

**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

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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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.

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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

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GINA KELL SPEHN, New Day Foundation for Families

PAT ZANZONICO, Memorial Sloan Kettering Cancer

Center

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

1:00 p.m.

1  
2  
3 MR. FRUMKIN: Good afternoon, everyone,  
4 and welcome. My name is Dan Frumkin. I'm going to be  
5 your facilitator for today's meeting. Good afternoon  
6 for those on the East Coast, Central Time. And  
7 Mountain, I guess it's still morning, maybe.

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

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

17 This meeting is not intended to collect  
18 comments. And although it will be transcribed,  
19 statements made during this meeting are not  
20 automatically included in the rulemaking docket. The  
21 purpose is to encourage attendees and stakeholders to  
22 provide feedback using the means discussed in the FRN.

23 That's feedback on the rulemaking.

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

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

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

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

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

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

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

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1 feedback be provided during the audio portion of the  
2 meeting.

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

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

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

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

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

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

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

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

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

17 With that, Kevin?

18 MR. WILLIAMS: Thanks, Dan.

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

25 Next slide, please.

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

5           By way of background, on December 12th of  
6 2022, the Commission approved the staff's  
7 recommendation to amend 10 CFR 35 to include certain  
8 nuclear medicine extravasations as medical events.

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

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

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

25           The comments we receive in response to

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

3 Next slide.

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

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

14 I now turn the meeting over to Irene Wu.

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

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

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

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

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

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

24 MR. FRUMKIN: Can you hear me?

25 MR. WILLIAMS: Dan, can you hear?

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

3 Go ahead, Irene.

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

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

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

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

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

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1 Next slide, please.

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

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

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

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

25 And the probability of an extravasation

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

7 Next slide, please.

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

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

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

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

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

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

11 And then ACMUI after their review agreed  
12 with the staff's recommendation during their September  
13 2021 public meeting. The Adams Accession number for  
14 that public meeting by ACMUI is ML21267A021.

15 Next slide, please.

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

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

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

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

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

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

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

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1 accelerate the rulemaking schedule without shortening  
2 the public comment periods.

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

7 MR. DIMARCO: Hi, everyone.

8 Thanks, Irene.

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

15 Next slide, please.

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

20 The deadline for comments on it is July  
21 18, 2023. So please be sure to go in and get your  
22 comments in through the ways we'll show you later on  
23 in the presentation.

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

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

3 Next slide, please.

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

11 Specifically, this preliminary proposed  
12 rule language includes updates to two sections, 10 CFR  
13 35.2 and 35.3045, as well as the addition of two  
14 sections, 10 CFR 35.42 and 35.2042.

15 Next slide, please.

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

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

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

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1 symptoms of a suspected radiation injury;

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

6 Next slide, please.

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

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

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

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

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1 little bit redundant there.

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

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

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

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

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

5 Next slide, please.

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

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

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

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

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

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1 definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

19 MR. FRUMKIN: Thank you.

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

25 MR. LIETO: Thank you. My name is Ralph

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1 Lieto. I'm a medical physicist from Michigan.

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

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

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

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

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1                   MR. FRUMKIN: The next question is from  
2 Daniel Gomez-Cardona. Please unmute yourself, state  
3 your affiliation and your question regarding the April  
4 19th FRN, the definition section.

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

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

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

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

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

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

3 MR. FRUMKIN: Thank you for your question.

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

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

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

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

25 And so our advocacy would be for all

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

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

10 MR. FRUMKIN: Thank you for your comment.

11 Okay.

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

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

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

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

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

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

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

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

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

20 MR. FRUMKIN: Thank you for your feedback.

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

25 We don't want to lose this input. That

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

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

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

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

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

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

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

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

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

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

25           So the level is not specifically at

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

5 So that's obviously a very ephemeral idea.

6 But that's why we included this information request,  
7 so we could nail down that reporting level as best as  
8 we could based on stakeholder input.

9 MR. FRUMKIN: Thank you for that question.

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

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

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

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

25 But I also heard and read in some of the

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

5 MR. DIMARCO: Yes.

6 DR. KILANI: The latter seems kind of  
7 ridiculous.

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

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

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

25 DR. KILANI: Sure. The point of this is

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

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

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

14 MR. DIMARCO: Thank you for that comment.

15 Please do send a comment through the Regulations.gov  
16 or other channels because we need to hear that  
17 commentary. Thank you.

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

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

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

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1       behalf of the ACR.

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

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

14                  MR. FRUMKIN: Thanks for that question.

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

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

20                  MR. FRUMKIN: All right.

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

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1 events.

2 So for this, you can see here that for any  
3 administration in which an extravasation can occur,  
4 the licensee must develop, implement, and maintain  
5 written procedures to provide high confidence that an  
6 extravasation that requires medical attention for a  
7 suspected radiation injury will be detected and  
8 reported in a timely manner and in accordance with  
9 35.3045.

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

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

22 Next slide, please.

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

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

5 Next slide, please.

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

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

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

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

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1 immediately after a radiopharmaceutical injection?

2 Next slide, please.

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

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

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

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

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

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1           extravasations.

2                       Next slide, please.

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

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

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

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

25                      Guidance is something that we are

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

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

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

13 With that, Pat?

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

17 My perception about most of these  
18 questions, but in particular 4 through 6, is that  
19 they're well beyond the scope of regulatory oversight.

20 This really is intruding, in my opinion, into medical  
21 practice, into how patients are managed and so forth,  
22 which obviously is an issue between the patient and  
23 the patient care team.

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

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1 questions. They just seem to delve far more into  
2 medical practice than regulatory issues typically do.

3 I will just leave it at that.

4 MR. DIMARCO: Thank you for that comment.

5 The answers to these questions specifically in this  
6 section of the FRN will likely be used to beef up any  
7 of the guidance, as well as any suggestions for  
8 procedural parts of that for specifically the guidance  
9 section of that.

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

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

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

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

25 I think it really needs to be clear -- I

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

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

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

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

23 MR. DIMARCO: Thank you for that.

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

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

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

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

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

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

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

22 MR. FRUMKIN: Thank you for your comment.

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

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1 Xander Arena.

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

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

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

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

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

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

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1 depending on the comments received from stakeholders.

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

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

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

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

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

20 MR. FRUMKIN: Attendees, please raise your  
21 hand and unmute yourself. If you have a comment in  
22 the chat you want us to read, let us know that as  
23 well. We have a few more sections, but I believe this  
24 is intended to be the largest section of the meeting.

25 If I get a head nod from Daniel on that, that would

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1 be -- okay, good.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. DIMARCO: I believe it is.

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

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

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

8 MR. DIMARCO: Yes. Thank you.

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

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

14 MR. FRUMKIN: Thank you.

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

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

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

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

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

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

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

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

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1 help deal with these extravasations.

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

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

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

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

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

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

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1 these concerns.

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

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

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

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

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

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

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

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1 radiopharmaceuticals that are being used or produced.

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

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

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

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

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

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

21 MR. FRUMKIN: This one?

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

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

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

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

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

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

19 MR. DIMARCO: Yes.

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

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1 are not vesicants.

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

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

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

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

23 Did that answer your questions?

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

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

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

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

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

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

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

25 DR. HARVEY: Thank you very much. Dr.

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1 Richard Harvey from Roswell Park Comprehensive Cancer  
2 Center.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 healthcare.

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

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

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

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

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

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

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

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

7 MR. DIMARCO: Yes.

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

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

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

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

22 MR. DIMARCO: Thank you for that comment.

23 MR. FRUMKIN: Thank you for that comment.

24 And please provide your feedback through the  
25 Regulations.gov information we're going to provide.

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

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

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

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

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

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

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

7           According to the NRC's own estimates, the  
8 new patient injury reporting criterion is expected to  
9 result in approximately 80 medical events reported  
10 annually, which is about 0.28 percent of the estimated  
11 28,000 occurrences of large extravasations.

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

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

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

25           MR. FRUMKIN: Thank you for your comments.

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

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

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

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

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

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

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1 among the questions that are being proposed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 you.

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

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

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

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

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

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

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

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

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

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

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

25 I respect the NRC's position and everyone

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

7 So I'll stop there. Thanks.

8 MR. FRUMKIN: Thank you for your comment.

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

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

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

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

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1 determine that.

2 I would respectfully say to my colleagues,  
3 I think that there are probably many, many  
4 extravasations in nuclear medicine that go undetected  
5 period because we're not looking. And there is the  
6 downstream thing, which has not been brought up here.

7 We're focused on the local effect of the  
8 extravasation.

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

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

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

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

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

9 And so the idea that training  
10 technologists is too expensive is laughable, frankly.

11 It's too expensive to protect patients with something  
12 that's as simple as just training people how to be  
13 better at IVs? I don't feel like I can get behind  
14 that.

15 MR. DIMARCO: Thank you for that comment.

16 I know we've been talking a lot about the questions  
17 on this one and getting comments on the questions, but  
18 I do want to remind people that we've put all of this  
19 preliminary proposed rule language in the FRN.

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

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

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

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

12 Secondly, my question is on question  
13 number 14. You identified a class of patients as  
14 being particularly vulnerable, I guess, or likely, but  
15 you failed to address several other classes of  
16 patients where extravasations tend to be more common.

17 Those are the obese patients, patients who have had  
18 chemotherapy, and also small children, infants.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           MR. DIMARCO: Thank you for that comment.

23           MR. FRUMKIN: Thank you for the comment.

24           There's a couple of comments in the chat.

25           If we don't get any more hands raised, we'll move on

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1 to the next section.

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

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

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

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

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

6 So with that, Irene?

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

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

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

19 Next slide, please.

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

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

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

10 Next slide, please.

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

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

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

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

8           All right. Next slide, please.

9           Okay, next steps. The public comment  
10 period for the information request ends on July 18,  
11 2023. We will be considering all of the comments we  
12 receive from you all on the information request in our  
13 development of the proposed rule.

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

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

25           And then after the proposed rule goes to

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

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

12 Next slide, please.

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

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

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

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

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

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

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

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

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

25 I do want to just reiterate a point that I

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

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

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

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

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

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1 business to monitor and report on. Thank you.

2 MR. FRUMKIN: Thank you for your feedback.

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

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

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

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

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

20 MR. DIMARCO: I can answer that. Not yet.

21 It will be though. It's still currently in  
22 development.

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

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1 people to see what it is.

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

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

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

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

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

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

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

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

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

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

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

16 What we put up to the Commission as part  
17 of the proposed rule package, the Commission will look  
18 at what the staff recommends as well as alternatives.

19 And it'll be up to them to decide which direction  
20 they would like us to proceed with.

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

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

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

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

9 MS. WU: Thank you.

10 MR. FRUMKIN: Thank you for your feedback.

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

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

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

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

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

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

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

11 Is that accurate, Daniel?

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

17 And so that's something that we're well  
18 aware of and we're trying to stay in the forefront of.

19 The answers to these questions will definitely help  
20 us with that. So thank you.

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

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

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

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

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

18 We know that there's differences in  
19 clearance from the site in different pharmaceuticals.

20 We don't necessarily know unless we're doing very  
21 specific imaging what the 3D distribution is doing in  
22 that tissue over time.

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

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

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

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

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

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

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

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

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

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1 MR. FRUMKIN: Thank you for your feedback.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 you very much.

2 MR. FRUMKIN: Thank you for your comment.

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

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

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

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

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

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

25 MR. DIMARCO: Yes. The requirements for

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

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

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

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

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

17 MS. PANICHI-EGBERTS: Okay. Thank you.

18 MR. FRUMKIN: Thank you for your comment.

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

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

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

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

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

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

19 And we're asking patients to monitor  
20 themselves for months or even years while they're  
21 waiting for an injury to present itself rather than  
22 proactively emphasizing the need for providers to  
23 identify and mitigate extravasations when they occur.

24 There is only one way to interpret this staff  
25 requirement, and that is that the patient's voice

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1 matters less to you than the industry voice.

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

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

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

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

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

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1 of quality procedures?

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

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

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

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

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1 injury.

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

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

12 MR. FRUMKIN: Thank you for your comments.

13 Irene provided all the information for submitting  
14 this in the Regulations.gov or other means.

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

18 DR. HARVEY: Yes. Hi again. Dr. Richard  
19 Harvey from Roswell Park Comprehensive Cancer Center.

20 I don't think I'm representing ACMUI on this, so I'm  
21 speaking as an individual.

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

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1 very serious concern.

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

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

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

20 MR. FRUMKIN: Thank you for your comments.

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

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1 remarks.

2 Irene?

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

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

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

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

22 I will see if Kevin is still on the line.

23 Maybe he can do some closing remarks as we bring this  
24 meeting to a close.

25 Kevin, are you still on?

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

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

5 Both Daniels, actually.

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

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

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

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

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

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

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

8 I'll turn it back to Daniel.

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

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

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

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