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NUCLEAR REGULATORY COMMISSION

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OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

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STAFF EVALUATION OF TRAINING AND EXPERIENCE

REQUIREMENTS FOR RADIOPHARMACEUTICALS:

DRAFT APPROACHES FOR COMMENT

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THURSDAY,

MAY 23, 2019

The public comment meeting was convened by teleconference, at 10:00 a.m., Sarah Lopas, Facilitator, presiding.

NRC STAFF:

SARAH LOPAS, NMSS, Facilitator

MARYANN AYOADE, NMSS

CHRIS EINBERG, NMSS

IAN IRVIN, OGC

ALSO PRESENT:

JASPREET BATRA, Johns Hopkins University

SAMUEL MAHGEREFTEH, Nuclear Medicine Residents Organization

MICHAEL PETERS, American College of Radiology

JOHN WITKOWSKI, United Pharmacy Partners, Inc.

C-O-N-T-E-N-T-S

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

10:03 a.m.

OPERATOR: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's call. At that time if you would like to ask a question, please press *1.

Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the meeting over to Ms. Sarah Lopas. You may begin.

MS. LOPAS: Hi. Good morning, everybody. Welcome to the NRC's public meeting or webinar to accept comments on the staff's draft approaches regarding training and experience requirements for different categories of radiopharmaceuticals.

My name is Sarah Lopas and I am the project manager for the training and experience evaluation. I'll be facilitating today's webinar and running the webinar, and I'll be giving a portion of the presentation.

I'm joined here by my supervisor Chris Einberg who is the Chief of the Medical Safety and Events Assessment Branch in the NRC's Office of Nuclear Material Safety and Safeguards; Ian Irvin, who's a lawyer from our office of general counsel; and Maryann Ayoade, who is a health physicist on the NRC's Medical Radiation Safety Team and the technical lead on the training and experience evaluation. Thanks for joining us today.

So we have a short agenda. In a moment I'm going to hand it over to Chris to give a welcome and purpose. I'm going to run through some webinar information. Then myself and Maryann will go through the slide set. And I'm going to cover just a very brief background on the T&E evaluation. Maryann will go through the draft approaches. And then we'll open it up to your comments. The rest of the time will be for your comments on the record.

So now I'm going to hand it over to Chris Einberg to talk about the purpose of today's webinar.

MR. EINBERG: Okay. Thank you, Sarah.

Yes, and good morning, everyone. Thank you for taking the time to attend today's webinar. Today's webinar is the second of two public comment meetings that the NRC is holding on the staff's draft

approaches regarding training and experience requirements for administering radiopharmaceuticals requiring a written directive.

The purpose of this webinar is to provide you with an updated status evaluation on the training and experience under Subpart E of 10 CFR Part 35 to discuss the draft approaches regarding the training and experience requirements that the staff are currently considering and then to listen to and record your comments on those draft approaches.

Before we get into the rest of the staff's presentation, I wanted to provide some context as to why the NRC decided to open a second public comment period and hold two additional meetings.

Back in the late fall of 2018 and through January 2019 the NRC conducted an initial public comment period on the staff's plan and evaluation of training and experience requirements for radiopharmaceuticals requiring a written directive. The staff reviewed and processed all the comments received during that time, whether they are captured in transcripts from the public meetings or submitted as written comments using regulations.gov.

Based on the feedback received and the sentiment from the public comments the staff formed

some preliminary ideas on how the staff could address the Commission's direction to evaluate whether it makes sense to create tailored training and experience requirements.

Some of the preliminary ideas, which we are calling draft approaches, go beyond creating a limited training and experience pathway or certain pathways for certain categories of radiopharmaceuticals. For instance, some of the staff approaches are more performance-based and would then prescribe a set number of hours of training and experience.

We thought that some of the draft approaches were different enough from what was discussed during the initial public comment period that it would be helpful for everyone if we had a second public comment period to introduce and talk about those draft approaches and get early feedback from the medical regulatory community. And that's why we're here today.

The comments we receive today and throughout the rest of the comment period will help shape the approaches we would include in our upcoming paper for the Commission. We will include comment summaries in our paper so that the Commission will be

informed on stakeholders' positions and the training and experience requirements.

So I want to thank you once again for participating in today's webinar and I'll turn it back over to Sarah.

MS. LOPAS: Thank you, Chris.

So just some general information. A PDF of the presentation and a copy of the May 2nd *Federal Register* notice that we're going to be referencing a lot today is attached to your webinar. It's under the handouts tab of your webinar. If you're not logged into the webinar, you can also get those slides from the meeting notice that was published for today and also the NRC's Training and Experience web site. So if you just Google NRC training and experience evaluation, that -- the first result that comes up is our web site that I maintain. And then our public meeting notice, you can just Google NRC public meetings and you can find today's notice that way.

As most of you are probably familiar, we refer to training and experience often as just T&E. And the same thing goes for authorized users. We say AU a lot. So you'll hear T&E and AU today.

Today's webinar is being transcribed by a court reporter so we can accurately capture your

comments for the docket, and the transcript of this webinar will be publicly available in about one week. I'll be posting a link to the transcript on the NRC's Training and Experience web site that I must mentioned. And I'll also be posting it to the docket site for T&E on regulations.gov.

So already the transcript from May 14th is available in both of those locations, so if you want to find the May 14th transcript. And I will be producing a meeting summary in the next day or two from the May 14th meeting. So look for that as well.

And then I wanted to also just note that oral and written comments have equal weight, so if you speak up today, you don't need to submit them again in writing via regulations.gov. You're welcome to do so, but it's not a requirement.

On this next slide, slide 6, I just want to begin by reminding everybody that when we talk about T&E, we're talking about the requirements specified under Subpart E of 10 CFR Part 35. And Subpart E specifically covers unsealed byproduct material that requires a written directive, or that may be commonly referred to as therapeutic radiopharmaceuticals. So when Maryann starts to go through our draft approaches, these draft approaches

applies to specifically to Subpart E.

So the NRC's T&E regulations under Subpart E at 10 CFR 35.390 provide three ways that a physician can authorized user to administer radiopharmaceuticals requiring a written directive. They can be board-certified by one of the NRC or Agreement State-recognized medical specialty boards.

They can complete something that we call the alternate pathway, which is specified under 35.390(b)(1). This involves 700 hours of total T&E, which breaks down to at least 200 hours of classroom and laboratory training plus another 500 hours of supervised work experience. This alternate pathway also requires preceptor attestation.

And then the third way is to be grandfathered by a previous NRC or Agreement State license.

So I've highlighted that middle bullet, the alternate pathway, because that's why we're here today and that's what we're evaluating.

Since the T&E regulations were revised in 2002 and 2005, the NRC has received several instances of feedback from the medical community stakeholders that the 700-hour requirement is overly burdensome, that doctors who want to treat their patients with,

for example, patient-ready radiopharmaceuticals are unable to do so because they can't leave their practices for that length of time to complete the 700 hours of required T&E.

The stakeholders contend that because the NRC's alternate pathway is discouraging non-nuclear medicine and non-radiation oncology doctors from becoming AUs, the T&E requirements are creating a shortage of AUs in this country. Some of the stakeholders also point out the disparity in patient access to therapeutic radiopharmaceuticals in the more rural parts of our country.

So over the years the Commission has heard these concerns, and in 2017 they directed the staff to examine the concerns. Specifically, the Commission directed the staff to evaluate whether it makes sense to establish tailored training and experience requirements for different categories of radiopharmaceuticals, how those categories should be determined, such as risks posed by groups of radionuclides or by delivery method, what the appropriate training and experience requirements would be for each category, and whether those requirements should be based on hours of T&E or more focused on competency.

So in 2018 the staff did some initial work in response to the Commission's direction and the staff concluded that while it may be feasible to create tailored T&E for certain categories of radiopharmaceuticals, and there could be ways to make this T&E more competency-based, the staff needed more outreach with the medical and regulatory community before making a recommendation to the Commission.

So this outreach, as Chris mentioned in his introduction, started last fall when we published our initial *Federal Register* notice. That FRN opened a 90-day public comment period on the T&E evaluation and asking just general questions about the current T&E requirements.

During that first comment period the NRC received 144 written comments and 35 comments were spoken during the four public meetings. All the public meeting transcripts, public meeting summaries and written comment submissions are available on the T&E docket on regulations.gov. So if you go to www.regulations.gov and in that search bar you put the docket, which is NRC 2018 0230, the first result that will come up will be the T&E docket. Click on that and you can then kind of sort through all the comments and transcripts and meeting summaries.

So I'm going to outline at a very high level what we heard during the last public comment period, but I want to stress that a more detailed summary of all the comments we received during the first comment period and during this comment period are going to be included as an enclosure with the paper that we're developing for the Commission.

I'll also be making publicly available in ADAMS a comment binning report that will show you how we extracted each individual comment and how we grouped similar comments together into what we call comment bins. So you'll be able to review every comment that we received on the T&E evaluation in two larger reports that will be publicly available. And these reports will become available when the Commission paper becomes publicly available.

So what did we hear during the first comment period? Citing concerns about quality of patient care and worker and public safety, there was strong opposition voiced to any changes in the T&E requirements. We heard this opposition form the nuclear medicine community and the related medical specialty boards and professional societies.

Going hand in hand for this support for maintaining the current T&E requirements was

opposition to creating tailored T&E requirements that would result in a limited authorized user. And when I say a limited authorized user, I mean, for example, an AU that would be only permitted to use a certain type or category of radiopharmaceutical.

Opposition to creating a limited AU today was primarily rooted in concerns about protecting the health and safety of patients. Basically folks thought that AUs needed to have the full depth of knowledge to be an AU and not have some limited amount of knowledge. Commenters also warned that limited AUs could be motivated by financial gain versus what was best for the patient.

And then on the other side of the spectrum citing concerns about patient care and patient access to medically-necessary radiopharmaceuticals, there was also support for tailored T&E requirements. And we heard this from physicians such as hematologists, endocrinologists, oncologists and urologists who wanted to be able to treat their patients with radiopharmaceutical therapies, as well as from the pharmaceutical industry, related trade groups and a rural health care advocacy group. These groups stated that creation of a limited AU pathway for certain categories or types of radiopharmaceuticals

could safely expand access to therapeutic radiopharmaceuticals.

Other commenters supported limited AU -- other commenters that supported limited AU pathways pointed out that the NRC's T&E requirements should be more risk-based and that in the NRC's evaluation of the T&E requirement staff should evaluate specific categories of radiopharmaceuticals such as routes of administration, radiation characteristics, preparation methods and unique practice setting requirements as part of its overall decision making process.

Some commenters pointed out that the precedent has already been set with regulations regarding T&E for administration of oral iodine-131. And that T&E carve-out already exists for this radiotherapy and the carve-outs work well.

Groups on both sides of the issues presented the NRC with detailed lists of basic radiation science and health safety topics and clinical training and experience requirements that they thought were necessary for either a full or tailored T&E. And then there was mixed support for moving toward the more competency-based evaluation of proposed AUs. For example, such as requiring a

formal radiation safety examination to become an AU and potential periodic reassessments.

So the NRC has been and will continue to coordinate with both the Advisory Committee on the Medical Uses of Isotopes, the ACMUI, and the Agreement States. The next two slides will cover those entities.

So in mid-February the ACMUI Subcommittee on Training and Experience issued their draft report on T&E for radiopharmaceuticals under Subpart D. A public teleconference was held on February 26th, 2019 with the Full ACMUI and NRC staff, and during the telecon the Full Committee endorsed the Subcommittee's draft report and the positions and recommendations in that report. The ACMUI's positions and recommendations are as follows:

The Committee strongly supports and reaffirms their 2016 submission on maintaining the current and existing AU pathways; that is, the board certification and the alternate pathways, which the Committee believes are adequate for protecting public health and safety. The Committee backed up this position by stating that radionuclide therapy poses the highest risk and highest impact of all nuclear medicine procedures.

The Committee concludes that there's no objective data to confirm an AU shortage.

The Committee does not recommend a limited- scope AU pathway for radiopharmaceuticals requiring a written directive.

And the Committee agreed that in order to ensure the safety of patients, personnel and the public if the NRC chooses to pursue the creation of a limited-scope AU pathway, the AU candidate must acquire all of the basic knowledge topics currently in 10 CFR 35.390 and the AU must satisfactorily complete a formal competency assessment.

The Committee further recommended that the individual's continued status as a limited-scope AU should be dependent on successfully completing formal periodic reassessments of radiation safety competency.

Slide 10 talks about what we heard from the Organization of Agreement States. The NRC has been coordinating with the board and other members of the Organization of Agreement States as a conduit for all 38 Agreement States. In their comment submission dated January 29th, 2019 the Organization of Agreement States reiterated their position on the adequacy of the current T&E requirements from when

the NRC reached out to them before in early 2018, and that position was that most Agreement States find the current AU pathways to be reasonable and accessible to physicians wishing to administer radiopharmaceuticals.

There was not however a consensus opinion among the Agreement States on whether there was a need to create tailored T&E requirements. Some states were open to exploring the idea of created limited AU pathways while other states felt that creating new limited pathways would just add unnecessarily complexity to what are already complex regulations.

The OAS did close out their comment submission with a suggestion that the NRC consider a less prescriptive approach to T&E, that perhaps putting regulatory focus on whether licensees are complying with 10 CFR Part 35.41, which is our regulation pertaining to written directives, and also focusing on the compliance of regulations regarding radiation protection at 10 CFR Part 20, that that approach could be a more effective way to regulate medical licensees.

Slide 11 is recycled from old meetings on this topic, but I thought it was important to include

because it shows where we are in this evaluation. The staff's current evaluation of T&E is not a rulemaking, so I wanted to clarify that. But there is a connection between this evaluation and the rulemaking process, and that connection is that the outcome of this evaluation could potentially be that the staff recommends to the Commission that the NRC should conduct a rulemaking that would amend the T&E requirements.

I have the first box, Input for Medical Stakeholders, highlighted on this slide because we're still in that phase as we were back in the fall and winter. And just as it did back then, the statement is true now: Your input will help us refine or edit the draft approaches that we've come up with and will determine whether or not they should be included in our paper that we're developing for the Commission.

Once we deliver our paper to the Commission, the Commission will review and consider the staff options and the staff's recommended path forward and the Commission will make the ultimate determination on how the staff should proceed, whether that involves a rulemaking or not.

So that brings us back to where we are today and we're here to listen to your comments on

the draft approaches that were outlined in our May 2nd, 2019 *Federal Register* notice. The link to that FRN that outlines the draft approaches is on this slide, but you can also just Google the *Federal Register* notice citation, which is 84FR18874, and that will bring it right up for you.

We would like your feedback on the draft approaches and also responses to a number of questions that we have asked in the FRN. And in a moment Maryann is going to walk us through those draft approaches, and later on I'll also run through the questions that are in the FRN, but I do want to note; and this is very important, so if you're sleeping, wake up, that we -- just today we published a *Federal Register* notice that extends the comment period for this effort.

So the comment period was originally June 3rd; and that's what you'll see in this *Federal Register* notice that I have cited on this side, but it has now been extended to Wednesday, July 3rd, 2019. That's a 30-day extension. And we granted that extension in response to several requests from stakeholders asking us for more time to comment on this important FRN. So just to reiterate, Wednesday, July 3rd is the new comment due date. We have no

more public meetings. Today is the last public meeting on this topic.

All right. At this point I am going to hand it over to Maryann Ayoade to walk us through the options, or the draft approaches.

Maryann?

MS. AYOADE: Thank you, Sarah.

So in the following slides you will see that we have numbered and listed the draft approaches using the same numerical headings as you will see in the *Federal Register* notice. The same thing also goes for the numbered questions that we are looking to get feedback on. The questions have the same number here in the slides as you will see in the *Federal Register* notice. With these approaches that we are presenting today, we want to emphasize that all of the approaches are preliminary.

I also want to mention that some of these approaches could add an additional pathway to the existing pathways in the regulations for physicians to become authorized users while some of these approaches could modify the existing training and experience regulations or keep the current regulations as is.

So I will go into the approaches starting

with this slide.

The first is the status quo approach. This approach would maintain NRC's current training and experience requirements, so radiopharmaceuticals requiring a written directive. Here physicians would still need to meet the training and experience requirements under 10 CFR 35.300.

And so the questions that we would like to get feedback on here is: If the status quo is maintained, how should the NRC prepare itself for the expected increase in the number and complexity of future radiopharmaceuticals? The second question is: Is there a challenge with NRC's current training and experience requirements such as concerns that are regarding patient access to radiopharmaceuticals that should be addressed through a rulemaking?

Next slide. This slide, slide No. 14, discusses tailored training and experience requirement approaches, and these four tailored training and experience approaches would modify the existing training and experience requirements for radiopharmaceuticals.

The first three approaches, which are: the limited authorized user for alpha or beta-emitting radiopharmaceuticals; the limited authorized

user for unit dose patient-ready radiopharmaceuticals; and the limited authorized user for anyone pertaining to radiopharmaceuticals. These three approaches would require a set amount of training and experience that would be tailored to the specific radiopharmaceuticals.

The fourth approach, the emerging radiopharmaceuticals approach. This approach would tailor the training and experience requirements for each new radiopharmaceutical as they would develop, similar to the approach for regulation new technologies that we currently have under 10 CFR 35.1000.

So the question we would like to get feedback on here is: How should the complexity of the radiopharmaceutical administration protocol be considered in establishing the training and experience requirements or the limited approaches?

Next slide. This is the first of the four tailored training and experience requirement approaches. This approach would allow for limited authorized users to administer one or more of a certain type of radiopharmaceutical, and in this case the physicians that are seeking authorized user status would be able to administer any alpha or beta-

emitting radiopharmaceutical.

The training and experience that would be required for the user is for the user to have completed at least 400 hours of training and experience of which 200 hours would be in classroom and laboratory training plus a minimum of 200 hours of supervised work experience that would be focused on alpha or beta-emitting radiopharmaceuticals. This approach would also require a preceptor attestation similar to what the NRC's current regulations require for the alternate pathway.

So the question that we would like to get feedback on here is: How should the NRC categorize radiopharmaceuticals that have mixed emissions?

Next slide. Again, just like the previous approach, this approach would allow for limited authorized users to administer one or more specific radiopharmaceuticals. For this approach the physicians that are seeking authorized user status would be able to administer any unit dose patient-ready radiopharmaceutical. Similar to the previous approach the training and experience here would be for the user to have completed at least 400 hours, which includes 200 hours of classroom and laboratory training plus a minimum of 200 hours of supervised

work experience that would be focused on unit does patient-ready radiopharmaceuticals. This approach would also require a preceptor attestation.

So the question that we would like to get feedback on here is: How should the NRC define patient-ready?

Next slide. So this is a third type of limited authorized user approach. Again, similar to the previous two approaches, this would allow for limited authorized users to administer one or more specific radiopharmaceuticals. In this case the physicians that are seeking authorized user status, they would be able to administer any one of the T&E radiopharmaceuticals.

The training and experience required here would be similar to the last two limited authorized user approaches that require at least 400 hours of training and experience of which 200 hours would be in classroom and laboratory training plus a minimum of 200 hours of supervised work experience, which would be focused on that one radiopharmaceuticals.

What is different in this approach than the other limited authorized user approach is that if the authorized user wants to administer any new additional radiopharmaceutical that comes along

that's different from what they have been authorized for, that authorized user would need another minimum of 80 hours of tailored supervised work experience. And so this approach would also require a preceptor attestation.

Next slide. This approach, the emerging radiopharmaceuticals approach. It is the fourth of the limited authorized user-type of approach. It would mirror that of NRC's current regulations under 10 CFR 35.1000, which is for other medical uses that do not fall under the other sections of the regulations in Part 35. It would require that the NRC conduct individual reviews of each new emerging radiopharmaceutical so that they can determine the specific training and experience requirements for each radiopharmaceutical.

The training and experience requirement here could be tailored to consider the potential users, so these would be individuals that are not your traditional nuclear medicine or radiation oncology physicians. So that would be, for example, a hematologist, a urologist or a medical oncologist that would like to administer one of the new radiopharmaceuticals that are coming up in the future.

And this approach would in turn be creating alternate training and experience pathways for each new radiopharmaceutical.

Next slide. This slide, slide No. 19, presents performance-based approaches, the first of which is a competency-based evaluation approach, and the second a credentialing of authorized users approach. These two approaches would remove prescriptive training and experience requirements from the regulations and instead it would focus on oversight -- it would focus oversight on the performance-based assets of a licensee's medical program's radiopharmaceutical administration.

Next slide. The first performance-based approach, the competency-based evaluation. This would require that proposed authorized users demonstrate competency in radiation safety topics and radiation safety-related job duties through a formal evaluation. And so for example, an examination or a preceptor attestation that would be something that would be used to assess or confirm that the individual is able to function independently as an authorized user for the uses that are being requested.

So the question that we would like to get feedback on under this approach is: Does a

competency-based evaluation as it relates to radiation safety job duties and topics ensure appropriate training and experience for authorized users? And if so, how?

Next slide. So the second performance-based approach is the credentialing of authorized users. In this case the NRC would no longer be involved in the review and approval process for users' training and experience under Part 35. Instead, licensees would be -- would have to develop and use their own policies and procedures to make self-determinations as to whether their credential submissions have the appropriate training and experience to be an authorized user. Also licensees would be required to maintain their own training programs to ensure compliance with the requirements for having procedures for administrations requiring written directives in 10 CFR 35.41. And also the requirement for radiation protection in 10 CFR Part 20.

So the question we would like to get feedback on here is: How could physicians in smaller practices be credentialed? So this is referring to physicians that are not associated with hospitals or other larger institutions with credentialing boards

that we typically see that would review and approve the physicians before they can practice at that facility.

Next slide. This slide, slide No. 22, presents team-based approaches. And so for the first two approaches the radiopharmaceutical team and the approach that involves teaming authorized users with authorized administrators who could introduce some new users. I want to point that these two approaches would be more performance-based. And so this would mean that the prescriptive training and experience requirements would be removed from the regulations and it would put more emphasis on the licensee to ensure that they have a program in place to accommodate authorization for any new uses that are being requested.

The third team approach, the approach that involves partnering a limited trained authorized users with an authorized user pharmacist. This approach on the other hand would require a more prescriptive training and experience requirement for authorized users because of the authorized user's more prominent in administrating radiopharmaceuticals.

So just to summarize these team-based

approaches, they would either be removing the prescriptive training and experience requirements for authorized users and would focus the training requirements on the competency of the entire team involved in the procedures or it would be revising the current 700-hour training and experience requirement for authorized users based on pairing the authorized user with another individual's expertise in administering radiopharmaceuticals. And I will go over these approaches in the coming slides.

So the question that we would like to get feedback on here is: For the team-based approaches how should the authorized user's radiation safety responsibilities be clearly distinguished from other members of the team?

Next slide. Under this first team-based approach the radiopharmaceutical team licensees would be required to have a team to administer radiopharmaceuticals. At a minimum the team would consist of an authorized user, a radiation safety officer and a nuclear medicine technologist. The team could also include some additional members like an authorized medical physicist, an authorized nuclear pharmacist, health physicists or other physicians that manage patient care.

The training and experience for the team in this approach would be performance-based and licensees would be required to develop policies and procedures that address how their teams would meet the requirements in 10 CFR 35.31, to have procedures for administrations that require written directives, and also to meet the requirements in 10 CFR Part 20, Radiation Protection.

Next slide. The second team-based approach is one that would team up authorized users with authorized administrators. And authorized administrator here would be an individual that the licensee would authorize to administer radiopharmaceuticals. So for example, a nuclear medicine technologist or a nuclear medicine exam associate, which is comparable to a physician-extended position or an extension of physician services by other providers.

With this approach licensees would need both an authorized user and an authorized administrator to administer radiopharmaceuticals. This approach would also be more performance-based and the training and experience for the authorized users would focus on written directives, patient-released criteria and medical event reporting. The

training and experience for the authorized administrators would focus on radiation safety and preparation and administration protocols and this would be in addition to the training that is required for the authorized users, which would be on written directive, patient-released criteria and medical event reporting.

Next slide. The third team-based approach. This is one that would partner up limited trained authorized users with authorized nuclear pharmacists. This approach would require that an authorized nuclear pharmacist must be present during the administrations by an authorized user. It would also require more prescriptive training and experience requirements for the authorized users due to authorized user's more prominent role in the administration of radiopharmaceuticals.

This approach would also require that an authorized user have at least 400 hours of training and experience, and this training and experience for the position partnering with an authorized nuclear pharmacist to be more focused on supervised work experience and position cases. And it would also require a preceptor attestation.

The training and experience for the

authorized nuclear pharmacist would remain as it is currently listed in NRC regulations in 10 CFR 35.55.

The authorized user in this approach would be -- still would be responsible for administrations in accordance with the written directives while the authorized nuclear pharmacist could be responsible for all the other radiation safety-related duties during the procedure.

And so the question that we would like to get feedback on here is: How should the radiation safety responsibilities be divided between the authorized user and the authorized nuclear pharmacist?

Next slide. And so I will hand it over to you to go over the rest of the questions in the FRN.

MS. LOPAS: Okay. Thank you, Maryann.

So the next three slides are additional questions we have in the FRN that are related to the draft approaches. I'm actually going to hold off on those for just a minute because -- and I'll come right back to them. So you'll see why in just a minute. So let me just skip through and we'll come back.

So what I do want to go to is slide 29, which is how you can submit your written comments.

So as I said earlier, the new comment due date is July 3rd. And so you just go to regulations.gov and you submit your comments that way. You can either just type directly in the text box on regulations.gov or you can upload any kind of document, a Word document, a PDF. I think -- I'm not sure what you're limited to, but a Word document and PDF would certainly be up-loadable.

I have here the link to the direct comment submission link, but it's very easy to navigate regulations.gov, I think.

I will note that when you go to regulations.gov right now, you will see two ''comment now'' buttons. Both are valid. You can click either one of those buttons. The reason why there is two is because we just published that new FRN today that extended the comment period and it's almost like -- one comment period ends June 3rd. That's one button. And then the second button is for the comment period ending on July 3rd. So you could hit either comment now button. I'm assuming that the June 3rd one will go away as of June 3rd, but that will leave the July 3rd comment button. So don't be confused when you go to regulations.gov and see that. You can't make a mistake. I'll just put it that way.

Either one is fine.

Also note that it does take about 11 working days for your comments to show up on the public facing side of regulations.gov. Unfortunately we don't have any control over that. That's just how long it -- it's an administrative process. It just takes that long. However, we do receive your comments immediately. I can access your comments immediately. I check in regulations.gov daily to see what has come in.

Your comments will also be in ADAMS. And as I mentioned before, we're also going to -- we're also going to be putting the comment summary reports in our paper to the Commission.

And I do just want to note that because this is not a rulemaking. We're not going to be responding to individual comments, but like I said, we'll be summarizing them. And we really do thoroughly process and review them.

Here are the next steps for the T&E evaluation. So this slide has been revised from when we met last on the -- on May 14th. So the comment period goes from May 2nd through July 3rd. In the month of July we're going to evaluate the comments that came in. We're going to finish developing the

draft Commission paper.

Then the ACMUI and the Agreement States both receive some time to provide us comments on that draft Commission paper. And I think what will be important to note is that in mid to late-October the ACMUI T&E Subcommittee will be holding a public teleconference where they will be discussing their draft comments on our draft paper, or their comments on our draft paper with the entire Subcommittee with NRC staff. And that's a telecon that if you're interested, you can call into and listen into. And I believe you can make comments at the end of that teleconference. Don't quote me on that, but you can certainly call in and listen to that.

So the best way to be notified about when that telecon is going to be scheduled is by joining the NRC's Medical List Server and signing up for the medical list server. So if you Google NRC Medical List Server, the first result that comes up is how to subscribe to that. And that's just a notification where that's how we send out all the news related to our medical regulatory activities like these meeting notices, any reports that we issue, et cetera. So I think it would be a good idea to sign up if you're interested.

Then following that ACMUI Subcommittee public teleconference we'll finalize our Commission paper. And we hope to -- pending no other delays, we hope to deliver the paper to the Commission at the very end of the year in late-2019, but we will keep you posted if that changes.

So here you go. Here are some links for more information. As I mentioned before, the T&E evaluation web site. I try to keep that updated. As I mentioned before, you can go to the regs.gov docket and get a bunch of good information and comments. And of course myself and Maryann are always here for your questions and for more information if you need it. Maryann is our technical point of contact as a health physicist, so she's good for technical questions. And I am the project manager. So if you have process-type questions, you can send them my way.

And if you have any issues submitting comments on regulations.gov, if you're at all worried that your comment didn't go through, you can go ahead and email it to me or Maryann, or both of us, and we will make sure that it gets covered, or it gets included.

And so now we come to the comment portion of the webinar. And so what I want everybody to do

is if you want to speak a comment over the phone, Allison is our operator. She's going to help us out with that. So all you do is press *1 on your phone. So you can go ahead and do that now if you know right away that you want to make a comment. Just press *1 and they'll -- and start a line.

And you can also submit shorter comments and questions over -- using the webinar function, the question function. I'm going to emphasize shorter because it's hard to read very long questions or comments on the -- via the webinar. So go ahead and do that now. And press *1 to make a comment and do your -- and -- or ask a question.

And while everybody's getting set up to do that, I am going to run back through the questions because I wanted to give folks time to get in line to make their comment or ask their question. And I'm going to run through the additional questions that are in the FRN while everybody's doing that.

So in the FRN we have these additional questions that apply to most of the draft approaches, and we would really appreciate the medical community's and regulatory community's input on these questions.

So question 10: What are the advantages

and disadvantages of the draft approaches?

Question 11: Are there significant costs or benefits associated with any of the approaches?

Question 12: Would any of the draft approaches impact patient access to radiopharmaceuticals or address the stakeholder concerns of overly burdensome regulatory requirements?

Question 13: For the draft approaches that consider tailored hours of T&E what are the appropriate numbers of hours and what radiation safety topics should comprise the limited T&E?

Question 14: Should the NRC consider incorporating a formal radiation safety competency assessment and periodic reassessment for any of the draft approaches above? If so, who should establish and administer these assessments?

Question 15: How would the draft approaches impact the medical organizations that use the NRC's T&E requirements as a basis for establishing their training program?

Question 16: Are there concerns regarding implementation and/or viability for any of the approaches discussed?

Question 17: Are there any unintended

consequences of the draft approaches?

Question 18: Which of the draft approaches best position the NRC to effectively regulate future radiopharmaceuticals?

And Question 19: Should the NRC continue to play a role in the review and approval of authorized users?

So those are our questions. Let's go back to the comment -- how to make your comments. So *1.

Allison, do we have anybody on the phone?

OPERATOR: Yes, we do have a question or a comment from Samuel.

Your line is open.

DR. MAHGEREFTEH: Hi, everyone. Thank you very much for this opportunity.

The Nuclear Medicine Resident Organization that I'm a part of, we're taking this issue very seriously. We're a branch of the ACNM, the College of Nuclear Medicine. And this is an issue that we -- as you know from our prior responses to questions like this, we take this very seriously and we think that it's potentially very dangerous to decrease the amount of training that's required for people to be able to give radiopharmaceuticals.

One of the things that I think isn't spoken about enough is that in nuclear medicine you're not just kind of treating everyone in the same way. In nuclear medicine every single patient that comes through the door is very unique. The reasons why we're treating each patient as unique, the specific tracer that we're giving and the specific molecular agent that we're giving are all unique. And then you have to consider things about the patients like their diet, their medication, their home life.

We never -- you should know that when people train in nuclear medicine we get to know the patient days, sometimes a week in advance of the patient ever coming to have the radiation administered. We're looking at the study. We're making sure it's appropriate. We're looking at previous imaging. We're calling the clinician. One of the reasons is because obviously we want to make sure that these patients, a lot of whom are cancer patients and have a very high expectation for accurate treatment and diagnostics -- we want to make sure that they're getting exactly what they need. That goes without saying.

Another thing that people don't think about is these procedures that we do in nuclear

medicine are extremely expensive. And if you have a patient come in and there's the slightest error in the way that the tracer is handled and the kind of treatment the patient should be getting, which again is very personalized in every case, you've lost per treatment tens of thousands of dollars sometimes. And that I think as molecular therapies and theranostics and things become more clinically relevant for us, this kind of economic hit to our practice can't be tolerated. I think we're risking getting into a situation where we're experimenting with patients' health and the -- kind of the economics of our community.

And I hope that as this conversation goes on these issues, specifically the fact that patients are really very, very unique in nuclear medicine -- it's unlike anywhere else in imaging when people come in for nuclear medicine diagnostics and therapy. They're treated as individuals in a highly personalized way.

MS. LOPAS: Thank you, Samuel. Do you mind providing your last name for the transcript?

DR. MAHGEREFTEH: Sure. It's Mahgerefteh. M like Mary, A-H-G-E-R-E, F like Frank, T-E-H. Again, I'm speaking kind of personally, but

also some of the ideas that I'm communicating here are the ideas of ACNM and the Nuclear Medicine Resident Organization. And you can actually -- people can look at our online publications to see more details of what nuclear medicine training is like.

One thing in particular comes to mind is the *Scintillator*, which is our quarterly online publication. The *Scintillator*. You can read about how the dedicated nuclear medicine training gets us ready to really deal with each patient on a very personalized way.

MS. LOPAS: Okay. Samuel, we appreciate those comments. Thank you.

DR. MAHGEREFTEH: Thank you very much.

MS. LOPAS: Okay. Allison, do we have another commenter on the line?

OPERATOR: Yes, our next question or comment is from John Witkowski.

Your line is open.

MR. WITKOWSKI: Thank you. This is John Witkowski with UPPI and I want to thank the NRC and the Project Committee to allow more comment publicly and to actually extend those comments for all the questions and information being sought to have time

to make submissions to that regard.

I do appreciate as you gave the presentation today to talk about those that have opposed to the training and education tailoring of hours and to bring up some very fine points, but it's also points that we can use in understanding how we can provide other information to support a variation. I also liked the comments from the Agreement States that they have a concern that there could be complexity added to the inspection and evaluation of the programs and that could be put forward. And that needs to be taken in consideration, too.

I can remember in our experience that there was a time in cardiology where nuclear cardiologists were able to receive limited training. And that led to an evolution within nuclear cardiology to a societal formation to a board certification and to working with nuclear medicine and radiology.

I just want to take a couple moments to speak about two things that are of interest with UPPI, and that's one of the things that we submitted was the idea of a radiopharmaceutical team and also training for potential users, non-nuclear medicine, non-radiology.

In our industry we're faced right now

with the U.S. Pharmacopeia making changes to their chapter on sterility, Sterile Preparation 797, and devising a new Chapter 825 for Radiopharmaceutical Preparation. I believe that this has come about as a means that the industry is improving and moving forward. There's new radiopharmaceuticals to come to the marketplace and there needs to be further definition of operations within the space of preparation of radiopharmaceuticals. And I believe there's a parallel to what we're discussing today.

I know from the regulations that everyone can look up, and we've elicited it earlier, that there is specific training for an authorized user and there is specific training for an authorized nuclear pharmacist. A lot of these trainings are parallel. And there is also other expertise that both of the parties have.

So with regards to a limited trained authorized user perhaps teamed with an authorized nuclear pharmacist, this is where the two can complement each other in their experience and definition of how the product could be administered safely to the patient and radiation safety concerns could be handled adequately with a teaming approach.

It is of notice that we do need to

distinguish what are the radiation safety responsibilities for any team that comes together. Some of that is already done, but as we look at hew radiopharmaceuticals that come to the marketplace that would involve alpha and beta therapy, whether it's an injection for metastatic spread as opposed to an injection of a much higher amount of radioactivity for an ablation, those things need to be defined. I believe that these can be done.

I also believe that there's been submissions of what could be a potential training program for limited trained authorized user, a non-radiologist, non-nuclear medicine, and those things can be used as a format to work out something that would be a training program tailored for a specific approach.

We think this is important because we believe there needs to be an outreach to be able to cover adequately the quality of care and the availability of care to patients that need therapies, radiotherapies, alpha and beta-type of therapies, and that it can be done in an adequate and safe -- and can be monitored and defined by these programs using a radiopharmaceutical team or a partner relationship with a limited-trained authorized user. And that's

what we will address in further communications to the NRC and the project management team. Thank you.

MS. LOPAS: Okay. Thank you, John.

So to make a comment over the phone, press *1. And you can also submit your shorter comments or questions using the webinar question function. So you can do either of those.

Allison, do we have another comment or question on the phone?

OPERATOR: We have no further questions or comments at this time.

MS. LOPAS: Okay.

MS. AYOADE: Hey, Sarah, this --

MS. LOPAS: Hi, Maryann.

OPERATOR: One more just came in.

MS. LOPAS: Okay. Hang on one second. We're going to let Maryann Ayoade speak, and then we'll go to the next commenter.

Maryann?

MS. AYOADE: Yes, I just wanted to point out for clarification, I did this at the last meeting that we had because we did have a similar comment about the training for the authorized nuclear pharmacist being similar to what you see for the training on the currently required for

radiopharmaceuticals as it relates to the alternate training pathway and the hours of training.

The authorized nuclear pharmacists, they do have an alternate pathway that requires 700 hours of training, but then the difference here is that the supervised work experience is supervised practical experience in a nuclear pharmacy. And so they would be required to look at some similar things as they relate to maybe radiation safety surveys and calculations, but it's different than the work experience that's in the 700-hour requirement for the authorized users because that work experience includes experience with administering doses.

So for the different types of radiopharmaceuticals they have work experience in patient case work as it relates to, for example, oral administrations of iodine-131 or any parenteral administration because that's what's currently required for the training and experience requirements for the authorized users to administer radiopharmaceuticals.

So I just wanted to clarify that point in case it comes up, and it came up in the previous meeting as well.

MS. LOPAS: Okay. Thank you, Maryann.

That is helpful. We appreciate that.

Okay, Allison, we are ready for that next comment.

OPERATOR: Okay. Next we have Jaspreet Batra.

Your like is open.

DR. BATRA: Hello. Hi, my name is Jaspreet Batra. I'm one of the residents getting trained at Johns Hopkins and I'm getting trained in peer nuclear medicine and I strongly echo the thoughts of Maryann as well as also Sam who just spoke before me.

And I certainly believe that we get trained in nuclear medicine over three years as peer nuclear medicine physicians and it requires all the essential training to administer as well as review and report nuclear medicine pharmaceuticals. And I strongly believe that providing an alternate pathway for people to do a short-term training is stupid. And here we are treating patients, not guinea pigs, and we should not be subjecting patients to such a low level of trained physicians or support staff to administer such therapies.

A pharmacist cannot do -- it's not their scope of practice to treat patients with

radiopharmaceuticals and a physician who's not well-trained in nuclear medicine will not do an accurate job. And we are subjecting patients to undue risk and probably also increasing the health care cost. And with that I strongly condemn any dilution of such recommendations. Thank you.

MS. LOPAS: Thank you, Jaspreet, could you spell your last name for us so we can get it for the transcript?

DR. BATRA: Yes. I'll give you my first and last name.

MS. LOPAS: Okay.

DR. BATRA: First name is Jaspreet. It's spelled as J as in Joseph, A as in apple, S as in -- sorry, J as in Joseph, A as in apple, S as in Sam, P as in Peter, R as in rose, E as in English, E as in English, T as in Tango. So that's Jaspreet.

MS. LOPAS: Okay. Jaspreet.

DR. BATRA: And last name is Batra, B as in boy, A as in apple, T as in Tom, R as in rose, A as in apple. And I'm a second-year nuclear medicine resident at Johns Hopkins Hospital.

MS. LOPAS: Excellent. Thank you, Jaspreet.

DR. BATRA: Thank you.

MS. LOPAS: Okay, everybody, *1 on the phone. And as we've been saying start by providing your name. You can also type a question or comment in using the webinar, and I can read that aloud for you.

Allison, do we have any other people on the phone?

OPERATOR: No questions or comments at this time.

MS. LOPAS: Okay. *1, everybody. So 11:01. So we're going to talk for a little while longer. We're not going to end quite this early because I know somebody out there wants to give us a comment.

So, Allison, I'm going to run through some of our questions again and if anybody hops on the line, just feel free to interrupt me.

OPERATOR: Okay.

MS. LOPAS: And again, you can also submit your question or comments by the question function on the webinar, if you're logged into the webinar.

So for question 10 we're asking about the general advantages and disadvantages of the draft approaches. And the NRC staff in our paper for the

Commission will be outlining advantages and disadvantages for each of the approaches that we put forward in our paper. So we'll be doing this, but we would like to hear from the medical and regulatory community that will be impacted by potential changes.

Question 11, which is similar: What are the significant costs or benefits associated with any of the approaches? And again, NRC staff will be coming up with a high-level cost-benefit analysis looking at the approaches that we're going to put forward in the paper. These will probably be costs and benefits from our perspective, so we -- from a regulatory perspective - we are really interested in hearing the medical community's perspective on potential costs and benefits associated with the approaches? For instance, would benefits outweigh some costs or vice versa? So that's what we're looking there for question No. 11.

Question No. 12: How would any of these approaches impact patient access to radiopharmaceuticals or would they address the concerns about overly burdensome regulatory requirements? So that was kind of -- those two concerns were kind of what got us here in this T&E evaluation in the first place and we're looking to

see if any of those approaches would help with that. So what do you think?

OPERATOR: Excuse me. This is Allison. We do have a comment on the phone.

MS. LOPAS: Hi, Allison. Excellent. Let's hear it.

OPERATOR: All right. Samuel, your line is open.

DR. MAHGEREFTEH: Hi, Samuel again. I'm grateful for this opportunity to take advantage of speaking as no one else is commenting. So I'd like to ask a favor of anyone else that's going to be speaking today.

I want to reiterate first of all molecular imaging and therapy has boomed really specifically because it allows personalization of care. And I'd like for people who are commenting on both sides, if you could, tell us how potential changes to the training are going to include a kind of training where the clinician will have had experience in personalizing, really tailoring care to each individual patient. I think that it's entirely possible that a pharmacist may have a great fund of knowledge and a deeper knowledge than even a nuclear medicine trainee in terms of how radiopharmaceuticals

ought to be handled.

But in a clinical setting, in a situation where you're dealing with an actual patient where you have to consider everything from the patient's home life, their diet, their exercise, who they're living with and their exact diagnosis, their imaging findings -- in a situation like that it's only appropriate in my mind for therapy to be done by a person who has had experience in tailoring the therapy and the imaging to account for all of these very unique factors. And again, in nuclear medicine one of the things that we learn as trainee in nuclear medicine is that every patient is unique.

So anyone who is commenting about decreasing or changing the training standards, I'd love if you could please comment on this on how the training -- the proposed new kind of training is going to account for this. How are you going to have clinicians come on the field who have had hands-on experience tailoring diagnostics and therapies, theranostics for individual patients? Thank you.

MS. LOPAS: Okay. Samuel, thank you. We appreciate that comment. And I want to -- and maybe Maryann can jump in.

I'll get started and then, Maryann, as

the technical lead, you can jump in.

But I do think there tends to be a blurred line in the interpretation of what the NRC regulates and the practice of medicine.

And, Samuel, what I'm hearing you discuss is related to the practice of medicine, the experience that comes with a very highly-trained nuclear medicine physician knowing how to care for a patient, whereas the NRC regulations are focused only on radiation safety, how to safely handle these materials. And that's the extent of what we try to limit our T&E requirements to - radiation safety - and not merge into patient care or practice of medicine.

Maryann, do you have anything that you want to follow up on with that?

MS. AYOADE: Not really. I think you hit the nail on the head. I just maybe would point out that as we're going through this evaluation and even just in coming up with these approaches we were and are always keeping in mind our medical policy statement, which as Sarah alluded to, we are taking into consideration and focusing on regulating the radiation safety aspect of the patient care.

And so that's part of what our medical

policy statement is and that's what we try to do as we develop these options, and as we're moving forward we're keeping that in mind. We don't want to intrude into the practice of medicine unless it's necessary to do so for radiation safety of the public, the workers and the patient.

MS. LOPAS: Okay. Thank you, Maryann.

Samuel, I don't know if you're still on the line, if you had anything you wanted to follow up on.

DR. MAHGEREFTEH: Thank you. I appreciate that. I realize what the role is for the NRC. I appreciate your comment.

What I'm describing is something that is -- all factors of a patient's therapy are interrelated so that if, for example, a patient is being -- has a different kind of home situation or if their therapy requires a different kind of dose. All of these factors have to be taken into consideration, and there's an interplay. There's interplay between getting the right therapy, the right amount of therapy, factoring in how much radiation is going to be involved, their home life. I don't think that any of these factors can be taken in isolation. That's what I mean when I say that these therapies are highly

personalized.

If it was just a question of how much radiation is coming out of this tube in isolation, then of course the conversation would end there and you could probably have a 10-minute conversation about how much training is required to manage that tube. But because we're talking about situations where there's potential waste and mistreatment, mismanagement, then all of these factors that are interrelated I think have to come into consideration. Thank you.

MS. LOPAS: Okay. Thank you.

Okay, everybody. *1. Maybe that jogged some comments on everybody's part. *1 or you can submit a comment via the webinar.

Allison, do we have anybody else on the line?

OPERATOR: No further questions or comments at this time.

MS. LOPAS: Okay. *1 if anybody wants to follow up on that. I'll note related to that comment, Samuel's comment, is that for some of the folks that were in support of tailored T&E or limited T&E --for some tailored category of radiopharmaceuticals, one of the points that they brought up is they thought

that the 700 hours that we currently require likely includes clinical aspects, more clinical aspects, patient care aspects -- under that training, and it's not just limited to what we have listed in our topics under 35.390(b)(1). So that's just what we heard, that some of that 700 hours probably includes some things that go beyond strict radiation safety and what we require at the NRC. I don't know if that will jog comments, too.

Allison, again just interrupt me if anybody pops on the line.

I'm going to go back to these questions. And again, you can submit your question or comment via webinar, and I can read you it aloud if you'd prefer it that way.

So I think we stopped at -- I can't remember. We'll just go with Question 13. So for the draft approaches that consider tailored hours of T&E what would be the appropriate number of hours and what radiation safety topics should comprise the limited T&E? So for some of our limited approaches we had specified at least 400 hours, and that broke down to about 200 hours of classroom and laboratory training, which is the same as what's required now under the limited pathway, and then 200 hours of

tailored focused supervised training experience.

So if you have ideas of a different number or what should be covered under that, we would love to hear that.

All right. Question 14 is should the NRC consider inclusion of a formal radiation safety competency assessment and periodic reassessments for any of the draft approaches above? And if so, who should establish and administer these assessments? During our last public meeting on May 14th we heard a number of people advocate for adding competency assessments onto our existing regulations.

So I'm assuming that that means adding it onto our alternate pathway, that our existing alternate pathway should stay the same, 700 hours, but we should add on an initial competency examination at the end of that, plus some folks suggested an annual reassessment of radiation safety competency. Somebody suggested that that annual assessment should be a laboratory exercise plus a graded quiz for the annual assessment. So that was one idea that we heard.

And it was noted by several members of specialty boards like ABNM, American Board of Nuclear Medicine, that they do -- obviously they have an

examination clearly for their board, but then they do periodic reassessments of competency as well. So they thought that the alternate pathway should also have regular reassessments as well.

Question 15. How would draft approaches impact the medical organizations that use NRC's T&E requirements as a basis for establishing their training programs?

Maryann, I'm going to ask you to explain this question a little bit, if you could.

(No audible response.)

MS. LOPAS: Maryann, you might be muted still. Question 15?

MS. AYOADE: Hey, Sarah. Sorry. Yes, I was muted. Okay. Sorry about that.

So the question was how would the draft approaches impact the medical organizations that use the NRC's training and experience requirements as a basis for establishing their training programs?

So we know that some medical boards that we see -- they also reference NRC's regulations as part of their training requirements, not as the full training. It's a part of their training curriculum.

I know we also see references to NRC's regulations within the hospitals credentialing some

kind of programs. So the hospitals -- like I mentioned before, bigger hospitals or larger institutions would have an additional credentialing board that they use to review and approve their physicians before they can actually let them practice at that facility. And so part of their requirements in addition to whatever it is that they have established for that physician would be are they are authorized users made with an NRC license or an Agreement State license.

So this is what we're referring to in terms of how would any of the draft changes that we're examining -- how would they affect the organizations that use NRC current training and experience requirements? And so that's what we would like to get feedback on.

MS. LOPAS: Okay. That was a good explanation, Maryann. Thank you.

It kind of related to the next question. And again, folks, please press *1. If you want to interrupt me at any time, press *1. That's how you get me to stop talking so you can talk. So *1 or submit a webinar question.

Okay. So what Maryann was just talking about, question 16, is are there concerns regarding

implementation and/or -- or, excuse me, I'm going to go 17. Question 17 related to what Maryann was talking about a little bit.

Are there unintended consequences of draft approaches? Are there any unintended consequences? So I would almost say that what Maryann was just discussing, how would these draft approaches impact the other medical organizations? That's kind of what we're talking about. That would be an unintended consequence that we would not be aware of and that's why we need your input on these questions.

So skipping back to question 16, are there concerns regarding implementation and/or viability of any of the approaches discussed? And these -- again, this is something where you're out there in the field. Tell us if some of these approaches just would not work. You just think, no, that's impossible. This -- that wouldn't work because of A, B or C. That's what we want to hear.

Question 18. Which of the draft approaches best positions the NRC to effectively regulate future radiopharmaceuticals? So we want to make sure that we position the NRC to be ready for an increased number of radiopharmaceuticals that are

going to come down the line and potentially increase complexity.

Or maybe the other side of the spectrum some of these radiopharmaceuticals will evolve into patient-ready doses, right? And so do patient-ready doses need 700 hours of T&E in order for a physician to be able to administer them? Especially let's say a medical oncologist who may be familiar with the toxicities of chemotherapy. Do they need 700 hours to administer a patient-ready dose? So that's something to think about.

And then question 19. Should the NRC continue to play a role in the review and approval of authorized users? And that the big question and it relates to our performance-based options. So we would like to hear from you. Should the NRC continue to be involved in this?

Okay. So those are our questions. *1 to make a comment or ask a question. It's 11:17. I'm going to give folks some more time to jump in and ask a comment, but if I don't hear anything in the next few minutes or so, we might end early because I don't know if you just want to sit here and listen to me talk. So *1.

I will point out that we did hear

statistics during last week's meeting, the meeting on November -- or excuse me, May 14th that cited that radiopharmaceutical therapy as a part of overall nuclear medicine right now is at 13 percent and that it's expected that by 2030 that percentage will increase to 30 percent. So that's what we're thinking about here.

We have this opportunity -- we've been asked by the Commission to look at training and experience for radiopharmaceuticals requiring a written directive and we feel like we have an opportunity to potentially suggest changes to our regulations to the Commission that would set us up for that future. So that's where we're coming from with question 18. We want to hear your ideas on that.

OPERATOR: Excuse me. This is Allison. We have a comment.

MS. LOPAS: Okay, Allison. Great. Thank you.

OPERATOR: Not a problem. Michael Peters, your line is open.

MR. PETERS: Hi, this is Mike Peters from the American College of Radiology. First I'd just like to thank NRC staff for extending the comment

period. It will be very helpful to us and to other stakeholders.

And also something came up in these conversations and sort of keeps coming up, but I would ask the NRC to please refrain from using the terminology patient-ready in its report and other communications on the AU teaming issue. This is really a reference to shipping of unit dose delivery systems shipped by nuclear pharmacies versus cold kits or generator-based prep.

But to the nuclear medicine resident's earlier comments, it is irrelevant to a physician's use of these therapies and actual patient care. So the -- if you look at the FDA-vetted labeling and pre-market documentation for these products, it does not include this concept with regard to physician services using the product.

So we would ask the NRC also to not use this terminology which is weighted by industry to intentionally diminish the responsibilities of AUs to patients, care team members, regulators and the public. Thank you.

MS. LOPAS: Thank you, Mike. We appreciate that comment. And we do hope that your -- ACR's comments that you submit to us in writing

will expand upon that because we specifically asked a question about that. So thank you.

Okay. I'm going to check here. We do have a question here on the webinar. The question is regarding the percentage I cited earlier - is that a per microcurie or per procedure statistic?

Lisa, I'm not 100 percent sure. I think that's number of procedures. The commenter's asking about the 13 to 30 percent increase in radiopharmaceuticals -- it's procedures - yes - - it's referring to procedures.

Okay. Allison, do we have anybody else on the line?

OPERATOR: No comments or questions at this time.

MS. LOPAS: Okay, folks. I'm going to give you a couple more minutes and to give everybody one last chance to press *1. I'm just going to again review the comment procedure. So July 3rd. That's a Wednesday right before you leave for your 4th of July vacation. Get your homework in. And your homework is to submit comments to us and help answer your questions that we have and so we can make an informed recommendation to the Commission.

If you have any issues again submitting

your comments, you can email them to me: sarah.lopas@nrc.gov.

And we have another question about the reference on that increase in radiotherapies. That was from I want to say -- was it the Cardinal Health web site? Michael Guastella, I can find that reference for you and send it to you. I have your email. I can send you that reference.

MS. AYOADE: This is Maryann Ayoade. Are you referring to that 13 percent?

MS. LOPAS: Yes.

MS. AYOADE: Yes, that -- I'm not sure where it was from, but I know it was Dr. Greenspan that brought it up, so I don't know if that helps.

MS. LOPAS: Yes, we had a commenter who brought that up, but I -- we had seen that percentage before, Michael, so I can find that link for you and send it to you.

Okay. And let's see. I think that's going to be it. One more chance. *1. I don't like ending this early, but it really is a little bit of radio silence and it's boring to talk to myself. But I appreciate everybody who has talked to us, because we do appreciate you. And thank you for your comments. And if you would like to submit written

comments, you know how to do it. And you know how to get in touch with Maryann and myself. I'll go ahead and put our emails up again. And I think that's going to be it. So thank you all for your time and we look forward to getting your comments and we will review them thoroughly. So thank you and have a great day.

OPERATOR: This now concludes today's conference. All lines may disconnect at this time.

(Whereupon, the above-entitled matter went off the record at 11:23 p.m.)