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NUCLEAR REGULATORY COMMISSION

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STAFF EVALUATION OF TRAINING AND EXPERIENCE

REQUIREMENTS FOR RADIOPHARMACEUTICALS:

DRAFT APPROACHES FOR COMMENT

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TUESDAY

MAY 14, 2019

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ROCKVILLE, MARYLAND

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The Session convened at the Nuclear Regulatory Commission, One White Flint North, Commissioners Hearing Room, 11555 Rockville Pike, at 1:00 p.m., Sarah Lopas, Facilitator, presiding.

NRC STAFF:

SARAH LOPAS, NMSS, Facilitator

MARYANN AYOADE, NMSS

LISA DIMMICK, NMSS

CHRIS EINBERG, NMSS

ALSO PRESENT:

BETH BLANKENSHIP, American Association of Physicists in Medicine (AAPM) *

MUNIR GHESANI, Society of Nuclear Medicine and Molecular Imaging (SNMMI) *

SHAEMUS GLEASON, Bayer Healthcare

ERIN GRADY, American College of Nuclear Medicine (ACNM) *

BENNETT GREENSPAN, SNMMI *

JUSTIN PEACOCK, Brooke Army Medical Center *

JOE RUBIN, United Pharmacy Partners (UPPI)*

DAVID SCHUSTER, Emory University *

GEORGE SEGALL, ABNM *

JEFF SIEGEL *

ARIF SHEIKH, Icahn School of Medicine at Mount Sinai *

BRUCE THOMADSEN, AAPM

*Present via telephone

P R O C E E D I N G S

1:01 p.m.

MS. LOPAS: Good afternoon, everybody. Thank you for coming today, for joining us here in person at the NRC in Rockville and also to those of you who are on the phone and logged into the webinar.

Welcome to the NRC's public meeting and webinar to accept comments on the staff's draft approaches regarding training and experience for radiopharmaceuticals requiring a written directive.

My name is Sarah Lopas and I'm the Project Manager for the staff's evaluation. And, I'll be facilitating today's meeting and also be giving part of the presentation.

And, our operator's name is Shirley and she's going to be helping me out with taking comments over the phone.

I'm also joined here at NRC headquarters by my supervisor, Chris Einberg. Chris is the Branch Chief of the Medical Safety and Events Assessment Branch in our Office of Nuclear Materials Safety and Safeguard.

We also have Lisa Dimmick who's the team lead for the Medical Radiation Safety Team. She's also at the table with us.

And also, Maryann Ayoade, and she's a Health Physicist and she's the technical lead for the T&E evaluation.

So, we have a short agenda for today because we know that the main point is public comments on our draft approaches. So, Chris is going to give a welcome and talk about why we're here today.

Then, I will be giving the presentation that will involve a very short background on why we're here. Next Maryann will go through the draft approaches and then we'll just -- I'll talk about how you can provide your comments on the record.

And then, we'll just go immediately into public comments.

We may or may not take a break. We'll probably just end up going straight through. But, you know, we're all adults, you can get up and the bathrooms are right out the door to the left when you go out these doors here.

All right, now I'm going to hand it over to Chris.

MR. EINBERG: Okay, thank you, Sarah.

Yes, and good afternoon, everyone. Thank you for taking the time to attend today's meeting, whether you are here in person or participating

remotely.

Today's meeting is the first of two public comment meetings that NRC will hold on the staff's draft approaches regarding training and experience requirements for administering radiopharmaceuticals requiring a written directive.

The purpose of today's meeting and the meeting on May 23rd are to provide you with an update on the staff's 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, 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 the training and experience requirements for radiopharmaceuticals requiring a written directive.

The staff reviewed and processed all the comments received during that time, whether they were

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 about how the staff could address the Commission's direction to evaluate whether it makes sense to create tailored training and experience requirements for certain radiopharmaceuticals.

Some of the preliminary ideas which we are calling draft approaches go beyond creating a limited training and experience pathways for certain pathways for certain categories of radiopharmaceuticals.

For instance, some of the staff's draft approaches are more performance based and wouldn't prescribed 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 and regulatory community.

And, that's why we are here today. The comments we receive today and throughout the rest of the comment period will help shape the approaches we'll include in our upcoming paper for the Commission.

We will include comment summaries in our paper so the Commission will be informed on stakeholders positions and the training and experience requirements.

So, I want to thank you again for joining us today and your participation is vital to our decision making process.

Thank you.

Sarah?

MS. LOPAS: Thanks, Chris.

So, just some housekeeping stuff before I move into the rest of my slides.

So, for those of you in the room, if you haven't signed in, I ask that you please sign in on your way out. I think everybody got the handouts that are there.

We have the Federal Register Notice, the May 2nd Federal Register Notice, and also, the copy of today's slides.

If you're on the webinar, if you go to

the handouts tab on your webinar, I have uploaded those two handouts there on the -- under that tab so you can go ahead and download those if you would like them.

I'll also note that both the slides and the FRN are also attached to the meeting -- today's meeting notice. So, if you know how to find the NRC public meeting notice, you can click through and find the slides and the handouts there.

And, that could be helpful for you if you're logged -- if you're on the bridge line but you didn't log on to the webinar for whatever reason, you can find the slides on our meetings notice and click along right now.

So, we're on slide five right now, for those of you that don't have access to the webinar.

During today's presentation and in the slides, we often refer to training and experience as T&E for short; and, authorized users as AUs.

We have a court reporter here today and he is transcribing today's -- everything that's being said today so that we're capturing your comments on the record.

So, there's no preferred way to submit your comments. You can submit written comments or

you could speak them here today over the phone or here in person. And, comments that are submitted by writing and spoken here today carry the same weight.

So, if you feel like you've said your peace today during the -- during today's webinar, or on the call, or here, you know, in person, then you don't need to submit duplicate written comments.

You're welcome to, but just letting you know.

And so, it's important that everybody speaks clearly, introduces themselves when they get up to speak their comments later on.

So, we will be waiting -- holding off on comments until the end of the presentation. And, that's when we're done our presentation, we'll open up the phone lines and Shirley's going to help us out.

And, I will be managing the webinar as well. And, I see somebody has already submitted a question. So, just give me a moment and I'll check that out.

But I'll be monitoring the webinar to see if anybody's sending questions or comments through that as we move forward.

So, let me start with a little bit of

background.

So, I wanted to remind everybody that when we talk about the T&E requirements, we are talking specifically about those requirements under Subpart E in 10 CFR Part 35.

So, Subpart E specifically covers the unsealed byproduct materials requiring a written directive. So, when Maryann gets to our draft approaches later on, just keep in mind that they are talking about changes to -- potential changes to just those T&E requirements under Subpart E.

So, currently, our regulations at 10 CFR 35.390, and that's under Subpart E, provide three ways a physician can become an AU to administer radiopharmaceuticals requiring a written directive.

They can be board certified by one of the NRC or Agreement State recognized medical boards.

Or, they can complete something that we call the alternate pathway which is specified under 10 CFR 35.390(b)(1).

And so, this is where it's the 700 hours total of T&E that breaks down to at least 200 hours of classroom and laboratory training plus another 500 hours of supervised work experience.

Plus, that alternate pathway requires

some case work and a preceptor attestation as well.

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

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

Since those regulations were revised, those tiny regulations were revised in 2002 and then amended in 2005, the NRC has received periodic feedback from medical stakeholders that the 700 hour requirement is overly burdensome.

Doctors who would like to treat their patients with, for example, patient ready doses of radiopharmaceuticals are unable to do so because they can't take the time to get that 700 hours of T&E.

So, some of these same stakeholders are also contend that because the alternate pathway is discouraging these non-nuclear medicine and non-radiation oncology physicians from becoming AUs, that we're creating a shortage of AUs.

So, these stakeholders also point out that there's a disparity in patient access to therapeutic radiopharmaceuticals in more rural parts of the country as well.

So, that's a little bit of background. And, over the years, the Commission has heard this feedback and subsequently, they directed the staff, in 2017, to examine some of these concerns.

So, this slide, slide seven, references staff requirements memorandum, SRM M170817. And so, that was dated August 17, 2017. And, that's where the Commission evaluated the staff -- or directed the staff to evaluate whether it makes sense to create those tailored training and experience requirements for different categories of radiopharmaceuticals, how those categories should be determined, and, for instance, such as by risks posed by groups of radionuclides or by delivery method, what the appropriate T&E requirements would be for each of those categories and whether those requirements should be based on hours of training and experience or should they be more focused on competency?

And so, in 2018, the NRC staff did some initial work in response to the Commission's directions.

And the staff concluded in a SECY paper from back in August 2018 that while it may be feasible to create tailored T&E for certain categories of radiopharmaceuticals and there could be ways to focus

this T&E more on competency, that the staff needed more outreach with the medical and regulatory community first.

So, that's where we are today and that outreach really started last fall when we published our initial Federal Register notice.

The Federal Register notice opened the 90-day public comment period. And, we held four public comment meetings during that time.

We received 144 written comments and there were 35 comments spoken during the public meetings. All the public meeting transcripts, the public meeting summaries and every single comment that we received are all available on regulations.gov.

So, if you go to www.regulations.gov and then, in the search bar, you enter in our T&E docket which is NRC-2018-0230 and you just search that docket, that webpage will pop right up and there, you can see everybody's comments. You can see the meeting summaries that we put together, the transcripts from last fall and winter.

So, I'm about to outline at a high level what we heard last fall and winter, but I want to note that, in the Commission paper that we're putting

together, we are going to be including more detailed comment summaries for each public comment period.

Those summaries will be included as one long enclosure to our paper for the Commission.

And, I'm also going to be making available in ADAMS a full comment binning report for each comment period. And, that will show how we reviewed your comments, how we processed, and how we extracted individual comments from overall submissions and put them into what we call comment bins.

Let's get into what we heard. So, citing concerns about patient and public safety, there was strong opposition voiced to any changes in the T&E requirements from the nuclear medicine community and the related medical specialty boards and professional societies.

Going hand in hand with support for maintaining the current T&E requirements was opposition to creating tailored T&E that would resulted in limited authorized users.

Opposition to creating limited AU pathways was primarily rooted in concerns about protecting the health and safety of patients and concerns about quality of patient care.

But other commenters also warned that limited AUs could be motivated by financial gain versus what would be best for their patients. And, that this would be detrimental, obviously, to patients, but also to the field of nuclear medicine in general.

On the other side of this spectrum, we had -- we heard cited concerns about patient access and care concerns that there was support for tailored T&E requirements from physicians such as hematologists, endocrinologists, oncologists, and urologists who would like to treat their patients with radiopharmaceutical therapies as well as from the pharmaceutical industry and related trade groups and also a rural healthcare 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 supporting limited AU pathways pointed out that the NRC's T&E requirements should be more risk based, that in its evaluation of the T&E requirements, the NRC should evaluate specific categories of radiopharmaceuticals, specific routes of administration, radiation characteristics,

preparation methods and unique practice settings requirements such as a physician's previous exposure or experience with toxic non-radioactive chemical therapies.

That we should include all these in our decision making process for potentially creating tailored T&E.

Some commenters also pointed out that the precedent has already been set for creating tailored T&E that, for instance, we have carve outs for radioactive iodine, iodine-131.

Groups on both sides of the issues presented for the NRC detailed lists of basic radiation science and health and safety topics and clinical training and experience requirements that they thought were necessary for either full or tailored T&E.

And, there was mixed support from moving towards a more competency focused evaluation or proposes AUs -- for proposed AUs. For example, such as requiring a formal radiation safety examination to become an AU and potential periodic reassessments.

The next couple slides, I'm going to talk about what we heard from our Advisory Committee on the Medical Uses of Isotopes, the ACMUI, and also

what we heard from the Agreement States.

So, it's important to note that both the ACMUI and the Agreement States are both going to get a chance to review our draft Commission paper this summer. So, they get another opportunity to provide us some input on to our evaluation process.

But, in mid-February, the ACMUI Subcommittee on Training and Experience issued their draft report on T&E under Subpart E.

And, a public teleconference was held on February 26th with the Full Committee and, during that public teleconference, the Full Committee endorsed the Subcommittee's draft report in their conclusions.

So, this slide summarizes the positions and recommendations. And, they are, that the Committee strongly supports and reaffirms their 2016 position on maintaining the current and existing AU pathways, that is, board certification and the alternate pathway.

And, the Committee believes that those pathways are adequate for protecting public health and safety.

And, the Committee backed up this position by saying that, radionuclide therapy poses

the highest risk and highest impact of all nuclear medicine procedures.

The Committee concludes that there is no objective data to confirm an AU shortage and the Committee does not recommend a limited scope AU pathway for radiopharmaceuticals requiring a written directive.

The Committee agreed that, in order to ensure the safety of patients, personnel and the public, if the NRC does choose to pursue creation of a limited scope AU pathway, that the AU candidate must acquire the basic knowledge topics that are listed under 35.390, and they must complete a formal competency assessment.

The Committee further recommended that there should be a periodic reassessment of radiation safety competency for these AUs, these limited AUs.

The NRC has been coordinating with the organization of Agreement States as the primary conduit for our outreach to all 38 of the Agreement States and we're going to continue to coordinate closely with the Agreement States throughout the rest of the staff's T&E evaluation.

We recognize the importance of the Agreement States in our evaluation because the

Agreement States regulate roughly 80 percent of the materials licensees in the United States.

And, any changes to our regulations directly impact the Agreement States as they must implement compatible regulations and requirements.

So, 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 and they reiterated this from when we reached out to them earlier in 2018.

So, their position is that, most Agreement States find that the current AU pathways are reasonable and accessible to physicians wishing to administer radiopharmaceuticals.

However, there was not a consensus 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 creating limited AU pathways, while other states felt that creating new limited pathways could just add unnecessary complexity to what are already very complex regulations regarding T&E requirements under Subpart E.

The OAS did close out their comment submission with the suggestion that the NRC consider

a less prescriptive approach to the training and experience requirements and that, perhaps putting in regulatory focus on whether licensees are complying with 10 CFR 35.41 - which is our regulation pertaining to written directives and also focusing on compliance with their regulations regarding radiation protection in 10 CFR Part 20 - this could be a more effective and efficient use way to regulate medical licensees.

So, this slide is recycled from my presentation from last fall and winter, but I thought it was important just to remind folks where we are in this evaluation.

So, just a reminder that this is not -- this evaluation is not a rulemaking. But the connection between this evaluation and a potential rulemaking is that, the outcome of this evaluation could potentially result in staff recommending to the Commission that the NRC should conduct a rulemaking to potentially amend the T&E requirements.

So, we conducted our initial public comment period. We reviewed and processed all those comments and we received the ACMUI and Agreement States positions and we developed these draft approaches that Maryann is going to talk about in just a minute.

I have input from medical stakeholders highlighted in this slide because we're still in that phase, obviously. And, your input, as Chris said, your input is going to help us refine and edit these draft approaches and determine whether or not they should be included in the paper that we're putting together for the Commission.

And, once we deliver our paper to the Commission, the Commission will review the options and our recommendation. And, they will make the ultimate determination of how we proceed, whether that involves a rulemaking or not.

So, that brings us to the current T&E Federal Register Notice, the one that was published on May 2nd.

So, again, if you're on the webinar, I've uploaded that for you as a handout and the handouts are here in the room.

It was published on May 2nd and opened up our public comment period which is a little more than 30 days. It ends on June 3rd. The FRN also announced today's meeting and a meeting on May 23rd that'll I'll talk about in a couple slides from now.

And, the most important aspect, obviously, of this FRN is that it outlines our draft

approaches that we're considering and it also includes a series of questions that we're really interested in getting input on from you all.

So, at this point, I'm going to hand it over to Maryann to walk us through those draft approaches.

MS. AYOADE: Okay, thank you, Sarah.

So, in the following slides, you'll see that we have numbered and listed the draft approaches with the same numerical headings as you will see in the Federal Register Notice.

The same thing goes for the numbered questions that we are looking for feedback on. So, these questions, they have the same number here in the slides as you will also see in the Federal Register Notice.

With these approaches 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 authorize -- to become authorized users.

While some of the approaches could modify the existing training and experience regulations, or

they could keep the regulations as is.

So now, I will go into the approaches starting with this slide.

So, the first approach is the status-quo approach. This approach would maintain the current training and experience requirements for radiopharmaceuticals requiring a written directive.

And so, 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 from you all is, if the status-quo is maintained, how should the NRC prepare itself for the expected increase in the number and complexity of the radiopharmaceuticals that we will see in the future?

The second question is, is there a challenge with the current training and experience requirements such as concerns that are related to patient access to radiopharmaceuticals that should be addressed through a rulemaking?

Next slide?

So, slide 14 discussed tailor, train, and experience approaches. And, these four tailored and experience approaches would modify the existing

training and experience requirements for radiopharmaceuticals.

So, the first three approaches which are, the limited authorized user for alpha or beta emitting radiopharmaceuticals, the limited authorized user for unit, dose, patient radiopharmaceuticals and the limited authorized user for any one parenteral radiopharmaceutical.

These three approaches would require a set amount of training and experience that is tailored to the specific radiopharmaceutical.

The fourth approach which is the emerging radiopharmaceuticals approach, this would tailor the training and experience for each new radiopharmaceutical as they were developed.

And so, it would be similar to the approach for regulating new technologies which is currently under 35.1000.

And so, the question that 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 for the limited approaches?

Next slide?

So, this approach would allow for limited

authorized users to administer one or more of a certain type of radiopharmaceutical.

So, in this case, physicians that are seeking authorized user status would be able to administer any alpha or beta emitting radiopharmaceutical.

The training and experience here would be for the user to have completed at least 400 hours of training and experience of which there would be 200 hours that should be in classroom and lab 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 written attestation similar to what the NRC's current regulations require under the alternate pathway.

And so, the question that we would like to get feedback on for this approach is, how should the NRC categorize radiopharmaceuticals with mixed emissions?

Next slide?

So, again, just like the previous approach, this approach would allow for the limited authorized users to administer one or more specific radiopharmaceuticals.

In this case, physicians that are seeking authorized user status would be able to administer any unit dose patient ready radiopharmaceutical.

And so, similar to the previous approach, the training and experience required here would be for the user to have completed 400 hours of training and experience which includes 200 hours of classroom and lab training plus a minimum of 200 hours of supervised work experience and it would be focused on unit dose patient ready radiopharmaceuticals.

This approach would also require a preceptor attestation.

And so, the question we would like to get feedback on here is, how should the NRC define patient ready?

Next slide?

This is the third type of limited authorized user approach. Again, similar to the previous two approaches, this approach would allow for limited authorized users to administer one or more specific radiopharmaceuticals.

In this case, physicians that are seeking authorized user status would be able to administer any one parenteral radiopharmaceutical.

The training and experience required here

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

What is different in this approach than the other limited authorized user approaches is that, if the authorized user wants to administer any new additional radiopharmaceutical that comes along and that is different from what they had been authorized for already, the authorized user would need an additional minimum 80 hours of tailored supervised work experience.

And so, this approach would also require a preceptor attestation.

Next slide?

So, this approach is the emerging radiopharmaceuticals approach. And, it is the fourth of the limited authorized user type of approach.

It would mirror that of the NRC's current regulations in 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 to 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, this would be individuals that are not your traditional nuclear medicine or radiation oncology physicians that we see currently.

So, that would be, for example, a hematologist, the medical oncologist or urologist that wants to administer radiopharmaceuticals.

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

Next slide?

Slide 19, this presents performance based approaches, the first of which is the competency based evaluation approach.

And, the second, the credentialing of authorized users.

These two approaches would be removing the prescriptive training and experience requirements from the regulations and, instead, they would be

focusing oversight on the performance based aspects of the licensee's medical program for radiopharmaceutical administrations.

Next slide?

So, the first performance based approach, the competency based evaluation approach, this would require that proposed authorized users demonstrate competency in radiation safety topics and radiation safety job related job duties through a formal evaluation.

So, for example, an examination is one way or a preceptor attestation, and that would be something that we would use to assess and confirm that that individual is able to function independently as an authorized user for the medical uses that are being requested.

So, the question that we would like to get feedback on here 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?

The second performance based approach is the credentialing of authorized users approach. In this case, the NRC would no longer be involved in the

review and approval process for authorized users training and experience under Part 35.

Instead, the licensees would have to develop and use their own policies and procedures to make self-determinations as to whether their credentialed physicians have the appropriate training and experience to be an authorized user.

Licensees would also be required to maintain their own training programs to ensure compliance with the requirements for having procedures for administrations requiring the written directive in 10 CFR 35.31 and also with the requirements for radiation protection in Part 20.

So, the question we would like to get feedback on here is, how could physicians in small practices be credentialed?

So, we are looking at physicians that aren't associated with hospitals or other larger institutions that have credentialing boards that review their physicians credentials and approve them before they can practice at their facility.

Next slide?

Slide 22 presents team based approaches. So, for the first two approaches, the radiopharmaceutical team approach and the approach

that involves teaming authorized users with authorized administrators which would also introduce some new users.

I want to point out that these two approaches would be more performance based. 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 make sure that they have a program in place that can accommodate the authorization of uses that are being requested.

The third team approach, the approach that would partner limited authorized limited trained authorized users with authorized nuclear pharmacists.

This approach, on the other hand, would require more prescriptive training and experience for authorized users because of the authorized users' more prominent role in the administration of Radiopharmaceuticals.

So, in summary here, these team based approaches would either be removing prescriptive training and experience requirements for authorized users and would focus the training and requirements on competency of the entire team involved in the procedure.

Or, it would revise the current 700-hour training and experience requirement for authorized users based on pairing the authorized user with another individual with expertise in administering radiopharmaceuticals.

And, I'll go over those in the coming slide.

But the question, overall question here for these team based approaches that we would like feedback on is, how should the authorized users radiation safety responsibilities be clearly distinguished and defined from the other members of the team?

Next slide?

Under the first team based approach, the radiopharmaceutical team approach, the licensees would be required to have a team that would administer radiopharmaceuticals. And, 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 such as an authorized medical physicists, an authorized nuclear pharmacist, a health physicist, or other physicians that manage patient care.

And so, 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 team would meet the requirements in 10 CFR 35.41, which is for procedures for administrations that require a written directive.

And also, to meet the regulations in Part 20 for radiation protection.

Next slide?

The second team based approach is one that would team up authorized users with authorized administrators.

Now, these authorized administrators would be individuals that the licensee would authorize to administer radiopharmaceuticals.

So, for example, a nuclear medicine technologist or a nuclear medicine advanced associate, which is comparable to a physician extended position or an extension of a physician services by other providers.

With this approach, licensees would need both an authorized user and an authorized administrator to administer the radiopharmaceuticals.

This approach would be more performance

based and the training and experience for authorized users would focus on written directives, patient release criteria, and medical event reporting.

The training and experience for the authorized administrators would focus more 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 in written directives, the patient release criteria, and medical event reporting.

Next slide?

The third team based approach 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 user due to their more prominent role in the administrations.

It would require that the authorized user have at least 400 hours of training and experience.

Now, this training and experience for the

physician partnering with the authorized nuclear pharmacist would be more focused on supervised work experience and patient cases.

And, it would also require a preceptor attestation.

The training and experience for the authorized nuclear pharmacist would remain the same as it is currently listed in 10 CFR 35.55.

The authorized user in this approach in this approach would be responsible for radiopharmaceutical administrations in accordance with the written directive and the authorized nuclear pharmacist would be responsible for all the other radiation safety related duties.

So, the question that we would like to get feedback on under this approach is, how should the radiation safety responsibilities be divided between the authorized user and the authorized nuclear pharmacist?

Next slide?

MS. LOPAS: Okay, now that Maryann has gone through the draft approaches, I'm just going to run through these questions. So, these are questions that were in the Section 4, the last section of the Federal Register Notice.

And, we put them at the end because they mostly apply to all the approaches and maybe these questions will help shape your feedback on these approaches because these are the things that we're thinking about.

So, question 10, what are the advantages and disadvantages of each draft approach?

Are there significant costs or benefits associated with any of the approaches? That was question 11.

Would any of the draft approaches impact patient access to Radiopharmaceuticals or address the stakeholder concerns of overly burdensome regulatory requirements?

Question 13 is, for the draft approaches that considered tailored hours of T&E, what are the appropriate numbers of hours of that T&E? Right now, we have 400 for quite a few of them.

And, what radiation safety topics should comprise the limited T&E?

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?

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

Question 16, are there concerns regarding implementation and/or viability for any of these approaches discussed above?

Question 17, are there unintended consequences of the draft approaches?

Question 18, which of the draft approaches best positions the NRC to effectively regulate the future of Radiopharmaceuticals?

And, question 19, should the NRC continue to play a role in the review and approval of AUs?

So, here, just some of the basics for getting us your comments.

So, like last time around, we're using regulations.gov again to submit your written comments. It's the same docket as last time. And, again, and like I said, if you just go to that regulations.gov and search that NRC 2018-0230 right in the search bar, it's the first thing that pops up.

So, it's pretty easy to submit your comments. But, if you have any issues submitting your comments, please know that you can email myself

and/or Maryann and we can get your comments that way as well. That's no problem.

So, just keep in mind that the -- when you get a confirmation from regulations.gov, you're not going to see your comment pop up right away. It takes about 11 working days to pull it down from Regs.gov, then get into ADAMS and then back up on regulations.gov, the public facing part of regulations.gov.

So, don't panic, if you got your confirmation notice on regulations.gov, the comment was submitted.

But, again, if you're at all worried, you can go ahead and email this to us as well.

So, all the comments are going to be in ADAMS, obviously. And, I do want to point out that because this is not a rulemaking, we aren't going to be providing responses to your comments.

But, as I mentioned, it is a very painstaking process that we go through to bin your comments and extract individual comments. So, and we are going to have what I hope are very good summaries of your comments in this Commission paper coming up.

So, we have an additional public meeting,

one more on Thursday, May 23rd. It's a morning webinar. It's just a webinar, so not in person, 10:00 a.m. to 12:00 p.m.

So, if you don't feel like talking today, but you want to talk on that date, please dial in at least the bridge line and you can register for the webinar as well.

Everything will be the same, the slides will be the same, so same meeting, just another opportunity for you to get your comments on the record.

And then, here are our next steps, just so everybody has an idea of kind of how the schedule got pushed back a little bit because we have this second public comment period.

So, right now, the public comment period May 2nd through June 3rd.

We're going to finish developing our paper in June 2019 after -- or in June after we get all your comments and review them.

Then, we expect that the ACMUI and the Agreement States will have about two months in the summer, maybe into September likely, to review our draft Commission paper.

We'll get comments back from them, and

we'll incorporate. And, it's also important to note that the ACMUI will have a public teleconference on their draft comments or on their comments on our draft Commission paper.

So, that's a public teleconference similar to what they had back in the end of February.

If you're interested in this topic, I encourage you to call into that teleconference.

And, the way you can find about that teleconference is making sure that you sign up for the NRC's medical List Server.

And, the way you sign up for the Medical List Server is you can just Google NRC Medical List Server and the first result that comes up is the -- tells you how to subscribe.

And, that's -- we send out emails, I think not too frequently, to be honest. But we send out emails, so it's not going to flood your inbox, but we send out emails with important announcements like meeting notifications, notifications of meetings, and reports, and whatnot. So, I encourage you to do that.

So, that telecon will hopefully be in mid to late September.

We would then finalize our paper in

October and November. And we'd have a Merry Christmas hopefully getting the paper out to our Commission.

So, that's our schedule for now. And then, for more information, I do try to do a good job maintaining the training and experience website, so check that out.

Of course, the, as I mentioned, the regulations.gov docket, you can read everybody's comments on there.

And then, please feel free to contact myself or Maryann at any time. You know, Maryann's our technical point of contact. I'm more the process person, so either questions about comments or process in general, you can reach out to me on those.

And so, with that, we're going to open up to public comments.

So, I just want to remind everybody that you're on the phone, if you're on the phone, you can go ahead and press star one. And that's going to indicate to Shirley, our operator, that you need your line unmated.

So, press star one if you're on the phone and you want to make a comment.

We have our court reporter here in the

room, so please speak clearly. Please start by providing your name and if you are responding to a specific question in the FRN, it'd be helpful if you had the question number, not the end of the world if you don't, but it might be helpful.

And so, I think that's it. And, the folks in the room, you do have to use the microphones. So, you can use either one of these aisle microphones and Irene also has a handheld. So, if you don't want to get up, we can bring you the handheld microphone, that's totally fine.

So, does anybody in the room want to start us off with comments?

Yes? Do you want to -- would you want to go to a podium or you want -- okay, all right. And, folks on the phone, we're going to start in the room and then we'll go to you.

And, I also want to point out that, if you are a little shy and you want to submit a comment via the webinar, I can read it aloud for you on the webinar.

Okay, go ahead.

DR. THOMADSEN: Well, thank you very much for the honor of being the first here. I will thank you officially for everybody for taking the time to

go to the stakeholders and get input on this important topic.

And, my name is Brice Thomadsen. I'm the current Chairman of the Board for the American Association of Physicists in Medicine, the AAPM, and, I will be speaking on behalf of them.

Just on a personal note, I was also a former -- or I am a former Chair of the Advisory Committee for Medical Uses of Isotopes and it's really nice to be back in the halls here.

The AAPM did respond to the October request in the Federal Register. And for the current request in the Federal Register, we are still preparing our answers to all of the questions.

And so, I do not have all comments that I can give you at this moment. There are four points that I can make that we have approved for bringing to you from the AAPM.

The first is that any arbitrary reduction in the training and experience will compromise the safety of these treatments for patients, staff, and the general public.

The training is more than just learning how to walk through a procedure, just as learning any skill requires multiple repetitions, so does

radionuclide therapy.

Experience in a residency does not just prepare somebody to mechanistically perform the procedure, but to know what to do when things go wrong and to have seen enough of these cases to know when things are going wrong, and, when it just doesn't feel right.

Understanding general radionuclide therapy just -- not just one example gives us ability to discern impending problems.

The second point is, there is no need to make a change. When this was first proposed, as you pointed out, the ACMUI did look at the distribution of AUs, and there seemed to be quite enough.

There are portions of the country, admittedly, where there is limited healthcare, not just for AUs, but for medical oncologists as well.

Citizens living in these areas know that they will have to travel for sophisticated, specialized treatments. Otherwise, they would be living in a city.

This is similar to requiring -- if somebody requires brain surgery, nobody is suggesting that an internists or a general family practitioner with a limited ten-week course should be doing brain

surgery.

Radiopharmaceutical treatments, not so much like brain surgery, but it is a lot like rocket science.

The third point is that the decrease in the use of some radionuclide therapies is not due to the lack of authorized users nor the refusal of authorized users to perform these procedures.

There is a rapid increase in the number of radiopharmaceutical treatments across the country right now. Authorized users are enthusiastic about doing this.

The decrease in the procedures that have been commented on is mostly due to the fact that the referrals from medical oncologists to authorized users to perform these has decreased markedly.

And, most facilities have found better ways to treat the particular diseases for these particular therapies that have come to this Commission.

The fourth and last is when considering what part to put the radium dichloride treatments, the ACMUI recommended three -- Part 300 in Title 10, commenting that the training for all radionuclide therapies is pretty much the same in order to develop

the understanding of the effects, the doses, and of the treatments, the hazards and the natures, which is covered in the current training.

But a lot of the treatments do require some additional training for the particulars of each evolving procedure. There shouldn't be a confusion between these two types of training.

In summary, the AAPM would maintain that the current training and experience requirements have worked well. There seems to be no real reason to change. And, changing to abbreviated versions could be hazardous to the patients, the staff, and the public, and could compromise the quality of patient care.

Thank you very much for this opportunity.

MS. LOPAS: All right, thank you, Dr. Thomadsen.

Okay, so, I'm going to check with Shirley to see if there's any comments on the phone before I go back to our room.

OPERATOR: Again, just press star one to ask a question.

We do have one question and that's from George Segall. Your line is open, go ahead with your question.

DR. SEGALL: Thank you very much.

This is George Segall, and my last name is spelled S-E-G-A-L-L. I'm a practicing nuclear medicine physician and I'm also the Executive Director of the American Board of Nuclear Medicine.

I would like to thank Bruce Thomadsen for his comments with which I fully agree.

I also would like to thank the NRC staff for an excellent review of the current training and education requirements and the rather detailed proposals that the staff had developed for consideration of stakeholders.

The development of these possible alternative pathways shows the very detailed understanding of the entire situation which is very confidence building.

The ABNM previously submitted written comments during the first comment period strongly supporting the current requirements for 700 hours of training and experience, including 200 hours of classroom and laboratory training. And, I won't repeat those comments.

I would like to address the performance based approach which is included as possibilities for new training and education requirements in the second

comment period.

One particular proposal by the NRC staff under consideration is that licensees would develop and use their own policies and procedures to make self-determinations of whether they're credentialed physicians have the appropriate training and education to be an authorized user for one or more radiopharmaceuticals under 10 CFR 35.300.

ACGME accredited nuclear medicine program directors and the American Board of Nuclear Medicine are aware of many reports of physician trainees showing up to observe the administration of a radiopharmaceutical and not fulfilling all of the requirements of 35.390(b)(1) bullet points A through G.

The reports that we have received is that program directors feel pressured by their superiors to attest to the training and experience that trainees do not have and this training is not fulfilling the NRC requirements.

This is of concern to us and we feel the situation would be exacerbated if licensees were allowed to develop and use their own policies and procedures.

And, the ABNM further believes that a

preceptor based attestation alone would not be sufficient to ensure public safety.

The second point that I would address in the competency based evaluation approach, specifically, the formal assessment such as an examination should be a requirement and periodic reassessments should also be required.

This position is based on the American Board of Nuclear Medicine pass rates for first time takers of its certification exam. These pass rates have traditionally, historically been 80 percent over the past two decades and that figure is very consistent.

What this means is, despite having the training and education currently required by the NRC to be an authorized user, 20 percent of physicians who have had that training are not able to demonstrate knowledge in a secure examination.

So, fulfilling simply the requirements without a formal examination would also, I believe, not be in the interest of public safety.

Furthermore, the ABNM has administered a reassessment examination given every ten years starting in 2002.

The first time pass rate on this

examination is 97 percent, which is good because the Board expects that most practicing physicians are, indeed, competent.

However, on the periodic reassessment examination, three percent of physicians in practice are unable to sufficiently demonstrate the knowledge required to practice competently and safely.

So, the Board feels that not only should an initial formal assessment be required in addition to whatever training and education is the requirement, but that periodic assessment is also necessary to reassure the public and to ensure the safety of therapies using radioactive materials.

Thank you.

MS. LOPAS: Okay, thank you very much.

Do we have anybody in the room that would want to speak a comment here in the room?

(NO AUDIBLE RESPONSE)

MS. LOPAS: All right, seeing nobody, star one for folks on the phone.

Shirley, do we have any star ones?

OPERATOR: We do have a question that comes from -- or a comment from Bennett Greenspan. Your line is open, go ahead.

DR. GREENSPAN: Hi, thank you very much

for this opportunity to speak. I'm Dr. Bennett Greenspan. I'm a nuclear medicine physician and radiologist and the immediate past president of SNMMI. And, I'm speaking for myself.

According to one of the companies, radiopharmaceutical therapy now comprises about 13 percent of nuclear medicine practice. However, it is projected to increase to 30 percent by 2030.

Therefore, I believe it is important that we get this right to provide appropriate requirements necessary for highly trained, skilled, and competent authorized users, the most important issue is patient safety.

And, just below that is safety of personnel and the public.

I recommend and extension for another 30 days for the comment period to July 3rd to have enough time to review evidence and answer the 19 questions posed by the NRC.

Regarding evidence, I request that the NRC provide a list of citations and also include -- which include, but not limited -- are not limited to any relation to training and work environment of the Department of Authorized Users cited.

Seven hundred hours may have been set

arbitrarily in the past, but it has worked over time. A reduction of 400 hours is arbitrary and with no supporting evidence.

The expert societies are unanimously opposed to reduction in requirements. This is not self-serving, but it is to protect our patients.

As far as competency, to me, competency means that the authorized users should be board certified by ABNM in nuclear medicine or by ABR in diagnostic radiology, nuclear radiology, radiation oncology.

Number two, pass duration safety exam.

Number three, the laboratory or department in which their work should be accredited.

And, number four, there should be periodic, probably annual, proficiency testing. And, this can be accomplished by a lab exercise and a quiz that is graded.

A team approach is, I think, a terrible idea, especially if the authorized user is offsite. I think there is a tremendous risk for problems.

However, I think the best approach of these kind of therapies is a multi disciplinary one with nuclear medicine, radiology, radiation oncology, radiopharmaceuticals, medical physicists, probably

radio chemists, and medical Oncologists, all involved in a team effort to treat these patients.

Number -- want to answer question seven briefly, how could physicians and small practices be credentialed?

Frankly, they probably shouldn't. Small practices in rural areas will not have sufficient infrastructure to handle these therapies any more than cabin surgery or neurosurgery as Dr. Segall mentioned.

People who live in rural or remote areas understand that they must -- that they need to travel for specialty or sub-specialty expertise.

I think tailored requirements will be difficult to establish and horrendously difficult to regulate. These therapies will become more complex as more agents are approved.

The radionuclides will be alpha and/or beta emitters with different energies, path lengths, and decay schemes and half lives. For instance, lutetium-177 PSMA is already being used in Germany and Australia and may soon be approved in the U.S.

Some radionuclides are both alpha and beta emitters such as actinium-225 and actinium-225 PSMA is being discussed and actually is being used in

Germany. It emits four alphas and three betas with each decay.

So, I appreciate the opportunity to speak and thank you very much.

MS. LOPAS: Hey, Dr. Greenspan, before you get off, this is Sarah Lopas. I just wanted to get some clarification.

You had made a statement regarding the NRC should provide a list of citations, and I missed what precisely you were talking about. I wonder if you can expand on that a little bit?

DR. GREENSPAN: Okay, thank you, yes.

Well, I know the NRC keeps a list of citations or violations of proper treatment and care. And, I think it would be useful to look at that list and compare it to the kinds of departments or physicians who were guilty of these citations or violations.

So, that information may be valuable in determining what kind of people should or shouldn't be providing radionuclide therapy.

And, by the way, I did want to mention that I agree with the comments of Dr. Thomadsen and Dr. Segall.

MS. LOPAS: Okay, excellent. Thank you

for that clarification.

DR. GREENSPAN: Thank you.

OPERATOR: We do have another comment on the phone lines, if you'd like to take it.

MS. LOPAS: Yes, that'd be great.

OPERATOR: Thanks. And, we have it from David Shuster, your line is open.

DR. SHUSTER: Yes, I'm Dr. David Shuster. Thank you for giving me the opportunity to comment.

I am a tenured professor at Emory University and I speak for our consensus opinion at Emory University, Emory Healthcare, both in nuclear medicine, radiology, and radiation oncology.

I want to also express my support for colleagues previous comments as well. They're all well taken.

A few more points to consider is that, even in the best of hands, and we have great experience with these therapies at our centers, it is very difficult and complex to operationalize these in a safe and effective manner.

And, I can tell you, so that it is complex enough that our own medical oncologists have not even expressed any demand for us or any requests for them to do this. They know that it is best and safe in

our hands.

So, I agree that we should not relax any requirements and, at the least, there should be a competency test, both initial and ongoing as we currently have administered by the appropriate boards, either the ABNM and/or ABR, to assess both initial and ongoing competence both in radiation safety as well as specific to these radiopharmaceutical therapies.

And, only in this way can I believe that we will be best serving the public good.

I agree with the previous comment that we would not do this for surgery, we would not do this for, you know, anyone just being allowed to, you know, do any kind of complex procedure.

And, if there are certain areas of the country that don't have adequate resources, I believe those patients do need to be referred to an appropriate center who do enough of these therapies that they can achieve some competency.

For example, we wouldn't let many rural hospitals do complex heart surgery, to give an example.

So, that is our consensus opinion at Emory and we believe that the current requirements

should be kept in place.

Thank you very much.

MS. LOPAS: Okay, thank you.

Do we have anybody in the room that would like to make a comment?

(NO AUDIBLE RESPONSE)

MS. LOPAS: Okay, I'll just keep checking.

Star one of the phone if you want to make a comment on the phone.

Shirley, do we have any other comments on the phone?

OPERATOR: We do have one and that's from Munir Ghesani. Your line is open.

DR. GHESANI: Hello, hello, everyone. Thank you for the opportunity to speak and thank you, NRC staff and the ACMUI for putting together this extensive work and collection of information that has culminated into numerous rounds of phone calls and opportunities to make written comments as well.

I'm the Chair of the SNMMI Government Relation Committee and member of the Board of Directors of SNMMI.

I am also one of the members of the American Board of Nuclear Medicine, a colleague of

George Segall who spoke earlier.

I also agree with George as well as others including Bruce Thomadsen, Ben Greenspan and David Shuster regarding the comments they have made so far.

The issue of training and experience requirements are the top concern for SNMMI. We have submitted public comments on this issue multiple times as well as expressed our recommendations through our constituents in the public meetings.

We have taken lengthy measures to make sure that what we represent is representation of the entirety of our membership which includes physicians most, but not all, of whom are authorized users. That also includes the technologists medical physicists, radio pharmacists, and radio chemists.

So, a broad cross section of all that are currently very heavily involved in both diagnostic as well as therapeutic nuclear medicine.

We have actually gone on to engage our patients as well as individuals and members of the advocacy groups of patients to ask their opinion about it.

And, our primary concern is it was expressed earlier, is the safety of the patients as well as the public. We want to emphasize the

importance of ensuring access to quality care, trying to expand the access to radionuclide therapy by using clinicians with limited authorize user training may result in its medical use at a facility that cannot provide needed medical care and may not have the systems to ensure radiation safety.

We suggest that the best practices is to have the radionuclide therapy performed at the facilities that have a team of medical professionals including authorized users who have extensive training and experience to perform the radiation therapy, radionuclide therapy very safely.

As well as patients, there are physicians who have expedited the medical care of complex patients that includes the radiologists, nuclear medicine physicians, and radiation oncologists with appropriate training and background in being able to handle these treatments and manage any potential complications.

Additionally, based on the readily available online data from the American Board of Nuclear Medicine as well as other medical boards including American Board of Radiology as well as broad licensing by NRC graduates from other programs like diagnostic radiology, nuclear medicine, and radiation

oncology.

There are numerous eligible individuals who have become authorized users. And, as it was pointed out earlier by Bruce and I completely agree with him, that issue of the authorized user limitation has been already demonstrated that it actually is nonexistent in terms of available users to administer these treatments.

In the future, even if the number of available treatments has risen above available approved types of medical treatment for radionuclide therapy may increase in the future.

So, based on the robust number of authorized users, both in the workplace currently as well as those who are in the training pipeline, we don't think that there's a shortage of authorized users.

So, in summary, the SNMMI does not support a change in the training and experience requirements. The safe use of radionuclide therapy requires an integrated system of medical care involving the team of medical professionals that I described earlier.

And, changing the NRC regulations with the intent of expanding access to radionuclide

therapy in the absence of improving the access to all types of adverse medical care can only result in therapy being administered to places that have adequate -- that don't have adequate medical expertise in their administration.

So, I again thank you for the opportunity to speak and would be open to hearing any comments from the room as well as from those on the phone.

Thank you.

MS. LOPAS: Thank you, Dr. Ghesani.

Shirley, do we have any other commenters on the phone?

OPERATOR: At this time, I'm showing no further commenters.

MS. LOPAS: Okay. So, folks on the phone, I want you to press star one. I do have a comment that I am going to read on the webinar. It's a lengthy one, so bear with me.

But, I do want to point out that if you're a little shy and you don't want to speak on the phone, you can type it in via the webinar, too, that works.

So, star one to get on the phone or go ahead and type your comments in.

So, I'm going to read a comment from Michael Baxter. So, this goes as follows:

(Michael Baxter) ''While we are still reviewing the question, most comments today are relevant to option D3.'' Which I believe was the pairing an authorized nuclear pharmacist and an AU, and question nine.

''On behalf of the American Pharmacists Association, Academy of Pharmacy Practice and Management, Nuclear Pharmacy Practice Specialist Special Interest Group (SIG) consisting of over 2,200 members, please consider the following comments to the NRC's request for comments on the T&E requirements for authorized users.

The APHA/AAPM nuclear pharmacy practice, SIG, recommends AU T&E requirements should recognize the various healthcare team members involved in handling and administering radiopharmaceuticals safely and effectively, including nuclear pharmacists, physicians, medicine technologists and health physicists.

As you may know, 90 percent of radiopharmaceuticals are dispensed by an authorized nuclear pharmacist, ANP.

Given the varying roles and expertise, the 700 hours requirements may need to be decreased. However, it is difficult to quantify a level of

expertise by set number of hours versus competency based training.

The current safety record to therapeutic and diagnostic radiopharmaceuticals are the result of the individuals on this team who must be recognized in any restructuring of AU T&E requirements.

Additionally, while alpha and beta emitting radiopharmaceuticals are dispensed and delivered to healthcare facilities as ready to administer doses, new alpha and beta emitters have added the important task of specialized calibration of the dose calibrator to ensure the correct amount of radioactivity is dispensed.

In conclusion, APHA/AAPM's nuclear pharmacy practice, SIG, and our over 2,200 members believes it's critical to recognize the important role of ANPs, authorized nuclear pharmacists, and their medication expertise in the healthcare team.

Thank you, again, for this opportunity to provide information on this important issue.''

All right, Mr. Baxter, I appreciate that comment.

I have another comment here on the webinar that I can read in just a moment, but I did want to check with Shirley to see if there are any

additional comments on the phone.

Shirley, anybody pressed star one?

OPERATOR: At this time, I'm showing no further comments. And, at this time, I'm showing no further comments.

MS. LOPAS: Okay, great, thank you, Shirley.

Okay, I want to check with the room, does anybody want to speak in the room?

(NO AUDIBLE RESPONSE)

MS. LOPAS: All right, I'm going to move back to this next comment here via the webinar.

This is from Steven Walter. (Steven Walter) ''My concern is related to both Part 35.200 and Part 35.300 uses as relating to this proposal, what consideration of Part 35 Subpart N enforcement was taken into account with each category?

Specifically, should anyone seeking authorized user status submit intentionally false information to the credentialing boards, how is the public assured that the NRC is providing oversight?

As of right now, we have no way of knowing when that happens. There is no avenue for those events to become public. This may result in users becoming an authorized user after submitting false

documents in violation of Subpart N.''

Okay, thank you, Mr. Walter, or Dr. Walter, we appreciate that comment and that's a good consideration that we will take down.

Okay, so, you can go ahead and continue to submit your comments via the webinar or press star one on the phone.

Shirley, do we have any other star ones on the phone?

OPERATOR: At this time, I'm showing no further comments.

MS. LOPAS: Okay. I'm going to run through some of the questions again just to jog any comments because we don't want to end the meeting too early.

We do, of course, have another meeting on May 23rd, 2019 and, again, that's from 10:00 a.m. until 12:00 p.m. Eastern Time.

It's another webinar and another transcribed public meeting to provide your comments.

And, I do want to look at some of these questions. And, these are, again, these are some of these questions that we're looking to get your general feedback on.

So, when you provide us your feedback on

some of these draft approaches, we certainly hear -- we do hear the opposition to any changes in our T&E requirements from the nuclear medicine community, and we're hearing that you would like our current T&E requirements maintained.

I've also heard a couple folks point out today that they would also like to see an initial competency assessment maybe for all the pathways and then they would like to see ongoing competency assessments.

So, that's a comment that we would like to see -- like to hear again.

In addition to that general opposition, it is helpful for us, though, to get specific feedback on some of our options.

Feedback on some of our approaches and even if it's feedback just on the general themes. So, we have the approaches kind of split out by theme, right, we have the performance based approaches, we have the tailored T&E approaches, we have the team approaches and then, of course, the status-quo.

So, even if you don't feel like splitting out your comments kind of by each approach, because there's a lot in them; there's ten in them, right? You can just kind of make overall comments and

concerns on those themes.

And, one thing that I'll point out is that we are also interested, for instance, that consideration that I just read about, you know, false reporting of the AU requirements.

That's a consideration, right, that's example of a consideration that we would like to hear from you all.

So, to the extent that you look at any of these approaches and you think, well, NRC, have you thought of this? Or have you thought of that? Or how would you handle that situation?

Those are the kind of things that would be really helpful for us in helping to refine these approaches to help us determine if they're, indeed, feasible.

You know, we're interested in the viability of these approaches and we're looking to the medical community because you are the ones doing this day in and day out. And you can give us that insight.

So, before I keep talking away, I did want to read -- I do want to read something from one of our staff members, Ms. Sophie Holiday. And, she's responding to the concern regarding false

credentials.

So, we have from Ms. Holiday, and she's an NRC staff member, in response to Dr. Walter's question or comment, license reviewers are expected to review documentation for authorized users, including T&E requirements prior to granting the license or amendments to add AUs.

''If an allegation is submitted regarding false credentials, the NRC will follow up through the allegation process. If it is found out that the individual violated Subpart N, enforcement action can and will be taken for licensees in the NRC's jurisdiction.''

And, I'm sure that the Agreement States probably have a similar course of action that they would handle as well.

And, if it's in the Agreement States' jurisdiction, we refer those -- that allegation to the Agreement States if we get it first, but typically goes to the Agreement States for them to handle.

So, thank you very much, Ms. Holiday, for that clarification and that answer. We appreciate that.

Okay, all right, Shirley, did we have any additional comments or questions on the phone?

OPERATOR: We do have one that's come in. One moment, please. And, David Schuster, your line is open. Go ahead with your question.

DR. SHUSTER: Thank you very much.

I would like to comment again, if you could be so patient on this last question about potentially giving false credentialing or the hours that one puts in.

I think, first of all, we appreciate the efforts of the NRC in enforcement. And, we all know that there are great penalties attached to putting in false hours and documentation.

But, to kind of speak to the elephant in the room, I think that it depends on how this credentialing is put in place and how the hours, if that -- we went down that route, would have to be documented.

So, if this were, for example, left in the hands of the various maybe companies that are producing, you know, these radiopharmaceuticals, you know, there may be kind of an easier pathway or maybe more leniency in -- because there is a vested financial interest in getting those sites online.

And, I have to say, we've seen that, unfortunately, with some other therapies which, you

know, not necessarily all radiation therapies, but I won't go into specifics here.

But even though there are great penalties attached, this is an enforcement after the fact. Okay? This is potentially after a patient gets hurt.

You know, it would be very difficult front line to say who's going to report these people who are potentially, you know, skirting the various rigorous documentation requirements.

I think, though, that if we had it in the hands of the boards such as ABNM and ABR who've developed very vigorous documentation requirements, both for hours as well as training as well as testing.

Then, you may have a much more robust method. Again, I do not agree that we should change the requirements at all and we do currently for both ABNM and ABR certified physicians have initial and ongoing certification.

But if we did go down that path at all, it should not be left in industry hands, as it's sometimes currently partly is, but also it should just be left in the hands of certifying boards.

Thank you very much.

MS. LOPAS: Okay, thank you, Dr. Shuster. We appreciate that.

I have a follow up comment from Steven Walter who originally submitted that concern about false credentialing or qualifications.

So, Steven Walter states that ''the public has no way to know when a violation may have occurred when the authorized user goes through certifying boards.

They do not make that process public and, as far as I know, they do not report it to the NRC in general.''

I'm not sure, Lisa, Chris, do you have anything that you want to follow up with that?

(NO AUDIBLE RESPONSE)

MS. LOPAS: Okay.

MR. EINBERG: We'll just take that comment.

MS. LOPAS: Yes, we're just going to take that comment and we'll -- we will look into that further.

Okay, Shirley, do we have any additional comments on the phone? Star one, just press star one on your phone if you want to make a comment.

OPERATOR: We do have two comments. Our first one, I believe, is from Arif Sheikh, your line is open.

DR. SHEIKH: Yes, hi. This is Dr. Arif Sheikh. I'm a nuclear medicine physician.

Just a quick question with regards to your -- about having a team based approach. I think in this day and age, especially the use of these more advanced therapies is going to require a team based approach.

The only quick comment I want to make is that I think, you know, at the center of that team based approach, the person who administers the therapy and makes the -- involved in the decision analysis needs to be a full AU, not a limited AU.

Because, generally speaking, when you are looking at teams of -- involving physicians in treatment of, you know, various modalities such as the cardiac cath, the center of that team is the full fledged cardiologist, not a limited cardiologist.

And, you know, and so with regards to these, make that case with oncology and others.

So, I think the person administering it really needs to be a full fledged AU with the full training as supported by the ABNM in order to lead that team. I don't support the idea that you would have a limited AU with the experience of only a single radiopharmaceutical delivering it to only a single

type of patient.

MS. LOPAS: Okay, thank you.

And, I want to clarify, Dr. Sheikh, that so for option D-1 or approach D-1, the way we look at it and we're obviously open to suggestions on how to approve this approach is that the AU that would be at the head of this radiopharmaceutical team would be a full AU and that they would be authorized to administer any radiopharmaceutical under 35.300 under Subpart E.

However, they would need to be supported by this team and the other big however is that the T&E would be performance based that, you know, the licensees would essentially be -- these facilities, these hospitals, would be credentialing and certifying that they trust in that AU to be the lead of that team essentially.

So, now, of course, we are open to all sorts of combinations of approaches and I know you had just -- you just kind of mentioned that you wouldn't support this team based approach if it was a limited AU who only had experience in, for instance, one radiopharmaceutical.

But do you feel differently about this team approach if it's a full AU, but it's performance

based T&E leading this team? Does that change your mind at all about this option or this approach?

DR. SHEIKH: No, I think, I mean, again, I still think that you do need a full AU. I mean, they need to be, yes, they need -- the AU also needs to be further trained. It's -- there are, you know, many physicians who are not maybe a full AUs or not is interested in therapies the same as others would be or inclined.

So, there would be some performance based as well, but I think, you know, there has to be some basis of standard hours given in terms of training and exposure prior to authorizing somebody to be able to deliver these pharmaceuticals and be involved.

Because, frankly, a lot of -- radiopharmaceuticals is not just a therapy much like say, other pharmaceuticals are given. There are some unique characteristics about it. There's a lot of knowledge about imaging coming into play that has to be accounted for.

So, there are some very unique aspects of this therapy. So, I think, you know, they really -- I would really support that the AU has to have training well beyond being able to just deliver a single radiopharmaceutical to the patient.

MS. LOPAS: Okay, all right, I appreciate that clarification.

Star one for any other comments on the phone. Shirley, do we have another commenter on the phone?

OPERATOR: We do, and that's from Joe Rubin, your line is open.

MR. RUBIN: Thank you very much.

This is Joe Rubin, I'm speaking on behalf of United Pharmacy Partners. UPPI is a consortium of radio pharmacies and they represent about 25 percent of the market, so a really significant player in this space.

We just want to comment that we really appreciate the NRC taking the time to evaluate the need for alternative approaches that are obviously are a significant number of exciting therapies that are coming down the pike.

And, we believe that will dramatically increase the demand for Radiopharmaceutical treatment beyond just the rural versus urban debate, but in general, that there will be a significant increase in demand.

So, the ANP approach that the ACMUI considered, the teaming approach was the ACMUI called

it novel, well intentioned and worthy of extensive consideration.

So, we really appreciate the NRC including that in the list of possible outcomes.

And, I want to reiterate, the need for a team has been discussed many times on this call and in other comments. And, an ANP has the same basic 700 hours of training as an AU.

So, when we talk about a full AU, we believe that an ANP from the context of the NRC should be considered practically equivalent.

So, thank you very much for your time and for your efforts. We really do appreciate it. And, we look forward to provided a more detailed response in the formal comment period.

MS. LOPAS: Okay, thank you, Mr. Rubin.

MR. RUBIN: Thank you.

MS. LOPAS: Okay, I want to check in with the room? All right, we have a comment in the room. All right

MR. GLEASON: Hello, and thanks for taking the time today. So, my name is Shaemus Gleason. I lead the Global Radiopharmaceutical Strategic Operations at Bayer Healthcare.

I'm here today to compliment the NRC and

staff on its engagement on this important issue and pursuing a risk informed and nonprescriptive approach to these next generation therapies.

The hazards associated with handling any administration of alpha emitting Radiopharmaceutical such as our product, Xofigo, represent a completely different type and scale of radiation risk to the associated missions, the quantities given and the way in which the product is provided to physicians.

We strongly support option three or any approach that encourages a risk informed approaching to the licensing of physicians. And, we are working on a comprehensive response to the questions listed in the FRN.

So, thanks again for the time today.

MS. LOPAS: All right, great, thank you for coming.

All right, any additional comments in the room?

(NO AUDIBLE RESPONSE)

MS. LOPAS: Okay, star one on the phone or if you have a relatively short comment, you can submit it by the webinar because I might do it justice reading it aloud.

So, star one or submit it via webinar.

Shirley, do we have any comments on the webinar -- or excuse me, on the phone?

OPERATOR: We do. We have one from Beth Blankenship. Your line is open.

MS. BLANKENSHIP: Hi, my name is Beth Blankenship. I'm a medical physicist. I also chair the Government Relations Committee for the AAPM. And, my colleague, Bruce Thomadsen is there also sharing the AAPMs current belief for what should happen for our traditional -- maintaining credential training for our physicians.

I bring forward another comment and I'm a medical physicist, and I'm also n ration and safety officer for multiple facilities.

And, two things come to mind. Again, we support the traditional status quo training that we have in place as the appropriate training that's necessary for these radiopharmaceuticals.

And, one of the challenge I think I see in the field and I wanted to share this is, if the safety responsibilities are shared between an authorized user or if the Radiation Safety responsibilities that are the responsibility of the authorized nuclear pharmacist, the authorized nuclear pharmacist isn't typically out off site so that

oversight can be a challenge because I think that's important to the safety of our patients and our staff.

So, that is one challenge that I will bring forward. I think further considerations to be thought through.

And, why I bring that forward is, I think the language that how we move forward with this, one of the challenges I currently see, even though we have traditionally trained physicians with multiple hours that do an excellent job, there's many times in outer smaller areas where an authorized user is responsible for the delivery of that Radiopharmaceutical.

However, if that physician is not directly onsite to administer that radiopharmaceutical, I think one of the things I would like for there to be a discussion regarding is what does the NRC, regardless of who is going to be allowed to produce or administer this radiopharmaceutical, what role do they have in this?

And, in by saying that they have the responsibility of the program, indeed, does that mean that that responsibility can be given to someone other than themselves to administer a radiopharmaceutical whether it's lutetium-177 procedure which is

extremely complex or any other new analogues that are coming along in the near future with lutetium based treatments will require a team.

But I would like comments from -- I'm looking forward to the comments from my other colleagues regarding what exactly do they expect, even with the 700-hour trained physician, is what I'm trying to get at.

So, I thank you. I think it's a very important topic. I think the questions will be certainly answered by the government relations committee at the APM point by point to explain our concerns and our desire for what we think in the future we should maintain.

But there are even additional things that we -- I don't see on these slides that I think we will probably make comment to, too, as it's an appropriate time to bring forward things that have been place that could be looked at.

So, thank you very much for taking my call and my comment. Thank you.

MS. LOPAS: Yes, thank you very much, Ms. Blankenship. And, exactly, please don't limit your comments. We want to hear all your concerns, you are not boxed in by our questions that we have in the FRN

or boxed in by the approaches.

So, thank you, we appreciate your time.

Shirley, do we have any other comments on the phone?

OPERATOR: At this time, I'm showing no comments.

MS. LOPAS: Okay. So, star one for the folks on the phone or if you want to submit a question via the webinar, you can do that as well.

I'm just going to once again read through these questions again and see if they jog any additional comments.

So, I'll let you know that when we put forward our Commission paper, we will likely have a list of options for our Commission to consider and we'll touch on the advantages and disadvantages of each.

So, for question ten, the NRC is certainly going to come up with advantages and disadvantages but we're interested in hearing from the medical community on what they think the advantages and disadvantages of the approaches would be.

Again, question 11, now the NRC will do their own cost benefit analysis but, if from the

medical community perspective, if you look at any of these approaches and you think, oh no way, that would, you know, that just doesn't make sense because these costs are prohibitive or they go beyond the benefits. That's what we'd want to hear there for question 11.

Question 12, again, we've talked a lot about patient access today. We're interested in hearing what approaches do you think would either help with patient access or help with those concerns about overly burdensome requirements.

And, I know not all of you have those concerns, but for those of you that do, we want to hear your input on that.

Question 13, for the draft approaches that consider those tailored hours of T&E, we want to hear what is the correct number of hours? What do you think those hours should be?

I've heard a couple comments that our numbers are arbitrary. So, we want to hear from you what you think they would be and what do you think the topics can be?

And, of course, we're looking into that as well. We're making a determination on that as well. But we take your input and we use it.

Question 14, should the NRC consider

inclusion of formal radiation safety competency assessment and periodic reassessments for any of the draft approaches?

We have heard some support for that today. So, thank you for that input.

And we had this question in our last FRN comment period process back in the fall and winter. So, we'll go back and look at that but we did have a question about who would establish and administer these assessments?

So, to the extent that you -- that some of you have already answered this question, we'll go back and look. But any additional thoughts would be helpful.

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

So, this question is kind of related to the unintended consequences question, the next slide. We're trying to think how would any changes to our T&E requirements ripple through the medical community?

Question 16, are there concerns regarding implementation and/or viability for any of the

approaches discussed above.

So, again, we're just looking to hear from you all out there in the field, you know, no way, option whatever wouldn't work. Or you know, oh, you might want to consider this, otherwise it doesn't seem like that would work. That's the kind of input we're thinking about for question 16.

Question 17, again, are the unintended consequences. Now, we're trying to think of as many considerations for these approaches as we can. But we really need from the folks out in the field their opinions on what that may be some unintended consequences of our approaches.

Question 18, we are trying to look toward the future of radiopharmaceuticals and position ourselves to best regulate what's going to be coming down the pike in the future for more complex and the increase in expected number of these radiopharmaceuticals.

I think somebody cited the increase of up to 30 percent in nuclear medicine by 2030. And the complexity of some of these administrations that are coming down the pike.

So, which draft approach, or is there one that you can think of that we don't have -- that we

didn't think of -- that would best set us up to regulate the future radiopharmaceuticals?

And then, finally, question 19 which I think is the big one, should the NRC continue to play a role in the review and approval of AUs?

Some of our performance based options led us to put this question in there and you'd probably answer it naturally in your critique of our performance based approaches.

But so those are our questions that we're hoping to get feedback on. I want to check in on the phone again with Shirley to see if we have any final comments via the phone?

OPERATOR: We do have one from Karen Grady. Your line is open.

DR. GRADY: Thank you so much, it's Erin Grady, E-R-I-N, sorry about that if it was hard to understand.

Anyhow, I am president of the American College of Nuclear Medicine. And, the ACNM is a professional organization that directly represents the interests of the nuclear medicine physicians before legislative or regulatory bodies and other medical organizations, media, and the public.

The college comprises physicians and

scientists dedicated to enhancing the practice of nuclear medicine through study, education, and important improvement of clinical practice.

The goal of ACNM is to ensure legislative, legal, regulatory, and economic framework to encourage the safe practice of nuclear medicine in the United States.

And, it's my pleasure to join you and it's also I would like to express my gratitude for you guys having this public forum where people can speak their opinions. It's very important.

So, I do want to say that the American College of Nuclear Medicine is going to be submitting formal comments in conjunction with the Society of Nuclear Medical and Molecular Imaging.

And, we are working toward a pretty comprehensive letter for you. I want to echo some other comments that I heard earlier today calling for lengthening of the time limit for comments.

I think Dr. Greenspan has indicated about a month extra would be very helpful if possible.

I want to go on the record for the ACNM as also being in favor of the status quo for the training and experience of requirements.

We feel that the both alpha and beta

radiopharmaceuticals pose unique concerns and safety issues for patients. And, these should not be taken lightly.

We feel that it's very important to protect the patients and public and not decrease the requirements.

In addition to this, I wanted to ask just a couple of other questions for the group providing the meeting today.

I was wondering if it would be possible to get the slides that were presented at the beginning of the meeting? I wasn't able to be here for the entire length of the meeting.

MS. LOPAS: Yes, the slides are available in a couple places. I don't know if you're logged into the webinar. If you're logged into the webinar, they're on the handouts tab of the webinar.

If you're not on the webinar, if you go to the NRC's public meeting page, so if you just Google NRC public meeting schedule, that'll bring you to the first result that pops up is the NRC public meeting schedule website.

And, if you click on that and you look at today's date, you should find the listing for this meeting, the training and experience meeting.

And, if you just kind of click through that, that meeting notice, I did post our slides there. They're an attachment that you can download. The FRN is posted as well.

So, that's how you can find the slides. They're also on the NRC's training and experience evaluation website, too. So, you could just Google NRC training and experience evaluation and if you kind of scroll through there, you can find the slides pretty easily as well.

DR. GRADY: Thank you very much.

OPERATOR: We do have another comment if you'd like to take it?

MR. EINBERG: Yes, before we move on, this is Chris Einberg. I wanted to acknowledge and thank you for your request for the extension. We've also received the request for extension from ACRS, ASTRO, and SNMMI in addition to AAPM and we're evaluating those requests at this time and we'll take it under consideration.

MS. LOPAS: Okay, Shirley, yes, we will take another comment.

OPERATOR: Thank you. And, that comes from Jeff Siegel, your line is open.

(NO RESPONSE)

OPERATOR: Please check your mute feature, your line is open.

(NO RESPONSE)

OPERATOR: Jeff Siegel, your line is open, go ahead with your comment.

(NO RESPONSE)

OPERATOR: We'll move on to the next one and that comes from Joe Rubin. Your line is open.

MR. RUBIN: Hey, just a quick follow up question with regards to the potential for a delay. The NRC is, I guess, in the process of evaluating the distribution of authorized users. Could you give us an update of that status? Is that completed? Is that -- where does that stand? And, how is that going to be incorporated into your evaluation?

MS. LOPAS: Yes, hi, Mr. Rubin, this is Sarah Lopas.

So, we are getting close to finishing that up so we have gone ahead and we've mapped all the NRC licensees who are authorized to use 35.300 materials.

We did put out the request to the Agreement States to provide us that same data and we heard back from -- I can't remember if it's like nine or ten Agreement States -- it was a voluntary request

to the Agreement States. So, we do have a handful of Agreement States that stepped up to the plate and gave us that data as well.

And, we're almost done mapping that and those maps are going to be in an enclosure to our Commission paper. So, that's when those maps will become publically available.

Does that help?

MR. RUBIN: Yes, thank you very much.

OPERATOR: We also have another comment if you'd like to take it?

MS. LOPAS: Yes, yes, we'll take all comments.

OPERATOR: Okay, thank you. That comes from Justin Peacock, your line is open.

DR. PEACOCK: Hi, this is Justin Peacock. I am currently a fourth year resident in radiology at Brooke Army Medical Center.

I'm also on the ACNM and the ASTRO board as well as the SNMMI trainee committee. And, our tasks are obviously involved with regards to nuclear medicine training, both residents and fellows and ensuring that we have good training and that we have successful careers in nuclear medicine.

My comments are with regards to -- and I

want to first of all state that we are very grateful for the NRC for allowing us the opportunity really to have this great opportunity to weigh in on policy and changes potentially to training. And, we're really grateful for the multiple opportunities you've given us to kind of voice our opinion on this matter.

I want to state that I agree wholeheartedly with Dr. Grady, Dr. Shuster, Dr. Segall and others from the nuclear medicine committee.

One thing that I wanted to bring up was, you know, there's several of these questions that I think are resolved really through the current processes of certificate on within the nuclear medicine radiology and radiation oncology worlds.

You know, so, with regards to question, for example, question one, you know, how do we ensure that, let me go back to it, sorry, how do we ensure that, you know, if the status quo is maintained, how do we expect to respond to the increase in number and complexity of future radiopharmaceuticals?

Well, I think, you know, the best way to do that is really through the ABNM, through the ABR and through other credentialing boards ensuring that not only the training is performance but also that

competency is assessed and reassessed over time through testing of radiologist, nuclear medicine physicians and radiation oncologists.

With regards to question seven, you know, in a lot of small practices, a lot of these radiopharmaceuticals aren't even able to be utilized because you require that whole team environment as well as the hospital network to support it.

And, I think, you know, within the text above that question, asserting that licensees could develop and use their own policies and procedures to make self-determination as to whether credential physicians have the appropriate T&E.

I think that leads down dangerous road. You know, I think we've had together with the NRC, I think nuclear medicine, radiology, and radiation oncology of has had a very successful history of maintaining safety with regards to radiopharmaceutical administration.

And, I think if we deviate from that by allowing licensees to develop their own policies with regards to how to credential physicians or AU status members, I think we run the risk really of having differential standards which would lead to potentially poorer patient outcomes, poor patient

care and potentially poorer outcomes with regards to those within the field that are treating these patients.

And then, I could go on, but you know, there's multiple questions from, you know, 15 through 19 really that I think address that, that really, this partnership between NRC and nuclear medicine, radiology, and radiation oncology has worked well for so many years now that to deviate from that and to allow people to have their own preceptors or their own credentials really would lead to, I think, substandard care or differences in standards of care that don't meet the needs of patients in terms of good patient outcome and patient safety as well as healthcare worker safety.

And, with that, I'll conclude. But, I think you know, really, a lot of these questions can be really addressed by the fact that we currently have a great system going and I think the current credentialing mechanisms through ABNM and ABR really meet the standards for ensuring that, in the future, new therapies, new radiopharmaceuticals, new diagnostic procedures will be conducted in a safe and efficient manner.

Thank you.

MS. LOPAS: All right, thank you, Dr. Peacock. We appreciated that comment.

Shirley, do we have other folks on the phone? Star one if you want to ask a question or make a comment on the phone, star one.

OPERATOR: At this time, I'm showing no comments.

MS. LOPAS: Okay. I'm going to read a question from the webinar.

''Form 313A, AUT, will expire 6/30/2019. Can you explain if there are any impacts on licensees prior to the teleconference in September 2019? So, I think he's referring to the ACMUI teleconference, their comments on our draft paper, or the final paper by the end of 2019 on the license applications for new AUs or renewals?''

We are getting a response from Dr. Donna-Beth Howe because she is our NRC expert on handling the forms.

DR. HOWE: The current NRC -- this is Dr. Donna-Beth Howe -- the current NRC form 313s for the new rule that took effect in January are not available at this point.

We are still looking for an OMB clearance for them. We expect to have those forms published

maybe the end of the summer.

In the meantime, we have instructions on our website for how to provide the information that is needed to meet the current requirements.

Having said that, for the NRC Form 313 which is any license application, it expires June 6, but there is an application into the Office of Budget and Management to extend that date and because we have an application into them, that date will be extended until the Office of Budget and Management has actually reviewed and approved the new -- the 313 and will -- so the form will continue to be used.

If you are an Agreement State, you can use the old 313 A series for training and experience. You will need to go into the NUREG-1556 Volume 9 Revision 2 to find copies of those documents.

So, that -- the 313, 313A's will continue to be used. The new ones won't be available until probably the end of the summer.

MS. LOPAS: Okay. And that was Dan Hill from Carinal Health who asked that question. So, Dan, I hope that answered your question.

Shirley, do we have any comments on the phone?

OPERATOR: At this time, I'm showing no

comment.

MS. LOPAS: Okay. All right, I want to give folks one last chance to get their comments in, so press star one or submit it via the webinar.

While you're waiting -- while I'm waiting to get any last minute comments, I just want to point out that we have received some several requests to extend our comment period by 30 days.

We have not made a decision on that, but when and if we do, we will make sure that everybody knows and it's thoroughly publicized.

But in the meantime, you know, move forward as if it's June 3rd and you're going to submit your comments via regulations.gov under that docket ID. If you have any issues at all, contact me or Maryann, we'll help you out.

And the transcript for this public meeting will become available in about a week or so. We'll get it up on our website, the training and experience website. I will also put it on regulations.gov and I will be putting together a meeting summary as well that's going to be available a couple weeks after that.

So, Shirley, I want to check in to see if there's any other comments on the phone.

OPERATOR: We do have one and that is from Jeff Siegel, your line is open.

DR. SIEGEL: Hi, I'm sorry about last time, my phone just died, so I had to dial back in.

So, in case I missed it, I'm sorry about that.

My name is Jeff Siegel, I have a quick comment and point to make. I haven't heard anybody talk about this, whether or not it was necessary for NRC to do a formal risk evaluation?

My assumption is that everybody or most people think that all agents are created equal and they all represent the same risk.

My understanding is that NRC cannot intrude into the practice of medicine unless it's a safety issue. So, I'm assuming that all agents are assumed to be equally risky and I hope that's not an outgrowth of the LNT and ALARA philosophy.

So, I'd just like to know if NRC ever intends to do a formal risk assessment and maybe that way it could tailor agents because, as everybody knows, 390 already has a tailor, that is either you're a full fledged, certified, exam taking, board certified, nuke med physician or you have a 700 hours.

And, what about 392 and 394 which already

requires 80 hours? I don't hear anybody saying that ought to be taken off the books.

So, I'd just like to hear if NRC believes they should do a risk evaluation or if they don't need to since every agent is highly risky.

Thank you.

MS. AYOADE: Hi, Jeff, this is Maryann Ayoade. Thank you for your comment.

You know, as part of this evaluation we're doing now, we're taking a look at our training and experience requirements under 35.300. But, we will take into consideration you question, you know, to further look into it in terms of a risk assessment.

I mean, yes, in terms of a risk assessment.

DR. SIEGEL: Well, that's great. Could you still hear me?

MS. AYOADE: Yes.

DR. SIEGEL: Because NRC, and I love NRC, don't get me wrong, NRC's requirements we know are risk based. So, if indeed they are, that's great.

But to have an overly burdensome regulation that isn't risk based, which would prevent somebody from administering a medically approved agent, I don't think is the right way to go.

But I know people believe that all therapeutics must pass the threshold of radiation risk and therefore there's no way to have a spectrum of T&E.

I don't agree with that, but I haven't heard anybody say anything about that yet. But, thank you, Maryann, for that comment.

MS. AYOADE: Well, thank you and I just want to add, you know, again, as part of even the NRC's Medical Policy Statement, our goal as we do this evaluation is to make sure that we're keeping in mind that we're not interfering with the practice of medicine and so I just wanted to add that to my comment.

DR. SIEGEL: Well, right, unless it's a safety issue, correct.

MS. AYOADE: Yes.

DR. SIEGEL: And, that's why I love the NRC. That's true.

MS. AYOADE: Great.

DR. SIEGEL: Thank you.

MS. AYOADE: Thank you.

MS. LOPAS: Okay, Shirley, do we have any other commenters on the phone?

OPERATOR: At this time, I'm showing no

further comments.

MS. LOPAS: Okay, I want to check back in the room, anybody have any final statements here in the room?

(NO AUDIBLE RESPONSE)

MS. LOPAS: Okay, nobody's moving.

All right. I'm going to go back to the staff and let the staff make some comments.

MS. AYOADE: Yes, there was a comment earlier related to the training of the nuclear -- authorized nuclear pharmacists being similar to that of the 700 hours requirement for the authorized user.

I just wanted to clarify that currently in the regulations, the authorized nuclear pharmacist can either come under the board certification pathway or an alternate pathway for 700 hours.

And, that's 700 hours is not exactly similar to what we require for the authorized users for Radiopharmaceuticals. The 700 hours does include the classroom and laboratory but, as it relates to the work experience, the supervisory work experience, it doesn't include that or it doesn't require that they have that experience in patient case work and all of the different categories that we currently have for the radiopharmaceuticals.

And so, I just wanted to clarify that it is different than what the 700 hours that we require as for radiopharmaceuticals.

MS. LOPAS: Thanks, Maryann, I appreciate that clarification as that relates to option D-3 regarding teaming an AU with an authorized nuclear pharmacist.

Okay, with that being said, I'm going to check in on the phone again. Star one on the phone, anybody? Shirley, anybody else on the phone?

OPERATOR: At this time, I'm showing no further comments.

MS. LOPAS: Okay, well, if you come up with another comment, that's great because you can submit it to us via writing, via regulations.gov or you can join us again on Thursday morning, May 23rd, 10:00 a.m. to 12:00 p.m. and we can get together again and do this all over again and hear your comments again. That will again be a transcribed meeting.

Chris and/or Lisa, do you guys have anything to say?

MR. EINBERG: I just want to thank everybody for your active participation and the excellent comments that we've received. We certainly evaluating those comments and they will be used as

part of the decision making process.

We've heard you as far as the request for extending the comment period by 30 days. We'll -- as soon as we make a decision as Sarah pointed out, we'll, you know, make sure that everybody knows that. We'll communicate that extensively.

If we've made that decision or when we make that decision, and so, thanks again for coming.

MS. LOPAS: Okay, thank you, everybody, this ends the meeting.

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