unmute yourself and ask your question about any part of the FRN questions.

DR. HARVEY: Thank you very much. Dr.

Richard Harvey from Roswell Park Comprehensive Cancer Center.

Just to reiterate and point out, the vast majority of these nuclear medicine injections that might lead to extravasations are not going to cause injury. We're not going to have deterministic effects from those. The concern really is for some of the theranostic therapeutic procedures that are becoming much more commonplace now.

I think it's important to point out that diagnostic injections of radiopharmaceuticals are not likely to cause these injuries. You have to have a cutoff, I think, somewhere on what you want to include as a medical event in the regulations and in the rulemaking. So thank you.

MR. FRUMKIN: Jim Sliney, Patients Rising, you can unmute yourself.

MR. SLINEY: Yes. Jim Sliney, Jr., from Patients Rising once again. I'm commenting on the healthcare inequities section, items 13 and 14.

I feel like the best way to ensure that people are not treated equitably is to let them leave the site without being screened afterwards because this puts them back into the environment in which they may not feel comfortable speaking with their doctor,

may have difficulty accessing transportation to get reevaluated, and so forth.

So it seems to me that the fairest way to do this to make sure that no patients are overlooked is to have some kind of cautionary screening at the end of a potential extravasation event. Thank you.

MR. FRUMKIN: Ralph Lieto, please unmute yourself, state your affiliation, correct my pronunciation, and ask your question about the FRN.

MR. LIETO: Thank you. My name is Ralph Lieto. I'm a medical physicist from Michigan.

I have a couple of questions going back to your procedures questions and a clarification. Did you state that these questions were generated from staff, or were any of these questions generated from the Commissioners' SRM, or both?

And could you kind of maybe clarify which were specifically Commissioner-generated questions about procedures?

MR. DIMARCO: Was there another question there? I don't want to cut you off.

MR. LIETO: Yes. I've got a couple of other ones, but different areas.

MR. DIMARCO: Okay. I can answer that one quickly then. These questions were all developed by

staff based on the Commission SRM. So I guess the answer is a bit of both for all of them.

MR. LIETO: Okay. And again under the procedures, you're asking about techniques, technologies, and so forth that are available to address extravasations or prevention and so forth, but nowhere do I see any concern or question raised about the cost or the practical availability of these technologies being a consideration.

Just the fact that something's available does not necessarily mean that in a community hospital setting it's going to be able to be purchased or even widely implemented across the area of injections.

So I think that needs to be a very important consideration going forward in questions that are answered because just because you think something's available doesn't necessarily mean it is, especially with the cost of healthcare and technologies being what they are.

When you're talking about you're going to have to implement something just to address some potential, I think you're going to find that medical facilities are going to start to consider, is this something that we even want to do. And that is definitely going to be harmful to the patient and to

healthcare.

So that's a statement. You don't need to respond to that, but that is definitely something I want to ask that NRC staff look at going forward in addressing these questions under procedures.

My last point is under healthcare inequities. I think this is a big overreach by the NRC. The NRC is not a healthcare agency and nowhere in their charge or scope inequities of health care part of their charge.

That's the practice of medicine. Whether something is appropriate to be administered or whether something is appropriate to be followed up as a result of clinical indication, that's the practice of medicine.

Nowhere, especially number 13 in terms of regulatory actions, should there be anything there that would be addressing the, quote, inequalities or inequities of administering this type of healthcare. That's my last statement. Thank you.

MR. DIMARCO: Thanks for those comments. I know you didn't say to respond to it, but I do want to respond to your second one.

To help alleviate that, one of the things that we're developing for this rulemaking is a

dosimetry model to help with the characterization of the extravasations. That will be part of the appendix of the guidance documents that we will eventually produce for this rulemaking. So thank you.

MR. LIETO: Quick follow-up question to that?

MR. DIMARCO: Yes.

MR. LIETO: So in looking at this, are you looking at also the cost and practicality of implementing this at just a technologist level?

MR. DIMARCO: I believe those discussions will come in with the --

MR. LIETO: A lot of what's being done out there and presented -- that's great if you have medical physicists on staff to either reference or consult with. But where most of this nuclear medicine is done at the community hospital, it's basically authorized user technologist level.

I think that gets lost a lot in what is done in terms of NRC putting forth not only guidance but regulations. Thank you.

MR. DIMARCO: Thank you for that comment.

MR. FRUMKIN: Thank you for that comment. And please provide your feedback through the Regulations.gov information we're going to provide.

I would like to read this question from Josh Knowland. Josh, if you could also provide your affiliation in the chat.

To the comment about diagnostics not being able to cause injury, what is that based on? Is it deterministic injury based on dose? Diagnostics including positron emitters can actually result in a dose of multiple gray.

That was in the chat. Josh, if you could provide your affiliation, that would be appreciated as well. He's from UT Knoxville.

Mary, I'm going to not pronounce your name properly. Mary, could you please unmute yourself, provide your name and affiliation, and a question about any part of the FRN?

MS. AJANGO: Yes. Mary Ajango, Young Survival Coalition and Patients for Safer Nuclear Medicine. I have a comment about the patient reporting and reportable extravasations.

The NRC is responsible for ensuring the protection of public health and safety regarding the handling of nuclear medicine materials in healthcare settings. The agency provides reasonable assurance of adequate protection by establishing regulations and enforcing compliance with those regulations.

According to a recent admission by the NRC, at least 28,000 patients are extravasated every year, which would exceed the agency's current medical event reporting requirements. But the proposed rulemaking to address this lack of protection regarding extravasations doesn't help.

According to the NRC's own estimates, the new patient injury reporting criterion is expected to result in approximately 80 medical events reported annually, which is about 0.28 percent of the estimated 28,000 occurrences of large extravasations.

So one of the main issues with self-reporting is that many patients may not even realize they have experienced it. And if centers are not actively monitoring, they won't be able to tell patients when one has happened.

Symptoms may not be immediately apparent and patients may not know what to look for. This is particularly worrisome for low-literacy educated patients.

And then even if the patient is informed of symptoms and recognizes signs, they may not report it to their healthcare provider or know what to do next. Thank you.

MR. FRUMKIN: Thank you for your comments.

Pat Zanzonico, please state your affiliation and provide your comments or questions.

DR. ZANZONICO: Yes. This is Pat Zanzonico again, Memorial Sloan Kettering Cancer Center in New York City. I just wanted to follow up on the comment by Ralph Lieto.

I think an additional question that I know you're asking specifically about is what, if any, unintended adverse consequences of universal screening for extravasations may that entail?

And by that I mean, I think it would inevitably reduce patient throughput in a busy clinical setting, as well as require additional equipment and staff costs, and so forth and so on.

So whatever the presumed benefits of screening for extravasations may be, I think it is important to recognize that there is at least a potential downside in terms of cost, patient throughput, availability of tests, and so forth and so on.

And if anything, those may have an unintended consequence of lesser availability of, for lack of a better term, high-tech imaging modalities in under-served communities. So I think it would be worth including a question to that effect explicitly

among the questions that are being proposed.

MR. FRUMKIN: I think the intention at this point would be we're asking you to provide that feedback in response to one or more of the questions that are here. Then we can consider that in the proposed rulemaking. And if I'm wrong, somebody correct me.

With that, Carmine Plott, you can unmute yourself, state your affiliation, correct my pronunciation, and ask your question about the FRN.

DR. PLOTT: Hi there. This is Carmine Plott. I work for Forsyth Medical Center in Winston-Salem, North Carolina. I am the Radiation Safety Officer for multiple nuclear medicine facilities in our community.

As an agreement state, I know I rule making process, but I don't understand with regard to NRC. And this to piggyback on the gentleman who just spoke and Ralph Lieto.

Are you required to actually do a financial impact statement or analysis as part of this rulemaking?

Because in addition to the technologies that are available with regard to proactively assess potential extravasations, while I agree that some of

the suggestions for follow-up are excellent suggestions such as imaging to actually consider the extent of the extravasation, you do need to include the financial impact of delayed imaging and whether or not you have a patient who cooperates and is willing to return to the department to actually characterize the half-life or the movement of that radioactivity from the site of injection.

You also have to consider -- for example, you mentioned technologist training. Granted, if you want to require them to undergo annual training, phlebotomy training, or whatever, there's going to be costs associated with that.

And like those gentlemen, I'm concerned that particularly in under-served communities that nuclear medicine -- unfortunately, because of the potential costs associated with it, I just hope that they're willing to continue to offer services.

Again, I fully support the idea for the theranostics, the therapeutics, simply because they require a written directive. And if you deviate from a written directive from the authorized user, of course follow-up is required. But to have a proactive approach to this, I'm just curious about the financial impact to licensees.

So my question is, are you required to actually do such an impact statement or analysis for such rulemaking?

MS. WU: Hi, Carmine. This is Irene Wu with the NRC. I'll jump in. I was going to touch upon this in some of the ending slides with the next steps.

Yes, our rulemaking package which we are working on for the proposed rule will include a draft regulatory analysis. So that includes the cost and benefit piece that you were talking about.

MR. FRUMKIN: And we have a lot of resources about our rulemaking process on the public website.

With that, Kathleen Hintenlang, you can unmute yourself. State your affiliation and we will hear your question about the FRN.

DR. HINTENLANG: This is Kate Hintenlang, a medical physicist querying on behalf of ACR.

So a follow-up to Carmine, Pat, and Ralph, if NRC is asking which steps may be clinically justifiable for each individual radiopharmaceutical product, are there any plans to consult with drug manufacturers, FDA, standards organizations, creditors, payers, and public health agencies? Thank

you.

MR. DIMARCO: I guess I can answer that one. At least on the technical side, yes. We're definitely getting information from as many sources as possible, which includes the FDA and our other federal partners as well as other stakeholders for that.

MR. FRUMKIN: Richard Harvey, you can unmute yourself, state your affiliation, and ask your question about the FRN.

DR. HARVEY: Thank you. Dr. Richard Harvey, Roswell Park Comprehensive Cancer Center. I have a few things.

The first is regarding our imaging. We image the same day that the patient has the dose administration. It's part of the procedure so we don't have to have somebody come back later.

If you miss an extravasation, you may be able to find it on imaging that day, which is part of the procedure. So you don't have to inconvenience the patient to have them come back.

The comment regarding my comment about diagnostic extravasations, if you look at the activities of diagnostic radiopharmaceuticals, their half-lives, those characteristics, where tissue reactions or radiation dose health effects or

biological effects occur, you're not likely if at all to see any tissue reactions from diagnostic injections of radiopharmaceuticals.

As Dan pointed out, there are always new things that are coming down the pipe. So could there be something like that in the future?

In 32 years, I've never seen diagnostic administration of a radiopharmaceutical ever cause a radiation injury or tissue reaction. So I just wanted to comment on that for -- I think it was Josh Knowland.

And I do strongly believe that extravasations are a very important quality assurance issue that need to be handled at each site, each facility, where it's incumbent upon us to get the radiopharmaceutical into the vessel so it can be used for its intended purpose. I just don't think that adding this as a medical event is really going to make that process any better.

It's incumbent upon us to make sure that we deliver this radiopharmaceutical properly, adequately, and mitigate any steps that occur. If we don't, we're not doing our job as a provider and we're not helping our patients.

I respect the NRC's position and everyone

else. Again, as I've stated before, I think where this could become an issue is when you get those theranostic type of therapeutic radiopharmaceuticals that may result in tissue reactions. But to include this for all radiopharmaceuticals injected is just not really going to improve anything in any way.

So I'll stop there. Thanks.

MR. FRUMKIN: Thank you for your comment.

Ramsey Kilani, you can unmute yourself, provide your affiliation, and ask your question on the FRN.

DR. KILANI: Ramsey Kilani, GSIS. I think -- and I've forgotten the name of the person now. If you can go back to the proposed terminology, the slide with the red writing? That there.

The challenge here is that as this is currently written here, suspected radiation injury, the only criteria you can really use to suspect a radiation injury particularly right after an injection, which is when you have a chance to do something about that, would be to use a dose threshold.

There is no other practical way to suspect a radiation injury immediately after an injection. So I think injection site dosimetry is an obvious way to

determine that.

I would respectfully say to my colleagues, I think that there are probably many, many extravasations in nuclear medicine that go undetected period because we're not looking. And there is the downstream thing, which has not been brought up here. We're focused on the local effect of the extravasation.

The other problem with dumping, say, 90 percent of your dose into the arm instead of into the vessels is that when the computers auto-level -- I'm speaking in layman's terms -- when the computers auto-level the image data for interpretation, if you don't know there was an extravasation, that can be done in a way that can actually alter your diagnostic interpretation. There are a lot of papers out there that show this.

So to act like it's not an important issue, I think number one, is a little bit disingenuous. And number two, to act like there's a way other than a dose threshold to assess this, I think, is also not well thought out.

And then thirdly, where else in radiology or in any other part of a hospital where IVs and other sticks are happening all the time would they accept an

extravasation or bad IV rate of up to 23 percent, as Ms. Wu reported earlier in the literature? That isn't even close to the standard.

So I suspect that if we had mechanisms to track this and report it, what will happen over time, as has happened in the rest of medicine, once we start tracking something and having to report it, we get a lot better at it.

And so the idea that training technologists is too expensive is laughable, frankly. It's too expensive to protect patients with something that's as simple as just training people how to be better at IVs? I don't feel like I can get behind that.

MR. DIMARCO: Thank you for that comment. I know we've been talking a lot about the questions on this one and getting comments on the questions, but I do want to remind people that we've put all of this preliminary proposed rule language in the FRN.

And please feel free to comment on the proposed rule language in your specific comments through the Regulations.gov, the mail-in, or anything like that. We're taking all comments, not just the ones that comment specifically on the questions of the preliminary proposed rule language. So thank you.

MR. FRUMKIN: Tracy King, please unmute yourself, and provide your affiliation and your question on the FRN.

MS. KING: My name is Tracy King. I'm a medical physicist in the Midwest with Medical Physics Consultants, with 36 years of experience consulting to community-based hospitals in nuclear medicine, X-ray, and radiation oncology.

I do have a question, but first I'd like to say I do agree strongly with Carmine about the issues she raised.

Secondly, my question is on question number 14. You identified a class of patients as being particularly vulnerable, I guess, or likely, but you failed to address several other classes of patients where extravasations tend to be more common. Those are the obese patients, patients who have had chemotherapy, and also small children, infants.

My last comment would be -- well, not my last. My second to last comment would be an example of how over-regulation is detrimental to patient safety. This is a great example.

You can have situations where you have two or three technologists working. And you have a patient come in who looks to be a difficult injection.

A senior technologist says, I'm not going to ruin my record of having no medical events or no NRC reports. You go do it. The newest person gets shifted.

That maybe isn't something you like to think about, but in reality that is a possibility. And also, as Carmine said, facilities may decide not to do procedures in order to avoid NRC violations. And we have seen that in nuclear medicine over the past 30 years.

My last comment is dose threshold on paper sounds very good but calculating that dose from an extravasation, or as we more commonly call it a sub-Q in nuclear medicine, is very difficult and requires patient-specific biological data to look at the clearance of that material, the volume of tissue involved.

Even with Versant and Lucerne's technology that they have available, I still question the accuracy of that dosimetry. Thank you very much.

MR. DIMARCO: Thank you for those comments. Just to regard your second comment there, it was not our intention to not include anyone else in these healthcare inequities.

Another that I've seen in studies are patients that are dealing with chemotherapy treatments

as well as radiopharmaceutical treatments. Typically the chemotherapy has a measured impact on vascular access. And so the intention there was not to leave out anyone there.

If you have any comments on any of these patients, on any of these different classes of healthcare inequities, please put that in your comments for the information request.

MR. FRUMKIN: Xander Arena, you can unmute yourself and provide your affiliation, please, and ask your question on the FRN.

MR. ARENA: Hello, everybody. Nuclear medicine technologist and an associate radiation safety officer at a large medical facility. These comments and my question are not reflective of my organization's position on the matter.

The question to the NRC, has the NRC considered substituting the word leakage for infiltration since infiltration is a more active process and leakage more passive? Potentially you could use both words, extravasation and then infiltration as the event that might be worth paying closer attention to?

MR. DIMARCO: Yes. The intention of our first question was to get information from

stakeholders, people who are more familiar with the actual processes themselves, for a more accurate definition of what we're looking at.

If you have a comment on that, please put it in our Regulations.gov or any of the other ways to comment on this rulemaking.

MR. ARENA: I'll put it in there. Just to add a few comments, I think reporting diagnostic infiltrations frankly, as others have opined, would be onerous.

Our radiologists, for example, in PET/CT can read through an infiltration of FDG. They look at the target SUVs, the background SUVs on liver. It's relative. It's a relative update.

So even if there is a fraction in the arm, they can still get diagnostic information from the exam. When we don't observe ill effects from those sorts of tracers, theranostics, I think it's a wise approach to consider a package like this.

Allowing facilities to come up with their own action plan as far as how they're going to address and protect their patients -- we all want to protect our patients. That should be implicit. But to leave it up to the facilities to determine that, I think, is a good position to take.

The other thing is that I read the proposal that initiated this rulemaking. Some of the proposed mechanisms, like the device that monitors flow from one arm to the other, that doesn't stop an infiltration. It can't stop it.

The infiltration is done by the time the device picks it up. So you're really not preventing anything by making this device be strapped to somebody's arm for every exam.

I think that the process of adding those extra steps and other sorts of things, and reporting and other things, as others have mentioned, would cause such a slog in the work flow of busy clinical settings and impact patient care adversely.

Those are my comments on the proposed rulemaking with respect to theranostics. It makes sense. You have a written directive. You have a target tissue. You want to get a certain amount in there. And if you didn't achieve that target, then it's probably a worthwhile medical event. That is all I have to add for the session. Thank you.

MR. DIMARCO: Thank you for that comment.

MR. FRUMKIN: Thank you for the comment.

There's a couple of comments in the chat. If we don't get any more hands raised, we'll move on

to the next section.

Josh Knowland, who provided that he's affiliated with Lucerno Dynamics, talked about 15 microcuries of a positron emitter in 5 ccs of tissue would be a significant dose and you're not likely to see it on the skin. I think we talked about that as well.

Brian Fairchild of Harry Truman Memorial Veterans' Hospital in Columbia, Missouri. I know my states. Other patients of concern for extravasation due to difficulty finding veins are patients with extensive tattoos at common IV injection sites. That was similar to what Daniel was referring to with cancer patients, obese patients, children, and the other commenter.

MR. DIMARCO: Yes. These are -- sorry. I just want to say these are all great comments. And even though it may seem a little redundant, please reiterate these through the comment period on this because I want these to be in the Register for us to look at for going forward with this comment period.

MR. FRUMKIN: And with that, I was using the comments in the chat to try to encourage that. But I really want people to be raising their hands and asking questions.

I think we can move on to the next section. Irene, if you would provide your insights on the preparing comments. We'll have more opportunity for questions and comments about everything that preceded.

So with that, Irene?

MS. WU: Yes. Okay, thanks. Thanks, Dan.

This next section is to really drive that point home about how you can prepare and submit the comments. We've heard a lot of great feedback in the meeting so far. We want to make sure that that's all on the record.

Even though we're transcribing this meeting for our public meeting summary, the formal way of getting those comments on the record, as has been said multiple times already, is to get those submitted in the different ways that are outlined in the FRN. I'll go through that shortly.

Next slide, please.

I just wanted to provide some quick tips on preparing your comments. Regulations.gov has a great document on their website that includes tips for submitting effective comments. You should be able to click on that link there. The link is also available in the slides. You can also access that document when

you're going in and submitting your comments through Regulations.gov.

I really urge you all, as you have been giving us feedback during this public meeting, to really go through the questions that we asked in the information request, look to answer those questions in the FRN, and comment on the preliminary proposed rule language. That will really help us as we move forward in developing the proposed rule package.

Next slide, please.

All right. You've heard this already but I'll reiterate it again. We've got these three methods for submitting comments. The information request Federal Register notice that was published back on April 19, 2023, again, has a 90-day comment period.

The three methods are to either submit your comments through Regulations.gov and go to our specific docket, which is on the screen, Docket ID NRC-2022-0218. You can submit a comment that way.

You can also email us with your comments via Rulemaking.Comments@nrc.gov. And lastly, if you prefer, you can always mail us your comments to the address on the slide and also listed in the Federal Register notice.

Again, I'll just try to drive the point home one more time. We really appreciate hearing all of your feedback during this meeting. But again, since this meeting isn't the venue for collecting comments to get on the record, please formally submit those comments using the methods that are on this slide and in the FRN.

All right. Next slide, please.

Okay, next steps. The public comment period for the information request ends on July 18, 2023. We will be considering all of the comments we receive from you all on the information request in our development of the proposed rule.

What comes next is the proposed rule is currently estimated to go to the Commission in the August 2024 time frame. Before it goes to the Commission, staff's going to be working on putting that rulemaking package together, getting it ready, and going through our internal review.

That rulemaking package not only has a Federal Register notice but it'll also include that draft regulatory analysis that I mentioned a little earlier with the cost and benefits in it, the draft environmental analysis, and a Commission paper.

And then after the proposed rule goes to

the Commission, the Commission will still have to vote and provide direction to the staff in a staff requirements memorandum, or SRM, before we can actually publish the proposed rule for notice and comment in the Federal Register.

When we do publish that proposed rule, it will also include getting comments on the draft regulatory analysis and the draft environmental analysis. And we'll also be making available for comment the implementation guidance as well. That is currently estimated for December of 2024.

Next slide, please.

Okay. That's the end of my presentation and talking about the next steps. I think at this time we wanted to give the public one more opportunity to ask any questions and provide us with your feedback on everything that's been discussed so far, not just the last bit on how you can submit comments on the rulemaking process.

If you thought more about the background of the rulemaking, any of the preliminary proposed rule language, or questions that were part of the information request, this is your last opportunity during the public meeting to ask your clarifying questions.

I will turn it over to Dan, our facilitator, to help facilitate this portion of the meeting.

MR. FRUMKIN: Thank you. And I have been watching the chat for questions.

If you have questions that you can't unmute yourself for, please let us know. This meeting is intended to get questions for the staff about the FRN.

Simon Davies, you can unmute yourself. Please state your affiliation and ask your question.

MR. DAVIES: Thanks again for the time. Simon Davies, Executive Director at Team Cancer America and a member of the Patients for Safer Nuclear Medicine.

I just wanted to say a point that we felt very strongly about in terms of feedback for you. We felt the Commission decision which led to the rulemaking was actually based on a flawed document with inaccurate, incomplete, and biased information. So we thought your starting point wasn't great.

Having said that, I applaud you for many of the questions that you've raised. The way in which you've structured this, I think, is very helpful.

I do want to just reiterate a point that I

think has been largely accepted. I've heard it come up a couple of times. The idea of patients self-reporting being the standard, I think, is quite unacceptable and ridiculous, especially when patients don't know what some of the effects might be when they might come up later. So we think that's really important to us.

In our view, the improvement of the monitoring, the training, and the technology will actually massively reduce extravasations. And we think that it will also improve equity because particularly, as has been stated, there are financial challenges for organizations.

If you reduce extravasations then you would reduce the late effects. And actually, that's going to be cheaper, not more expensive. We think that this is a useful investment.

We do want to just raise the point that if you have another type of nuclear accident and you have to report it, it could be less harmful than an extravasation. And yet here we are saying that something intravenous might not be reported.

That just seems an absurd inequity when you think about the other type of reporting for spills, et cetera, that the NRC has made it their

business to monitor and report on. Thank you.

MR. FRUMKIN: Thank you for your feedback.

Please raise your hands, unmute yourself, and ask your questions. The slides are free for navigation, so you can also see the contact information and acronyms at the end or navigate throughout the slide deck.

Gina Kell Spehn, you can unmute yourself, state your affiliation, and ask your question. You're unmuted on our side.

If anybody else has a question, raise your hand or unmute yourself and ask your question.

DR. CUTLER: Hi. This is Cathy Cutler. I'm from Brookhaven National Laboratory. I also have a leadership role in the Society of Nuclear Medicine.

I was curious because you had indicated that you have developed a dose model. Has that been put out and looked at by people outside of the NRC to comment on?

MR. DIMARCO: I can answer that. Not yet. It will be though. It's still currently in development.

This is something that we'll have with the guidance document that will be going out. So it's currently in development, but there will be a time for

people to see what it is.

MR. FRUMKIN: You may raise your hand or unmute yourself.

There's a question in the chat from Kathleen Hintenlang. Is the NRC planning to review national standards at the institutional level, Q&A practices to ensure that any regulation or guidance on these topics does not impose upon existing IV practices?

MR. DIMARCO: I can answer that. The NRC is not regulating IV access or any of that, vascular access. The intention of those questions is just for other sorts of procedures of best practices for things that we can wrap into our guidance.

And so I would hope that we would get information that would be harmonious with current IV practices or better to help with these vascular access problems. On the strictly regulatory side, we're not interested in regulating vascular access at this time.

MR. FRUMKIN: Ralph Lieto, please provide your affiliation and ask your question.

MR. LIETO: Thank you. Ralph Lieto, a medical physicist from Michigan.

A question for -- probably this is for Irene and the other NRC staff. Is this proposed

rulemaking an absolute, shall I say, going to happen type of a thing?

Or based on responses to these questions and procedures, is there the potential for something other than a medical event reporting methodology being possible to be implemented for licensees? And a follow-up question on that also.

MS. WU: Yes. Thanks for the question. We're going to be taking all of the feedback that we get.

We're going to take all of the comments that we receive from this information request to help inform our development of the proposed rule. We'll also take into consideration the direction that we got from the Commission.

What we put up to the Commission as part of the proposed rule package, the Commission will look at what the staff recommends as well as alternatives. And it'll be up to them to decide which direction they would like us to proceed with.

So I think there's still definitely some room for this to change as we are informed by stakeholder comments.

MR. LIETO: Okay, just a last statement. Having been involved with medical event reports and

their analysis over many years, medical event reporting is not a process of proven mechanism. I think that there are definitely better avenues to go about addressing this issue and improving patient care and safety without medical event reporting.

So again, thank you. I appreciate all you guys have done, and taking comments and responding to everybody today.

MS. WU: Thank you.

MR. FRUMKIN: Thank you for your feedback.

William Hinchcliffe, please give us your affiliation and ask your question.

MR. HINCHCLIFFE: Thank you. William Hinchcliffe, Radiation Safety Officer at Bridgeport and Yale New Haven Hospital.

I just wanted to reiterate a little bit. I know the concerns already brought up initially by Pat Zanzonico and reiterated more recently by Kathleen on behalf of ACR, but I do share the concern of the questions, especially 4 through 8, in terms of the practice of medicine in the NRC.

I know, Daniel, you have already discussed not incorporating into regulation but rather soliciting information to include in guidance. Again, I caution that guidance can often be incorporated

during the licensing process into licensees' commitments, and therefore sort of translating that guidance into requirement.

So just stating that and adding to it. Thank you for clarifying that you're soliciting it for guidance, but it does not really diminish my concern.

MR. FRUMKIN: I come from the reactor side, but generally the guidance is to support a regulation. The guidance doesn't stand alone without something attached to it.

Is that accurate, Daniel?

MR. DIMARCO: I would say that that's accurate. That's actually something that's been brought up in the working group, not having the guidance set too far into being regulations. Guidance in name only; regulations in spirit.

And so that's something that we're well aware of and we're trying to stay in the forefront of. The answers to these questions will definitely help us with that. So thank you.

MR. FRUMKIN: Bryan Lemieux, I believe. Please unmute yourself and provide your affiliation.

MR. LEMIEUX: Bryan Lemieux. I'm a medical health physicist from Kentucky commenting on my own behalf.

I wanted to echo the comments of one of my physics colleagues earlier on regarding the accuracy of the dosimetry models. In an ideal world, good dosimetry would be indicative of biological end-point and biological harm.

We know, however, even when we know the dose fairly accurately for cutaneous skin injury from fluoroscopic X-rays and other cases that the biological responses that are actually seen is widely variable, even at very large doses at 15 gray, 20 gray, 10 gray. So just a grain of salt in terms of how accurate is the dosimetry.

I have looked at the Knoxville tool. It's model-based dosimetry, right? If we're evaluating patients in-clinic for clearance, we're looking at clearance from site. That's the early clearance. Is there a pharmaceutical sticking there?

We know that there's differences in clearance from the site in different pharmaceuticals. We don't necessarily know unless we're doing very specific imaging what the 3D distribution is doing in that tissue over time.

And so really, to get truly accurate dosimetry is a non-trivial challenge. We can get some idea. I think that's what Dr. Harvey kind of was

alluding to on some level. Where do we focus our efforts for the greatest avoidance of patient harm and where do we focus our efforts for protecting the most people?

That's why a lot of times our attention is the theranostics, the therapies, the written directives. These are the things that are most likely -- not that it isn't theoretically possible to cause injuries from a diagnostic injection. I think there's one or two cases, maybe three reported in the literature over the last ten or 15 years. There's certainly a paucity of them, but it's possible. That's why we think that.

I wanted to segue that into another issue. The theranostics stuff is really taking off. Unfortunately, I logged in a little late so I didn't know -- while NRC is considering how to regulate this and how to look at how licensees manage this for the safety of patients, and particularly as we're looking at higher risk procedures, one of the things to consider is the growing volume and the growing numbers of sites and organizations that we'll be looking at doing these sort of theranostics procedures.

Things like Pluvicto, there's a lot of different places that want to start doing them outside

the major academic medical centers that have that infrastructure, that physics support, and things like that.

So that's something that the regulatory community, if you are making these things, you have to think about that as well, in addition to how this pushes out to those community hospitals, how this pushes out to those smaller licensees that do not have the physics infrastructure and that may not have 3D imaging to be able to take a spec scan on a patient after they do a Pluvicto injection.

They might only have a planar camera. Or it may be an oncologist's office that wants to do Pluvicto and they want to do a license, but they don't even have a camera. They're just going to do a parenteral administration. Or they want to do Xofigo at an oncologist's office and there's no imaging equipment there. You can't image.

So there's a lot of complexity there that I would hope the NRC would consider in the dosimetry guidance, in how you roll out this regulation, and in how you consider licensees' ability to adapt their programs to protect patient safety and also come up with some sort of meaningful solution to this. Thank you.

MR. FRUMKIN: Thank you for your feedback.

It does look like we have a queue of questions, but I would like to take a five-minute break now. Let's see if I get a nod from some folks and take five minutes. We've been going at this for two hours. We will go all the way to 4:00 if need be, if that's where the questions take us.

So let's just take a break now. You can leave your hands raised and we will get to them in order. We'll see you all at 3:07, by the time on my computer.

(Whereupon, the above-entitled matter went off the record at 3:02 p.m. and resumed at 3:07 p.m.)

MR. FRUMKIN: Thank you for returning to our public meeting.

Tracy King, if you are there, you can unmute yourself, provide us your affiliation, and ask your question on the upper end.

MS. KING: Thank you. My name is Tracy King. I'm with Medical Physics Consultants.

My question is when will the dosimetry model that you've referred to be available?

MR. DIMARCO: So not the actual coding itself, but the model will be there -- I believe by the end of the summer is what the schedule is for

that. The dosimetry model itself in its full form will be released with the guidance document that we'll be releasing with the proposed rule.

MS. KING: Okay, next question then. Have you considered that dosimetry model may likely show that only therapeutic agents need to be considered? And if so, that will drastically affect the comments.

So should we maybe extend this comment period until that dosimetry model that the licensees could use is actually available for peer review?

MR. DIMARCO: The dosimetry model itself will just be the tool. We're not intending for it to be part of the regulation itself. And so the licensees themselves and the stakeholders affected by this are free to use it if they want to, but it will not be a requirement to use that.

MS. KING: However, it's likely the only tool that many community hospital licensees have at their disposal. So much like in the other NRC regulatory guides for patient release, they give us the models to use, the calculation, the equation to use.

I think we need that before we can accurately assess the affect of this proposed regulation on the practice of nuclear medicine. Thank

you very much.

MR. FRUMKIN: Thank you for your comment.

Michele Egberts, you can unmute yourself -- you've done that already -- and state your affiliation.

MS. PANICHI-EGBERTS: Hi. My name is Michele Panichi-Egberts. I am the radiation safety officer for several outpatient theranostic facilities, as well as a couple of imaging facilities.

My concern is will we be required to somehow investigate every administration for extravasation or only those that we suspect there is leakage? Like the gentleman two speakers ago said, there is no way that we can image anything.

Let me just tell you. It's more common than not these are going to be administered in urology clinics as well as radiation oncology therapy centers, which there is no imaging involved. So just saying, that's who these manufacturers are targeting at this point in time, not hospitals.

MR. DIMARCO: I believe the question in there was on the requirements.

MS. PANICHI-EGBERTS: Will we have to investigate every one?

MR. DIMARCO: Yes. The requirements for

those -- our medical event reporting regulations do not require monitoring of any procedures.

MS. PANICHI-EGBERTS: So only when we suspect that there is an extravasation do we look into it?

MR. DIMARCO: I can't say what the procedures would be for any specific medical facility. Hopefully, our guidance documents will help the medical facilities comply with our regulations. But at least at this stage of the game, we're still in the pre-proposed rule stage. So I can't comment on what any medical facility will do.

MS. PANICHI-EGBERTS: I'm not saying what we would do, but what we would be required to do.

MR. DIMARCO: I can't comment on what that requirement would be at this stage.

MS. PANICHI-EGBERTS: Okay. Thank you.

MR. FRUMKIN: Thank you for your comment.

Gina Kell Spehn, thank you for coming back and giving us another chance. You can unmute yourself and ask your question. And state your affiliation too, please.

MS. KELL SPEHN: Hi. Thank you. Sorry about that earlier. I'm not sure what happened. I'm not sure how far I got in my comments. I'm with New

Day Foundation for Families and I'm with Patients for Safer Nuclear Medicine.

My comment today, first of all, I want to reiterate what one of the callers mentioned earlier, which is that the Commissioners' decision which led to this rulemaking is based on a flawed document with inaccurate, incomplete, and biased information. And so I just want to preface my comments with that.

While acknowledging that the reporting exemption for extravasations is no longer supportable, you're initiating a rulemaking that would place responsibility for identifying a radiation safety-significant extravasation on the patient. And that's not an improvement.

So we want to make sure to mention that. We're asking patients to detect radiation injury when clinicians themselves often disagree on how injury should be identified.

And we're asking patients to monitor themselves for months or even years while they're waiting for an injury to present itself rather than proactively emphasizing the need for providers to identify and mitigate extravasations when they occur. There is only one way to interpret this staff requirement, and that is that the patient's voice

matters less to you than the industry voice.

So not only is the decision to put the burden on the patients wrong, but now that you know that many patients are being exposed to high tissue doses when they receive extravasations, nothing has changed for today's nuclear medicine patients.

Technologists are going on LinkedIn. They're complaining that patients are asking about extravasations.

Leaders in nuclear medicine are no different. The radiation safety officer representative on the ACMUI thinks that facilities who accidentally inject large amounts of radiation into a patient's tissue instead of the vein shouldn't have to report this as a medical event.

And I thought that medical event reporting was designed to ensure that accidents that result from human error, lack of quality procedures, or lack of training that then expose patients to high doses of radiation are supposed to be investigated, shared with the patient and their physician and with the NRC.

My question is, is an accidental injection of a large dose of radiation into a patient's tissue not the exact situation of some combination of these things that are human error, lack of training, or lack

of quality procedures?

So instead of relying on subjective assessments of the patients and instead of delaying a correction for a couple more years now in the rulemaking process, we're asking the NRC to simply reaffirm the objective criteria that is used to identify as in any other medical event.

To help patients right now, we're asking NRC to immediately issue interim guidance on just three points. One is that the patient must be informed when they've experienced a radiation safety and procedure-significant extravasation. We think this is a basic patient right to have this information.

They need to know as soon as it happens to mitigate tissue damage and do what needs to be done to hopefully help them. They must be informed of how much radiation has entered their tissue so that they can better understand the impact to their procedure and care as well.

Number two, patients must be provided with simple written information to help identify symptoms of extravasation injuries. And they must know when these symptoms might appear because often times there are no immediate visible symptoms of underlying tissue

injury.

Finally, we would ask that patients receive written instructions from their providers explaining where to go and who to talk to if they experience symptoms. This is necessary to ensure that their suspected radiation injury is in fact reported to the NRC.

This is something, like I said, that we're hoping to have immediate interim guidance while we're waiting for these rulemaking decisions to come through. Thank you for your time.

MR. FRUMKIN: Thank you for your comments. Irene provided all the information for submitting this in the Regulations.gov or other means.

The next question is Richard Harvey. You can unmute yourself, state your affiliation, and ask your question.

DR. HARVEY: Yes. Hi again. Dr. Richard Harvey from Roswell Park Comprehensive Cancer Center. I don't think I'm representing ACMUI on this, so I'm speaking as an individual.

Just to clarify the last comment, yes. I don't believe that these extravasations need to be classified as medical events. I believe that they should handled at the institution level because it's a

very serious concern.

I just don't want anyone to think that I don't think this is a serious issue. I think it's a very important quality assurance issue that needs to be resolved at that level. People need to identify extravasations when they occur, at the time of administration, or I would recommend when they perform imaging afterwards. I understand not everyone does perform imaging.

So I think it's very important to identify this, mitigate it, and then provide the patient with everything that they need. And again, it should be identified at that time, not put on the patient. I don't think the intent here is for anyone to put this on the patient.

I think this should be these extravasations need to be identified on the day of administration. So I just wanted to clarify my position on that. Thank you.

MR. FRUMKIN: Thank you for your comments.

If people have more questions for the staff on the FRN, please raise your hand or unmute yourself and speak up. It looks like we're winding down. If I don't see anything in a couple of moments, we will open it up for Irene to provide some closing

remarks.

Irene?

MS. WU: Okay. If you can go to the next slide, I can provide some contact information and resources.

Again, here are the main contacts for this rulemaking. I've also included a link to our extravasations rulemaking public website, as well as the overall NRC rulemaking process website to help you stay connected with us on this rulemaking.

And then lastly, if you'd like to provide us some specific feedback on this public meeting, we used to provide forms. Now you just have to go and click back to the public meeting notice where you got the information to click into this meeting.

There should be a new link there that was added where you can click on it and provide feedback to us. That's separate. That's more feedback on the public meeting itself versus providing us comments on the questions and the preliminary proposed rule language in the FRN.

I will see if Kevin is still on the line. Maybe he can do some closing remarks as we bring this meeting to a close.

Kevin, are you still on?

MR. WILLIAMS: I am still on. Thank you.

I'd like to thank everybody for their contributions. I'll start with -- I'll get his name right this time -- Daniel, thank you for facilitating. Both Daniels, actually.

Daniel, thank you for addressing the questions and walking us through this.

And Irene, thank you for setting this up and being able to take us through the process of what we're going to be doing here.

As we have stated, the importance of providing good feedback is going to help make the process better. So we thank all of you who engaged us in meaningful conversation here. It will help to inform our process as we navigate through the next steps.

We appreciate everyone's comments. And as stated, please make sure that you do submit your comments as has been outlined in this process. I know there will be another opportunity as we go through here to comment on the rule itself. We will engage appropriately.

I really want to appreciate all of the energy that's around this and the high level of engagement that was demonstrated by you all. So thank

you for your participation. Thank you for all who had a hand in bringing this meeting together.

We really appreciate the feedback that we get, and really appreciate the staff for the opportunity to come in and meet with everyone to ensure that we have a well-informed product. So thanks to everyone.

I'll turn it back to Daniel.

MR. FRUMKIN: Not hearing any more comments and having heard some closing remarks, the slides are available online. The feedback form and rulemaking interfaces are all available.

With that, we will close the meeting. Thank you all for your participation.

(Whereupon, the above-entitled matter went off the record at 3:21 p.m.)